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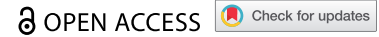


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RESEARCH PAPER



# Integrating the CARD (Comfort Ask Relax Distract) system in a mass vaccination clinic to improve the experience of individuals during COVID-19 vaccination: a pre-post implementation study

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## ABSTRACT

Many people have negative experiences with vaccination due to stress-related reactions including fear and pain. We used a pre-post study design to evaluate the impact of implementing a modified version of the CARD (Comfort-Ask-Relax-Distract) system on stress-related reactions in individuals aged 12 y or older undergoing COVID-19 vaccinations in mass vaccination clinics. Vaccine recipients reported their level of pain, fear and dizziness during vaccination. Clinic staff reported their attitudes about CARD and use of CARD interventions. CARD improved client symptoms across genders and ages with an average reduction in needle pain, fear and dizziness of 75%, 40% and 44%, respectively. CARD was more effective in younger individuals. Clinic staff reported positive attitudes about CARD and uptake of selected CARD interventions. In summary, the modified CARD system reduced stress-related responses in a general population undergoing COVID-19 vaccinations in a mass vaccination clinic, was feasible and acceptable to staff. Future implementation efforts are recommended that include more diverse cultural contexts and incorporate education of individuals about CARD ahead of time.

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## Introduction


Vaccines protect individuals and populations against morbidity and mortality caused by infectious diseases.<sup>1</sup> At present, most vaccines are administered by needle injection.<sup>2</sup> This administration method is stressful for many vaccine recipients because of concerns about associated fear and pain.<sup>3–7</sup> Across the lifespan, a significant percentage of individuals report being afraid of needles.<sup>3</sup> One large study found a prevalence rate of needle fear of 63% in children and 24% in adults. Needle fear contributed to vaccination noncompliance in 8% of children and 7% of adults, respectively.<sup>8</sup> Having a fear of needles can therefore undermine the effectiveness of immunization programs.<sup>3,8,9</sup>


To date, strategies aimed at improving vaccination uptake have overlooked addressing concerns about needle fear and associated immunization stress-related responses (ISRR),<sup>10</sup> including pain, dizziness and fainting. A plethora of evidence-based strategies exist to mitigate such adverse reactions to vaccination across the lifespan, and they have been summarized in a clinical practice guideline on this topic.<sup>11</sup> Examples include procedural techniques such as fast injections without aspiration, and psychological techniques such as distraction.<sup>11</sup> Although most techniques are cost neutral, they must be integrated in the vaccination delivery system to be effective.

In foundational work leading up to this study, a vaccination delivery framework called the CARD (Comfort Ask Relax Distract) system was developed to facilitate uptake of evidence-based strategies into practice.<sup>12</sup> CARD systematically integrates

strategies from the guideline into vaccination planning and delivery activities, and includes changes to three domains: the environment (e.g., minimizing visual cues that elicit fear, such as needles), education of providers and individuals undergoing vaccination (e.g., pamphlets and posters that educate about coping strategies in each of the letter categories of the C-A-R-D acronym), and provider–client interactions (e.g., inviting participation of individuals in the vaccination process and supporting them with their preferred coping strategies). CARD was demonstrated to reduce ISRR when implemented in school-based vaccinations.<sup>13,14</sup>

To our knowledge, there are no studies that have integrated the CARD approach into a mass vaccination clinic outside of the school setting and evaluated impact on ISRR. The COVID-19 pandemic provided an opportunity to examine implementation of CARD in the general public undergoing vaccination at mass vaccination clinics. In the present study, we adapted CARD for vaccine recipients aged 12 y and older who were receiving COVID-19 vaccinations in a mass vaccination clinic in Southwestern Ontario. The objectives were to determine feasibility, effectiveness and acceptability in a real-world setting where there was limited access to resources and clientele could not be educated ahead of time. This contrasts with our initial work, which also included implementation support and education of vaccine recipients prior to vaccination. The current approach reflects the constraints that were present in the COVID-19 pandemic context.

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## Materials and methods

### Study design and setting

We used a quasi-experimental pre- (baseline) and post- (CARD) implementation study design. Approval was granted from the University of Waterloo ethics committee (ORE 43288). The intervention was implemented at the COVID-19 mass vaccination clinic run by a large team-based primary care health clinic in partnership with the School of Pharmacy, University of Waterloo. The clinic was set up as one of the three mass vaccination clinics in a region with a population of 600,000.<sup>15</sup> It had a maximum capacity of 800–1000 vaccinations per day and ran between March and August 2021. The clinic only administered the Pfizer-BioNTech vaccine and used provincial eligibility criteria. At the time of the study, the focus of the clinic was on the first two doses of the vaccine series that were to be administered, as early as 21 d apart but at a recommended interval of 8 weeks.<sup>16</sup> During the study period, the clinic was open to all members of the public aged 12 y and older. The clinic staff included many different team members with responsibilities to direct flow, vaccinate, and provide client and staff support. Team leads included the physician lead, responsible for providing recovery support and special assessments; the nurse lead, responsible for clinic flow; and the pharmacist lead, responsible for the safe preparation of doses. Vaccinating staff included nurses, physicians, pharmacists, and healthcare trainees. Volunteers and intake staff were responsible for general clinic support, check-in, post-vaccination recovery monitoring, and checkout.

### Clinic setting, layout and flow

The setting was in the University of Waterloo School of Pharmacy building. The physical layout featured a waiting area outside of the building, a screening area, a large lecture theater modified for client check-in and another lecture theater adapted to include seven vaccination stations. In addition, two small study rooms were used as private vaccination stations. A third large lecture hall and a café area provided observation waiting rooms for the 15-minute post-vaccination mandated by the provincial vaccination program. A third small study room was adapted as a medical recovery space with monitored medical beds and first aid supplies for vaccine recipients experiencing an adverse reaction. After the recovery time elapsed, vaccine recipients were directed to the exit where they were assisted in finalizing paperwork, booking the next dose (if applicable), and receiving their vaccination certificate. Throughout the process, volunteers directed clientele through the different stations until exiting the clinic. There were no specific strategies or resources available for either staff or vaccine recipients to address ISRR.

### Overview of the CARD system

The CARD system was reviewed for interventions that could be adapted for use.<sup>12,17</sup> There are two main time periods, or phases, relative to vaccination in which CARD interventions

are recommended. The first is the preparation and planning period prior to vaccination while the second is on the day of vaccination. The first phase involves educating vaccinators about CARD, ensuring the clinic space is adequate, and educating vaccine recipients and other important stakeholder groups such as parents/guardians. Through training sessions, such as half-day workshops, vaccinators learn about the rationale for CARD and the specific interventions they can implement.<sup>13</sup> Vaccine recipients can be educated by vaccinators. Resources can also be accessed online (via websites from reputable sources such as Immunize Canada).

The second phase involves ensuring the clinic space set up and flow incorporate interventions to minimize stress-related reactions. During vaccine administration, vaccinators use language and behaviors that foster a positive and calm environment and incorporate client-selected coping strategies throughout the procedure. They also use injection techniques that minimize fear and pain.

### Modified CARD intervention

Owing to the COVID-19 pandemic context, clinic managers determined that a modified version of the CARD system could be implemented. The vaccinator education consisted of electronic dissemination of CARD resources, including a CARD poster and health-care provider checklist rather than a workshop session. At the start of each vaccination shift for the first week following implementation, the clinic pharmacy lead team member briefly reviewed the material in a 10-minute pre-shift huddle with vaccinators. CARD posters were hung in various places for clients to review and to serve as a visual distraction. This included the pre-vaccination area, vaccination rooms, and post-vaccination (recovery) areas. The CARD resources that were used are included in Appendices 1–5 (supplemental material).

### Data collection procedures

Vaccine recipients were invited to complete a paper-based feedback survey while in the post-vaccination area on selected days prior to and post-CARD implementation. For the baseline/pre-CARD phase, data were collected June 11–12, 2021. Post-implementation data were collected during CARD implementation, on July 14–15 and again on July 22–23, 2021 (N. B. more dates were used post-implementation due to reduced clinic hours and fewer staff). The survey inquired about level of pain, fear and dizziness experienced during vaccination (using a 0–10 numerical rating scale), concerns about vaccination and preferences for specific interventions (privacy, support person, distraction items, topical anesthetics) for making vaccinations more comfortable in the future. Demographic information included age (in years), gender (male, female, other) and COVID-19 vaccine dose number (dose 1 or dose 2). Syncopal and pre-syncopal episodes were documented by clinic physicians.

Vaccinators involved in both pre- and post-CARD implementation phases were invited to complete a paper survey inquiring about their attitudes about CARD and changes in practices. Level of agreement to a set of statements from three categories was graded using five-point

Likert scales (strongly agree, agree, neutral, disagree, strongly disagree). The first category asked about attitudes regarding the importance of client comfort (3 questions). The second category asked about the vaccine environment (11 questions) and the third asked about attitudes toward CARD (13 questions). Additionally, vaccinators were asked about their actual practices to improve vaccine recipient coping after CARD compared to before (19 questions) (less, same, more). Demographic characteristics included age, clinic role and gender.

### Sample size calculation and data analysis

Based on a prior study, approximately 2000 individuals were deemed sufficient to detect a difference in symptoms (pain, fear, dizziness) during vaccination.<sup>14</sup> Symptoms were compared between groups (i.e., before and after CARD implementation) using 1000 trials of stratified bootstrapping with ordinal regression analysis.<sup>18,19</sup> Variables considered in the models were age (in years), gender (male, female, other), dose number (first or second dose) and presence of any external factors that increased stress on vaccination day such as needle fear and vaccine side effects (yes, no). The effect of each factor, as well as their two-way interactions, were calculated. The treatment effect was expressed using the odds ratio and associated 95% confidence interval. Non-significant factors ( $p > .05$ ) were removed from the model. Vaccinator feedback was analyzed using descriptive statistics (e.g., mean, standard deviation).

## Results

A total of 2,488 vaccine recipients completed the survey, including 1,118 before CARD implementation out of a total 1,474 possible respondents (response rate of 75.8%) and 1,370 participants post-implementation out of 2,212 possible respondents (response rate of 61.9%). The pre-implementation survey was collected by two research assistants per day while the post-implementation survey was collected by one research assistant per day, which impacted the response rate. A total of 41 vaccinators completed the staff survey out of a possible 67 vaccinators (response rate 61.2%). Characteristics of vaccine recipients and vaccinators are shown in Table 1. There was important imbalance between groups in number of clients receiving their first (or second) COVID-19 vaccine dose.

The odds ratio and related 95% confidence intervals for pain, fear, and dizziness scores are displayed in Table 2. The analysis model for needle pain demonstrated that the intervention (CARD), gender (male) and increasing age were associated with significantly lower odds for pain. The pain model also revealed a significant interaction between CARD and age indicating diminished effectiveness of CARD in older individuals. The needle fear model demonstrated that the intervention (CARD), gender (male), increasing age, and dose number (dose 2) were associated with significantly lower reported needle fear. The survey response “concerns about vaccination side effects” was associated with higher fear. The fear model revealed a significant interaction between CARD and age, indicating diminished effectiveness for older individuals. The dizziness model demonstrated that the intervention (CARD) and increasing age (years) were associated with lower odds of dizziness.

**Table 1.** Demographic characteristics of vaccine recipients and vaccinators.

Vaccine recipients			
	Before CARD implementation	After CARD implementation	<i>p</i> -Value
Age in years (mean, SD)			
	31.6 (14.0)	38.4 (17.8)	<.001
Gender ( <i>N</i> , %)			
Male	586 (55.6)	664 (50.6)	.022
Female	450 (42.7)	626 (47.7)	
Other	18 (1.7)	23 (1.8)	
COVID-19 vaccine dose ( <i>N</i> , %)			
First dose	923 (88.8)	99 (7.5)	<.001
Second dose	117 (11.3)	1222 (92.5)	
Vaccinators			
Age in years ( <i>N</i> , %)			
16–20		4 (9.8)	
21–30		16 (39.0)	
31–40		10 (24.4)	
41–50		9 (22.0)	
51–60		2 (4.9)	
Gender ( <i>N</i> , %)			
Male		32 (78.0)	
Female		8 (19.5)	
Other		1 (2.4)	
Role ( <i>N</i> , %)			
Physician		10 (24.4)	
Pharmacist		2 (4.9)	
Nurse		16 (39.0)	
Health Profession Student		5 (12.2)	
Security/Volunteer		7 (17.1)	
Other		1 (2.4)	

**Table 2.** Estimated odds ratio with 95% confidence intervals for self-reported pain, fear, and dizziness in COVID-19 vaccine recipients.

	Odds ratio (95% confidence interval)		
	Needle Pain	Needle Fear	Dizziness
After implementation of CARD	0.25 (0.15–0.41)	0.60 (0.37–0.99)	0.56 (0.43–0.74)
Gender (Male)	0.54 (0.45–0.65)	0.39 (0.32–0.47)	-
Age (Years)	0.96 (0.95–0.97)	0.97 (0.96–0.98)	0.98 (0.97–0.99)
Vaccine (Dose 2)	-	0.48 (0.32–0.73)	-
Side effects concerns	-	5.50 (3.96–7.64)	3.15 (2.17–4.56)
Needle fear concerns	-	-	1.47 (1.10–1.97)
CARD:age interaction	1.04 (1.03–1.06)	1.02 (1.00–1.04)	-

Concerns about vaccination side effects and needle fear were associated with higher dizziness. On the pre-CARD implementation survey days, there were two pre-syncopal episodes and on the post-CARD implementation survey days, there was one individual who fainted and one pre-syncopal episode.

Across the entire study sample, distraction was selected most frequently for improving the vaccination experience (35.8%), followed by having a support person present (21.2%), vaccination in privacy (18.6%), and topical anesthetics (6.3%).

The responses of vaccinators to feedback surveys ( $n = 41$ ) are summarized in Tables 3 and 4. The results revealed strong support for comfort and education, a conducive environment to implement CARD, and positive attitudes about CARD (Table 4). Vaccinator practices shifted after CARD. The most common strategies utilized more frequently after CARD implementation included omitting cleansing of the skin with alcohol swabs prior to injection, use of deep breathing by clients, use of muscle tension exercises, and asking clients about their preferred coping strategies (Table 3).

## Discussion

We implemented a modified version of the CARD system—an evidence-based framework for delivering vaccinations—for a COVID-19 mass vaccination clinic in Southwestern Ontario. At the time of the study, both adults and children aged 12 and above were eligible for vaccination. We found that CARD was associated with diminished levels of stress-related responses during vaccination, including pain, fear, and dizziness, especially among younger clients. To our knowledge, this study provides the first evidence for the effectiveness and feasibility of the implementation of CARD in a pandemic mass vaccination situation.

We postulate that the observed benefit on ISRR was due to the combined effects of education of vaccine recipients and vaccinators and use of CARD strategies during vaccination. Systematic efforts at reducing stress-related responses in individuals undergoing vaccination have not been a prioritized aspect of immunization even though they are iatrogenic harms of vaccination and well-documented to contribute to decreased vaccine acceptance, including COVID-19 vaccination.<sup>20</sup> This study shows that a relatively simple intervention, with limited staff training, can be integrated in vaccination delivery. Vaccine recipients also endorsed having CARD interventions available to improve the

vaccine experience. Importantly, client preferences for coping should be accommodated within clinics and are an important aspect of person-centered approaches to health-care delivery.<sup>21,22</sup>

We found that individuals who identified as male self-reported lower vaccine stress-related responses. These results are consistent with prior studies showing higher prevalence

**Table 3.** Summary of vaccinator attitudes about vaccine recipient comfort, the clinic environment and adoption of the CARD system.

	Mean (SD)
<b>Attitudes about vaccine recipient comfort</b>	
I believe that pain and fear during vaccination can have a negative effect on patients	4.4 (0.5)
Patients should be given information about how to make vaccinations more comfortable	4.2 (0.7)
Clinic staff should be given information about how to make vaccinations more comfortable	4.4 (0.8)
<b>Clinic Environment</b>	
The clinic staff work together as a well-coordinated team	4.7 (0.5)
I experience good collaboration with other clinic staff and managers	4.7 (0.5)
I experience good collaboration with patients	4.5 (0.6)
I can easily speak up if I perceive a problem with patient care in my clinic	4.3 (0.8)
Disagreements in my clinic are resolved appropriately	4.3 (0.7)
It is easy for staff in my clinic to ask questions when they do not understand something	4.7 (0.5)
The levels of staffing in my clinic are sufficient to handle the number of patients	4.6 (0.5)
Meetings/huddles are regularly performed to discuss work processes in my clinic	4.6 (0.6)
I value meetings/huddles in my clinic	4.3 (0.7)
I regularly provide input during meetings/huddles in my clinic	3.7 (0.9)
My input is well received during meetings/huddles in my clinic	4.1 (0.7)
<b>Attitudes about CARD</b>	
I am willing to try new ways to deliver vaccinations	4.3 (0.7)
I understand the individual components of the CARD system	3.9 (1.2)
The CARD system is aligned with our organizational goals for delivering vaccinations	4.2 (0.8)
I believe that the CARD system improves the patient experience during vaccinations	4 (0.9)
I believe that the CARD system reduces stress-related reactions like fear and dizziness	4.1 (1.0)
I am confident in my ability to use the CARD system to reduce pain and fear in patients	3.7 (1.1)
I am willing to try all components of the CARD system	4.1 (0.9)
I believe the CARD system is being used in my clinic	3.9 (1.0)
I believe patients should know about the CARD system before coming to the clinic	3.7 (1.1)
I have the support I need from other personnel and leads to implement the CARD system	4.0 (0.9)
I would recommend the CARD system to improve the vaccination experience	3.9 (0.9)
I think it is realistic to continue to use the CARD system in our setting	4.0 (0.9)
I am likely to continue to use the CARD system in the future	3.9 (1.0)

Agreement with items assessing using 5-point Likert scale: strongly disagree, disagree, neutral, agree, strongly agree.

**Table 4.** Vaccinator practices after implementation of CARD system (vs. usual practice).

	Selection (%)		
	Less	Same	More
<b>Actions specific to vaccinators</b>			
Obscure needles	4.2	87.5	8.3
Have a support person present	8.0	88.0	4.0
Allow seating for support person	4.0	84.0	12.0
Provide privacy to patients	0.0	85.2	14.8
Use neutral language (e.g., say 'vaccine' instead of 'shot')	0.0	71.4	28.6
Inject patients while they are lying down	0.0	75.0	25.0
Omit alcohol swab from injection process	8.3	41.7	50.0
Inject without aspiration	3.7	96.3	0.0
Inject vaccine quickly (i.e., <2 seconds)	3.8	88.5	7.7
Counsel patients about using topical anaesthetics in the future	13.0	60.9	26.1
<b>Actions involving vaccine recipients</b>			
Ask patients about their level of fear before injection	3.6	64.3	32.1
Ask patients about preferred coping strategies	7.4	51.9	40.7
Invite patients to ask questions before injection	0.0	64.3	35.7
Ask patients to keep arm loose and still	0.0	88.9	11.1
Ask patients about their symptoms after injection	4.0	68.0	28.0
Ask patients to use muscle tension	4.3	47.8	47.8
Ask patients to use verbal distraction (i.e., talk to you or someone else)	0.0	72.0	28.0
Ask patients to use devices as distraction items (e.g., cell phone)	0.0	64.0	36.0
Ask patients to use relaxation breathing techniques (e.g., deep breathing)	0.0	54.2	45.8

rates for pain and fear in females.<sup>3</sup> While this might be protective for males, it can also be an indication of the long-standing social norm in which males are expected to brave stress and pain.<sup>23,24</sup> Interventions to support clients to better manage pain and fear are strongly recommended for all individuals, regardless of gender.<sup>25,26</sup>

CARD was perceived as acceptable and feasible to vaccinators. Vaccinators reported positive attitudes about CARD and many confirmed using evidence-based interventions post-CARD implementation. We note that our national vaccination administration guidelines<sup>27,28</sup> recommend alcohol skin antiseptics prior to injection while the World Health Organization (WHO) recommends against it.<sup>29,30</sup> We adopted the WHO guidance in CARD implementation due to the lack of proven effectiveness of this intervention and the potential to reduce fear. We recommend reexamination of our national guidelines in light of the WHO's recommendations as well as a review published during the COVID-19 pandemic.<sup>30</sup>

At the time the study was undertaken, there was no possibility of including education for vaccine recipients about CARD before coming to the clinic. This would have been expected to further improve the impact as individuals could be educated and better prepared for vaccination. It is possible that many individuals would have chosen to bring a support person with them or some other coping intervention. Education ahead of time using online scheduling systems is recommended for future implementation efforts, to further augment the effectiveness of CARD.

Limitations of the study include the lack of randomization of participants. There was evidence of imbalance in baseline characteristics between groups. We implemented 1000 trials of stratified bootstrapping to correct for these; however, we cannot rule out residual confounding due to the presence of variables that were not measured and therefore not accounted

for in the analysis. Our survey was designed to be brief and consequently included only the primary variables of interest to maximize response rate. While the results are limited to one vaccine center providing COVID-19 vaccinations in one geographical region with limited cultural diversity (about two-thirds European origin, one-fourth Asian origin),<sup>31</sup> the vaccination setup and procedures conformed with our governmental recommendations for setting up mass COVID-19 vaccination clinics in our province. Therefore, we expect the results to be generalizable to other mass vaccination clinics serving similar populations.

Strengths include the real-world approach to CARD implementation, which prioritized feasibility. We demonstrated that a busy mass vaccination clinic, where there is little time for vaccinators to receive additional training or to spend long periods with individual vaccine clients, can implement a simplified version of CARD and achieve a clinical benefit. Moreover, the high survey response rates (>60%) for both vaccine recipients and staff improve the confidence of the findings.<sup>32</sup>

In summary, this study demonstrated feasibility, effectiveness and acceptability of an adapted version of the CARD system in mass vaccination clinics among individuals aged 12 y and older. The CARD framework offer a feasible way of reducing ISRR and addressing vaccine hesitancy related to stress-related reactions. Future studies should evaluate CARD implementation across cultural contexts.

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## Disclosure statement

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