

RESEARCH ARTICLE



CARD (Comfort Ask Relax Distract) and community pharmacy vaccinations: Evaluation of implementation outcomes from a cluster randomized trial

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ABSTRACT

The CARD system (Comfort Ask Relax Distract) is a protocol for vaccine delivery that includes interventions that facilitate vaccine recipient coping and improve the vaccination experience. CARD was compared to control (usual care) in a pragmatic hybrid effectiveness-implementation cluster randomized trial. Of 25 participating community pharmacies, 12 were randomized to CARD and 13 to control for all vaccines administered between November 2023 and January 2024. Implementation strategies planned to support CARD integration included an educational webinar, customized implementation recommendations, change equipment, online chat group, and audit and feedback. Educational outreach was added to improve intervention fidelity. This paper reports on implementation outcomes of the trial. Provider surveys and focus groups revealed acceptability and feasibility of CARD and implementation strategies. Vaccinators in CARD pharmacies (vs. control) reported higher satisfaction with vaccine recipient interactions and that overall, CARD was time neutral. They also reported higher utilization of some CARD-recommended injection techniques. Administrative data verified utilization of the CARD coping checklist, which solicits vaccine recipient coping preferences, in 96% of vaccine recipients that participated. Post-vaccination feedback surveys were available for 90% of vaccine recipients that participated. Implementation results were aligned with trial effectiveness outcomes, and support routine use of CARD in community pharmacies.

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Introduction

Across settings, mass vaccination delivery involves multiple challenges related to both planning activities and procedural aspects.^{1,2} Community pharmacies, a relatively new and convenient setting for vaccinating large numbers of individuals,³ are no exception. Pharmacy professionals report that vaccinations are often performed in addition to and in between other tasks, which is time-consuming and stressful. In addition, negative reactions (e.g., pain, fear and other immunization stress-related responses (ISRR)) experienced by vaccine clients, especially children, further escalate the time and stress.^{4,5} In the long-term cumulative negative experiences with vaccination can negatively affect both providers and vaccine recipients. For providers, it can reduce willingness to continue providing vaccination services. For the public, it can reduce willingness to accept community pharmacy-based vaccination services in the future.⁴ Because of the increasing role community pharmacies are playing in the delivery of

vaccinations worldwide, including vaccinating increasingly younger individuals, research that explores ways to optimize vaccination delivery in this setting is warranted. This includes exploring the perspectives of pharmacy professionals and vaccine recipients to ensure that barriers to vaccination are adequately addressed for both groups.

The CARD system (C-Comfort, A-Ask, R-Relax, D-Distract) is a knowledge translation tool that integrates multiple evidence-based interventions that reduce pain, fear, and other ISRR and improves vaccine recipient and provider experiences.⁶ Vaccine recipients select coping options from the different letters of the CARD acronym (C-A-R-D) that they want to use during vaccination to reduce negative symptoms and improve their experience. Providers follow the CARD 4E model (Education, Environment, Engagement, Evaluation), which includes supporting vaccine recipient coping choices as well as using other evidence-based interventions (e.g., reducing fear cues; see also: www.cardsystem.ca).

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In prior studies, we demonstrated positive attitudes in providers who implemented CARD across various mass vaccination settings including schools and pop-up clinics.^{7–10} To date, only one small study involving community pharmacies has been performed and while pharmacists had positive attitudes about CARD, its use was limited to children receiving COVID-19 vaccinations and the implementation was supported by onsite CARD content experts.^{11,12} These factors limited the generalizability of the findings.

In the present study, we undertook a large pragmatic hybrid effectiveness-implementation¹³ cluster randomized trial in community pharmacies to further evaluate CARD. This paper includes results for implementation outcomes, including acceptability, feasibility, and fidelity. In a separate paper, we report on intervention effectiveness outcomes, including client satisfaction, symptoms (pain, fear, dizziness), and coping strategies used during vaccination.¹⁴

Materials and methods

Frameworks

Several frameworks guided the project. First, the Knowledge to Action (KTA)¹⁵ cycle was used as the overarching framework. The KTA specifies steps involved in translating research into practice.¹⁵ The Consolidated Framework for Implementation Research (CFIR)¹⁶ was used to inform the selection of evidence-based implementation strategies, questionnaire development, and data analysis. CFIR identifies factors that positively and negatively affect implementation of complex interventions such as CARD. The implementation strategies included a set (or bundle) of ways used to increase the uptake of CARD by providers and vaccine recipients, and were presented according to the taxonomy from the Expert Recommendations for Implementing Change (ERIC).¹⁷ Finally, implementation outcomes were selected from Proctor's Implementation Outcomes Framework¹⁸ and included acceptability (satisfaction with various aspects of both the CARD intervention and the implementation strategies used), feasibility (extent to which CARD interventions and implementation strategies could be carried out) and fidelity (compliance with implementation strategies and CARD interventions/quality of CARD implementation).

Design, setting and participants

We conducted a pragmatic hybrid effectiveness-implementation cluster randomized controlled trial. In this design, the implementation outcomes of a specific implementation bundle (i.e., a set of implementation strategies used to increase the use of the CARD intervention) and of the CARD intervention itself were evaluated simultaneously with the clinical effectiveness outcomes of CARD. This approach uses a more pragmatic approach to implementation than traditional efficacy and effectiveness trials, resulting in more realistic estimates of the clinical effectiveness of CARD.¹³ This paper reports on the implementation outcomes of the trial. The effectiveness outcomes are reported in a separate paper.¹⁴

Clusters included independent community pharmacies associated with Wholehealth Pharmacy Partners (WHPP) in Ontario, Canada. Participants included all individuals receiving vaccination services (herein, vaccine recipients), their caregivers, and pharmacy staff. Individuals unable to understand English were excluded.

Study procedures

The project began with the development of a multi-sector and multi-disciplinary project team that included organizational leaders from WHPP and CARD experts. Implementation steps and strategies used for both groups are briefly described here (additional details are available in Appendix 1). The study team undertook project planning activities, which included co-developing the project's protocol and implementation blueprint (i.e., document including project goals and implementation strategies, training materials, and data collection tools). After obtaining funding for the project, organizational leaders recruited community pharmacy members, oversaw training, ongoing communication and data collection.

Twenty-five pharmacies were selected for participation based on positive responses on a readiness survey disseminated by organizational leaders. They were randomized to either CARD ($n = 12$) or control (usual care) ($n = 13$).¹⁴ Both groups (CARD and control) were trained about data collection processes in separate one-hour webinars. A separate online chat group (WhatsApp™) was created for each group to facilitate ongoing communication. The study team held meetings throughout the implementation phase to review ongoing implementation, vaccine recipient feedback and milestones.

Implementation strategies used for CARD pharmacies

An integrated bundle of approaches was applied in CARD pharmacies to increase the use of CARD. Firstly, pharmacy staff received training about CARD during the webinar. A toolkit with change equipment (e.g., posters, surveys, signs, bins, clipboards) was subsequently shipped to them with a follow-up e-mail containing tailored recommendations about how to incorporate the change equipment into their pharmacy spaces and how to redesign their workflow based on videos of their vaccination processes that they submitted to organizational leaders. Examples of recommended environmental changes included hanging up posters and directional signs, removing clutter, hiding needles from view, ensuring seating was available in the vaccination room for vaccine recipients, a support person and the provider, and providing privacy during vaccination, including closing doors and covering see-through windows. Examples of workflow redesign included disseminating a paper survey (i.e., CARD coping checklist) to all vaccine recipients at appointment check-in to solicit information about level of fear of needles, history of fainting, and preferred coping strategies for vaccination. The checklist was reviewed prior to vaccination to guide interactions.

Feedback of clinical performance based on ongoing vaccine recipient responses to online evaluation surveys was planned for each pharmacy mid-way through CARD implementation

(i.e., audit and feedback). If results were below expectations (i.e., <40% of participants stating their experiences were better than their last vaccination), potential mitigation strategies were discussed with pharmacy staff.

'Check-in' visits conducted in a convenience sample of CARD pharmacies revealed low intervention fidelity (e.g., posters and signs not consistently hung up, clutter not removed, seating not available for support person and/or vaccinator, and see-through clinic room windows not covered). This resulted in the addition of educational outreach visits to all CARD pharmacies whereby study team members met with individuals or teams in their workspaces to educate them about CARD with the intent of improving fidelity of the CARD intervention. These visits were organized throughout the data collection period, according to convenience, but before audit and feedback summaries were provided. Additional communication (electronic and verbal) took place to follow-up, if required.

Data collection

All data collection tools and approaches were adapted from prior studies and incorporated aspects of the CFIR¹⁶ framework. General vaccination attitudes surveys were administered in vaccinating and non-vaccinating pharmacy staff in both groups (CARD and control) to rule out baseline differences. Staff indicated their level of agreement with included statements using a 5-point Likert scale (1-strongly agree to 5-strongly disagree).

Implementation outcomes were assessed using a variety of data approaches. Perceptions of acceptability and feasibility were obtained using staff surveys and focus groups. Fidelity was obtained using staff surveys, administrative data and focus groups. Additional details regarding the nature and timing of these data approaches are provided below.

Pharmacy staff in the CARD group completed attitude surveys immediately after the training webinar and then again at the end of the study that probed level of agreement with statements related to CARD implementation outcomes using a Likert response scale with 5 levels (from strongly agree to strongly disagree). Staff also provided feedback about the webinar used to train them on CARD immediately afterward, including whether they understood the information and the amount of information included: responses were rated on a 3-point ordinal scale.

Vaccinating staff in both groups completed online surveys after each vaccination interaction with a vaccine recipient that probed aspects of CARD acceptability and feasibility. First, their satisfaction with the interaction was rated compared to normal (less, same, more) and second, the duration of the interaction was compared to normal (less, same, more). Those in the CARD group additionally reported how much CARD helped (using a Likert scale with 4 levels, from not at all to a lot). Separately, vaccine recipients also completed feedback surveys after vaccination to solicit their symptoms (e.g., pain, fear, dizziness) and experiences (e.g., better than last vaccination); these effectiveness outcomes are discussed in more detail in our companion manuscript reporting on the trial's effectiveness outcomes.¹⁴

At the end of the study, vaccinating staff in both groups completed a survey about their vaccination practices (i.e., behaviors) relative to recommended practices, probing aspects of CARD fidelity. Response categories were dichotomous (yes/no). Those in the CARD group were additionally asked about whether their behaviors changed from baseline (more, less, same).

CARD fidelity was also assessed with respect to compliance administering the CARD coping checklist and the post-vaccination feedback survey to every vaccine recipient. This was done by calculating completion rates using administrative data. The number of pharmacies that participated in the WhatsApp chat group was also counted to evaluate engagement with this implementation strategy.

At the end of the study, a convenience sample of pharmacists from the CARD group and organizational leaders participated in a virtual one-hour interviewer-facilitated focus group. A semi-structured interview guide was used to probe perceptions of CARD, implementation strategies and suggestions for improvement.

Ethics approval

Ethical approval was provided by the Research Ethics Board (REB) of the University of Toronto. A waiver of consent was granted for survey data. Pharmacy staff that participated in focus groups signed a consent form. The trial was registered (NCT06098703).

Sample size and analysis

The sample size was based on the primary effectiveness outcome, vaccine recipient experience compared to their last vaccination, and is described in our companion manuscript reporting on effectiveness outcomes.¹⁴ The sample size for implementation outcomes, the focus of this paper, was limited by the number of pharmacies and staff involved in the project. Based on our prior work in the community pharmacy setting, focus groups were planned with a maximum of 5 individuals per session and up to 3 sessions.¹²

For quantitative data, responses were summarized using descriptive statistics. Differences within and between groups were compared using inferential statistics. The statistical program SPSS (Version 29) was used to analyze the data. A P-value of < 0.05 was considered significant. Qualitative data from focus groups were transcribed verbatim and analyzed using directed content analysis using CFIR¹⁶ with results organized by implementation outcome (acceptability, feasibility, fidelity). Three researchers were involved in coding transcripts. They made notes immediately after interviews and then one researcher coded the transcripts and circulated the results to the other team members. Disagreements were resolved by consensus. Reviews of pharmacy videos, field notes from site visits and discussions supplemented the information.

Results

The study took place between Nov 3, 2023 and Jan 20, 2024. Altogether, 57 staff from both groups ($n = 35$ CARD and

Table 1. Pharmacy staff attitudes about vaccination services in CARD and Control group[†].

	CARD (n = 35) [‡]	Control (n = 22) [‡]	P-value*
It is important to help patients have positive vaccination experiences	1.1 (0.4)	1.2 (0.4)	.424
It is important to create processes for vaccination that lead to positive experiences for patients	1.2 (0.4)	1.2 (0.4)	.445
Getting feedback from patients/clients about their feelings and experiences during vaccination is an important part of providing vaccination services	1.4 (0.6)	1.3 (0.6)	.810
Patients should be given information about how to make vaccinations more comfortable	1.3 (0.4)	1.4 (0.5)	.813
Pharmacy professionals should be given information about how to make vaccinations more comfortable for their patients	1.2 (0.5)	1.3 (0.5)	.613
Patients should be given the opportunity to participate in their vaccinations by choosing how they want to cope during vaccinations	1.4 (0.8)	1.3 (0.5)	.608
Pharmacy professionals should support patients in their preferred coping strategies during vaccinations	1.3 (0.6)	1.4 (0.5)**	.401
Getting feedback from staff about their feelings and experiences during vaccination is an important part of providing vaccination services	1.4 (0.6)	1.4 (0.5)	.898

[†]Values range from 1 to 5 on a 5-point Likert scale: 1-strongly agree, 2-agree, 3-neutral, 4-disagree, 5-strongly disagree.

[‡]Includes 21 vaccinating and 14 non-vaccinating staff in the CARD group and 17 vaccinating and 5 non-vaccinating staff in the control group.

*t-test.

**n = 1 missing.

n = 22 control) completed general attitudes surveys, and 52 (n = 26 CARD and n = 26 control) completed vaccine recipient vaccination interaction surveys. Thirty-three staff from the CARD group completed CARD-specific attitude surveys. Three focus groups were held with 8 vaccinating pharmacists from the CARD group (4 pharmacists x 2 focus groups) and 3 organizational leaders (3 leaders x 1 focus group).

General vaccination attitudes of pharmacy staff in the CARD and control groups are displayed in Table 1. Attitudes were positive across included items, with no statistically significant differences between groups.

Quantitative outcomes

Staff in the CARD group held positive attitudes about CARD immediately after training and post-study, with higher post-study scores for self-reported understanding and use of CARD in the pharmacy (Table 2). With respect to the educational webinar, 90% of CARD pharmacy staff reported they

understood all the information included and 94% said the amount of information was just right.

Perceptions of providers in both groups about their interactions with vaccine recipients during vaccination are shown in Figure 1. With respect to acceptability, vaccinators in the CARD group (vs. control) reported being more satisfied with their interactions with vaccine recipients. With respect to feasibility, the pattern of responses for duration of provider-client interactions differed significantly between groups – there were more interactions rated as either shorter or longer for the CARD group when compared to the control group. Overall, CARD was perceived as time-neutral. Furthermore, vaccinators in the CARD group reported that CARD helped in 77.5% (725/936) of vaccination interactions (45.1% a little bit, 23.7% medium amount and 8.6% a lot). Table 3 displays provider self-reported compliance with CARD-recommended practices during vaccination. Vaccinators in both groups reported using recommended practices. Some injection techniques, including omitting alcohol skin antisepsis, refraining from changing the needle after drawing up the dose and before injection, and not

Table 2. Pharmacy staff perceptions after CARD training and implementation[†] (n = 33)[‡].

Implementation outcome domain and attitude statement	Baseline (after CARD training)	Post-study (after CARD implementation)	P-value*
Acceptability			
The CARD system is aligned with national professional standards	1.6 (0.6)	1.5 (0.6)	.374
The CARD system is aligned with our pharmacy's goals and values	1.4 (0.5)	1.4 (0.6)	1.000
I believe that CARD improves vaccination planning and delivery processes	1.7 (0.9)	1.7 (0.7)	.601
I believe that CARD improves the patient's experience during vaccinations	1.6 (0.8)	1.6 (0.8)	.414
I believe that CARD improves staff experiences during vaccinations	1.6 (0.8)	1.9 (0.9)	.165
I believe that CARD improves parent/caregiver experiences during vaccinations	1.5 (0.6)	1.7 (0.8)	.088
I believe that CARD improves collaboration between staff and patients	1.6 (0.7)	1.6 (0.9)	.572
I believe that CARD helps to promote vaccination	1.8 (1.0)	1.9 (1.1)	.540
I believe that staff and patient feedback used to monitor CARD implementation is important for optimal integration	1.6 (0.7)	1.5 (0.6)	.258
I understand the individual components of the CARD system	1.6 (0.6)	1.3 (0.5)	.006
I believe the practice resources available to help implement CARD are useful	1.5 (0.6)	1.5 (0.6)	.744
I am willing to try all components of the CARD system	1.5 (0.6)	1.6 (0.7)	.211
I am confident in my ability to use the CARD system	1.6 (0.7)	1.5 (0.5)	.096
Feasibility			
I believe that after full integration, CARD is time neutral in our pharmacy	2.1 (0.9)	2.1 (1.2)	.879
I believe CARD reduces the time involved during vaccine injections/appointments	2.5 (1.0)	2.5 (1.3)	1.0
Fidelity			
I believe the CARD system is being used in our pharmacy	1.7 (0.7)	1.4 (0.6)	.027

[†]Values range from 1 to 5 on a 5-point Likert scale: 1-strongly agree, 2-agree, 3-neutral, 4-disagree, 5-strongly disagree.

[‡]Includes 20 vaccinating staff and 13 non-vaccinating staff in the CARD group.

*paired t-test.

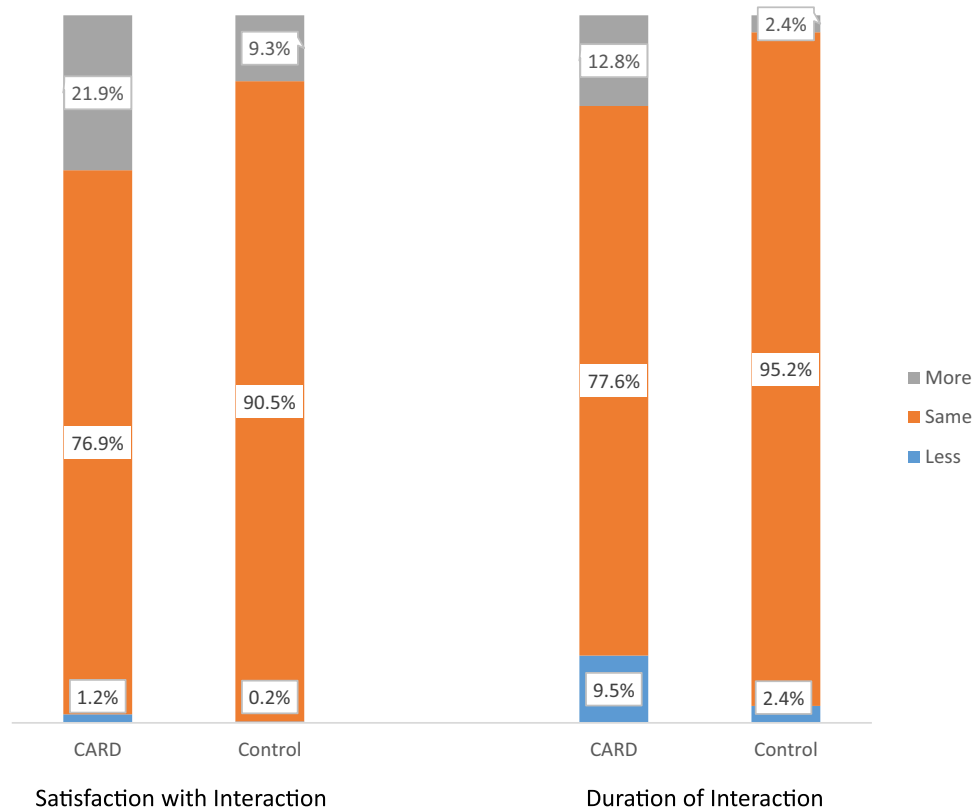


Figure 1. Vaccinating staff perceptions of their interactions with vaccine recipients in CARD and Control groups. Values are percent. Data collected for all vaccine recipient-vaccinator interactions; includes 936 vaccine recipients and 26 vaccinators in the CARD group and 1268 vaccine recipients and 26 vaccinators in the control group ($n = 1$ missing value for satisfaction with interaction in the CARD group). Data compared between groups using random effect ordinal logistic regression. $p = .04$ for satisfaction with interaction. $p < .001$ for duration of interaction.

aspirating before injection, were reported as being used more often by vaccinators in the CARD group. The majority of vaccinators in the CARD group reported using recommended interventions ‘more’ after the study compared to baseline.

Administrative data revealed that 96% of vaccine recipients had a completed CARD checklist and 90% had a completed feedback survey. Altogether, 75% of CARD pharmacies ($n = 9$) actively participated in the WhatsApp™ chat group.

Qualitative outcomes

The results for qualitative analyses of focus groups is presented below, organized by implementation outcome (see also Table 4, with selected participant quotations). When comments related to multiple outcomes, results were condensed to minimize overlap.

- (i) *Acceptability*: Across all focus groups, participants reported positive attitudes about CARD. Organizational leaders commented on alignment of CARD with organizational priorities and incentives, and the role of pharmacy professionals with respect to vaccine recipient-centredness. They recommended that external organizations update their policies to align with CARD recommendations (e.g., option to remove alcohol skin antisepsis prior to injection). Pharmacists reported positive

experiences from involving vaccine recipients in their care. Many CARD interventions were preferred over routine practice (e.g., CARD coping checklist, environmental changes, specific coping interventions). Pharmacists suggested expanding education about CARD to new pharmacy professionals for learning how to provide care to vaccine recipients. They reported higher confidence in their skills managing children specifically, and higher utility of CARD for younger clients compared to older clients. Pharmacists planned to continue to use CARD interventions after the study.

- (ii) *Feasibility*: Many implementation strategies were reported to be consistent with usual organizational practices when implementing new innovations. This includes how pharmacies were selected, educated and participated in ongoing communication. Pharmacists reported that CARD interventions fit within pharmacy workflows and that CARD was time neutral after a brief initial learning period. Participants reported adapting CARD surveys (vaccine recipient CARD coping checklist and vaccine recipient feedback survey) with elderly clients to overcome some of the challenges observed with their use in this population.
- (iii) *Fidelity*: Organizational leaders believed that the implementation strategies used were sufficiently comprehensive to achieve desired clinical outcomes. They

Table 3. Self-reported fidelity with recommended vaccination practices in CARD and Control group[†].

	CARD (n = 21)	Control (n = 17)	P-value*	More than usual, CARD group only (%)
Educate patients/clients about what will happen and how they can prepare for vaccination ahead of time. This can be done via website and/or during appointment booking.	19 (95.0) ^a	12 (80.0) ^f	.167	11 (52.4)
Educate parents/caregivers about what will happen and how they can prepare for vaccination on the day of vaccination.	18 (90.0) ^a	11 (78.6) ^g	.354	12 (57.1)
Provide distraction items/activities in all areas (i.e., waiting, injection, and aftercare area).	17 (85.0) ^a	10 (58.8)	.074	16 (76.2)
Minimize auditory and visual fear cues in all areas (e.g., close doors, play calm music, cover/conceal sharps container, needles).	18 (90.0) ^a	12 (75.0) ^e	.230	12 (57.1)
Provide seating for patients in waiting, injection and after care areas.	21 (100)	17 (100)	n/a	6 (28.6)
Provide seating for support persons in waiting, injection and after care areas.	21 (100)	17 (100)	n/a	5 (23.8)
Invite patients to get ready for vaccination by removing extra clothing such as coats in the waiting area.	19 (95.0) ^a	14 (87.5) ^e	.418	6 (28.6)
Provide privacy during vaccination (i.e., patients are not visible to others).	20 (100) ^a	17 (100)	n/a	6 (28.6)
Arrange seating during vaccination so that patient is not facing needles or other fear-inducing equipment.	18 (90.0) ^a	16 (94.1)	.647	10 (47.6)
Introduce self to vaccine patient.	20 (100) ^a	14 (93.3) ^f	.241	4 (19.0)
Use neutral language (e.g., say 'vaccine' instead of 'shot').	18 (90) ^a	16 (94.1)	.647	10 (47.6)
Screen patient level of fear of needles.	16 (80.0) ^a	15 (88.2)	.498	10 (47.6)
Screen patient history of dizziness and fainting during needle procedures.	19 (95.0) ^a	14 (82.4)	.217	7 (33.3)
Invite patient to ask questions.	20 (100) ^a	17 (100)	n/a	7 (33.3)
Invite patient to select preferred coping strategies during vaccine injection.	15 (78.9) ^b	14 (82.4)	.797	11 (52.4)
Triage patient within a family (or group) by level of fear (most fearful first).	17 (85.0) ^a	14 (82.4)	.828	11 (52.4)
Vaccinate children separately and independently of siblings.	14 (73.7) ^b	10 (62.5) ^e	.478	8 (38.1)
Hide/conceal needles and other visual fear cues from view.	16 (80.0) ^a	13 (76.5)	.795	10 (47.6)
Sit beside patient during vaccination.	18 (90.0) ^a	11 (68.8) ^e	.109	5 (23.8)
Avoid interruptions during vaccine injections.	20 (100) ^a	16 (94.1)	.272	4 (19.0)
Support patient coping strategies during vaccine injection.	18 (90.0) ^a	17 (100)	.180	8 (38.1)
Ask patient to keep arm loose and still during injection.	20 (100) ^a	17 (100)	n/a	5 (13.2)
Omit alcohol skin antisepsis from injection process.	14 (70.0) ^a	2 (11.8)	<.001	11 (52.4)
Inject 2 vaccines in the same limb rather than separate limbs.	14 (73.7) ^b	8 (50.0) ^e	.149	11 (52.4)
Inject the most painful vaccine last if administering more than one vaccine in the same appointment.	16 (84.2) ^b	9 (60.0) ^f	.112	6 (28.6)
Do not change the needle prior to injection (if also drawing up vaccine from vial).	16 (84.2) ^b	4 (23.5)	<.001	4 (19.0)
Do not aspirate prior to injection.	19 (95.0) ^a	12 (70.6)	.045	4 (19.0)
Inject vaccine quickly (i.e., <2 seconds).	18 (90.0) ^a	12 (70.6)	.133	5 (23.8)
End appointment on a positive note (e.g., congratulate patient for getting vaccinated, complement their coping choice).	18 (90.0) ^a	17 (100)	.337	8 (38.1)
Use patient feedback surveys.	13 (65.0) ^a	9 (52.9)	.457	16 (80.0)
Use staff feedback surveys.	9 (45.0) ^a	8 (47.1)	.900	10 (55.6) ^c
Review patient feedback surveys to inform future vaccination processes.	14 (73.7) ^b	7 (46.7) ^f	.107	14 (73.7) ^b
Staff debriefs/huddles/meetings to inform future vaccination processes.	13 (65.0) ^a	13 (81.3) ^e	.279	9 (52.9) ^d

[†] Values are frequency reporting 'yes' (percent). For all items, yes responses represent best practice. For the CARD group only, the relative frequency of practice compared to baseline ('more,' 'less,' 'same') was also queried; the frequency responding 'more' only is included.

*t-test.

^bn = 20; ^bn = 19; ^cn = 18; ^dn = 17; ^en = 16; ^fn = 15; ^gn = 14.

believed that partnering with external implementation advisors was beneficial to assist with project management and site visits. They identified the importance of following-up with pharmacies after didactic learning (webinar) to ensure they knew how to operationalize the recommended practice changes. Site visits, as well as audit and providing feedback were perceived as important implementation strategies for improving the fidelity of CARD. The CARD coping checklist was believed to be the most important component of CARD and guided pharmacists' interactions with vaccine recipients. One pharmacist shared how they started engaging in conversations with children rather than just speaking to parents. Another, however, stated children did not always complete their CARD checklists independently in their pharmacy, raising concerns about their autonomy.

Table 5 summarizes adaptations to included CARD interventions and study data collection approaches suggested to facilitate continued use and expansion of CARD implementation. Suggestions were primarily directed to expanding vaccine recipient and provider education and altering vaccine recipient surveys.

Discussion

Community pharmacies have been shown to be a convenient and increasingly utilized setting for providing vaccinations to the public; however, there is a scarcity of research that evaluates practice models to optimize the experiences of vaccine recipients and providers. We developed the CARD system to address this care gap.⁶ This study examined implementation outcomes from a pragmatic hybrid effectiveness-implementation cluster randomized trial with CARD in

Table 4. Selected focus group quotes from pharmacist vaccinators and implementation leaders† (*n* = 11).

Implementation domain	
Acceptability - Satisfaction with various aspects of the CARD system and/or implementation strategies used	
<i>i) Inner setting</i>	
Mission alignment – organizational goals and purpose	Immunization is one of the core interests of Wholehealth, so looking to what might be the best practices and rolling that out into our pharmacies makes a lot of sense. That's why we're interested in CARD. (P6)
Incentive system	Since our scope of practice around vaccine administration in a pharmacy began there's never really been a lot of innovation in the area. And like we are independent pharmacies; how can we differentiate ourselves from others? We wanna be the destination. What CARD brought to the table was something unique, something different. Something truly innovative that pharmacists could really gather around and rally around. (P7)
Culture – recipient centredness	We have this group of pharmacists that understands we need to involve patients in decision making and involve patients in their own healthcare. It's right in our name – whole health – like we look more comprehensively at the care of our patients. (P6)
<i>ii) Outer setting</i>	
Policies and laws	It's a real mind-set shift from what pharmacy may be used to. A lot of the time, in traditional pharmacy, we're telling patients: <i>'This is what you should do with this medication'</i> , or <i>'This is what you should do for this condition'</i> , etc. And as the scope of practice changes in Ontario and across Canada, we're stepping more into that clinician role, so the value of bringing patients in for shared decision-making is becoming more and more important. And that's where I think there was a lot of reevaluating what best practice looks like when you're trying to best support patients in this scenario, right? (P5)
Performance measurement pressure	It's very important that there's uniformity. So like, if we're not doing alcohol, I don't think it's very helpful if one pharmacy says this and the other pharmacy says no, we should be doing it because of a lack of, for better word <i>'education'</i> . (P2)
<i>iii) Innovation</i>	
CARD, overall – using client feedback	I personally had a really good experience . . . and the people liked it. We have gotten really good feedback, people actually like the whole process: <i>'Like you guys are taking suggestions from us and also getting feedback,'</i> which people liked. . . (P1)
Relative advantage – CARD checklist	That helped me to know what they wanted, and so made the interaction a lot easier, a lot more, you know, patient-centered, and I think they had a better overall better experience . . . boom like you're in and out! (P10)
Relative advantage – structural characteristics	The posters we found were very helpful for a lot of patients. And defining the initial screening area a little bit more for the patients helped with the flow. (P3) With the kids, giving them some games, . . . or those posters. We put them on the wall so they can actually go and play inside for a while, so they get relaxed before. They even forgot they are here for a needle. And a couple of parents actually told us: <i>'We have never had such a smooth vaccination process ever!'</i> (P1)
Relative advantage – changes to vaccination process	The first thing that was different was the set-up of the room, concealing anything that may trigger anxiety. We were preparing the vaccines in a separate room, so the client was seeing nothing, and we were offering the numbing cream. We weren't doing that before. The patients did really appreciate that we did that extra step. (P2) We always used to use alcohol – wiping before we do the injection. So (not doing that) was a huge difference in terms of saving time, made it a lot quicker and simpler, avoided that anticipation that people start getting. (P9)
Innovation design – educating new pharmacists	When you're starting out in pharmacy, you don't know your patients. I think this opens up the door for new pharmacists to be able to learn about their patients in order to be able to service them better in all aspects of community pharmacy, right? Not just for vaccinations, but to have this conversation with the patient and to know more about how they like to have things done. (P3)
<i>iv) Individuals</i>	
Innovation deliverers – capability	The confidence in doing vaccination for the kids was the biggest change that we had here because of the tools that were provided. It helped me with that demographic, so overall, it's been a positive experience for patients as well as staff, so like I'd say it's a <i>win-win!</i> (P9)
Innovation recipients – need	So, asking patients what they would like to do during the vaccination that would help us with the process was a very new thing for me . . . I felt like it was the families and younger generation that were more inclined to, they're more receptive to the CARD checklist, and they actually filled it out more intently, whereas the elderly and the ones that are very experienced, like they have been coming, they, just were like: <i>'Give me the shot'</i> - and then go. They were just, you know, ok, done! (P10)
Innovation deliverers – motivation to continue to use CARD	I think we're just keeping it as is, right, ongoing. We're going to just continue with it. (P8) I've kept all my stuff up. Nothing's coming down. The posters are there, the fidget, the gadgets, and all the toys and things. Those are all there. So yeah, I'll continue with it. (P10)
Feasibility - the extent to which the CARD system and/or implementation strategies could be carried out	
<i>i) Implementation process</i>	
Assessing context	When we approach a program, we usually select pharmacies that raise their hand, that want to be innovative, that has the resources or is willing to put in the time and effort to do so – which we spent time to try and identify at the beginning of this project . . . (P5)
Engaging innovation deliverers	In terms of communicating the project, not only talking about the clinical outcomes that have been shown to work in some of the research but also, how can we translate it into benefit for their particular pharmacy, or benefit for the banner from a financial or patient relationship or other nontangible benefits. So I think there's, you know, approaching it from different perspectives to be able to convince and encourage that pharmacy to participate. (P5)
Tailoring strategies – implementation strategies	The videos (submitted by pharmacies) were good because in some of the situations we had no way of going into a pharmacy, either once or multiple times, to see the output. (P5)

(Continued)

Table 4. (Continued).

Implementation domain	
ii) Inner setting	
Access to knowledge and information - implementation strategies used	I thought we did a pretty fulsome job preparing everyone involved – inviting them for education with a webinar, giving them readings and quizzes afterward, then watching how the project unfolded, and then having a way to encourage each other. We had a group chat, e-mail, and often we went ‘old school,’ ringing up the pharmacy. Seeing how very important it is to have at least initial check-ins with every site, and then having a way to encourage each other ... (P6)
Communication – implementation strategies used	We have (implementation leaders), and (name of person) is the best, like very, very up to date and then we have our chat group as well, where there’s always questions being asked about practice. They used to do the Thursday Therapeutics ... So there are programs within Wholehealth where they can kind of disseminate information. (P2)
Compatibility – changes to vaccination process	The assistant would do the intake as well as the CARD, handed out the checklist and explained the program. Then that would come to me to draw the vaccine and go into the consultation room. And he would communicate to me whether this person needs anesthetic cream, So, then I’ll go right away to put it on them and then go to my other tasks. I think it worked out well. (P10) It was mainly myself, and at busy times I had an assistant helping me, so the assistant would hand out the checklist at the beginning, they would bring the form and I would quickly peruse it and go from there. (P3)
Compatibility – CARD is time-neutral	I would let a pharmacist who’s gonna implement CARD know that, for example, I keep the vaccine appointments to every 15 min, so I would let them know until you get familiarized with the workflow, I would say keep it to like, every half an hour. Then once you are used to it, then you can go, like every 15 min. That would take, like, a day or two, not that long. Also let them know that your patient will be more satisfied with your vaccination process compared to not using CARD. (P4) For most patients, it added a little bit of time, right? Because they are usually in and out ... but for a handful of patients with whom you would normally struggle just to get them through the process, it does really fast track things and it makes it so much easier! So, I think for the time that it takes, it probably evens out. (P8)
iii) Innovation	
Adaptability – client CARD checklist and feedback surveys	So, they were mostly elderly patients ... Beginning with the questionnaire (CARD checklist) that they had to fill out, it was too hard for them to go through, and they didn’t see really the benefit of it. I had a really hard time with the iPads. I would quite often have to ask them the questions, and then they would respond to me ... (P3) (Implementation lead) gave us some questionnaires, we laminated them so that instead of having the (elderly) patients actually fill them out on the tablet, I would have a technician go out and go through the checklist with them by asking them the questions, because that way they’re not reading it, they’re not checking it off. They’re not feeling pressured. And that communication with a live person makes it a lot easier for them. (P9)
Fidelity - compliance and quality of the CARD system and/or implementation strategies	
i) Implementation process	
Tailoring strategies – implementation strategies used	With the research team and our head office team, we had to come to compromises at times with what’s needed for the fidelity of the project versus what the pharmacy team is gonna be capable of doing. As we learned more about each of those different areas it became easier to work together to find where we might be able to make those compromises. (P5)
Teaming – implementation leaders and external facilitators	So, we had other researchers (CARD experts) partnering on this as well. It was almost like a ‘divide and conquer.’ Go out and see what’s happening. Bring back those insights and contribute to action plans to address them as a team and make the best recommendations we could to manage whatever issues were unfolding in the pharmacies themselves. We wouldn’t be here with these results without the whole team. (P6)
Reflecting and evaluating – educational outreach	It’s gonna change the way we do everything going forward to other projects, like having regular touch points to make sure we have fidelity in those as well, because we don’t wanna have whatever intervention done, you know, completely different at every single site. (P6)
Reflecting and evaluating – audit and feedback	I found the audits to be very helpful in terms of making CARD more consistent across each of the sites. (P5)
ii) Individuals	
Innovation deliverer – capability	This ‘better than last time experience’ so, ‘patient centeredness’ I feel that that really is the core of CARD. It came through in the results. Putting the patients in the middle of their healthcare decision and giving them choices. Even though a lot of them didn’t pick much but they felt cared for. So, I think you know, all the other aspects of CARD certainly contributes, but for me, a key takeaway is that even if you implement CARD in a way that wasn’t ‘true’ fidelity, it still makes a difference for the patient, and that’s the most important thing. (P6)
Innovation deliverer – capability	I know, like, what patients want at the time of giving the vaccine, I know what I’m doing ... I am more confident. (P11)
Innovation deliverers – opportunity	We were talking a lot more to the kids than we were before. Before we were talking to the parents mostly. (P2)
Innovation recipients – opportunity	If they are really younger, I don’t think any of the kids, like filled that checklist ... older ones helped them. If they are like, 10 or 12 plus, I would say, yeah. (P11)

†Results are organized according to implementation outcome and specific barrier or facilitator, see text for details. Participants are identified by number (P1, P2, P3, etc.).

community pharmacies in Ontario, Canada that are members of the WHPP national pharmacy banner.

WHPP organizational leaders co-created an implementation blueprint and selected pharmacies for participation. Implementation strategies used to train pharmacy staff included a virtual webinar, tailored implementation recommendations, audit and feedback and ongoing communication. A toolkit with change equipment was also provided to facilitate practice change. During the conduct of the study, educational outreach visits were added to improve fidelity with

implementation. Pharmacy staff in the CARD group held positive attitudes about CARD which persisted over time. Vaccinating staff in the CARD group (vs. control) reported more satisfaction during vaccination interactions and that duration of vaccination interactions was time-neutral. Vaccinators in the CARD group reported using some recommended injection techniques more frequently than vaccinators in the control group. Implementation strategies and CARD interventions were reported to be suitable for practice and to improve practices during vaccination. CARD-recommended

Table 5. Recommendations from pharmacist vaccinators and implementation leaders for adapting CARD†.

Aspect of implementation	Specific suggestion
Education and preparation	
Training for pharmacy professionals	<ul style="list-style-type: none"> – Update webinar to incorporate new information/learnings from the study. – Provide guidance on incremental implementation (e.g., minimal or core components vs. comprehensive approach). – Educate new pharmacy professionals, including international pharmacy graduates that seek licensure in Canada.
Training for all knowledge users	<ul style="list-style-type: none"> – Expand education about CARD to all relevant knowledge users in the community (e.g., schools, parents, long-term care facilities, policy makers).
Education of vaccine recipients about CARD ahead of time	<ul style="list-style-type: none"> – Include information about CARD on pharmacy website and/or online booking application. – Provide CARD coping checklist to vaccine recipients ahead of time (via pharmacy and/or online booking application).
Vaccination day activities	
Adapting vaccine recipient CARD coping checklist to improve acceptability and feasibility across vaccine recipient populations	<ul style="list-style-type: none"> – Make changes to the vaccine recipient CARD coping checklist (e.g., streamline/shorten list of coping options, show pictures of coping options) and how it is presented (e.g., integrate into vaccine consent form, laminate to allow re-use with dry-erase marker, display as a poster in the pharmacy, read coping options to elderly vaccine recipients). – Disseminate to selected vaccine recipient populations (e.g., those that self-identify as afraid). – Record coping options used by vaccine recipients in the pharmacy profile and use to guide future discussions with them about their coping choices for subsequent vaccinations.
Adapting vaccine recipient CARD post-vaccination feedback surveys to improve acceptability and feasibility	<ul style="list-style-type: none"> – Make changes to the vaccine recipient CARD feedback survey, including format (paper, online, dry-erase to allow re-use), length (streamline/reduce number of questions), and how it is presented (provide online link/QR code to facilitate completion in the pharmacy, message ‘trigger’ for online completion later/at home). – Obtain vaccine recipient feedback systematically only when required. For instance, deploy for benchmarking and when changes are being introduced in the vaccination process.
Adapting distraction items according to vaccine recipient age	<ul style="list-style-type: none"> – Provide age-appropriate distraction items for vaccine recipients that are suitable for the specific vaccine recipient population.

† Data summarized from multiple sources, including focus groups, qualitative comments on surveys and field notes.

interventions fit within workflows, streamlined vaccine recipient-provider vaccination interactions and improved confidence delivering vaccinations, particularly in children. Vaccinators reported their intention to continue to use CARD after the study. There were challenges with using the CARD coping checklist and feedback survey in elderly vaccine recipients and suggestions were provided to improve acceptability and feasibility in this population.

This study builds on prior research demonstrating positive implementation outcomes for providers that utilized CARD during vaccinations.^{7–9,8,8,11,8,8,12} Organizational leaders considered it important to track pharmacy staff perceptions in the present study because they can influence how well they integrate CARD interventions, including environmental and workflow changes that allow participation of the vaccine recipient and support coping, which ultimately impact vaccine recipient experiences during vaccination. That providers reported positive attitudes and experiences confirms and supports the positive effectiveness outcomes in vaccine recipients observed in the trial.¹⁴ Importantly, more positive experiences for providers bodes favorably for sustaining pharmacy vaccination services, especially for younger vaccine recipients.

Positive results were obtained across implementation outcomes. In terms of acceptability, pharmacy staff maintained positive attitudes about the webinar training. They also held positive attitudes about CARD throughout the study, including perceived alignment with practice standards, usefulness of included toolkit equipment (e.g., posters, coping checklist), and perceptions of overall clinical effectiveness. With respect to feasibility, CARD implementation strategies incorporated contemporary and established approaches being used by WHPP. This included assessing implementation readiness

with an online survey, webinar training, provision of change equipment, and an online forum for ongoing communication. Organizational leaders added a tailored recommendation summary that was emailed to each pharmacy to help translate the theoretical learning from the webinar into practical application steps and improve fidelity of implementation. They also included a midpoint audit and feedback step to review clinical performance because pharmacy staff did not have access to online vaccine recipient feedback survey responses. Implementation leaders believed the implementation strategies used were robust, including multiple components, and that their use contributed to improved fidelity of CARD implementation. The engagement of vaccinating staff with the various intervention strategies, together with self-reported increases in their use of pain management interventions and higher confidence in vaccination delivery provide further evidence of fidelity. Finally, the high rate of completion of the CARD coping checklist and feedback surveys by vaccine recipients also provides evidence of intervention fidelity.

We have used similar implementation strategies in prior CARD projects,^{7–12} with the main exception being the inclusion of a face-to-face component to provider training rather than an exclusively virtual approach. The present study was designed to have a completely virtual approach because of the expansive distance among participating pharmacies (about 600 km separated the two most distant pharmacies). The webinar, in particular, provided a convenient and accessible way for pharmacy staff to learn about CARD and they reported that it met their learning needs with respect to understandability and amount of information. Subsequent ‘check in’ visits made to a convenience sample of CARD pharmacies, however, revealed that many CARD interventions had not yet been implemented.

Organizational leaders therefore decided to add educational outreach visits to supplement learning and improve fidelity of implementation.

The observed deficits in CARD implementation revealed during site visits may suggest that the virtual implementation approach was ineffective. However, this conclusion is premature. Deficiencies in provider comprehension and readiness to implement CARD have been observed across multiple CARD implementation projects, including when face-to-face training was included^{7,8,12} and may reflect issues related to ‘content’ rather than ‘mode of delivery.’ As a result of the feedback received from organizational leaders and providers in the present study and other CARD implementation projects, we created a new comprehensive online CARD training course to try to improve organizational and provider training and readiness to implement CARD.¹⁹ The course combines information about the scientific rationale for CARD with practical implementation tips. It includes many demonstrations and practice opportunities to promote skill development, consistent with best practices in continuing medical education.²⁰ The online CARD course is freely available on our website (www.cardsystem.ca).

It is important to note that there are differences between the CARD and control groups that were not captured by self-reported vaccination practices. Most pharmacy professionals in both groups self-reported that they followed recommended vaccination practices. Our experience across decades of research in this area, however, reveals that providers commonly overstate their use of evidence-based interventions and their own effectiveness implementing them. What may be more insightful is the within group change in practices reported by providers in the CARD group. This is because they would better understand the rationale for the included interventions and how to implement them after learning about CARD. Indeed, the pattern of responses suggests improvements in practices across recommended interventions (e.g., more frequent preparation of vaccine recipients, more frequent use of distractions). What distinguishes CARD from traditional vaccination delivery approaches is the inclusion and prioritization of the person being vaccinated (i.e., vaccine recipient-centredness). In this regard, key CARD interventions include inviting vaccine recipients to complete the CARD coping checklist and supporting them in their choices during vaccination (e.g., do vaccine recipients want to be distracted and if so, how?). The control situation comprised of the standard of care as per each individual pharmacy’s own protocol. Some interventions consistent with CARD may have been included but none would have systematically prioritized the vaccine recipient and their preferences (e.g., distraction use and method according to pharmacist preferences). When the philosophy of CARD is understood and internalized, the individual interventions that are recommended are likely to be delivered with higher fidelity in a manner most helpful for the vaccine recipient.

As with the implementation of any evidence-based innovation, CARD implementation incurred some costs. WHPP organizational leaders were engaged throughout (approximately 2 hours/week for two senior managers throughout the

planning and execution phases of the project, for approximately 6 months). Costs were also required for materials, including posters, table-top display boards, bins with toys and snacks, topical anesthetics, surveys, yoga mats, and tablets (approximately \$500 CAD). A few pharmacies acquired additional items to achieve compliance with recommended interventions (e.g., floor sandwich boards to provide directional signage; privacy adhesive film to obscure see-through injection room windows). Because of the inclusion of research components, pharmacies received compensation related to attending the webinar, completion of surveys and participation in focus groups (approximately \$500). Beyond the study, sustaining CARD will require some ongoing resources for re-stocking items (e.g., distraction toys, topical anesthetics) and onboarding and training new staff. Using re-usable items can reduce some of the costs (e.g., cleaning toys between users, collecting vaccine recipient coping choices on laminated cards that can be erased).

It should be noted that it is possible to offset the costs of CARD implementation by increasing the number of vaccine recipients. Individuals may seek out specific pharmacies that use CARD because they will have a better vaccination experience. In this and other studies, individuals that were aware of CARD have indeed reported that it positively impacted their decision to be vaccinated in those settings.^{10,14,21,22} Any vaccination setting that uses CARD is encouraged to include information about CARD on their website and/or online booking application to attract additional vaccine patrons.

There are numerous strengths of the study. First, CARD was applied using a pragmatic approach, which included vaccinations performed across the lifespan, and utilization of feasible implementation strategies. Second, the rigorous design, including a cluster randomized trial, improves internal validity of the findings. Third, feedback obtained from key individuals involved in implementation was consistent across effectiveness and implementation outcomes and data sources, improving credibility of the findings.

There are several limitations. First, both CARD and control group pharmacies were self-selected and may represent a subpopulation of pharmacies whose staff are highly motivated to optimize vaccination services. This is consistent with positive responses received on the general vaccination attitudes survey. This could reduce the generalizability of the results. Second, the study started after fall influenza and COVID-19 vaccination campaigns had already commenced, and there was a lack of study preparation time and competing demands for pharmacy staff which prevented trialing aspects of CARD implementation. It is likely that challenges to using CARD surveys, particularly in elderly vaccine recipients, would have been identified and rectified prior to the launch of the study if they had been trialed first. For instance, a visual checklist could have been used, which provides pictures of coping strategies (rather than just words) to facilitate comprehension (see www.cardsystem.ca for sample visual checklists). Third, much of the data related to fidelity was based on provider self-report, which may over-estimate compliance with CARD-recommended interventions in both groups. Direct observation of vaccine recipient interactions with pharmacy professionals was not feasible. Lastly, participating pharmacies were

independent and typically included a small number of staff. Non-vaccinating staff did not participate in focus group interviews precluding their views from being captured. However, the pattern of their responses on CARD attitude surveys were positive, which suggests that it is unlikely that they harbored negative attitudes.

In summary, pharmacy professionals held positive attitudes about the CARD system and the implementation strategies (individually and collectively) used to introduce it to community pharmacy-based vaccinations. Together with the positive effectiveness outcomes observed in the trial presented in our companion manuscript¹⁴ and prior research, we recommend CARD as the standard of care for vaccinations administered in the community pharmacy setting.

Disclosure statement

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AT, JM, CL, VG, LMB, CMM, MY, RM were involved in conception and design. AT, JM, CL, VG, LMB, CMM, MY, MF, RM, NEM were involved in analysis and interpretation of the data. AT wrote the first draft of the paper. AT, JM, CL, VG, LMB, CMM, MY, MF, RH, NEM were involved in revising it critically for intellectual content. All authors provided final approval of the version to be published, and all authors agree to be accountable for all aspects of the work.

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