The CARD™ System for improving the vaccination experience at school: Results of a small-scale implementation project on student symptoms

By

Tamlyn Freedman

A thesis submitted in conformity with the requirements for the degree of Master of Science

Department of Pharmaceutical Sciences
University of Toronto

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Department of Pharmaceutical Science

University of Toronto

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Abstract

**Background:** Many students fear vaccinations. We implemented a novel, multifaceted knowledge translation intervention in the school vaccination setting incorporating evidence-based coping strategies—The CARD™ System (C-Comfort, A-Ask, R-Relax, D-Distract)—and evaluated impact on knowledge, symptoms, coping strategies, and fidelity.

**Methods:** Five experimental schools (ES) and five control schools (CS) in a controlled clinical trial. ES students completed a knowledge/attitudes survey during a CARD™ educational session and selected coping strategies before vaccinations. CS students received the usual vaccine lesson. Nurses recorded strategies used and students rated symptoms. Fidelity to CARD™ was evaluated.

**Results:** CARD™ increased knowledge and coping strategy use. Distraction, deep breathing, support and privacy were most selected. CARD™ (vs. control) was associated with less high fear and high dizziness; pain and vaccination rate did not differ. High fidelity to CARD™ components was observed.

**Discussion:** CARD™ improves student symptoms during school-based vaccinations. Research in different settings is recommended to confirm results.
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Chapter 1 - Introduction
Chapter 1 – Introduction

1.0 Overview

We conducted a controlled clinical trial to assess the effects of a student-centred, multifaceted Knowledge Translation (KT) intervention incorporating evidence-based coping strategies (The CARD™ System) on the school vaccination experience. We measured whether CARD™ (C-Comfort, A-Ask, R-Relax, D-Distract) had an impact on outcomes consisting of: knowledge; pain, fear, and dizziness during vaccination; and coping strategies used. The results support further study of how this novel KT intervention can be used for vaccinations and other medical procedures, inside and outside the school setting.

1.1 Importance of Vaccinations

Vaccines have played a significant role in the prevention and control of infectious diseases, estimated to have saved more lives than any other health intervention in the past 50 years [1,2]. For example, vaccines in the U.S. have reduced the number of cases of nine vaccine-preventable diseases by more than 90% to 99% or, in some cases, eliminated them [3-4]. Vaccines protecting against 13 diseases were estimated to prevent nearly 20 million cases and 40,000 deaths in a birth cohort of all American children born in 2009 [5]. An analysis of vaccination programs to protect against 10 diseases in 94 low-income and middle-income nations estimates that the $34 billion spent on vaccinations yielded savings of approximately $586 billion in reduced healthcare costs and about $1.53 trillion in indirect economic benefits [6].
1.2 School-based Vaccinations

All Canadian youth are offered free vaccinations in school-based programs [7]. School vaccination programs allow the immunization of large numbers of students in a short time period [8,9]. The vaccinations are convenient for parents who do not need to take their children to a health care provider for vaccination [10]. School-based vaccination is associated with high uptake rates [11]. Despite concerns that low school enrolment in some countries would impact school-based vaccination uptake, data from low and middle income countries indicated that vaccine uptake at school-based vaccination programs is high: 82.6% in Peru; 88.9% in Uganda; 96.1% in the second year in Vietnam and 70% in India with a mixed school-based and health facility-based strategy [12].

Childhood vaccination programs have increased in scope to include newly developed vaccinations, such as Human Papillomavirus (HPV) vaccines [11]. HPV vaccine uptake in school-based vaccination programs has been higher than uptake in health facility-based vaccinations. In the 7 countries of the Gardasil Access Program, school-based uptake was 93.8%, health facility based was 77.1% and mixed strategy was 93% [13]. Uptake was 14% higher in the 11 regions of Spain giving the HPV vaccination in school-based programs than in the 8 regions with health facility-based vaccinations, although the difference was not statistically significant [14]. With new vaccines being developed, more school-based vaccination programs are likely to be utilized in the future.

Although school-based vaccination programs have the potential to vaccinate large numbers of students, needle fear and current school practices are barriers. Students participating in school-
based vaccinations, frequently experience fear and even fainting caused by fear [15] or by vasovagal response [16] that can cause injury [8, 17]. Given that Canada's vaccination rate is considered too low [18, 19] and new vaccines are available, interventions that will minimize vaccine avoidance at school-based vaccination programs, and elsewhere, are needed. A study by Bucci, Macdonald, Sondagar, and Taddio [20] of students and schools regarding the school-based vaccination experience revealed the extent that vaccine pain and fear exist among students, as well as an eagerness to learn coping strategies. They conducted mail surveys of 277 Grade 6 students and 13 school staff members from 13 Canadian schools. The surveys were based on the research team’s previous studies [21-22]. Students reported that pain (35%) and fear (59%) were the worst aspects of vaccination. Although students described using distraction and rewards as coping strategies, only 20% of schools had distraction kits or rewards of food or prizes on school vaccination days. About 50% of students reported that they did not know ways to mitigate vaccine pain and fear and 37% expressed an interest in learning such techniques. Only 17% of the schools prepared students for vaccination day and 29% prepared their staff. Responses from the students and staff indicated that there was access to private rooms (88%) and comfortable chairs (57%) in schools for vaccinations, with schools willing to make further accommodations such as parental presence and allowing topical anesthetics.

1.3 Terminology Related to Needle Fear and Pain

To better understand and address the barriers to school-based vaccinations, key concepts are described in this section.
1.3.1 Pain

Pain is an unpleasant experience involving the senses and emotions, accompanied by tissue damage or potential tissue damage [23]. Pain is subjective [23]. Brief episodes of pain can be adaptive but pain can also have harmful, long-lasting consequences when it causes significant distress, suffering and restrictions of activities [24]. Self-reporting of pain is the most common measurement method due to its subjective nature, however, if self-report is not possible due to disability, impairment or is not reliable due to age (less than five years), observation or other pain assessment methods may be used [24]. Self-reporting scales used with children to measure pain include the following tools: visual analog scales [25]; numerical rating scales [25]; verbal rating scales with pain descriptors [25]; faces pain scales [26-29]; colour analog scales [30] and poker chips where the child chooses the number of poker chips that represent the pain experience [31].

1.3.2 Fear

Fear is an alarm reaction to an imminent, real or perceived threat that mobilizes the individual for fast response, including fight or flight [32-34]. Self-report measures of fear have been developed specifically for many different fears using numerical, verbal descriptors, and verbal scales. The Children’s Fear Scale [37] is a face-rating scale developed to assess fear in children.

1.3.3 Anxiety

Anxiety is a negative emotional state often characterized by apprehensiveness about a future threat [40]. To be considered an anxiety disorder in DSM-5, the apprehension has intensified to an excessive level that is disproportionate to the threat and is interfering with the ability to function [35, 40]. Thinking about going into the situation can typically elicit anticipatory anxiety [41]. While low-to-moderate levels of anxiety can be adaptive in protecting an individual from
danger, high levels are typically dysfunctional, causing over-cautiousness and avoidance of the feared situation or anxiety source. In the pain literature, the terms ‘fear’ and ‘anxiety’ are often used interchangeably in discussions of results and assessment [24], which can hinder the understanding of the processes involved. For example, the Faces Anxiety Scale is used to gather self-reported fear in adults [24]. Self-reporting anxiety questionnaires have been developed for general and specific sources of anxiety [42]. Levels of anxiety are also measured objectively using functional MRI [43] and other physiological tests, such as heart rate, blood pressure, skin conductance, palmar sweat prints and forearm electromyography [44].

1.3.4 Needle Fear and Phobia

A phobia is a long-lasting extreme form of anxiety and fear with respect to a stimulus or situation that elicits a reaction that is not proportionate to the danger or threat [24]. As defined by the DSM-5, a specific phobia involves an unreasonable fear of an object or situation which persists over time, resulting in distress or impairment that is linked to the fear and avoidance [24, 46].

Although vaccination is a beneficial public health measure, a negative aspect is that it usually involves a painful needle injection [56-57]. Although the acute pain from a needle usually subsides within a short time, there can be longer-lasting emotional consequences such as a fear of needles [24]. Low levels of needle fear are to be expected as a natural, adaptive response at all ages [24]. Long-lasting, extremely high levels of needle fear, however, are not typical and may cause the individual to cry, freeze or leave the vaccination setting [24]. In the DSM-5, the specific phobia category of blood-injection injury phobia is used to describe the unreasonable fear of needles or invasive medical procedures [35]. In a study of syncope after vaccination it was found that 77.4% of those who fainted were age 20 years or younger and 57.5 % were
female [58]. Fainting occurred within 5 minutes or less after vaccination in 63.2% of cases and within 15 minutes or less after vaccination in 88.8% of cases [58]. Some individuals who fainted incurred significant injuries [58].

Needle fear and distress during vaccination is common. It is estimated that about 25% of the population has a moderate-to-severe fear of needles and 10% of the population has a level of fear severe enough to be considered needle phobia [59]. Typically, the early childhood vaccinations take place without the benefit of fear and pain management techniques [56, 60], contributing to a higher risk of subsequent needle fear [24]. About 90% of infants, aged 15 to 18 months, and 45% of children, aged 4 to 6 years, exhibit signs of distress while being vaccinated [61]. Early negative experiences with unmanaged pain during needle procedures can lead to an exaggerated memory of pain [62], which can cause augmented distress at future procedures [63-64]. Addressing children's needle pain and fear is, therefore, important to prevent further distorted memories and anticipatory anxiety. Increased anxiety and fear of needles has been associated with increased perceived pain [22, 24, 37, 50, 65-66]. It is believed that needle fear and the intense fear that is considered blood-injection injury phobia start at about age five to ten years [67-69] when most Canadian children have already received more than twelve injections [1]. A study of children from early childhood to adolescence found that the percentage of children with severe distress during routine venipuncture decreases as the child ages: 83% of children aged 2.5 to 6 years; 51% of children aged 7 to 12 years; and 28% of children aged 12 years or older [70]. Adults who have sustained a fear of needles, however, may model their fears to their children who could become more likely to exhibit needle fear, thus passing fear to future generations [24]. In a study of travelers, with a median age of 25, it was reported that 21.7% had a fear of
needles, which was found to be most commonly associated with a fear of pain, size of needles used and a past experience of fainting [71]. A study of 449 Canadian women found that 21.2% had a mild to extreme fear of needles, with 4.9% having a level of fear labelled "phobic" [72]. Researchers found that 27% of 177 U.S. college students had a fear of needles that was so severe that it prevented them from donating blood [73]. Mitigating needle fear and pain in early vaccinations could prevent some of the needle fear and anxiety that can develops when previous negative experiences result in a cycle of increased fear and increased perceived pain [24].

1.3.5 Dizziness and Vasovagal Syncope

Dizziness is a sensation that is often classified into one of the following four categories: vertigo, a false feeling of motion such as spinning; disequilibrium, being off-balance; presyncope, feeling faint; and lightheadedness, vague feelings of being disconnected from one's surroundings [38]. Dizziness may be caused by underlying physical conditions, medication side effects or psychiatric conditions [38].

Vasovagal syncope (i.e., fainting) is losing consciousness when blood pressure and heart rate increase and then overcompensate by suddenly decreasing, resulting in inadequate blood flow to the brain and fainting [24]. The fainting is often preceded by dizziness, lightheadedness, sweating, seeing spots and/or feeling nauseous [24]. The vasovagal syncope response occurs more in individuals with a blood-injection injury phobia than in those with other phobias [24]. Of individuals with vasovagal response, about 70% have an extreme fear of blood and about 56% have a severe fear of needles [39]. Dizziness, fainting, lightheadedness and other subjective physiological reactions associated with blood donation can be measured using the Blood
Donation Reactions Inventory [74]. By extension, this inventory could be used for other needle-based procedures, such as vaccination.

1.3.6 Distress

Distress is a negative or unpleasant emotion defined customarily as a high level of anxiety, sorrow or pain [24, 45]. In the pediatric pain literature, distress is often the term used to describe the behaviours when it is hard to determine if they are caused by pain, fear, or other processes. Distress is subjective [24]. It can be adaptive when it draws attention to a problem situation or maladaptive when it impairs ability to function [24]. Children may not be capable of reliably self-reporting their level of distress so observation of their behaviour might be used for assessment [24].

1.4 Vaccination Avoidance Due to Needle Fear, Anxiety, Distress and Phobia

Needle fear and extreme anxiety can contribute to students' refusal to being vaccinated and may carry over into adulthood, leading to avoidance of future vaccines and blood tests or negative emotional or physical reactions [24]. In its 2014 report, the World Health Organization (WHO) Strategic Advisory Group of Experts (SAGE) Working Group on Vaccine Hesitancy stated that acute pain during vaccination is a factor contributing to vaccine hesitancy [48]. The group mentioned pain mitigation as a strategy to confront the problem, referring to the evidence-based guidelines authored by some members of this research team [49].
Needle fear is the reason that approximately 4% to 6% of the population avoid vaccinations and procedures involving needles [22, 50-51]. In a survey of 475 parents of at least one child of age six years or less, almost all had their child(ren) vaccinated or intended to do so but their most common (44.2%) vaccine concern was the pain from injections given at one vaccination session [52]. There was a 30% increase in parents' willingness to be vaccinated themselves and a 40% increase in the willingness to have their children vaccinated against influenza if the vaccination was given in a non-painful way [22]. The fact that parents are concerned about the pain of vaccination was emphasized in a U.S. study that found that parents were willing to pay extra for polyvalent vaccines so that their children could avoid the pain and emotional distress from childhood vaccinations by getting fewer injections [43]. In another study, parents, nurses and physicians were all concerned about vaccination pain although there was no agreement about whether there was less pain if 3 injections are given in 1 visit or over 2 visits [54]. In a different study, an increase in the number of vaccine injections given on the same day when a child was between 4 and 6 years of age, was associated with an increase in the likelihood that the child had a fear of needles five years later [55]. These studies indicate how common needle fear is and how vaccine uptake could be increased if concerns about vaccine pain were addressed.

1.5 Vaccine Fear and Efficacy of Vaccines

In addition to potentially leading to vaccination avoidance, fear of vaccination can more directly affect the efficacy of vaccines. Distress and anxiety have been associated with vaccination immune responses that were later, weaker and/or did not last as long [74]. High perceived stress has been associated with a lower immune response to the meningitis vaccination [75]. Improving the vaccine experience, therefore, could affect the strength of the immune system's response to
the vaccine. Given the emerging field of treating cancer with vaccines [76], it is important that there is optimal functioning of the immune response, undiminished by extreme stress.

**1.6 Strategies for Mitigation of Vaccine Pain, Fear and Dizziness**

1.6.1 Knowledge

The needle experience can be improved by educating children so that they are prepared for the vaccination and, therefore, have less anticipatory anxiety. Studies have suggested that the education should cover the following information: details about what will be done, length of the procedure; how the injection feels, discomfort level and coping strategies [77-79]. Preparation through knowledge allows children to better understand medical procedures, deal with their fears and decrease their anxiety [78]. Students who were prepared for venipuncture with information provided to them, given local anesthetic, and/or had their parents present were less distressed before and after the procedure compared to unprepared students, irrespective of injection history and level of parental anxiety [80]. In a study in which children learned about needle procedures and injected water into sponges, even children who had refused to be vaccinated reported that they had less fear of needles after the education lesson [81]. Taken together, these results suggest that education could improve future vaccination experience.

1.6.2 Distraction

Distraction is an important intervention in mitigating vaccination pain [83-84]. The gate-control theory [83-84] is an early pain model, which hypothesizes that cognitive attention involved in a distraction could affect the central nervous system's processing and, in turn, one’s perception of pain [85]. This theory is consistent with neurophysiological findings on imaging showing less activity in the pain-processing areas of the brain while individuals are completing distraction
tasks [86-88]. The limited-attentional theory is consistent with the gate-control theory and proposes that when some attention is given to a distracting task there are fewer attentional resources to allot to pain [89].

Many objects and activities have been used in studies of distraction to decrease pain and distress in medical procedures, including injections [85]. Distraction of young children with cartoons or music or stories was found to decrease pain and distress during injections [91-93]. Other distractions used include bubbles, kaleidoscopes and movies [78]. A meta-analysis of 19 studies with 694 children, aged 2 months to 15 years, who underwent medical procedures, including venipuncture, concluded that distraction lessened pain (10 studies) and distress (15 studies) [94]. Another meta-analysis of 26 studies of 2,548 children aged 2 to 19 years also found that distraction reduced self-reported pain and distress and observed distress in needle-related procedures [95]. It appears that the more engaged the child is with the distraction (i.e., the more attention the child gives), the less pain and less distress experienced [90-91]. Having children select their preferred distraction for vaccination, therefore, makes sense because they will be more likely to be engaged with their chosen distraction. The convenience of using distraction and the evidence-based support of its effectiveness makes distraction an important intervention for pain and distress associated with pediatric vaccination [85].

1.6.3 Deep Breathing

Slow, deep breathing is a psychological intervention that uses relaxation to mitigate needle fear and pain [96]. Deep breathing is associated with reduced stress levels, as measured by decreased
heart rate and lower salivary cortisol levels [97]. When breathing is used along with blowing toys or activities, such as bubble blowing or blowing party toys, it is also a distraction that diverts attention away from the needle procedure [96]. Breathing exercises have shown the following effects on children's vaccination experiences: decreased children's self-reported pain [98] (deep breathing at the time of injection); decreased children's observer-rated distress [98-99] (bubble blowing); decreased children's nurse-observed distress [100-101] (party blowers blowing); and decreased children's self-reported distress in one study [101] but did not affect their self-reported distress in another [99].

Deep breathing has also been shown to reduce pain in other needle procedures with children. Children between the ages of three to seven years who did deep breathing before and during an injection of local anesthesia for dental treatment exhibited less behavioural manifestations of pain, compared to the control group who did not do breathing exercises [102]. A randomized control trial (RCT) with 60 children, aged 6 to 12 years who underwent catheter insertion for thalassemia found that the group who did breathing exercises ("Hey-Hu" breathing technique, exhale saying "Hey" and inhale saying "Hu") and the group who blew bubbles (breathing and distraction) had decreased self-reported pain and behavioural pain symptoms than did the control group [103]. In another RCT with 100 children, aged 6 to 15 years, undergoing intracathedral injection (lumbar puncture) in treatment for leukemia, those who used Hey-Hu breathing during the procedure had decreased self-reported pain and observer-rated behavioural pain than did children in the control group who did not do breathing exercises [104].
1.6.4 Muscle Tension

Muscle tension exercises can be used to increase blood pressure and blood flow to the brain to prevent individuals with a history of vasovagal syncope from fainting [5, 105]. In the cyclical technique, the individual learns to alternate the repetition of tensing muscles for 10 to 30 seconds and releasing the muscle tension for 20 to 30 seconds to prevent or stop fainting symptoms [5]. The other muscle tension technique involves remaining tense for as long as possible or until the fainting symptoms decrease [106-107].

1.7 Clinical Practice Guidelines to Address Needle Pain, Fear and Dizziness

Students have expressed an interest in learning coping techniques that would improve the school vaccination experience [20-21]. Although evidence-based interventions providing coping strategies for vaccination exist, they are not consistently used [24, 59]. The Public Health Agency of Canada and the World Health Organization have brought attention to this knowledge-to-care gap [108-109]. Mitigation of vaccine pain and fear is a goal of the Immunization 2020 strategy of Ontario's Ministry of Health and Long-Term Care [110].

A Canadian interdisciplinary group, Help ELiminate Pain in Kids (HELPinKIDS), was formed in 2008 to lead KT activities to improve childhood vaccination pain management [111]. The team developed the first clinical guidelines for managing vaccination pain in 2010 which included pamphlets and videos [111]. The group later expanded to include adult vaccination and became Help ELiminate Pain in Kids and Adults (HELPinKids&Adults) [111]. After a systematic review highlighted research evidence about interventions that reduce vaccination pain, fear and fainting, in 2015 the team developed a Clinical Practice Guideline (CPG) with a focus on low-to-moderate
levels of needle-related fear [111]. Individuals with high levels of needle fear are more appropriately treated with cognitive therapy, often incorporating exposure-based interventions [112]. Evidence-based recommendations specifically for the school vaccination setting were not included because primary research in this context was lacking [113].

1.8 The CARD™ System for School-based Vaccination

To address the knowledge-to-care gap in the school vaccination setting, selected members of the CPG panel, the Pain, Pain, Go Away team, undertook research for an evidence-based KT intervention which would adapt the CPG recommendations to the school setting [114]. Experiencing pain entails a complex interaction of a pain stimulus and various psychological and social influences [115]. The complexity involved made development of a multifaceted, comprehensive intervention essential and also made it necessary for researchers assessing the effectiveness of the intervention to measure fidelity in its implementation.

Partnering with a public health unit (Niagara Region Public Health) and school board, we obtained feedback from 9 students and other stakeholders in school-based vaccination (12 nurses, 6 school staff members, 7 parents) [116]. In focus groups, the stakeholders described the following information and opinions: their school vaccination experiences; barriers and facilitators to a positive vaccination experience; their needs and preferences of particular fear, pain and fainting mitigation interventions; preferences for learning about vaccination; required resources (e.g. time, personnel, technology); and feasibility of incorporating pain, fear and fainting interventions in the existing processes and infrastructure. Feedback about KT interventions was also obtained from the stakeholders after they viewed the following CARD™ components: a video about vaccination; a video about pain and fear mitigation strategies; a slide
presentation about the vaccines to be given in school, and pain, fear and fainting mitigation interventions; and a pamphlet about the mitigation strategies. Transcripts of the discussions were analyzed using directed content analysis [117], as guided by the Consolidated Framework for Implementation Research (CFIR) [118].

The focus group discussions among stakeholders in school vaccinations [116] revealed concerns based on past vaccination experiences. Among others, students wanted information on ways to cope with pain and fear that would be presented in a video rather than in a ‘dull’ PowerPoint lecture by a nurse [116]. They wanted to know more about topical anaesthetics for vaccination. Students and adults expressed a need for nurses and teachers to be compassionate when dealing with students getting vaccinations. All groups suggested that having a parent or friend present for support would be beneficial. Some students preferred having a private room for vaccination. Some nurses proposed that a small physical barrier to block needle preparation from the student's view would help to mitigate fear. Nurses and school staff expressed a need for better communication, collaboration and definition of roles to improve the chaotic atmosphere that often exists. Documentation of students' levels of fear was considered helpful for future clinics. These focus group results were used ultimately in creating CARD™.

Using the feedback from stakeholders [116] and published literature, the team created The CARD™ System, a multifaceted approach to school-based vaccination that promotes student-centred care and coping strategies, including planning before and delivery on the school vaccination day [7]. The KT tools for pain, fear and dizziness mitigation were grouped using the acronym "CARD", for pain and fear mitigating strategies to be used for school vaccination [113]
"C" - Comfort (e.g. presence of a friend); "A" - Ask (e.g. answering students' questions); "R"- Relax (e.g. deep breathing); "D"- Distract (e.g. bubbles, cell phones) (Figures 1-2).

The CARD™ System includes the following interventions:

**Preparatory Interventions**

- Public health unit-to-school communications and planning checklists for preparation
- Training resource materials for nurses

**Interventions Used/Disseminated at Education Sessions**

- A slide presentation for students about vaccinations and pain, fear and fainting mitigation strategies
- A video for students about vaccinations, reasons for vaccination, eligibility for vaccination (Video 1)
- A video for students about CARD™ coping strategies to mitigate pain, fear and fainting (Video 2)
- A CARD™ Pamphlet for students to fill in which coping strategies they would like to use on clinic day
- Case scenarios for students to practice applying CARD™ to different situations
- School posters
- Take-home brochures for students and for parents
- Brochures for school staff

**Interventions used for Vaccination Clinics**

- Communications and planning checklists for vaccination day for nurses
- Assessment and management materials for injecting nurses
Audit and feedback materials for vaccination clinics to record symptoms, interventions used, injections given, returning unwell students

Distraction toolkits (bubble pens, spinners, pipe cleaners)

Table dividers to hide injection preparation

1.9 Preliminary Research with CARD™

The researchers conducted focus groups about three CARD™ tools with stakeholders in school-based vaccination programs, with 22 students, 10 nurses, 16 school staff and 3 parents [114]. Each stakeholder group had a separate focus group session, led by the lead researcher’s graduate supervisor, with three components: surveys before the tools on knowledge about vaccine pain, fear, and dizziness mitigation strategies and their attitudes about individual differences in the vaccination experience; reviewing the main tools of CARD™, (two videos and pamphlets) and group discussion; and surveys after the tools. Across all stakeholder groups, knowledge about vaccines and strategies for pain, fear, and dizziness increased post-tool. Scores of student fear decreased post-tool review. Stakeholders’ attitudes post-tool showed a greater understanding of how the vaccination experience varies for each individual, so they seemed to be more tolerant of the negative aspects of the vaccination experience. Most reported that the information was understandable, useful, and that an appropriate amount was provided.

Three KT tools of the CARD™ System, two videos (Video 1 and Video 2), and the pamphlet (for students to choose their coping strategies) were assessed. Eleven grade 7 students participated in focus groups before and after school vaccination day and completed knowledge and attitude surveys before and after the KT tool intervention [119]. Knowledge scores were
higher post-tool than at the pre-tool baseline but fear scores and attitudes about vaccination were the same before and after the tool intervention [119]. They complained that nurses and teachers did not adequately create a positive vaccination experience by, for example, failing to offer a private setting for vaccination and prohibiting some of the coping strategies that the KT tools had recommended [119]. The students believed that the KT tools helped prepare them for vaccination day and that all students should use them [119]. The study concluded that the three KT tools from the CARD™ System were acceptable and relevant for students but for proper implementation, there was a need for improved involvement of teachers and/or nurses [119].

Through the studies reviewed above, the three main KT tools of CARD™ were shown to be acceptable, relevant to the needs of students and other stakeholders and effective. Student fear decreased as knowledge about vaccinations increased and attitudes improved. However, the effects of CARD™, when fully implemented, on the student experience during school-based vaccinations had not yet been examined. We, therefore, undertook a small-scale controlled trial to determine the impact of CARD™ on the school-based vaccination experience [7]. We assessed the effect of CARD™ on students' knowledge about mitigation strategies, students' use of pain and fear mitigation strategies and the ratings of their symptoms (pain, fear and dizziness) during vaccination [7].

1.10 Overview of Thesis

In an earlier phase of the research study, we developed CARD™, a KT intervention for the planning and delivering of school vaccines. My Master’s thesis project is the final portion of the larger study examining the effects of CARD™ when fully implemented in the school setting. For my thesis, my primary outcomes of interest were self-reported levels of pain, fear, and dizziness
immediately after vaccination of Grade 7 students at schools implementing CARD™ compared to students at control schools. We collected these data at all round 1 (fall vaccination clinic) and round 2 (spring vaccination clinic) vaccination clinics coinciding with the immunization schedule for Grade 7 students, as determined by the region’s public health unit (Appendix A). My secondary outcomes included a comparison of scores on knowledge questionnaires about vaccination pain, fear, and dizziness mitigation strategies before and after the CARD™ education session at schools implementing CARD™ (Appendix B), and fidelity in the implementation of CARD™ (Table 9, Appendices C-E). To collect the knowledge questionnaire data, the lead researcher was present at each education session and additionally drafted observational field notes. The lead researcher evaluated fidelity through the completion of several fidelity checklists at both the education sessions and vaccination clinics. Fidelity as an outcome was measured as an outcome because in order to assess effectiveness of CARD™, fidelity in its implementation is important. Lastly, there was an examination of which mitigation strategies were used during vaccinations by students at schools implementing CARD™ and by students at control schools (Appendix E). The lead researcher collected these data at the vaccination clinics.
Chapter 2: Written Manuscript

2.0 Overview and Contributions

This chapter includes the manuscript accepted for publication, as formatted for Paediatrics & Child Health. This manuscript was published on March 29, 2019.

My contributions to the manuscript include: data collection and entry, transcribing audio recordings of focus groups, assisting to analyze and interpret the qualitative data with members of the research team; assisting in interpretation of the quantitative data, which was statistically analyzed by a statistician; and drafting and finalizing the manuscript with input from the co-authors.

The purpose of the study was to objectively measure the effect of CARD™ on students’ vaccination pain, fear, and dizziness using quantitative measures. The qualitative findings were included as part of the manuscript to increase understanding of the students’ subjective vaccination experiences but are not part of my thesis. The results examining fidelity to using The CARD™ System were not included as part of the manuscript, so the findings are presented in ‘Chapter 3: Fidelity Results,’ following this chapter.
2.1 Published Manuscript

The CARD™ System for improving the vaccination experience at school: Results of a small-scale implementation project on student symptoms

Tamlyn Freedman BAS¹, Anna Taddio BScPhm PhD¹,², Leslie Alderman RN³, Tori McDowall RN³, Christene deVlaming-Kot RN MHSc³, C. Meghan McMurtry PhD⁴, Noni MacDonald MD⁵, Angela Alfieri-Maiolo RN MPH², Derek Stephens MSc², Horace Wong MSc¹, Heather Boon PhD¹; the Pain Pain Go Away Team

Affiliations: ¹Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, Ontario; ²The Hospital for Sick Children, Toronto, Ontario; ³Niagara Region Public Health & Emergency Services, Thorold, Ontario; ⁴University of Guelph, Guelph, Ontario; ⁵Dalhousie University, Halifax, Nova Scotia

Correspondence: Anna Taddio, Leslie Dan Faculty of Pharmacy, University of Toronto, 144 College Street, Toronto, Ontario M5S 3M2. Telephone 416-978-8822, fax 416-978-1833, e-mail anna.taddio@utoronto.ca


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Abstract

Background

Many students are afraid of receiving vaccinations at school. We implemented a novel, multifaceted knowledge translation intervention incorporating evidence-based vaccination coping strategies—The CARD™ System (C-Comfort, A-Ask, R-Relax, D-Distract)—and evaluated impact on student attitudes, knowledge, coping strategies used, and symptoms during school-based vaccinations.

Methods

Mixed methods. Ten schools participated in a controlled clinical trial: five experimental and five control. Experimental School (ES) students completed a knowledge and attitudes survey during an in-class CARD™ educational session prior to school vaccinations and selected coping strategies for upcoming vaccinations. Control School (CS) students received the usual vaccine education lesson, which did not include information about or selection of coping strategies. At all schools and during both vaccination clinic visits (fall and spring), injecting nurses recorded specific coping strategies used, and students independently rated their fear, pain, and dizziness during vaccinations. Focus groups were conducted at five schools after all clinics were completed (three ES, two CS).

Results

ES students had higher knowledge (P<0.001), less fear (P=0.03), and greater willingness to be vaccinated (P=0.001) after the in-class education session. Students rated the education as
understandable, sufficient, useful, and that it prepared them for vaccinations. During school vaccination clinics, ES students selected more coping interventions than CS students. There were fewer students with high levels of fear (P=0.008) and dizziness (P=0.04) in the ES group. In round 2, fewer students (P=0.02) in the ES group returned to the clinic post-vaccination because they were feeling unwell. ES students participating in focus groups scored higher on their knowledge test (P<0.001) compared with CS students and reported learning and benefitting from CARD™.

Discussion
This small-scale implementation study provides preliminary evidence of the effectiveness of CARD™ in improving vaccination experiences for students at school. Future research is recommended that examines CARD™ in different settings to confirm these results.
BACKGROUND

Vaccines are considered integral to prevention and control of infectious diseases (1). All Canadian youth are offered free vaccination via school-based programs. Many of them can have negative experiences or refuse vaccines due to fear of injection-associated pain (2). Public health institutions routinely provide vaccine-related education; however, it emphasizes information about diseases and vaccines. Students have expressed a desire to learn coping techniques for improving the school vaccination experience (3,4). Although evidence-based interventions are available (5), they are not widely implemented (2). Knowledge Translation (KT) strategies that facilitate uptake of interventions have not been adapted for the school vaccination setting.

A program of research was initiated to address this knowledge-to-care gap (6,7). Using feedback from students and other stakeholders involved in school-based vaccinations (nurses, school staff, parents) and published literature, we developed a multifaceted KT intervention called The CARD™ System (C – Comfort, A – Ask, R – Relax, D – Distract)—herein called CARD™—to try to improve the vaccination experience for the students (3,4,8). CARD™ provides a framework for planning and delivering school vaccinations that is student-centred and promotes coping. Preliminary research demonstrates that key tools of CARD™ are acceptable and relevant to the needs of students and other stakeholders (9,10). However, its effects when fully implemented in the school setting have not been examined. We therefore planned a small-scale controlled implementation study that examined the impact of CARD™ on different vaccine delivery program outcomes. In this article, we report on the effectiveness on improving students’ knowledge, attitudes, use of pain, fear and fainting mitigation strategies, and symptoms (pain, fear, and dizziness) during vaccination. Separately, we report on other program delivery outcomes (11).

METHODS

Design

The study utilized both quantitative and qualitative components, including a controlled clinical trial and focus group interviews in a subsample of participants.
Participants and setting

Participants were grade 7 students from ten schools serviced by Niagara Region Public Health in Niagara Region, Ontario. Five schools acted as the experimental schools and five acted as the control schools. The schools were selected with the input of the school board and matched on size and socio-economic status of residents in the neighbourhood.

Procedures and measures

Two vaccine clinics were held in both experimental and control schools; one in the fall (round 1) and one in the spring (round 2). Students were typically given one dose of both hepatitis B and human papilloma virus vaccine in each clinic. Quadrivalent conjugated meningococcal vaccine was provided at one of the two clinics.

Public health personnel involved in the school vaccination program included nurses assigned to each school (school liaison nurses) and vaccine clinic nurses (charge nurses and injecting nurses). The school nurses plan the fall clinics, including: confirming spaces, delivering in-class education to students about vaccination, distributing consents to students, and organizing returned consents in preparation for the clinic. The liaison nurses are present at all fall clinics and are involved in triaging students, supervising waiting students, and acting as supports for students during the clinic.

Charge nurses and injecting nurses are present at both clinics. Charge nurses ensure the clinic room space is arranged appropriately, support injecting nurses during the clinic, and oversee clinic statistics and consent forms. Charge nurses work with liaison nurses to make sure all students are seen and that there is good flow with school activities. Charge nurses assume responsibility for organizing consents, triaging and supervising students when the liaison nurses are not present. Vaccine clinic nurses are primarily responsible for vaccination administration and documentation activities but can also be involved in making telephone calls (to parents), clinic flow and triaging. Additional details regarding the preparation and delivery of vaccinations for the two groups is described below.
Prevaccination in-class student lesson

Experimental schools

Prior to the first set of school vaccination clinics in the fall of 2017, an in-class education lesson lasting approximately 80 minutes (i.e., two class periods) was delivered by a school liaison nurse. The lesson consisted of baseline questionnaires, a multimedia presentation, and post-presentation questionnaires. At baseline, students independently completed a knowledge test (10 yes/no questions about the effectiveness of various strategies to reduce pain, fear, and fainting) (7), and then answered questions regarding their level of fear of vaccination needles (11-point scale, from 0 to 10), and willingness to get vaccinations (five-point Likert scale, from yes to no (1=yes, 2=maybe, 3=don’t know, 4=maybe no, 5=no) [Appendix A].

The nurse then delivered a multimedia presentation consisting of information about: a) the specific diseases being protected against with the vaccines being offered (PowerPoint slides), b) how vaccines work, possible side effects, and school-based vaccination procedures (CARD™ video 1: https://youtu.be/z57vTpb19wQ); and c) instructions on coping with pain, fear and fainting during vaccination (CARD™ video 2: https://youtu.be/c41HvgEKQSk).

A researcher was present to assess fidelity throughout the education lesson, observing and documenting the process. The researcher completed an education lesson checklist (Appendix B) and documented whether the two videos were watched and the number of case scenarios that were reviewed (out of a total of five). The researcher wrote down the question asked by students and the answers given by the school liaison nurse. During the pre-lesson and post-lesson questionnaire, the researcher checked all completed forms and asked students to fill in omissions.

After the presentation, the nurse distributed a pamphlet to students that summarized CARD™ (7). The pamphlet included a list of strategies for each of the letters of CARD™ and blank spaces for students to list the strategies they wanted to use for their upcoming vaccinations. Students recorded their preferences, and they were reviewed by the nurse and lead author for the purposes of planning the vaccination day (see below: Organization and preparation of vaccination clinics). If there was time, the nurse discussed hypothetical scenarios with students and the CARDS that could be played to mitigate the concerns presented in the scenarios. The
same knowledge and attitudes questionnaires were then administered. An additional survey about
students’ opinions of the education session was then completed, with questions about level of
understanding, amount of information, usefulness of information, and student level of
preparedness for vaccination (7). Scores were dichotomized for analysis.

At the end of the education session, the nurse distributed and reviewed the vaccination consent
package for students to bring home, which consisted of a pamphlet with information about the
diseases and vaccines being offered to students, a CARD™ pamphlet for parents (7), and the
vaccination consent form that was to be completed and returned to the school before the first
school vaccination clinic date. After the session, the nurse reviewed all the CARD™ pamphlets
(approximately 10 minutes, depending on the number of students) to record special requests
(e.g., privacy) for the clinic. The nurse provided teachers with a poster about CARD™ for the
classroom.

Control schools

In the fall of 2017, nurses delivered an in-class education lesson lasting approximately 40
minutes (i.e., 1 period). This included a 15-minute slide presentation with information about
vaccine-preventable diseases and vaccines being offered to prevent them, and how to prepare for
vaccination (e.g., wearing appropriate clothing, eating breakfast). There was some overlap with
the slide presentation in the experimental schools. After the presentation, there was a brief
question and answer period. The school nurse distributed and reviewed the vaccination consent
package, which included the same information as the intervention school package except it
excluded the parent pamphlet about CARD™. Students did not complete knowledge or attitudes
questionnaires, nor select strategies for coping.

The researcher and liaison nurse were present at all control schools’ in-class education lessons
where they took observational field notes and documented any questions students had for the
nurse.

Both experimental and control school liaison nurses visited their respective schools a few days
before the fall clinic date to collect and organize returned consent forms. For experimental
schools only, the nurse briefly reviewed CARD™ with individual students who were absent on
the day of the in-class education lesson (approximately 5 minutes, depending on the number of students involved). They also reviewed any scenarios that were not discussed during the lesson because of time constraints with the entire class (approximately 5 to 10 minutes).

In all experimental schools, the liaison nurse contacted the principals prior to round 2 clinics to remind them of upcoming clinics and asked them to provide reminders to school staff, students and parents via usual school communication methods (e.g., school announcements, classroom announcements, electronic messages). Nurses then ensured that these reminders were provided. In control schools, the charge nurse contacted the principals to remind them of upcoming clinics. The principals may or may not have communicated this information with school staff, students, and families.

*Organization and preparation of vaccination clinics*

**Experimental schools**

The experimental school liaison nurses and the researcher were present at both school vaccine clinics. The researcher was present to assess fidelity of the clinic. A checklist was used for proper clinic setup (Appendix C). The researcher documented clinic preparation, clinic arrangements, materials needed for CARD, clinic flow, consent form retrieval and other clinic processes. For both rounds, the charge nurse and injecting nurses attempted to minimize visual cues that could increase fear when setting up clinic spaces. A separate waiting area was set-up for students waiting for vaccination outside the clinic room (i.e., outside the school library). Dividers were placed on the tables so that equipment (needles, syringes) was not easily visible to students. Over time, additional measures were taken, including covering the clinic windows to prevent viewing of clinic activities from the outside, setting up chairs so that students faced opposite to other students and nurses, providing more space between the clinic tables, and making the clinic space inaccessible to individuals not associated with the clinic. If there were two ways to access the main clinic space, then one served as an entrance and the other an exit so that students did not cross paths. A separate office in the library served as the privacy room for students who selected this option. In addition, a distraction toolkit was provided for each clinic workstation, consisting of bubble pens, fidget spinners, and pipe cleaners.
Before the vaccination clinic began, the liaison nurse briefly reviewed CARD™ strategies with the students and introduced the injecting nurses to the entire class (approximately 5 minutes). The classroom teacher distributed the students’ CARD™ pamphlets. Liaison nurses coordinated the order in which the students were called from class according to their selected coping strategies on their CARD™ pamphlets. Changes could be made by students on the day of vaccination. Students who identified as highly fearful, seeking privacy, or requesting a specific friend for support were triaged. Liaison nurses assisted with managing crowd control and distracting students waiting for their turn to be vaccinated.

Control schools

In control schools, liaison nurses were present during round 1 clinics only. The charge nurse assumed the role of the liaison nurse in round 2. Students all waited in the same room and could see peers being vaccinated. There was no attempt to modify the tables and student positioning to prevent students from seeing each other or equipment. There was no private space. Students were called out of classrooms in alphabetical order.

For experimental and control groups, a few students were taken out of class at a time; this corresponded roughly with the number of injecting nurses (between 2 and 5). In round 1 clinics, the first group of students were accompanied by the liaison nurse, with subsequent groups of students going to and from the clinic unsupervised. In round 2, the charge nurse led the first group of students down to the clinic if the liaison nurse was not present. In experimental schools, students could be left unattended while waiting outside the clinic. They were allowed to use electronic devices or other distractions while waiting.

Vaccination process

Experimental schools

When it was a student’s turn for vaccination, the student was directed to the injecting nurse by the charge nurse. The nurse introduced herself, carried out a medical history, and asked students about their level of fear. In the first round of school clinics, injecting nurses inquired about student fear using a dichotomous scale (yes/no) prior to vaccination. In the second round, this question was changed to a continuous scale (0 to 3) to improve sensitivity of the assessment. Injecting nurses then asked the student ‘what CARDS he or she would like to play’ during
vaccination. The researcher monitored the nurse-student conversations to ensure that that phrase was being used for every student. Nurses accommodated their requests. Nurses invited students to use any of the items from their distraction toolkit if students wanted a distraction and did not have one. Some teachers sent students to the clinic with the CARD™ pamphlets in round 1; however, these were retained by the classroom teacher in round 2 as they were determined not to be necessary (i.e., students did not use them).

In addition to the above described observations, for assessment of fidelity, the researcher closely monitored 10% of student-nurse interactions at each school clinic (Appendix D). The researcher documented the nurse-student conversation, coping strategies used, relative length of the nurse-student interaction, and the researcher’s assessment of the quality of the nurse-student interaction. The injecting nurses fill out an identical questionnaire to be compared later to the researcher’s form for fidelity.

Control schools

Injecting nurses followed the same approach as in the experimental schools except that they did not inquire about student level of fear and did not ask students about the strategies they wanted to use. Some nurses brought their own distraction items (e.g., stickers); however, this was not standardized. Injecting nurses engaged in dialogue during the vaccination process to try to distract students. They directed students to inhale while the nurse counted down from three and then to exhale when the nurse administered the vaccine. Occasionally, injecting nurses instructed students to look away.

In both experimental and control schools, immediately after being vaccinated, students were sent to a work station in the clinic room to independently complete a questionnaire where they rated their pain, fear, and dizziness during vaccination on an 11-point scale from 0 to 10 (8) (Appendix E). Injecting nurses recorded the coping strategies used for pain, fear and fainting on a checklist (8). The number of students that returned to the clinic because they were feeling unwell was recorded for each group.

As done in experimental schools, for 10% of nurse feedback questionnaires, the lead author conducted reliability checks on the data recorded by the injecting nurses to confirm fidelity. The
researcher documented the nurse-student conversation, coping strategies used, relative length of the nurse-student interaction, and the researcher’s assessment of the quality of the nurse-student interaction. Thirty-one checklists were completed in duplicate in each round and the per cent agreement on the individual items was 100%.

Nurse training and measures taken to prevent contamination

Ten nurses were trained in CARD™ prior to its implementation in experimental schools (two liaison nurses and eight injecting and charge nurses) via an educational workshop (8,10). They were provided with policies and procedures, CARD™ resources (videos, pamphlets) and supported throughout the study by department managers, an internal study champion, and external content experts (via the study champion and department managers). Part-way through the year, a new liaison nurse was trained in CARD™ by the study champion to take over the responsibilities for another liaison nurse who left the program. Nurses trained in CARD™ did not deliver education or vaccinations to control schools and control school nurses did not deliver education or vaccinations to experimental schools. Nurses trained in CARD™ did not discuss CARD™ with nurses not trained in CARD™. Control nurses followed usual practices.

Focus groups interviews

Within 2 weeks of the completion of round 2 vaccination clinics, invitations were sent by school principals to students, parents, and school staff of participating schools to participate in focus group interviews to share their experiences with school vaccinations. In this study, we report on the data for students; the data for other groups are reported separately (10). Focus group interviews consisted of quantitative and qualitative components, including knowledge and fear questionnaires (same tool as for the in-class education session in experimental schools) and a facilitated focus group interview led by the second author using a semi-structured interview guide. In experimental schools, students reflected on their vaccination experience at school in round 1 and 2 clinics, and on CARD™. In control schools, students reflected on their vaccination experience in round 1 and 2 clinics. In both experimental and control schools, students were asked for their opinions as to how to improve school vaccinations.
The study received ethical approval from the University of Toronto Health Sciences Research Ethics Board and local school board. Informed consent was obtained from all focus group interview participants. Consent was waived for in-class education and clinic data to allow for collection of population level data.

**Sample size and analytic strategy**

The number of schools selected was based on feasibility. With 120 students per group, we could detect a 50% reduction in the rate of students with high levels of fear (score > 6 on a scale that ranges from 0 to 10) if the rates were 30% in the control group and 15% in the experimental group rate with a power of 80% and alpha=0.05 (SamplePower™).

For the experimental group, student acceptability of the in-class education (yes/no) was summarized descriptively. Pre–post-education knowledge test scores and attitudes were analyzed using a paired t-test. Use of specific coping strategies (yes/no) was compared between groups using Chi-squared test. Student symptoms (i.e., fear, pain, and dizziness scores) were compared using repeated measures analysis of variance using Proc Mixed adjusting for sex and number of injections, with clustering (schools) accounted for by fitting a random effect. We examined group, time and group x time interactions (i.e., whether the effect of treatment depends on time). Outcome data were dichotomized into yes/no using a cut-off of > 6 out of 10 (this is the usual threshold for severe pain and was applied to fear and dizziness as it was deemed to be clinically significant to stakeholders), then data were analyzed using logistic regression using Genmod and Glimmix, adjusting for sex and number of injections. Clustering was accounted for by fitting a random effect. Group, time, and group × time interactions were similarly examined. The number of students returning to the clinic after vaccination because of postvaccination symptoms was compared using Chi-squared test. Focus group knowledge test scores and fear levels were compared between groups using a t-test. All analyses were conducted using SAS v.9.4 and SPSS v.24; the significance level was 0.05.

A maximum of one focus group per school was conducted with a target sample size of 3 to 12 participants. The focus groups were audio recorded, transcribed and analyzed by three individuals that identified themes together. Using directed content analysis, themes were
categorized according to the domains of the Consolidated Framework for Implementation Research (CFIR) (12).

RESULTS

The study was conducted from June, 2017 to June, 2018. Altogether, 163 and 160 students were in grade 7 in the five participating experimental and five control schools, respectively. A total of 124 and 123 students, respectively, were vaccinated at school in round 1 in the experimental and control schools, respectively. One student in the control school had special needs and was vaccinated with the assistance of an Educational Aid. For round 2, there were 111 and 112 vaccinated students, respectively. There were no differences in the characteristics of students in each group (Table 1). Five focus group interviews were conducted with students in three experimental schools and two control schools, including a total of 23 students (13 in the experimental group and 10 in the control group) (see Table 2 for participant characteristics).

Quantitative data

Table 3 displays pre- and post-education knowledge and attitudes of students in the experimental group. Knowledge scores were higher post-education ($P<0.001$). Student level of fear was lower ($P=0.03$). There was an increase in willingness to be vaccinated ($P=0.001$).

Table 4 displays student feedback from students in the experimental group regarding the in-class education. The majority of students reported that: a) they understood the information, b) the amount was just right, c) the information was useful, and d) they felt prepared for vaccination.

Table 5 displays the frequency of use of different coping strategies during vaccination. There were a significantly greater number of students in the experimental group that used the following strategies at round 1 and 2 clinics ($P\leq0.03$ for all analyses): external distraction aid, friend as a support person, privacy, deep breathing. The frequency of verbal distraction was higher in the experimental group in round 2 clinics ($P=0.02$). There was no difference between groups in the utilization of topical anaesthetics or lying down during the procedure.
Mean student fear, pain, and dizziness scores are displayed in Table 6. Fear scores showed a group × time interaction (P=0.04). Scores were lower for the experimental group at time 2 (P=0.02), however, there were no differences between groups at time 1 (P=0.17). Pain scores showed a group × time interaction (P=0.004). There was no evidence of a difference, however, between groups at time 1 (P=0.80) or time 2 (P=0.22). Dizziness scores showed no significant effects of group (P=0.07), time (P=0.85) or group × time (P=0.96).

Dichotomized (high/low) fear, pain, and dizziness scores are displayed in Table 7. Fear showed a significant group effect (P=0.008); fear was lower in the experimental group (OR=0.47; 95% confidence interval [CI] 0.27 to 0.82). There was no significant effect of time (P=0.39) or group × time (P=0.69). Pain showed no evidence of group (P=0.87), or time (P=0.43) effects, and no group × time interaction (P=0.67). Dizziness showed a significant group effect (P=0.04); dizziness was lower in the experimental group (OR 0.26; 95% CI 0.07 to 0.91). There was no evidence of time (P=0.28) effects, or a group × time interaction (P=0.71).

Six students in the control group and 1 in the experimental group returned to the clinic because they were feeling unwell in the first round of clinics (P=0.054). In the second round, it was 8 and 1, respectively (P=0.02). No students fainted in either clinic 1 or clinic 2.

In focus groups, students in the experimental group scored higher on the knowledge test compared to control group students (P<0.001) (Table 8).

**Qualitative data**

Student responses from the focus groups were categorized into two domains of CFIR: 1) intervention characteristics; and 2) characteristics of individuals. The themes that emerged from the focus groups are described below, with example quotations. The students are identified by study group (ES – experimental school, or CS – control school) and participant number.

**Intervention characteristics (The CARD™ System)**

*Education session: General*
Experimental school students reported increased vaccine-related knowledge after the prevaccination education session. Students felt that CARD™ helped prepare them for vaccinations. ES4: “The CARD strategy definitely helped me with learning how to distract myself and different ways to calm myself and relax myself.” ES3: “I agree with everybody here. I think that it did help me and you should continue to do that because it comforted me a lot more knowing what was gonna happen and what I could do.”

Some students in the control schools expressed a need for information on ways to cope with vaccinations. CS1: “I think for people who get nervous or dizzy over needles, I think it’s good to have tactics or things you could do to make it better, probably it would help a lot.”

Even though the experimental school focus groups were conducted 7 months after their educational sessions, students recalled the components of the CARD™ acronym. ES11: “The C stood for comfort, the A stood for ask and then the R stood for relax and D is distract.” ES3: “I know [CARD]. And I know my strategies that work best for me and it helps me.”

Conversely, students in the control schools had difficulty remembering the brief, standard lesson. “Facilitator: Do you remember the lesson you had at school with the vaccine nurse in the fall where she came and talked to you a little bit about vaccination? … CS2: “No.” CS3: “I don’t remember it at all.”

**Education session: Videos**

The video portion of the educational lesson was especially appreciated by students in experimental schools. Students found it helpful to know what to expect in the vaccination process. ES1: “…nothing was really a surprise. The videos were almost spot on with everything that was gonna happen so they helped out a lot.” Students in control schools expressed a desire for a prevaccination video that would prepare them. CS6: “[Having] a video. Like a visual representation of them explaining how they feel and how it felt and how you can, like, coping strategies.” Experimental school students found the educational videos to be comprehensive. ES11: “I think it was good. Like they covered everything and made sure we… knew what we were doing… showing you how they were actually gonna do it. They were trying to count down the steps to how they’re gonna do it to make you prepared.”
Reminders

Students from experimental schools stated that the nurses’ reminders of vaccination day approaching and a brief review of CARD™ were helpful. ES6: “When the time was closer to the vaccination the nurses came in again just to remind us that there—it was coming close. So I did, I kept it in my head that—things to do when I do have to have the needle. And strategies to work with it.”

Relative advantage: Choosing to be vaccinated at the school clinic over the doctor’s office

Experimental school students found the nurses provided a more comforting experience than the doctor’s office. ES11: “… it’s just like the manners of the different nurses. Like the nurses at school, they’re more caring and like, comforting. But the nurses at the doctors’ offices are just like trying to get through everybody…” Some students pointed out that doctors’ offices do not often provide distraction techniques, unlike their schools, which adopted CARD™. ES6: “… But I was never given the strategies that I was for [CARD] because at the doctors they don’t give as much before, they just give you the needle.”

Class introductions

Experimental school students appreciated the way the injecting nurses were introduced to them in their classroom before the clinic started, rather than meeting the injecting nurses for the first time as they sat down just before their injection in the clinic. ES6: “I liked how the nurses came in the classroom because I saw like who was doing it, like the people around, like they’re professional. Like to remind us that we’re getting them done to help us and benefit us…”

Relative advantage: Compared to students vaccinated at school in the past

Students at the experimental schools valued the role of CARD™ in improving their vaccination experience at school. ES6: “… some people in the past grades didn’t have [CARD]… my grade got it, but if now that that we have this in our head, that we have these ideas, we won’t have to feel the pain of the other… we have strategies now to work with it. But before they didn’t, so
they might have to do the vaccinations without any help. That’s why this CARD System worked for me.”

**Clinic process**

Some experimental school students commented on being able to be vaccinated with a friend. ES1: “...I brought my friend with me, so that made it better in the sense that I had someone with me.” Several students in control schools expressed that they believed fearful students should be able to go to the clinic with someone they were friends with, as opposed to following alphabetical order. CS10: “... it’s in alphabetical order and unless you’re friends with the person that’s beside you in the alphabet, you’re kinda just with someone like that you know that’s in your class but you’re not very close with.”

Experimental school students could not see students being vaccinated because they were waiting out in the hallway. In control schools, students waited in the same room (i.e., library) where the vaccinations were given. CS1: “They had chairs against the wall and then 5 people would wait there and then they’d go and call 5 more people.” A control school student described seeing others in the library while he was waiting for his turn, which increased nervousness. CS6: “… everyone was looking around and started getting nervous cause they were seeing the nurses preparing the needles and the injections and everybody getting it and making those faces…”

**Privacy**

Students in experimental schools appreciated having the option of privacy. ES1: “... I had the private room as well, that made it better... it was actually way more helpful...” Some control school students would have preferred vaccination in private. CS1: “The first time I was with one of my friends, and he started crying... he got really nervous watching all of us... I prefer not being in a room with people because I don’t really like people watching me ...” CS6: “I think privacy is the best thing because that way it shows that the nurses care about the students and how they’re feeling and all that.” Privacy was not a preference for other control students. CS3: “To see other people go through it and still be calm gives me courage to stay calm and go through it without going crazy.”
Distractions

Many experimental school students liked having the option to use external distraction aids as part of their school vaccination experience. ES4: “… I like how there was a lot of distractions that they provided us with. There [were] different toys you could play with and we were allowed to have our electronics with us.” When asked if the distraction aids helped this student, the participant answered, “Yeah, definitely.” ES5: “Well I brought my friend and there was a lot of fidget toys there… and I just like distracted myself and I looked away and I was like focusing on my friend and I was fidgeting.”

Experimental school students appreciated that school staff allowed them to bring their electronic devices to school for distraction purposes. ES1: “We usually bring our phones to school and we put them away ‘cause we’re not really supposed to be on them. But like for this occasion I think like our teacher understood like all of us were nervous and if we have our phones there it would take away our nervousness.” Students felt that they are old enough to be trusted to use their devices responsibly. ES3: “I think [we] should be trusted enough by grade 7 to know just to go on games and they shouldn’t be going on anything else.”

The students at experimental schools found having a ‘buddy’ present at the vaccination served as a distraction and helped to relax students. ES10: “He just distracted me. We just talked.” ES11: “My buddy helped me. He let me blow bubbles in his face and then he was trying to catch them so like it made me laugh and relax.” In discussing the qualities of a good buddy, students mentioned knowing their buddy well and enjoying their buddy’s company. ES11: “They’ve been around for me like my whole life so I know them and they’re nice to be around.”

The control school students acknowledged that some students would benefit from having a friend with them when vaccinated. CS1: “My friend who was like crying, I think it would’ve been better if he had one of his friends because he went in with one of the girls- he didn’t have anyone- company I guess who could’ve maybe made him feel better about it.”
CARD™ strategy flexibility

Some experimental school students mentioned they liked the flexibility of changing strategies between clinic 1 and clinic 2, picking the ones that would be most beneficial. ES11: “the first time I just did the distract CARD and I was just talking to my buddy.” ES12: “but the second time I used the R and the D CARD. I was distracted by my buddy.” ES9: “and we were blowing bubbles at each other, so it was fun and got my mind off the needle.”

Characteristics of individuals

Knowledge and beliefs: Disclosing fear and preferred vaccine accommodations

Students in both experimental and control schools expressed that their willingness to identify their fear of vaccines varied between students. ES1: “… Everyone has a different like take on that. So it’s like 50/50—half of them may have said like, “oh like I’m really scared” and some of them may have just like kept it to themselves…”

Some control school students suggested that it would be a good idea if students could indicate they were fearful. CS5: “… there should be an option on that paper like is there like, um, like is there any way like we can help them not be scared or like any way, you know. If he needs privacy while doing it, should be an option on the form that says that.” CS6: “there should be an option on the piece of paper cause that way they can look at the paper and they know, oh here, she needs the privacy.”

Self-efficacy: Being a supportive buddy

The experimental school students felt that with the CARD™ strategies, they were empowered to help their peers and younger students. ES10: “So if you know what people need you can help, you can help your buddy out by doing the specific tasks and such like helping them like distract them or just keeping their eyes away from the needles.” ES7: “Yeah, I’ll probably like pass it down. So like some of them … have a needle when [they’re] younger.”

Self-efficacy Using CARDTM
Some students in experimental schools mentioned that CARD™ prepared them for school vaccinations because they knew about coping strategies. ES3: “… [CARD] comforted me a lot more knowing what was gonna happen and what I could do.” CARD™ also helped them be less afraid. ES3: “In past experiences I was really afraid so that’s why I was afraid when I first got my vaccines at school. But now I’m not as afraid of needles because of the strategies I was taught.” The students in the experimental schools said that they planned to use CARD™ in the future, in other settings. ES12: “I’ll try to take what we learned here and bring it to the doctor’s office… tell them like tell us to relax, and if they have any distractions, [use] them.”

Nurse role

Students in the experimental schools appreciated the nurses focusing on the students’ needs and wishes during the vaccination process. ES6: “Well the nurses that were doing it really helped because they, even before, even after all the lessons that we learned about it, they still asked when we were getting it, “what can we do?” Like, “at this time, you’re getting it now, what should—what do you want now?” Like, “We’ve asked you before, but it’s—now this is the time, so what do you want us to do to help you?” In contrast, some students at the control schools expressed that nurses controlled the vaccine process. CS2: “[The nurse] said, ‘I’m going to pinch your arm so you don’t feel it as much, so it doesn’t hurt as much.” Facilitator: ‘Did she know you wanted her to help you?’ CS2: “No. No. She just told me she was going to do that.”

Teacher role

Some students appreciated teachers reminding them about the CARD™ coping strategies before the vaccinations. ES2: “Our teacher reviewed the CARD™ system and she also answered questions that some of the kids had…” In control schools, some students considered their teachers to be removed from the vaccination day process. CS1: “[The teacher] kind of just sent us down…I’m not sure how much he actually knew...” Experimental school students described expecting more involvement of their teachers. ES11: “I think our teacher should be aware with our feelings. Like be more involved as a teacher… if you like have the watery eyes they’ll ask and like our teacher, he’ll go until you like start crying and then he’ll ask you if you’re okay.”

Parent role
Students at experimental schools mentioned that some of their parents were familiar with and supported CARD™. ES1: “They thought it was like a good thing for us to have and they wanted me to use it if I was nervous and actually on that day I wasn’t really that nervous cause I know that I had like the CARDs there...” ES6: “Yeah they did [look at the CARD parent pamphlet]. They mostly looked at the strategies to do when there was a needle so, um, yeah they just reminded me of what to do and mostly distraction.” Other parents of students in experimental schools seemed to be less involved. ES10: “I didn’t talk to my parents that much about the vaccine. They asked me how it was and did it hurt. I told them it was good and no, it didn’t hurt.” Some control school students mentioned they had limited discussions about vaccination with their parents. CS3: “I gave them the form to sign and we didn’t talk about it because my parents know like there’s not much more that I need to know about it.”

Some children who are highly fearful of needles reported not being vaccinated at school. ES13: “Well it wasn’t really my decision. It was my parents’ decision ‘cause I’m really afraid of needles and my parents didn’t trust public health at all ‘cause they didn’t know what would happen.”

**DISCUSSION**

This is the first study to implement a student-centred multifaceted KT intervention (The CARD™ System) in the school vaccination setting and evaluate its effects on student-important outcomes. We demonstrated a positive impact of CARD™ on student knowledge, attitudes, use of coping strategies and some vaccination symptoms. Students reported they understood the information and that it prepared them for vaccination.

These results are consistent with the feedback obtained from adult stakeholders (i.e., public health staff, school staff, and parents) in the same study, described in detail in a separate manuscript in this series (11). Briefly, nurses and school staff reported that students in CARD™ schools were prepared for vaccination and had less fear. They similarly reported distractions, friends, and privacy as the most frequently used coping strategies (11). All stakeholder groups recommended continuing CARD™ after the study.
Since CARD™ is a multifaceted KT intervention, it is likely that multiple components of the intervention led to the observed benefits. Based on the results of student knowledge and attitudes testing and qualitative feedback, the in-class education lesson appears to have been an integral component. The mnemonic aspect of CARD™ likely facilitated student learning (13), especially in light of the level of anxiety associated with the subject matter (14). Use of evidence-based interventions during vaccination would have contributed to implementation success as they have previously been shown to reduce symptoms. The context for implementation is also expected to have contributed to the success of the intervention, including the willingness of the public health unit and school board involved to undertake the project and their commitment to its success. Students reported being impressed by the accommodations made for them and the caring attitudes displayed by adults. These are important factors in the development of trust in the health care providers and in the vaccination program (15).

The results are consistent with prior studies whereby we demonstrated acceptability and knowledge acquisition in students who viewed CARD™ resources (9,10). In one of these studies, however, students reported that nurses and teachers did not do enough to make vaccinations at school a positive experience (10). In that study, however, students alone (i.e., not adults) were educated about CARD™ and no changes were made to the school vaccination program by the school or public health unit.

Prior research shows that one of the most common concerns students have about getting vaccinated is needle pain (16). The broader literature supports providing procedural and coping information for patients undergoing different medical procedures (2,17). Education is hypothesized to prepare individuals in multiple ways. First, it provides knowledge about the procedure. This can reduce fear of the unknown. Next, it allows individuals to plan coping strategies. This can assist in establishing feelings of trust, control and promoting self-efficacy for coping (17). The results of the present study support education of students to reduce their fear and promote coping. We previously demonstrated a reduction in student fear about vaccination after CARD™ education (9). Separately, reduced fear of needles and increased willingness for future vaccination was demonstrated in a Japanese study of school-age children given a pain-related training session (18).
In our preliminary work leading up to this trial, students reported wanting to use external distraction devices (e.g., cell phones) during vaccination (8). We therefore ensured that distraction items were permissible for use during the vaccination clinics. We found that external distraction devices were the most frequent student-selected coping strategy in experimental group students. Students confirmed their preferences for external distractions in the focus group interviews, expressing their wish to be trusted by adults to use their electronic devices responsibly.

Another frequently utilized student-selected coping strategy was having a friend present during vaccination. Students similarly mentioned wanting a buddy to accompany them in our prior studies (8,10). Given that school vaccinations are often the first medical encounter involving a needle procedure that students experience without the presence of a parent, it is perhaps unsurprising that many of them would prefer to have a support person present. Concerns have been raised about the effectiveness of peers as supports by nurses, school staff and parents. There were some instances in the present study whereby nurses reported that students were ineffective in this role and they intervened (11). However, this was not raised as a common or significant issue. More effective education of students was recommended to improve their efficacy in this role. Incorporating a case scenario about supporting a buddy in the in-class education lesson may be one way of enabling peer supports to be more effective. It is important to note that an added benefit of having students serve as support persons is that it might lead to a concomitant diminution in the number of adults required to serve in this role.

Being vaccinated in private was another popular student-selected coping strategy. Once again, students advocated for privacy in our prior work leading up to this trial (8). Vaccinating in public spaces has been reported to be problematic (16). Despite this, privacy is usually only made available for students being vaccinated at school that are required to disrobe for vaccination. Interestingly, some experimental group students mentioned wanting partial privacy, meaning more separation between clinic tables. A positive feature of the included experimental schools was the presence of a separate office within the main clinic space (i.e., library). This layout may not be available at certain schools and other suitable spaces would need to be identified (e.g., health room).
One limitation is that this was a small study, involving only one public health unit, 10 schools, and grade 7 students, limiting the ability to generalize the findings. Second, the study was not randomized and there is the potential for selection bias. Third, the study was not blinded and there is the potential for performance bias. Nurses in the control group, however, were not aware of the intervention, therefore the risk of bias is low. Contamination is unlikely as control nurses were unaware of CARD™ and CARD™ resources were inaccessible to them. Also, nurses trained in CARD™ did not attend control schools. There are several strengths of the study. First, participants (i.e., students) were blinded, which minimized outcome detection bias. Second, we included all vaccinated students, minimizing the potential for attrition bias and improving generalizability. Third, we used a rigorous and comprehensive approach to data collection, evaluating CARD™ using both qualitative and quantitative methods. Our qualitative analysis utilized a deductive approach guided by the CFIR domains. In future studies, we recommend adding an inductive approach to capture the specific feedback of individuals not involved in intervention implementation (i.e., patients), since their feedback was not originally considered in the current domains of CFIR.

In summary, this study provides preliminary evidence of the effectiveness of The CARD™ System in improving the school vaccination experience. Together with the other data from this program of research (8–11), Niagara Region Public Health decided to implement CARD™ across the entire school vaccination program as of September, 2018. To further support public health and school staff, an additional training video was developed specifically for them (https://youtu.be/FXj6ELi4BVg). Additional research is recommended to further explore this novel KT intervention for procedural pain and fear management, inside and outside of the school setting. Before undertaking this work, modification of CARD™ resources may be necessary to ensure that they are suitable for diverse medical contexts.

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Pain Pain Go Away Team: Lucie M Bucci BA6, Christine Halpert RN MA7, Anthony N. T. Ilersich1, Angelo L. T. Ilersich1, Cathryn Schmidt2, Evelyn Wilson MAEd BPHE8, Jocelyn Cortes RN9, Srdjana Filipovic PhD2, Melanie Badali PhD10, Kate Robson11, M. Mustafa Hirji MD MPH3

1Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, Ontario; 2The Hospital for Sick Children, Toronto, Ontario; 3Niagara Region Public Health & Emergency Services, Thorold, Ontario 6Immunize Canada, Ottawa, Ontario; 7British Columbia Centre for Disease Control; 8Ontario Institute for Studies in Education, University of Toronto; 9Ontario Ministry of Health and Long-Term Care; 10AnxietyBC, Vancouver, British Columbia; 11Canadian Family Advisory Network

REFERENCES


Chapter 3: Fidelity Results

Fidelity assessments are displayed in Table 9.

*Fidelity of the CARD™ Education Session*

The lead researcher used process checklists and observational field notes to measure fidelity in the implementation of The CARD™ System during the education session (Table 9). There were, however, several departures from the study protocol. All CARD™ students watched the two videos in the education lesson and chose coping strategies, but not all classes managed to review each of the five case scenarios within the allotted education lesson period. The liaison nurse returned to the schools that missed some case scenarios but it is unknown whether CARD™ students who were absent on the day of the initial education lesson reviewed all of the case scenarios in their catch-up lesson. The lead researcher was not present during catch-up sessions. In addition, one CARD™ school out of the five was given an education session by a school nurse who did not make it clear to the students that they were to only write down coping strategies that they wanted to use, as opposed to writing down every strategy that was mentioned in the education session.

*CARD™ Education Session – Fidelity of the Pre-Post Knowledge Questionnaires*

The researcher ascertained that the vast majority (97%) of pre-lesson and post-lesson knowledge questionnaires on coping strategies (Appendix B) were completed by the students with the exception of three post-lesson questionnaires that were omitted because those students left early.
**Vaccination Clinics**

Fidelity to the protocol was evaluated using several measures at the vaccination clinics. For 10% of students at each clinic, a total of 31 students in each clinic round, the lead researcher closely watched the student-nurse interactions. The researcher documented that there was 100% fidelity to the CARD™ intervention in which injecting nurses ask students what CARD™(s) they wanted to play before getting their vaccines. There was also 100% fidelity of the nurses’ documentation in their post-vaccination questionnaires regarding coping strategies used by each student, relative length of each student’s vaccination, and satisfaction of the nurse’s interaction with each student. All students and injecting nurses completed their post-vaccination questionnaires, except one student (0.01%) with special needs in one round. There were, however, several deviations from procedures put in place for the CARD™ vaccination clinics. One CARD™ school did not set up the chairs outside the clinic, so students were watching their peers getting vaccinated. Additionally, one school refused to allow students to use personal electronic devices for distraction during vaccination, but the school’s tablets were permitted as an alternative.
Chapter 4: Discussion

4.0 Summary of Findings

This study is the first to measure the impact of The CARD™ System, in a school-based vaccination program. CARD™ was created as an adaptation of the evidence-based Clinical Practice Guideline (CPG) interventions [49]. CARD™ aims to help with reducing fear, pain, and dizziness often associated with vaccinations [114]. CARD™ gives a framework and process for interventions to be available to all students. By allowing students to make choices about pain, fear, and dizziness mitigation strategies, CARD™ is consistent with a patient-centred care approach [119]. The benefits measured in this study were likely due to a combination of the various components of CARD™, as it is a multifaceted, complex intervention.

Our study found that CARD™ had a positive effect on student knowledge about vaccination, and the use of coping strategies. Distraction, support and privacy were the most selected coping strategies. CARD™ was associated with less fear and dizziness but was not associated with less pain [7]. There was no difference in vaccination rates in CARD™ schools compared to control schools [119]. CARD™ students accepted the length and content of the educational session. A high degree of fidelity was observed while using the different components of CARD™.

The findings are consistent with feedback from the other stakeholders in the study (nurses, school staff and parents), reported in a series of articles about CARD™ [119]. Both nurses and school staff in CARD™ schools reported that students were calmer and less fearful and most often chose distraction, support and privacy as strategies to mitigate pain, fear and dizziness [106].
The remainder of this chapter will serve to provide a discussion of: 1) student symptom ratings (fear, pain, dizziness); 2) CARD™ students’ knowledge on vaccine coping strategies; 3) fidelity of using The CARD™ System; 4) selected coping strategies; 5) strengths and limitations; 6) clinical implications of study findings; 7) future research considerations; and 8) conclusions.

4.1 Primary Outcome: Student Symptom Ratings

CARD™, is an adaptation for school-based vaccinations of evidence-based CPG interventions for mitigation of pain, fear and fainting, with preferred interventions selected by each student for his or her own vaccination procedure [111], so the CARD™ interventions would likely have contributed to the improvements in student symptoms found in this study. Furthermore, allowing students to choose which coping strategies they would use during vaccination after the lesson, reinforced patient-centred care that would probably be more effective than "one-size-fits-all" accommodations and techniques.

4.1.1 Fear

There was a statistically significant difference between CARD™ students and control students in the mean level of fear reported at round 2 but not at round 1 (Table 6) In addition, there was a significant group x time interaction (Table 6). When dichotomizing the fear ratings to high versus low, there was a significant group effect, indicating that CARD™ had helped to decrease the level of fear in intervention students (Table 7).

Both CARD™ students and control students had lower mean levels of fear at vaccination round 2 than at round 1. The CARD™ students had a greater decrease in fear, indicating that CARD™ might have made the vaccination experience at round 1 positive enough that by round 2, CARD™ students' fear levels had subsided further, given their previous success using CARD™
strategies. More specifically, CARD™ may have increased the CARD™ students' feelings of self-efficacy and their confidence in the ability to use coping strategies effectively to lower their fear rating.

Feeling prepared for vaccination, armed with coping strategies, helps lower fear of the vaccine and the pain involved [24, 56-58]. It is possible, then, that CARD’s education lesson with the videos and slide presentation and the incorporation of chosen CARD™ strategies played a role in the lower fear rating in CARD™ students. Their fear can be reduced with knowledge about vaccines and mitigation strategies, and knowing that accommodations will be made for their unique requests. Seeing students in the videos being vaccinated and giving testimonials about their positive experiences can be reassuring and serve to decrease fear. Additionally, trust in the medical system and health care professionals decreases fear and the probability of vaccination hesitancy [48]. In the CARD™ educational videos, CARD™ students observed nurses carrying out vaccinations in a favourable manner, which may have imparted a positive impression on the students, allowing them to feel more at ease. The in-class visits and introductions by injecting nurses to all CARD™ classrooms prior to the start of each clinic may also have played a role in the students’ trust, in stark contrast to students and nurses meeting upon point-of-vaccine delivery. In the qualitative portion of the study reported in Chapter 2, it was found that CARD™ students in focus groups commented on their appreciation of the caring manner of the adults participating on vaccination day and of the accommodations made for them. These comments are consistent with the findings from focus groups conducted with CARD™ nurses reported in a separate article [119]. CARD™ nurses felt more confident in their ability to assess and manage the students' fear, and expressed better student-nurse interactions compared to control nurses [119].
Fear and its Impact on Vaccination Rates and Refusal

In a prior study, fear was cited as the main reason for immunization avoidance for 7% of parents and 8% of children [22]. Therefore, we expected that fear reduction would play a role in increasing vaccination rates. The school vaccination rate, however, did not increase after students had the CARD™ education lesson in the experimental schools. Nor did the acknowledgement of vaccination pain and fear in CARD™ cause an increase in student fear and vaccine hesitancy. It can be noted that in debriefing with the lead researcher, injecting nurses reported that CARD™ helped them vaccinate some highly fearful students who might have refused vaccination at the clinic otherwise, despite having signed consent previously.

Furthermore, it may be that vaccination rates in the future for CARD™ students may be higher than rates for control students due to a better, less fearful vaccination experience.

Students and parents who refused vaccination, in both groups, were not asked the reason for refusal, and fear may have been only one of possible explanations. Approximately 4% to 26% of people refusing vaccination do so because of needle fear [22, 58, 69]. People also avoid vaccination for other reasons such as religion and personal beliefs about vaccination and its side effects [108-109]. CARD™ would not be expected to affect the vaccination rate of those who are avoiding vaccines for reasons other than needle pain and fear. It is also possible that those with extreme levels of needle fear may not want to be vaccinated at school, preferring parental support and complete privacy. It has been recommended that such individuals with high levels of needle fear and/or phobia and fainting be treated by mental health practitioners, using exposure-based, psychological and physical interventions [49]. Future studies could ask those who refuse vaccination to identify the reason for refusal.
4.1.2 Pain

There was no significant difference found in level of pain between CARD\textsuperscript{TM} and control students. From the finding that there were significantly lower levels of fear in CARD\textsuperscript{TM} students compared to control students, it could be expected from the literature that they would have a significant reduction in pain as well [24, 50, 63]. A potential explanation for the lack of significant difference in level of pain in CARD\textsuperscript{TM} and control students is that the vaccine is administered with a sharp, metal needle puncture, which inevitably causes some degree of pain, regardless of most interventions (students used topical anesthetics only infrequently in this study). It is possible that although the pain remains present with CARD\textsuperscript{TM}, it is an expected and less emotionally traumatic pain for CARD\textsuperscript{TM} students who are less fearful and have chosen ways to cope with the brief pain experience. These strategies may be beneficial to combat anxiety-inducing memories of vaccinations and procedures as time passes, minimizing a fear of needle procedures in the future [60, 62].

Although there was no significant difference between CARD\textsuperscript{TM} schools and control schools in the students' self-reported mean levels of pain (Table 6) and no significant difference in the number of students reporting more extreme levels of pain (i.e. more than the cut-off of 6 out of 10) (Table 7), there were some trends in the data indicating CARD\textsuperscript{TM} might have affected pain. For example, between round 1 and round 2, at CARD\textsuperscript{TM} schools the mean level of pain decreased from 3.5 to 2.9, while fear level decreased from 3.8 to 2.7. In contrast, between round 1 and round 2 at control schools the mean level of pain actually increased from 3.4 to 3.7, while fear level decreased only slightly from 4.6 to 4.3 (Table 6). It is possible that CARD\textsuperscript{TM} students
would be less likely to avoid vaccination in the future with this observed, relative improvement over time, which could reach statistical significance in a larger sample.

To directly address needle pain, the increased use of topical analgesic creams or patches has been recommended [22]. In previous focus groups conducted with children from four to 14 years of age, there was support for routine use of analgesics to deal with vaccination pain [21]. Although there was interest expressed in topical anesthetics when strategies were chosen at the CARD™ education session, not many students came equipped with the analgesics. Several students who did bring the anaesthetic did not apply it properly. Use of analgesics requires planning so that the vaccination is administered at the optimal time after application of the analgesic.

4.1.3 Dizziness

There was no significant difference between CARD™ students and control students in their mean scores for dizziness at both rounds 1 and 2, nor was there a group x time interaction (Table 6). Few students in the CARD™ group or control group elected to lie down when getting vaccinated (Table 5). When dichotomizing the dizziness ratings on the ten-point scale to high versus low, there was a significant group effect, demonstrating that CARD™ may have helped to decrease dizziness in intervention students (Table 7). These findings are likely related to the levels of fear of the students: the CARD™ students had lower levels of fear and would thus be less likely to experience physiological manifestations of fear and anxiety, which can be associated with light-headedness and dizziness [30]. Although muscle tension techniques were demonstrated to CARD™ students in the education session video and the tension methods were practiced during the education session, few students chose muscle tension as a strategy to mitigate dizziness.
4.2 Secondary Outcomes

4.2.1 CARD™ Student Knowledge of Vaccine Coping Strategies

The CARD™ tools taught at the education session demonstrate coping strategies that can reduce pain, fear and dizziness and promote feelings of control and self-efficacy during medical procedures [24, 109]. It is hypothesized that the informative education session allowed students to know what to expect at the vaccination clinic which minimizes the "fear of the unknown." The session included case scenarios in which the students were presented with various situations that could arise in the vaccination process and asked how they would apply CARD™. This exercise served to bolster feelings of self-efficacy, giving students familiarity and confidence in their ability to use CARD™. This beneficial effect of education about vaccination pain has been shown in a Japanese study in which 194 children, 7 to 9 years old, had a reduced fear of needles and an increased acceptance of future vaccinations, after a training session about vaccines and needle injection [20]. In addition, a survey of 277 Canadian grade 6 students found that 50% did not know how to reduce pain during vaccination and 37% were interested in learning how to manage vaccine pain [19]. To satisfy this need, the CARD™ education session serves to inform and prepare students for the vaccination experience. Furthermore, the mnemonic likely assisted in the students remembering the content of the session [121-122], and therefore, the CARD™ strategies were more likely to be used on vaccination day. Having such an aid to memory is especially useful in circumstances where anxiety is present, such as in a vaccination setting, because anxiety generally impairs memory [123].

The CARD™ students’ scores on the pre-post knowledge questionnaire about vaccine coping strategies (vaccine fear, pain, dizziness mitigation) significantly increased after the education
session (Table 3). Earlier phases of our study showed that didactic-styled education sessions alone have limited benefit because each student's unique preferences are ignored in the vaccination process [21]. The results are consistent with previous research done on implementing CARD™ in school in which students’ scores on the knowledge questionnaire improved after the CARD™ educational session [21, 112, 119]. As control students did not complete the pre-post questionnaire in their standard education session, it is unknown whether they gained knowledge from their vaccine lesson.

4.2.2 Fidelity

CARD™ is a multifaceted, complex and comprehensive intervention for which assessing fidelity and implementation is important. Many individuals (e.g., school administrators, nurses, teachers) are involved in its numerous components (e.g., approval for a private space and device usage, education lessons, parental contact, in-class announcements, clinic set-up, the vaccination process). Fidelity measurement is necessary for improvements to be made, outcomes to be explained and for study replication [114]. In addition to the complexity of the CARD™ intervention, CARD™ uses behavioural interventions which require measures of fidelity to assess and further augment reliability and validity [114]. Departures from the CARD™ intervention protocol could affect results, and therefore, influence the assessment of the effectiveness of CARD™.

As mentioned in Chapter 3, ‘Fidelity Results,’ there were deviations from the study protocol in both the education lesson and the vaccination clinics. The school that did not set up the clinic space according to the study protocol had waiting area inside the clinic, so the feeling of being watched could have increased the level of anxiety of some students at that school.
Fidelity checklists assisted in achieving a high degree of fidelity at the education lesson and at the vaccination clinics. The injecting nurses were never given templates or scripts for various situations in their CARD™ training. Given that the student-nurse interaction is so important for the comfort of the student, to enhance the degree of fidelity, it is worthwhile to consider giving more structured guidance to nurses on the optimal way to interact using CARD™ during the vaccination clinic.

4.2.3 Use of Selected Coping Strategies

CARD™ students made use of the techniques presented in the education session to cope with their vaccinations. As shown in Table 5, compared with students in the control group, there was a significantly greater number of CARD™ students who used the following coping strategies: external distraction device/object, deep breathing, a support person, privacy, and verbal distraction (round 2 only).

A significantly higher number of CARD™ students chose to use an external distraction object as a coping strategy than other strategies. The popularity of this choice was consistent with the enthusiasm for external distraction objects, such as mobile devices, bubble blowers, and fidget spinners, as expressed in focus groups held in the Niagara region to assist in the development of CARD™ [116]. Arrangements had to be made with school staff to allow these devices on vaccination day, although, as mentioned above in ‘Fidelity of Vaccination Clinics,’ out of the five schools, one refused to allow students to use their personal devices. Getting students to pay attention to something other than the procedure can decrease pain, as being distracted has been shown to lower pain [85, 125-126]. A meta-analysis of 19 studies of children, aged 3 to 15,
found that distraction reduced pain (10 studies of 535 children) and reduced distress (15 studies of 491 children) [95]. Studies that have assessed external distraction during venipuncture with children have utilized bubble blowers [99], party blowers [101], watching videos [91, 127], and kaleidoscopes [128]. It is best if students can choose the objects of their distraction so that they will be more interested [50].

Deep breathing is a technique that has demonstrated effectiveness in promoting relaxation during a medical procedure [96]. Deep breathing reduces stress levels, and when used with blowing toys or activities, such as bubble blowing or party blowers, distraction from the needle procedure also occurs [96-97]. There was a significantly higher number of CARD™ students who incorporated deep breathing as a coping strategy than the number of control students who used deep breathing. This difference may be attributed to the recall of guidance provided in the CARD™ video on how to use deep belly breathing to stay calm during vaccinations [119]. Additionally, the CARD™ nurses were given explicit training on how to instruct students to use deep breathing while getting their vaccines, so they may have chosen to incorporate it as part of their dialogue with students. The researcher noted that while conducting fidelity checks on 10% of nurse-student interactions, CARD™ nurses, and even some control nurses, guided students to use deep breathing.

Having a support person, such as a friend, teacher or nurse, present during vaccination was another often-selected coping strategy among the CARD™ students. School vaccinations are usually adolescents’ first medical procedure with needle injection without parents present, so it is not surprising that they would want support. This choice was also encouraged by students in
earlier phases of the research leading up to the development of CARD\textsuperscript{TM} [21, 116]. When the lead researcher debriefed with the CARD\textsuperscript{TM} nurses after the vaccination clinics, some nurses mentioned that some friends were not effective supports and appeared to actually contribute to increased fear. Occasionally, the injecting nurse would then have to take more time and effort to de-escalate the situation, sometimes seeking extra assistance from other nurses present. In these debrief sessions, the nurses also mentioned that additional student education on being an effective support, including a case scenario in the education session, modeling ways to be a good support person in the vaccination setting, would be valuable.

Consistent with findings in the literature and with previous research for the development of CARD\textsuperscript{TM}, [21, 116] CARD\textsuperscript{TM} students often chose to be vaccinated in private. In control schools, the option of privacy was not offered. Being vaccinated in open, visible areas in the school can have negative effects [131]. A room that is not visible to students' peers can offer the privacy that some students need, unlike the public spaces usually used in vaccination clinics [50].

Previous research reveals a preference for a private vaccination space option in the general public. An online survey of male adolescents, aged 11 to 17 years, indicated that embarrassment about possibly fainting during the vaccination was a concern which could be mitigated by a private vaccination setting [130]. Surveyed parents of adolescents, aged 11 to 14 years, indicated that privacy was an important reason for preferring doctors' offices rather than pharmacies for vaccinating their children (school-based vaccination was not included in the study) [131]. A qualitative study of adult employees' attitudes about mandatory influenza vaccination revealed that privacy during vaccination could mitigate anxiety [132].
Typically, schools provide private vaccination space only if disrobing for vaccination will take place. The CARD™ schools in this study all had an adjacent space for private vaccinations but, in the future, an adjacent room may not be available and a nearby, separated room for vaccination may need to be designated. For some CARD™ students, partial privacy was sufficient, such as increased separation between vaccine tables [7].

4.3 Strengths, Limitations, Clinical Implications, and Future Directions

Strengths

This study had various strengths and limitations. One strength of the study design was choosing a parallel clusters design rather than analyzing the data at an individual level because of the possibility of contamination, as well as acknowledging the real-world implications of its use. It is easier to control for contamination between groups, as we did, by having all students naïve to the intervention. Controlling for contamination at the individual level within a school would present some challenges. If only a subset of students at a given school were taught CARD™, there is a possibility they would tell their non-CARD™ educated peers about what they had learned. In addition, it is more practical to offer The CARD™ System to all students in a school, rather than to just some. As this was a preliminary study to determine the effectiveness of CARD™ interventions, there was no formal sample size calculation.

Having all students naïve to the intervention also had other benefits. The CARD™ students were not told that CARD™ was outside of usual vaccination care. Social desirability bias was, therefore, minimized with CARD™ students because they were not aware that they were receiving special, additional care and education that students at other schools were not receiving.
If CARD™ students had known that students in control schools did not have the same student-centred intervention, they could have exaggerated the positive effects of CARD™ on their surveys. In addition, control students were unaware that they were lacking the special intervention that students at other schools received for coping with vaccination pain and fear. Being naive could minimize response bias in that control students might have exaggerated their pain, fear and dizziness if they were aware that other schools had a special vaccine program that they did not have.

Consent for vaccinations to be administered was obtained from all parents and students, but no consents were obtained from the parents and students in the experimental schools for their participation in this study assessing CARD™. The University of Toronto Research Ethics Board allowed this exception to the requirement of obtaining participants’ consent prior to data collection, as described in Article 3.7A of the Tri-Council Policy Statement, as being necessary to address the research question, and not having an adverse impact on the welfare of participants [133]. Requiring consent for CARD™ could have affected vaccination rates negatively, if parents had concerns about their children's participation in an experiment. In addition, having consent forms for CARD™ participation would make the CARD™ students aware of the CARD™ intervention, which could have resulted in a social desirability bias (minimizing their pain, fear and dizziness) because they were aware that they had a special intervention not usually provided in school-based vaccinations.

Another strength of the study was that all students who received vaccination were included in the study analysis except the one student with special needs who failed to complete the post-vaccination questionnaire. Attrition bias was minimized due to a high level of fidelity to the
study protocol. In addition, the inclusion of all vaccinated students improved generalizability to the broader population.

CARD™ students and control students were matched on several demographic variables, which contributed to internal validity. All in Grade 7 at participating schools in the Niagara region, so age and some other demographic characteristics were matched in the two groups. In addition, both CARD™ and control schools varied in size and were matched.

The numerical rating scales used in the study also contributed positively to the quality of the assessment. The research team chose to have the students report their levels of pain, fear, and dizziness after each vaccination session using an 11-point numerical rating scale, ranging from 0 to 10 (NRS-11). This scale is commonly used in this age group and has been validated for use in children over eight years of age in three studies that compared it to visual analog scales and to the Face Pain Scales Revised [134] and in studies of children aged 2-12 years and 6-16 years [135]. Using the numerical rating scale also allowed us to use a cut-off point (more than 6 out of 10) to represent a severe degree of pain which was also applied to the measurement of fear and dizziness because it was considered of clinical significance to stakeholders [7]. A visual analog scale was not used because the latter requires the researchers to measure each response with a ruler [107], adding extra work and possible error. The decision was also made to not use a face rating scale showing various degrees of pain, with faces ranging from no pain to extreme pain, because students expressed dissatisfaction with using a face rating scale in preliminary testing of the study’s data forms (unpublished).
Another strength of the study was the fact that the nurses in control schools were unaware that injecting nurses at other schools were receiving special training and accommodations for students, designed to improve the vaccination experience. Outcome detection bias was avoided because if the control nurses had been made aware that they were not given The CARD™ System, they might have deliberately tried to compensate by rating the vaccination experience more positively than it actually was. Similarly, being unaware of the CARD™ intervention program at other schools minimized a performance bias that might be present if the nurses were trying to overcompensate by paying special attention to students’ needs.

Contamination of nurses in the control schools was unlikely because they were unaware of CARD™ and they did not have exposure to CARD™ resources. This separation prevented control nurses from possibly picking up new techniques to incorporate into their practice.

It was likely that response bias was minimal with respect to the quality of the student-nurse interaction. There was 100% agreement between the researcher's documentation of 31 vaccinations at each vaccination round and the injecting nurses' own evaluation of the student-nurse interaction.

An additional strength was that the researchers were able to identify potential gaps in CARD™ using a comprehensive approach to obtain student feedback about the KT tools at several time points: with a questionnaire after the educational session (CARD™ students only) and with being asked on vaccination day, as part of their student feedback survey, as to whether they had any suggestions for improvement of the vaccination experience (both CARD™ and control students).
Limitations

There are demographic factors at CARD\textsuperscript{TM} and control schools that are potential limitations. The ten schools participating in this pilot study were a convenience sample and not randomly selected. It is possible therefore, that validity was affected. Schools were matched on various factors, however, which would limit the importance of not being randomly selected. This included having similar school sizes, geographic region and socio-economic status. Needle fear has been shown to exist in different nations \cite{40}, therefore, it is likely that the results have some generalizability more broadly.

Results and generalizability may also have been affected by ethnic and cultural backgrounds of the participants, which have been shown to affect the way stress and anxiety are expressed and managed \cite{125-126, 129}. The CARD\textsuperscript{TM} and control schools may have excluded some religious and ethnic groups. This study did not identify or examine the students’ ethnic and cultural backgrounds. Future studies with CARD\textsuperscript{TM} can examine students’ backgrounds to assess potential impact on CARD\textsuperscript{TM}’s effectiveness and to inform modifications to CARD\textsuperscript{TM} to meet needs of specific groups.

Another limitation is that there may have been self-selection bias in participating students, however, it is unlikely that this bias was largely impactful. In the CARD\textsuperscript{TM} student group, the participating students were those who consented to being vaccinated. They may have less fear of vaccination than students who refused to be vaccinated. Such bias would be non-differential, however, because self-selection bias could also exist in the control group which also consisted of those students who consented to school vaccinations.
There additionally may have been bias in the CARD™ school nurses. They were aware of the CARD™ intervention, trained and using CARD™ throughout the school-vaccination process. They could not be blinded because they were collaborating with the research team and NRPH. There was, therefore, a potential for performance bias among CARD™ nurses. They could have made an extra effort to meet students' needs, in addition to CARD™, because they knew they were in a study and had received extra training. Knowing they were in the study and that a researcher was observing the vaccinations and analyzing results, could possibly result in outcome detection bias, with CARD™ nurses possibly being more attentive to student needs and describing the vaccination experience in a more positive manner than usual.

If there was a performance bias in CARD™ school nurses, its effect would be decreased because there could be a similar performance bias in the control nurses. Although control nurses were not made aware of the CARD™ intervention, they were aware that a study was being conducted that may have contributed to performance bias due to changing the way they cared for students. While control nurses were not explicitly informed that an experimental study was being conducted and that they were in the non-intervention group, the nurses had to fill out a form after each student’s vaccinations, which was not part of usual care. In addition, the control nurses were aware that they were being observed by the researcher. The control nurses were also aware that the students were rating their pain, fear, and dizziness, so they, therefore, may have been more cognizant of needle pain and fear than they would typically, and may have unintentionally changed their level of care towards the students. The list of coping mechanisms a student could use that is displayed on the nurse feedback form may have prompted control nurses to give extra support, nurse-led distractions or other interventions than if there were no study. The presence of
the researcher may have also influenced the nurses’ behaviour. For similar reasons as discussed above, there could have been outcome detection bias when control nurses had to rate the quality of the student-nurse interaction following each student’s vaccination.

Response bias may have taken place when students sought help from the non-blind researcher in filling out the pain, fear and dizziness rating questionnaires in that when they had trouble choosing a rating, the researcher may have unintentionally influenced the student to answer in a particular way. In future studies, it would be beneficial to have a blind individual present to help students fill out questionnaires on clinic day.

The data entry involved 2 different individuals – the lead researcher and another lab team member (i.e., all data entry was double-checked), minimizing the risk of random error. Neither, however, were blinded to group allocation. The statistician who analyzed the data was also not blinded to group allocation. It is not clear that this impacted on accuracy of the results as the qualitative results support the quantitative analyses.

The study did not examine whether CARD™ met the needs of specific subgroups of students [114], which could affect generalizability and could reveal where modifications to CARD™ should be made. There was adjustment for sex, however, in the analysis of participants’ symptoms (fear, pain, and dizziness scores) and when outcome data were dichotomized of high levels of symptoms of using a cutoff of > 6 out of 10. In the future, more studies can explore the role of gender on the effectiveness of CARD™ and on the use of different coping strategies for its optimal implementation and valid outcome assessment. Similarly, the study did not address whether CARD™ met potentially unique needs of students with very high levels of needle fear or those of different cultural or ethnic backgrounds. It is possible that the intervention would
need to be modified for different subgroups of students and that some subgroups may require a different intervention [49]. Individuals with high needle fear, for example, may require treatment, such as exposure-based interventions and applied tension [136], such as those with high needle fear, may require a different intervention.

The study did not assess what the best interval would be between the education session and vaccination and whether more discussion, reinforcement or practice based on the session would be beneficial before vaccination day [113]. These issues have been raised in prior research on education and preparation for procedures and findings have been mixed. Information given too long before or too near the time of an upcoming medical procedure has been shown to increase children's anxiety [137-138]. Optimal timing of vaccine information should be examined in future studies [139-140] by comparing the effects of different time interval options on results (e.g., one month versus one week).

Students at CARD™ schools who were absent when the education session was presented were given a shorter, ‘catch-up’ session by the liaison nurse who gave the education session for four of the five CARD™ schools. The catch-up sessions were not observed by any member of the research team. The findings may have been affected by the fact that the researchers included those students in the study, who may not have received a lesson of the same quality as the other CARD™ students. This only happened to a small number of students and reflects real-world implementation of CARD™. Future studies can explore the difference in effectiveness of different levels of education.

This was a preliminary study to determine the effectiveness of CARD™ interventions, and the
sample size was limited by feasibility. The results can be used to plan future research with CARD™.

Given that dialogue templates were not provided to vaccinating nurses for a variety of situations that may arise, it is worthwhile to consider giving more structured guidance to nurses on the optimal way to interact using CARD™ during the vaccination clinic to promote standardization in the delivery of CARD™ and to ensure students’ comfort.

**4.4 Clinical Implications of Study Findings**

The CARD™ intervention can reduce fear and dizziness, and increase students’ knowledge about strategies to mitigate pain, fear, and dizziness. By improving the vaccination experience, use of CARD™ may decrease vaccine avoidance when students are offered vaccines in the future (after having a successful vaccination experience using the CARD™ intervention). In this study, there may have been no difference in vaccine uptake between CARD™ and control students because the choice of being vaccinated or not being vaccinated was made after the CARD™ education session but before actual vaccinations took place. It is possible that CARD™ students, once vaccinated, having experienced less fear and dizziness than they anticipated, and other benefits from CARD™, may have less vaccine avoidance in the future.

The CARD™ System also provides knowledge about coping mechanisms that increase feelings of self-efficacy. People who fear needle pain are more likely to avoid preventative and therapeutic medical procedures involving needles such as blood tests, vaccinations and dental procedures [24]. Vaccine avoidance can lead to spread of diseases that are preventable and
refraining from preventative and diagnostic procedures and treatments with needles can contribute to unnecessary delay, disease progression and morbidity [22, 24]. The development of interventions like CARD™ that reduce needle pain and fear may decrease disease in individuals who avoid vaccination because of fear and could increase herd immunity [22]. If CARD™ is adapted for widespread use and implemented broadly it could have a significant impact on healthcare globally.

4.5 Future Research Directions

Further research could examine use of The CARD™ System for vaccination pain and fear, both inside and outside of the school setting. CARD™ could be studied for application with other medical procedures and for stressful situations of a non-medical nature but CARD™ interventions might need to be modified for adaptation to different specific situations. Research on a larger, more racially diverse student population is needed in order to be able to better generalize findings. Further study should be conducted on the impact of CARD™ on different subgroups according to gender, pain sensitivity or degree of needle fear, for example, so that modifications can be made if necessary for those individuals. Assessing CARD™ in schools in other parts of the province, rural and urban, would help the team modify the intervention so that it could be adapted to various school layouts and personnel (public health and education) scenarios.

4.6 Conclusions

This study demonstrated that The CARD™ System, improved the school-based vaccination experience as a student-centred intervention incorporating evidence-based coping strategies. There were statistically significant lower levels of fear and dizziness in CARD™ students
compared to control students. There was no significant difference between groups in levels of pain. There was a significant increase in CARD\textsuperscript{TM} students’ knowledge about vaccine fear, pain, and dizziness mitigation strategies after the education session. In this study, throughout the implementation of CARD, a high degree of fidelity was achieved. Further research with a larger, more diverse sample is needed so that CARD\textsuperscript{TM} may be broadly used for school-based vaccinations. With adaptation, CARD\textsuperscript{TM} could potentially be utilized for other medical procedures and non-medical contexts.
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Tables
**Table 1.**
Demographics of students vaccinated in round 1 and round 2 clinics*

<table>
<thead>
<tr>
<th>Clinic visit</th>
<th>Experimental (CARD™)</th>
<th>Control</th>
<th>P-value**</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinic visit 1 (round 1)</strong></td>
<td>(n=124)</td>
<td>(n=123)</td>
<td></td>
</tr>
<tr>
<td>No. of females</td>
<td>51 (41)</td>
<td>60 (49)</td>
<td>0.23</td>
</tr>
<tr>
<td>Mean number of injections</td>
<td>2.5 (0.6)</td>
<td>2.6 (0.6)</td>
<td>0.37</td>
</tr>
<tr>
<td><strong>Clinic visit 2 (round 2)</strong></td>
<td>(n=111)</td>
<td>(n=112)</td>
<td></td>
</tr>
<tr>
<td>No. of females</td>
<td>47 (42)</td>
<td>59 (53)</td>
<td>0.12</td>
</tr>
<tr>
<td>Mean number of injections</td>
<td>1.6 (0.5)</td>
<td>1.7 (0.5)</td>
<td>0.14</td>
</tr>
</tbody>
</table>

*Values are frequency (percent) or mean (standard deviation).
**Chi-squared test or T-test.
Table 2.
Demographics of students who volunteered to participate in focus group interviews*

<table>
<thead>
<tr>
<th></th>
<th>Experimental (CARD™) (n=13)</th>
<th>Control (n=10)</th>
<th>P-value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Females</td>
<td>5 (39)</td>
<td>6 (60)</td>
<td>0.31</td>
</tr>
<tr>
<td>Mean Age in years</td>
<td>12.4 (0.5)</td>
<td>12.4 (0.5)</td>
<td>0.94</td>
</tr>
</tbody>
</table>

*Values are frequency (percent) or mean (standard deviation).

**Chi-squared test or T-test.
Table 3.
In-class education pre–post-knowledge, fear, and willingness to be vaccinated scores for students in the experimental (CARD™) Group (n=142)*

<table>
<thead>
<tr>
<th></th>
<th>Pre-education</th>
<th>Post-education</th>
<th>P-value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge(^a)</td>
<td>6.1 (2.3)</td>
<td>6.9 (2.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Fear Level(^a)</td>
<td>4.4 (3.6)</td>
<td>4.1 (3.6)</td>
<td>0.03</td>
</tr>
<tr>
<td>Willingness to be vaccinated(^b)</td>
<td>1.7 (1.1)</td>
<td>1.5 (1.0)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

*Values are mean (standard deviation).
**Paired t-test.
\(^a\)Values for knowledge and fear range from 0 (none) to 10 (maximum).
\(^b\)Values for willingness to be vaccinated range from 1 (yes) to 5 (no).
Table 4.
Student attitudes about in-class education in the experimental (CARD™) group (n=141)

<table>
<thead>
<tr>
<th></th>
<th>Frequency (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understood all or most of the information</td>
<td>134 (95)</td>
</tr>
<tr>
<td>Amount of information “just right”</td>
<td>113 (80)</td>
</tr>
<tr>
<td>Information useful</td>
<td>116 (82)</td>
</tr>
<tr>
<td>Feel well prepared or over-prepared for vaccination</td>
<td>117 (83)</td>
</tr>
</tbody>
</table>
Table 5.
Coping strategies used by students in round 1 and round 2 clinics*

<table>
<thead>
<tr>
<th></th>
<th>Experimental (CARD™)</th>
<th>Control</th>
<th>P-value**</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinic visit 1 (round 1)</strong></td>
<td>(n=124)</td>
<td>(n=123)</td>
<td></td>
</tr>
<tr>
<td>Verbal distraction</td>
<td>120 (97)</td>
<td>119 (97)</td>
<td>0.99</td>
</tr>
<tr>
<td>External distraction device/object</td>
<td>74 (60)</td>
<td>11 (9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Deep breathing</td>
<td>103 (82)</td>
<td>88 (72)</td>
<td>0.03</td>
</tr>
<tr>
<td>Friend present</td>
<td>58 (47)</td>
<td>4 (3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Topical anaesthetic</td>
<td>0 (0)</td>
<td>1 (1)</td>
<td>0.32</td>
</tr>
<tr>
<td>Privacy</td>
<td>34 (27)</td>
<td>1 (0.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Lying down</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>0.99</td>
</tr>
<tr>
<td><strong>Clinic visit 2 (round 2)</strong></td>
<td>(n=111)</td>
<td>(n=112)</td>
<td></td>
</tr>
<tr>
<td>Verbal distraction</td>
<td>106 (95)</td>
<td>97 (87)</td>
<td>0.02</td>
</tr>
<tr>
<td>External distraction device/object</td>
<td>60 (54)</td>
<td>3 (3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Deep breathing</td>
<td>86 (77)</td>
<td>67 (60)</td>
<td>0.005</td>
</tr>
<tr>
<td>Friend present</td>
<td>53 (48)</td>
<td>4 (4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Topical anaesthetic</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>N/A</td>
</tr>
<tr>
<td>Privacy</td>
<td>22 (20)</td>
<td>0 (0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Lying down</td>
<td>3 (3)</td>
<td>2 (2)</td>
<td>0.64</td>
</tr>
</tbody>
</table>

*Values are frequency (percent), as documented in the injecting nurse’s checklist (yes/no).
**Chi-squared test.
Table 6.
Mean fear, pain, and dizziness scores in students undergoing vaccination in round 1 and round 2 clinics*

<table>
<thead>
<tr>
<th></th>
<th>Experimental (CARD™)</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinic visit 1 (round 1)</strong></td>
<td>(n=124)</td>
<td>(n=123)</td>
</tr>
<tr>
<td>Fear(^a)</td>
<td>3.8 (3.0)</td>
<td>4.6 (3.2)</td>
</tr>
<tr>
<td>Pain(^a)</td>
<td>3.5 (2.2)</td>
<td>3.4 (2.0)</td>
</tr>
<tr>
<td>Dizziness(^a)</td>
<td>0.8 (1.7)</td>
<td>1.3 (2.5)</td>
</tr>
<tr>
<td><strong>Clinic visit 2 (round 2)</strong></td>
<td>(n=111)</td>
<td>(n=112)</td>
</tr>
<tr>
<td>Fear(^a)</td>
<td>2.7 (2.9)</td>
<td>4.3 (3.0)</td>
</tr>
<tr>
<td>Pain(^a)</td>
<td>2.9 (2.4)</td>
<td>3.7 (2.1)</td>
</tr>
<tr>
<td>Dizziness(^a)</td>
<td>0.6 (1.4)</td>
<td>1.2 (2.0)</td>
</tr>
</tbody>
</table>

*Values are mean (standard deviation).

\(^a\)Values for fear, pain, and dizziness range from 0 (none) to 10 (maximum).

ProcMixed repeated measures analysis of variance results:

Fear: There was a significant group × time interaction (P=0.04); fear scores were lower in the experimental group at time 2 (P=0.02) but not at time 1 (P=0.17).

Pain: There was a significant group × time interaction (P=0.004); however, there was no evidence of a difference between groups at either time 1 (P=0.80) or time 2 (P=0.22).

Dizziness: There was no evidence of group (P=0.07) or time (P=0.85) effects, and no group × time interaction (P=0.96).
Table 7.
Frequency of high fear, pain, and dizziness scores in students undergoing vaccination in round 1 and round 2 clinics*

<table>
<thead>
<tr>
<th></th>
<th>Experimental (CARD™)</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinic visit 1 (round 1)</strong></td>
<td>(n=124)</td>
<td>(n=123)</td>
</tr>
<tr>
<td>Fear</td>
<td>24 (19)</td>
<td>38 (31)</td>
</tr>
<tr>
<td>Pain</td>
<td>13 (10.5)</td>
<td>11 (9)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>4 (3)</td>
<td>12 (10)</td>
</tr>
<tr>
<td><strong>Clinic visit 2 (round 2)</strong></td>
<td>(n=111)</td>
<td>(n=112)</td>
</tr>
<tr>
<td>Fear</td>
<td>17 (15)</td>
<td>33 (30)</td>
</tr>
<tr>
<td>Pain</td>
<td>10 (10)</td>
<td>11 (10)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>1 (1)</td>
<td>5 (5)</td>
</tr>
</tbody>
</table>

*Values are frequency (percent) of high scores.

aValues for fear, pain, and dizziness range from 0 (none) to 10 (maximum); scores dichotomized into high (>6 out of 10) or low (0–6).

Glimmix logistic regression results:

Fear: There was a significant effect of group (P=0.008); fear was lower in the experimental group (OR = 0.47; 95% CI 0.27–0.82). There was no evidence of time (P=0.39) effects, and no group × time interaction (P=0.69).

Pain: There was no evidence of group (P=0.87), or time (P=0.43) effects, and no group × time interaction (P=0.67).

Dizziness: There was a significant effect of group (P=0.04); dizziness was lower in the experimental group (OR 0.26; 95% CI 0.07–0.91). There was no evidence of time (P=0.28) effects, or group x time interaction (P=0.71).
Table 8.
Knowledge and fear level in focus group participants*

<table>
<thead>
<tr>
<th></th>
<th>Experimental (CARD™) (n=13)</th>
<th>Control (n=10)</th>
<th>P-value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge(^a)</td>
<td>9.1 (0.9)</td>
<td>6.5 (1.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Fear Level(^a)</td>
<td>4.3 (3.7)</td>
<td>4.6 (4.3)</td>
<td>0.84</td>
</tr>
</tbody>
</table>

*Values are mean (standard deviation).

\(^a\)Values for knowledge and fear range from 0 (none) to 10 (maximum).

**T-test.
Table 9.

Fidelity of Implementing The CARD™ System

<table>
<thead>
<tr>
<th>Activity</th>
<th>Task(s) Evaluated</th>
<th>Tools to Assist and Evaluate Fidelity</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education Lesson</td>
<td>Playing CARD™ Videos 1 &amp; 2</td>
<td>- In-Class Education Checklist (Appendix C)</td>
<td>5/5 CARD™ schools</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Observational field notes</td>
<td></td>
</tr>
<tr>
<td>Reviewing 5 case scenarios</td>
<td></td>
<td>- Observational field notes</td>
<td>2/5 CARD™ schools *</td>
</tr>
<tr>
<td>Filling out CARD™ Pamphlet</td>
<td></td>
<td>- Documented student coping strategy choices from CARD™ pamphlet (Figure 2)</td>
<td>5/5 CARD™ schools</td>
</tr>
<tr>
<td>Completing pre-post knowledge questionnaires</td>
<td></td>
<td>- Counted pre/post-lesson questionnaires (Appendix B)</td>
<td>5/5 CARD™ schools</td>
</tr>
<tr>
<td>Vaccination Clinics</td>
<td>Clinic set-up:</td>
<td>- Clinic Process Checklist (Appendix D)</td>
<td>4/5 CARD™ schools</td>
</tr>
<tr>
<td></td>
<td>- Arrangement of tables</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Private area</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Waiting area</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student-nurse interactions:</td>
<td></td>
<td>- Nurse Fidelity Checklist (Appendix E)</td>
<td>100% of those observed (10% of students at CARD™ and control clinics)</td>
</tr>
<tr>
<td></td>
<td>- Nurses asking which CARD™ students wanted to play</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Coping strategies used</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Relative time to be vaccinated</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Quality of student-nurse interaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-vaccination Student Feedback Questionnaires</td>
<td></td>
<td>- Researcher directly monitored every student as they filled out their questionnaire</td>
<td>247/247 students in Round 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Counted questionnaires</td>
<td>222/223 students in Round 2</td>
</tr>
</tbody>
</table>

* Only one school reviewed all five case scenarios within the allotted education lesson period. Two CARD™ schools reviewed four of five scenarios, one CARD™ school reviewed three of five, and one school reviewed all case scenarios when the liaison nurse returned to the class at a later date due to time constraints.
Figure 1. CARD™ Pamphlet (front side) [114]
Figure 2. CARD™ Pamphlet (back side) [114]
Appendices
Appendix A- Student Feedback Questionnaire

**Your feedback is important to us!**

Please tell us about your experience with school vaccinations today.

1. Tell us how much the needle hurt. If you had more than one needle, just tell us about how much it hurt overall. Pick a number from 0 to 10, where 0 is no pain and 10 is worst possible pain.

   0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

2. Tell us how scared you were about the needle. If you had more than one needle, just tell us about how scared you were overall. Pick a number from 0 to 10, where 0 is no fear and 10 is worst possible fear.

   0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

3. Tell us whether you were dizzy before, during or after the needle(s). Pick a number from 0 to 10, where 0 is not dizzy at all and 10 is most dizzy possible.

   0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

4. Do you have any suggestions for how to make school vaccinations a better experience for you next time?

_________________________________________________________________________
Appendix B - Pre-Post Knowledge Questionnaire

(Baseline Survey before in-class student lesson – experimental schools):

The needle poke from vaccine injections can cause pain. Also, we know that some people are afraid or worried about the pain from needle pokes. Tell us if you think any of the ways described below can help to make needles more comfortable, either by making the needle poke hurt less, or by making it less scary. Put a checkmark ( √ ) for “Yes” or “No” or “Don’t know” for each of the statements and explain your answer.

<table>
<thead>
<tr>
<th>Ways to make needles more comfortable</th>
<th>Yes</th>
<th>Sometimes</th>
<th>No</th>
<th>Don’t know</th>
<th>Explain why you think it works or doesn’t work</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have someone with you like a parent or friend</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Have privacy so people cannot see each other getting the needle</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Use medicine to numb the skin so you don’t feel the needle</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Distract yourself so you are paying attention to something else</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Relax by taking deep belly breaths to help you stay calm</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Ask questions so you know what will happen</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Relax the arm getting the needle so that it is jiggly like spaghetti</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Sit down in a comfortable position</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Look away from the needle</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Make your legs and tummy muscles tight (or tense) so you don’t feel dizzy</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
</tbody>
</table>
Here are some statements about pain and fear. For each statement, tell us how much you agree with it from strongly agree, to agree, to no opinion, to disagree, to strongly disagree.

<table>
<thead>
<tr>
<th>Statements about pain…</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neutral/No opinion</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Vaccine injections cause the same amount of pain in everybody.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. I am satisfied with how my pain has been managed during vaccine injections.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. We don’t need to do anything about students’ pain during vaccine injections at school because pain is a normal part of the procedure.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Doctors and nurses should help make vaccine injections at school less painful for children.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Parents and students should be given information about how to make vaccine injections at school less painful for students.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Teachers should be given information about how to make vaccine injections at school less painful for students.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statements about fear…</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neutral/No opinion</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Vaccine injections cause the same amount of fear in everybody.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. I am satisfied with how my fear has been managed during vaccine injections.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. We don’t need to do anything about students’ fear about vaccine injections at school because fear is a normal part of the procedure.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Doctors and nurses should help make vaccine injections at school less frightening for students.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Parents and students should be given information about how to make vaccine injections at school less frightening for students.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Teachers should be given information about how to make vaccine injections at school less frightening for students.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Do you think you should get vaccinations?  
☐ Yes  ☐ Maybe ok  ☐ I don’t know  ☐ Maybe no  ☐ No

How afraid are you of getting vaccination needles? Pick a number from 0 to 10, where 0 is no fear and 10 is worst possible fear.

☐ 0  ☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5  ☐ 6  ☐ 7  ☐ 8  ☐ 9  ☐ 10  ☐ Don’t know/remember  ☐ It depends/sometimes

Tell us more: ________________________________
The needle poke from vaccine injections can cause pain. Also, we know that some people are afraid or worried about the pain from needle pokes. Tell us if you think any of the ways described below can help to make needles more comfortable, either by making the needle poke hurt less, or by making it less scary. Put a checkmark (✓) for “Yes” or “No” or “Don’t know” for each of the statements and explain your answer.

<table>
<thead>
<tr>
<th>Ways to make needles more comfortable</th>
<th>Yes</th>
<th>Sometimes</th>
<th>No</th>
<th>Don’t know</th>
<th>Explain why you think it works or doesn’t work</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have someone with you like a parent or friend</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Have privacy so people cannot see each other getting the needle</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Use medicine to numb the skin so you don’t feel the needle</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Distract yourself so you are paying attention to something else</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Relax by taking deep belly breaths to help you stay calm</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
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<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Relax the arm getting the needle so that it is jiggly like spaghetti</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Sit down in a comfortable position</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Look away from the needle</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Make your legs and tummy muscles tight (or tense) so you don’t feel dizzy</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
</tbody>
</table>
Appendix C – In-Class Education Checklist

_In-class Observer Checklist (all schools)_

Location: ____________________________________________________________

**Pre-Clinic Teaching (Round 1 only):**

Date of teaching (dd/mm/yyyy): __________  Time/duration (hr:min-hr:min): __________

- # students in class: class 1 ________ class 2 ________ class 3 ________ □ N/A
- # students present: class 1 ________ class 2 ________ class 3 ________ □ N/A

Date of teaching (dd/mm/yyyy): __________  Time/duration (hr:min-hr:min): __________

- # students in class: class 1 ________ class 2 ________ class 3 ________ □ N/A
- # students present: class 1 ________ class 2 ________ class 3 ________ □ N/A

☐ Consent forms distributed?  Date (dd/mm/yyyy): ______________________

**Intervention school only:**  □ CARD system review (videos, # case scenarios ____)
- practice with CARD system during class
- practice with syringe during class
- other (specify): ____________________________

<table>
<thead>
<tr>
<th>Issue</th>
<th>Occurred?</th>
<th>Number if Occurred and Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fearful students self-identified</td>
<td>□ Yes</td>
<td>□ No</td>
</tr>
<tr>
<td>Questions about pain</td>
<td>□ Yes</td>
<td>□ No</td>
</tr>
<tr>
<td>Accommodations requested</td>
<td>□ Yes</td>
<td>□ No</td>
</tr>
<tr>
<td>Other</td>
<td>□ Yes</td>
<td>□ No</td>
</tr>
</tbody>
</table>

**Additional notes:**
Appendix D – Clinic Process Checklist

Process Issues Documentation Checklist

Location: ____________________________________________________________

Pre-Clinic Teaching and Consent Process (Round 1 only):

Date of clinic (dd/mm/yyyy): _______________ Time of day (hr:min-hr:min): _______________

☐ students in class: class 1_________class 2_________ class 3 _________ N/A
☐ students present: class 1_________class 2_________ class 3 _________ N/A

☐ Consent forms checked? Date (dd/mm/yyyy):___________________________

# consent forms returned: _________

# phone calls made: _________ ➔ Date (dd/mm/yyyy):___________________________

Able to use class list to determine missing consents? ☐ Yes ☐ No

Reminders to return consents (general to class, specific to student, robocalls to all):

_____________________________________________________________________________________

Who was involved in providing these reminders (principal, secretary, teachers, etc.)?
Please specify.

_____________________________________________________________________________________

_____________________________________________________________________________________

Process Issues Documentation Checklist – ALL ROUNDS

Location: ____________________________________________________________

Date of clinic (dd/mm/yyyy): _______________

Time of day for arrival (hr:min-hr:min): _______________

Time of day for departure (hr:min-hr:min): _______________

Set-up of room: Draw a basic diagram of the vaccination clinic room and waiting area set-up, including: tables, entrances/exits, bookcases/barriers, windows, and childrens’ and nurses’ positions.
Process Issues Documentation Checklist – ALL ROUNDS

# VPD nurses giving injections (excluding Charge Nurse): ______

Did the Charge Nurse also give injections? ☐ Yes. ☐ No.

# Gr. 7 classes: ______  # Gr. 8 classes: ______

Was a class list used? ☐ Yes. ☐ No. ☐ List was unavailable.

Describe the process used to retrieve students from their classroom?

_________________________________________________________________________________

Describe the process used to make students wait for their turn to be vaccinated?

_________________________________________________________________________________

Describe the process used to return students to their classroom?

_________________________________________________________________________________

Was the school nurse present? ☐ Yes ☐ No  If yes, what was her role?

_________________________________________________________________________________

Were there any setting-specific or over-arching factors/characteristics of the vaccination day?
E.g.: Special location or timing for vaccinations of fearful children.

_________________________________________________________________________________

Process Issues Documentation Checklist – ALL ROUNDS

Document if the time needed to deliver vaccinations was impacted by any of the following issues.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Occurred?</th>
<th>Number if Occurred and Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>School breaks (recess, lunch)</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td>Record analysis</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td>Option sheets (for absences)</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td>Phone calls</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td>Panorama issue</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td>Cold chain</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td>Double needle sticks</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td>Faint</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
</tbody>
</table>
Anaphylaxis  □ Yes  □ No
Highly fearful children  □ Yes  □ No

<table>
<thead>
<tr>
<th>CHILDREN RETURNING TO NURSE BECAUSE:</th>
</tr>
</thead>
<tbody>
<tr>
<td>… feeling ill</td>
</tr>
<tr>
<td>… feeling faint</td>
</tr>
<tr>
<td>… have a headache</td>
</tr>
<tr>
<td>… want ice</td>
</tr>
<tr>
<td>…other (specify below)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Number of Doses Given</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B</td>
<td></td>
</tr>
<tr>
<td>Menactra</td>
<td></td>
</tr>
<tr>
<td>Gardasil</td>
<td></td>
</tr>
<tr>
<td>Other (specify):</td>
<td></td>
</tr>
</tbody>
</table>

Document the number of doses of each vaccine administered at the clinic.
Appendix E – Nurse Fidelity Checklist

Observer Fidelity feedback tracking form

<table>
<thead>
<tr>
<th>Specify sex of the student</th>
<th>male</th>
<th>female</th>
<th>other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>c</td>
<td>c</td>
<td>c</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Which vaccine(s) were given?</th>
<th>Hep B</th>
<th>HPV</th>
<th>Meningococcal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>c</td>
<td>c</td>
<td>c</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Did the student get all the vaccines they were eligible to receive?</th>
<th>yes</th>
<th>no</th>
<th>comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the answer is NO, was refusal because of fear, anxiety, or pain?</td>
<td>c</td>
<td>c</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Injection details for each vaccine given</th>
<th>Hep B</th>
<th>HPV</th>
<th>Meningococcal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>c</td>
<td>c</td>
<td>c</td>
</tr>
<tr>
<td>Put a check mark in the box if it occurred:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distract – verbal</td>
<td>c</td>
<td>c</td>
<td>c</td>
</tr>
<tr>
<td>Distract - object (game, phone, music, book, other)</td>
<td>c</td>
<td>c</td>
<td>c</td>
</tr>
<tr>
<td>Deep breathing</td>
<td>c</td>
<td>c</td>
<td>c</td>
</tr>
<tr>
<td>Friend present</td>
<td>c</td>
<td>c</td>
<td>c</td>
</tr>
<tr>
<td>Parent present</td>
<td>c</td>
<td>c</td>
<td>c</td>
</tr>
<tr>
<td>Educational Aid present</td>
<td>c</td>
<td>c</td>
<td>c</td>
</tr>
<tr>
<td>School nurse present</td>
<td>c</td>
<td>c</td>
<td>c</td>
</tr>
<tr>
<td>Topical anaesthetic</td>
<td>c</td>
<td>c</td>
<td>c</td>
</tr>
<tr>
<td>Privacy during vaccination</td>
<td>(reason:____________________)</td>
<td>c</td>
<td>c</td>
</tr>
<tr>
<td>Lying down</td>
<td>(reason:____________________)</td>
<td>c</td>
<td>c</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Was an accommodation made for the student that is not captured above? (e.g., which arm to inject)</th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, explain:</td>
<td>c</td>
<td>c</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Did the student faint?</th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, explain:</td>
<td>c</td>
<td>c</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How long did the entire visit with this student take relative to normal?</th>
<th>less time</th>
<th>same</th>
<th>more time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>c</td>
<td>c</td>
<td>c</td>
</tr>
</tbody>
</table>
**Explain if you answered LESS or MORE time:**

<table>
<thead>
<tr>
<th>How satisfied were you with the interaction with this student relative to normal?</th>
<th>less satisfied</th>
<th>same</th>
<th>more satisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>c</td>
<td>c</td>
<td>c</td>
</tr>
</tbody>
</table>

**Explain if you answered LESS or MORE satisfied:**