





COVID-19 Vaccination Delivery in Long-Term-Care using the CARD (Comfort Ask Relax Distract) System: Mixed Methods study of Implementation Drivers

Anna Taddio (Da.b., Katherine S. McGilton C.d., Nancy Zheng Lydia Yeung Benoit Lafleure, Jollee S.T. Funge, Noni E. MacDonaldf, Melissa K. Andrewf,g, and Chris P. Verschoore,h

aLeslie Dan Faculty of Pharmacy, University of Toronto (UofT), Toronto, Canada; bChild Health Evaluative Sciences, The Hospital for Sick Children, Toronto, Ontario, Canada; 'Toronto Rehabilitation Institute, University Health Network (UHN), Toronto, Ontario, Canada; aLawrence S Bloomberg, Faculty of Nursing, UofT, Toronto, Ontario, Canada; eNorthern Ontario School of Medicine (NOSM), Sudbury, Ontario, Canada; Faculty of Medicine, Dalhousie University (DU), Halifax, Nova Scotia, Canada; ⁹Canadian Center for Vaccinology, Halifax, Nova Scotia, Canada; hHealth Sciences North Research Institute, Sudbury, Canada

ABSTRACT

Objectives: CARD (comfort, ask, relax, distract) is a vaccine delivery framework that includes interventions to improve the patient's experience. CARD has not been previously implemented in long-term care (LTC) settings. This study evaluated drivers to implementation for COVID-19 vaccinations in an LTC facility.

Methods: Postimplementation interpretive evaluation including qualitative interviews and quantitative surveys with eight participants. The Consolidated Framework for Implementation Research (CFIR) was used for analysis. Adverse reactions to vaccinations and CARD interventions, including local reactogenicity and systemic reactions, were abstracted from medical charts of residents.

Results: Eight CFIR constructs emerged. Staff perceived CARD was complex because it added steps to vaccination delivery. Motivated to meet residents' needs, a receptive implementation climate of support among staff led to using strategies within CARD, such as administering topical anesthetics and omitting alcohol skin antisepsis prior to injections. Having an effective network like the residents council positively influenced implementation by allowing residents to voice their opinions. Facilitators to implementation included staff knowledge and beliefs and staff's commitment to their organization, which was focused on person-centered care. Barriers included lack of available resources (inadequate staffing), insufficient communication between management and staff and lack of awareness of CARD, and external policies not aligned with CARD. Chart reviews conducted for 93 vaccinated residents corroborated perceptions of vaccination and CARD intervention safety, revealing a low rate of local and systemic adverse reactions and no cases of skin infection.

Discussion: We identified positive and negative implementation drivers. Future research is recommended to expand the strategies employed and involve residents more directly.

Objectifs: Le système CARD (confort, aide, relaxation, distraction) est un cadre d'administration de vaccins qui comprend des interventions pour amèliorer l'expérience du patient. Le système CARD n'a pas été mis en œuvre précédemment dans les établissements de soins de longue durée. Cette étude a évalué les facteurs de sa mise en œuvre pour la vaccination contre la COVID-19 dans un établissement de soins de longue durée.

Méthodes: Évaluation interprétative après la mise en œuvre, y compris des entretiens qualitatifs et des enquêtes quantitatives auprès de huit participants. Le Cadre consolidé pour la recherche sur la mise en œuvre (CFIR) a été utilisé pour l'analyse. Les effets indésirables à la vaccination et aux interventions CARD, y compris la réactogénicité locale et les réactions systémiques, ont été extraites des dossiers médicaux des résidents

Résultats: Huit construits du CFIR ont émergé. Le personnel a perçu que le système CARD était complexe car il ajoutait des étapes à la vaccination. Motivé à répondre aux besoins des résidents, un climat de mise en œuvre réceptif suscitant le soutien du personnel a conduit à l'utilisation de stratégies propres au système CARD, telles que l'administration d'anesthésiques topiques et l'omission de l'antisepsie cutanée à l'alcool avant les injections. Le fait d'avoir un réseau efficace comme le conseil des résidents a influencé positivement la mise en œuvre en permettant à ces derniers d'exprimer leurs opinions. Les facilitateurs de la mise en œuvre comprenaient les connaissances et les croyances du personnel et l'engagement de celui-ci envers l'organisation, qui mettait l'accent sur

ARTICLE HISTORY

Received 29 May 2022 Revised 22 July 2022 Accepted 18 August 2022

KEYWORDS

long-term care; frail elderly; implementation science; COVID-19 vaccination; CARD system; pain management

CONTACT Anna Taddio 🔯 anna.taddio@utoronto.ca 🗈 Leslie Dan Faculty of Pharmacy, University of Toronto, 144 College Street, Toronto, ON M5S 3M2,

Supplemental data for this article can be accessed online at https://doi.org/10.1080/24740527.2022.2115880

les soins centrés sur la personne. Les obstacles comprenaient le manque de disponibilité des ressources (effectifs insuffisants), l'insuffisance de la communication entre la direction et le personnel et le manque de connaissances au sujet de CARD, de même que les politiques externes non alignées avec le système CARD. Un examen des dossiers effectué pour 93 résidents vaccinés a corroboré les perceptions de la sécurité de la vaccination et de l'intervention CARD tout en révélant un faible taux d'effets indésirables locaux et systémiques et aucun cas d'infection cutanée.

Discussion: Nous avons identifié des facteurs de mise en œuvre positifs et négatifs. Des recherches futures sont recommandées pour élargir les stratégies utilisées et impliquer plus directement les résidents.

Introduction

Long-term care (LTC) has been defined by the World Health Organization as "the activities undertaken by others to ensure that people with or at risk of a significant ongoing loss of intrinsic capacity can maintain a level of functional ability consistent with their basic rights, fundamental freedoms and human dignity." Recipients of LTC services typically include older adults who are frail and may have physical and/or cognitive limitations. LTC strives toward a holistic approach to care provision, incorporating the care recipient's perspective, thus allowing more focus on the care recipient preferences, autonomy, and selfdetermination. The focus on the care recipient's perspective (i.e., person-centered care) has led to inclusion of quality indicators that consider patient-important outcomes, such as pain and satisfaction with care.

In 2015, we created a clinical practice guideline² about reducing immunization stress-related responses (ISRRs) in vaccine recipients, including pain, fear, and fainting.³ Then in 2019, we developed a framework called the CARD (comfort, ask, relax, distract) system that converted the guideline recommendations into actionable steps for health care providers and vaccine clients.4 Within each letter category of the word CARD, there is a group of evidence-based activities that health care providers and individuals can use (or "play") to minimize ISRR and improve the vaccination experience. Comfort strategies include interventions that encourage serenity and physical ease, such as welcoming clinic settings with comfortable seating. The ask category invites individuals to ask questions about issues that concern them so that they can feel informed and prepared. Relax strategies include interventions that help keep people calm. Finally, distract strategies take an individual's mind off the procedure. Importantly, vaccine clients are invited to participate in the vaccination process and to select their preferred coping strategies.

CARD was shown to reduce ISRRs and improve the vaccination experience in children undergoing vaccinations at school.^{5,6} To date, there have been no studies that have examined implementation of CARD in the LTC setting. During the current COVID-19 pandemic, priority has been given to developing tools that increase vaccine acceptance and promote return visits for the second (and booster) doses, particularly in vulnerable populations, including individuals working and residing in LTC facilities given the high risk of COVID-19-related morbidity and mortality in residents and the high effectiveness of COVID-19 vaccines.⁷⁻⁹ The development of COVID-19 vaccine delivery processes in LTC settings therefore needs to be a coordinated effort by facility-based quality care teams and provide the necessary education and processes to address the needs and preferences of residents and staff. In this study, CARD was introduced to quality care team members in an LTC facility as a framework for vaccination delivery to help staff and residents prepare for upcoming COVID-19 vaccinations. The objective was to evaluate the experiences of staff, residents, and essential caregivers with CARD implementation.

Materials and Methods

Conceptual Frameworks

The Consolidated Framework for Implementation Research (CFIR) was used to guide items to probe in data collection and analysis related to drivers (i.e.,

Table 1. Summary of key phases and activities of CARD intervention recommended.

Education of staff providing vaccination services	Tailoring CARD implementation to address local activities and processes
	Creation of tools/resources to support local implementation and shared with staff
Education of residents and essential caregivers	Web-based educational sessions to ask questions about vaccination
	CARD pamphlets
Clinic day	Invite residents to use their preferred coping strategies
	Assess resident level of pain/fear
	Triage residents with special needs
	Minimize number of residents waiting
	Resident attire: short-sleeved shirt/loose- fitting sweater
	Injection technique: Omit alcohol swab use
	Analgesic options: Topical anesthetics for
	injection pain and acetaminophen for
	postinjection reactions
	Availability of distractions

barriers and facilitators) of CARD implementation.¹⁰ The research paradigm was postpositivist.

Study Design

This was a prospective observational study, including qualitative and quantitative components. Reporting of qualitative aspects follows the standards for reporting qualitative research checklist. 11

Setting and Participants

The setting was a publicly funded not-for-profit health care institution in an urban center in northern Ontario, Canada, that oversees a moderately sized LTC home (defined as between 69 and 200 beds). 12,13 Participants were recruited using purposive and snowball sampling techniques, to be able to include representation of facility staff, including members of the quality care team, residents, and essential caregivers.

CARD Intervention

Researchers provided members of the quality care team in the participating facility with resources (i.e., pamphlets) about CARD directed to all of the relevant facility groups: staff coordinating and delivering vaccinations, other facility staff, residents, and essential caregivers (see Supplemental Digital Content 1 for all pamphlets). A supply of topical anesthetics (liposomal lidocaine cream) was offered to the facility because they were not a part of standard care; however, it was up to the quality care team regarding whether they would be used. One member of the research team and expert on vaccination offered to lead web-based information sessions to answer questions about COVID-19 vaccinations and CARD. The overall goal was to adapt standard of care practices to incorporate CARD, including education about vaccination and minimizing adverse reactions, including acute pain during injection and postinjection adverse reactions. The quality care team decided what interventions to implement in their facility using their usual decision-making processes. A summary of the components of the CARD intervention used is provided in Table 1. Briefly, CARD pamphlets were disseminated to individuals involved in vaccination in the facility; virtual educational sessions were conducted for staff, residents, and essential caregivers (n = 10); and vaccine administration procedures were altered to try to improve the experiences of residents. This included application of topical anesthetics, omission of alcohol skin cleansing, and administration of acetaminophen.

Data Collection

Individual interviews were held virtually (using the Zoom (TM) platform) after the second COVID-19 vaccine dose was administered to residents and included facilitated discussion with one of the researchers (AT) using a semistructured interview guide. For facility residents who participated in the study, a staff member set up a facility computer for the resident to be able to use. Interview questions related to positive and negative experiences with vaccination, including implementation of CARD and the impact on the vaccination experience. Participating additionally answered intervieweran administered survey including questions about their age, role, and attitudes about vaccination and CARD, whereby participants provided their level of agreement with statements using a 5-point Likert scale.⁶

Due to lack of data in this population and concerns about safety, the medical charts of vaccinated residents were reviewed to ascertain adverse events occurring within 14 days of receipt of the vaccine. 14 Data were extracted into an Excel (TM) spreadsheet and included local and systemic adverse events (pain, swelling, fever) as well as behavioral changes (e.g., delirium/more aggressive behavior).

Sample Size Estimates and Data Analysis

The sample size for the qualitative components was based on our prior research^{6,15} that demonstrates that 5 to 12 participants is sufficient to identify major themes. Audiotapes of participant interviews, identified by a study code, were transcribed verbatim and analyzed using directed content analysis using CFIR.¹⁰ All transcripts were coded separately using NVivo software (https://www.qsrinternational.com/nvivo-qualita tive-data-analysis-software/home) by two team members (LY, analyst 1 and NZ, analyst 2]. Analysts' codes were compared and discrepancies were resolved using consensus. Codes were aggregated into memos, arranged by construct and grouped by participant. Ratings were assigned by each analyst using the rating rules provided by CFIR.16 This involved assessing valence (±) and strength (0, 1, 2) with a summary supporting the rating. "Mix" was used when memos within the construct had varying viewpoints. The individual valence and strength ratings were then aggregated to produce an overall rating for each construct. Analysts met to compare and come to a consensus for each construct and summary and 15% of the ratings were validated with a third analyst (KSM). Constructs were then identified as influential factors for implementation. Constructs were labeled as "strongly

Table 2. Valence ratings assigned to Consolidated Framework for Implementation Research (CFIR) constructs identified from qualitative interviews (n = 8).

Domains and constructs	Operational definition	Rating assigned to construct
I. Intervention characteri	stirs	
Evidence strength and quality	Perception of the quality and validity of the evidence supporting the use of CARD	+1
Relative advantage	Perception of the advantage of implementing the CARD program versus an alternative solution	+1
Adaptability	The degree to which the CARD program can be adapted to meet the needs of residents	+1
Complexity	Perceived complexity of the CARD program as reflected by the degree of disruptiveness to existing workflows and number of steps involved in using the intervention as intended	-2
Design quality and packaging	Perceived quality of the CARD program and how well these components are bundled and work together	Mixed
II. Outer setting		
Resident needs and resources	The degree to which residents' needs are known and prioritized by the organization (i.e., patient-centeredness)	+2
Cosmopolitanism	The degree to which the organization is networked with other external organizations	+1
External policy and incentives	Policies and incentives that support or hinder the implementation of CARD	-2
III. Inner setting		
Structural Characteristics	The social architecture, age, maturity, and size of the organization	-1
Networks and communications	The quality of the communication networks that support the implementation of the CARD program	-2
Culture	Norms and values of the organization	+1
Implementation climate	The absorptive capacity for change, shared receptivity of involved individuals to the CARD intervention, and the extent to which use of CARD will be rewarded, supported, and expected within their organization	+2
Compatibility	The degree of fit between the CARD program and the facility's values, norms, needs, and existing workflows and systems	+1
Relative priority	Stakeholders' perception of the importance of implementing CARD	+1
Leadership engagement	Commitment, involvement, and accountability of leaders and managers with the implementation	+1
Available resources	The level of resources dedicated for implementation and ongoing operations, including money, training, education, physical space, and time	-2
IV. Characteristics of indi	viduals	
Knowledge and beliefs	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention	+2
Individual identification with organization	A broad construct related to how individuals perceive the organization and their relationship and degree of commitment with that organization	+2
Other personal attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style	+1
Planning	The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance and the quality of those schemes or methods	+1
Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities	+1
Executing	Carrying out or accomplishing the implementation according to plan	-1
Reflecting and evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience	Mixed

influential," "weakly influential," or "not influential" based on the rating strength and nature of comments. We extracted specific quotes from transcripts that appeared most appropriate to the construct.

The sample size for quantitative components, including attitudes surveys and adverse events during vaccination, was fixed to the sample of participants and the number of residents vaccinated in the facility, respectively. Data entry was double-checked and analyzed descriptively. The approaches used are consistent with those of our prior studies.

Ethical Approval

The study was approved by the Health Sciences North Research Ethics Board (No. 21-002). All interview participants signed a consent form. All vaccinated residents were included in the chart review unless they (or essential caregivers) signed an opt-out form.

Results

Data were collected between June 16 and November 29, 2021. Altogether, eight individuals participated in oneon-one interviews, including six female staff (31-54 years old) and two male residents (74 and 75 years old). Staff roles spanned managerial (n = 2) and direct care (n = 4) staff positions, including two individuals involved in overseeing vaccination delivery and administering vaccinations.



Qualitative Findings

Table 2 describes the barriers and facilitators of implementation along with a rating signifying the degree to which it impacted implementation on CARD interventions. Of 39 CFIR constructs assessed across five domains, 8 were most relevant (and had the highest valence and strength ratings) for barriers or facilitators to CARD implementation. These spanned four domains: (1) intervention characteristics, (2) inner setting, (3) outer setting, and (4) individual characteristics. Barriers included complexity, networks and communication, external policies and incentives, and available resources. Facilitators included residents' needs and resources, implementation climate, knowledge and beliefs, and individual identification with organization. These factors are described in detail below, in the order presented in CFIR. 10 Participants are identified by numbers P1 to P8, without explicit specification of role to maintain confidentiality.

Intervention Characteristics

Complexity. The COVID-19 vaccination process was described as complicated: "It was kind of a little bit upside down, you know, we had the health department here, there was a bunch of nurses walking around and trying to get stuff organized" (P7). CARD was reported to increase complexity, primarily due to the use of topical anesthetics. Two individuals were involved in applying topical anesthetics, and there was a waiting period for them to take effect:

We went around, and we made sure that all the residents had their anesthetics, with a tape on it—an Opsite tape. Um, we just made sure that we did the 20 minutes beforehand, um, and then got all of our vaccination stuff ready to go. And then we go onto the unit and then provide the vaccines. (P6)

Residents responded differently to topical anesthetics with respect to accepting them, further complicating their use:

We were sitting—25 residents—in the dining room, and they kind of froze our arm with the lidocaine. And I said: "What is that for?" "Well, so it won't hurt you." So, I said, "Okay." So, 15 minutes later, they passed around and they gave me the shot and I didn't feel nothing. ... A couple of persons there with dementia, that didn't want it, they yelled a little bit. (P7)

One staff member described the challenges with topical anesthetics for individuals with cognitive impairment:

All the residents received the anesthetic, um, except for the ones who were resistant to it. They were refusing to get the cream—the dementia residents don't tend to like cream. As soon as you put on a cold cream, they will not like—it's the feeling of it that they don't like. Sometimes they wouldn't even let us approach them, because they had a long sleeve, and we had to try to get their arms out, which was impossible because it was a very tight long sleeve. So, just that would irritate them enough not to accept the cream. So, we did all that effort for nothing pretty much. (P6)

Though CARD recommended comfortable vaccination environments, staff had to follow directives from public health that contradicted the protocol and led to time constraints, including vaccinating residents during mealtimes for efficiency. "One unit ... of residents got vaccinated while they were eating their breakfast because those were the time constraints we had ... from public health" (P6). Differing instructions from governing bodies disrupted workflow and the CARD intervention:

We wanted to vaccinate our residents in their rooms . . . it was discouraged ... at a senior management level and discouraged by the public health level. . . . We want to use their environment where we would decrease the stresses for them ... we tried for that, but at the end of the day, we weren't able to do that. (P1)

One participant suggested a less complicated vaccination process that would be more comfortable for residents:

We were all congregated down in the dining room. . . . It was pretty congested down there as far as I'm concerned. They could bring less people down and have somebody at the door with the list as you come in and just have a table where to go, and then they keep coming, giving you the shot, and they can see that this table is finished okay there they go and then the next table goes ... and they go back to there, too. (P8)

Outer Setting

Patient Needs and Resources. This construct represents the idea that the implementation site comprehended and sought to address the organization's priorities, which were focused on person-centered care. Numerous examples of staff members' person-centered approaches were noted, which was a strong facilitator for implementing CARD:

... it's all about trying to keep them comfortable. [Staff] know who's nervous, they know who's anxious, you know, and providing that little extra stroke of care, and that reassurance, those kinds of things that I've seen, for just even everyday activities, that would be extended during a scary time. (P5)

CARD reminded staff their approach mattered:

The whole concept of supporting the person before the vaccination, during the vaccination, after the vaccination. I think a lot of times nurses get caught up in the task of actually giving-drawing up the vaccine and administering it—rather than thinking about even the fact that their resident or patient might be scared and

what can they do to prepare them. What can they do to alleviate some of their fears, to make them more comfortable? (P2)

External Policy and Incentives. This construct negatively influenced implementation. More specifically, public health regulated the vaccination of residents in LTC, such as vaccination location, timing, and how the vaccination should be executed. Due to these externally based policies, staff and the facility were constrained in many aspects. One participant summarized the experience with public health:

The lack of control that we had over the immunization program—that has been extremely frustrating and, really, public health tied our hands. We had put forth a tremendous effort trying to get ready for receiving vaccine that we could administer ourselves. We had staff who had taken the provincial COVax [vaccination registry database] education. (P2)

Overall, external policies and influence negatively affected the facilities' autonomy that they often have with other vaccines. Furthermore, public health was seen as having a negative impact on the CARD implementation: "I do think that it impacted the CARD implementation. I think the other huge factor there was the lack of control that we had over the immunization program" (P2).

Participants unanimously agreed that policies and impacts from public health inhibited CARD implementation in general; another prominent issue was vaccination location. Residents and staff believed that best practice for patient-centered care was implementing vaccinations in a private space, consistent with CARD. This was done in past vaccination programs such as with influenza. With COVID-19 vaccination, however, public health mandated mass vaccinations in dining rooms: "Sadly . . . one unit got vaccinated while they were eating their breakfast because those were the time constraints we had from public health" (P1). By doing so, the external factor placed by public health caused the comfort portion of CARD to not be implemented because residents' needs were not at the forefront.

Inner Setting

Networks and Communications. Most participants believed that CARD was not clearly communicated from management to the staff, who were crucial in implementing many aspects of CARD. Many staff and resident participants mentioned that they had not heard of CARD prior to the interview, though they acknowledged aspects within CARD that may not have been named as part of CARD: "... again there's that whole missing gap of the communication of work, who it was first sent to and why it didn't get any further" (P4). Communication and networks between staff, however, were viewed positively because staff felt that they could rely on their colleagues for support in implementing CARD.

One of the researchers (AT) was able to meet with the residents' council, a network for residents to discuss issues relating to the organization, and residents felt that this was a good pathway to communicate aspects of CARD and allowed residents to communicate their thoughts and feedback:

I'm just appreciative of the study and that you gave the residents an opportunity to share their voice, and for that I thank you. It's really important. We have so few residents right now in long term care that don't have a cognitive disability and are able to have these conversations. It was such a pleasure for them to be treated like . . . a member of the community again and to have that consult and to be felt like their opinion mattered and they wanted ... their feedback matters. (P4)

Residents appreciated having an expert speak about vaccinations and address their concerns, which is part of the A (ask) category of CARD:

... I think they appreciated the opportunity to talk to somebody outside of the organization to talk to a doctor, to ask questions about the vaccine ... we need to include them more in it, so I think this study did that. It gave the right residents the right opportunity to get those feelings that they had out, you know. (P4)

Changes were made in how subsequent doses of the vaccines were administered because of staff listening to the residents' council viewpoints about the vaccination setting: "They do not want to be approached at the dining table, especially for any type of treatment, any type of shot. They want that to be a separate treatment in their rooms in the privacy of their own rooms" (P4).

Implementation Climate. This construct represents the facility's capacity for change, shared receptivity of involving all key stakeholders in CARD, and the extent to which use will be rewarded, supported, and expected. Staff were quite open and willing to implement aspects of CARD that were new to them, such as removing alcohol swabs, using topical anesthetics, and wearing loose clothing. Though there were some questions regarding removing alcohol swab skin cleansing prior to injection (due to perceptions that alcohol skin antisepsis protects against skin infections), staff and caregivers trusted the team and education provided:

[Removing alcohol swabs] was presented . . . and we did have questions and some concerns from some staff and caregivers that we weren't using an alcohol swab, and I said, "You know, it really just adds to the sting and



dries the skin" and providing that education, was good -everyone kind of just trusted in what we were doing, and the second time around it wasn't even questioned because we had no site issues. (P1)

Residents were not seen as being afraid of vaccinations because they had been given many vaccinations in the past, but staff perceived that CARD aligned with how they supported them:

They're treated with dignity and respect. Some of them may have varying levels of dementia, but they're treated with dignity and respect, and they're heard, like, even when-I've seen, when we're doing our flu vaccine clinics, the nurses are upbeat, they're having fun! (P5)

Residents supported CARD, which enhanced the implementation climate. One participant mentioned how they had received positive feedback:

A few of the residents were quite happy that they were getting a topical anesthetic-when I say a few, we'd probably heard from four or five, so, not a big number, but that expressed that "Oh, this is great." We also had some caregivers . . . some family members that were very happy that that was offered to the population. (P1)

Available Resources. Participants consistently stated inadequate staffing and training time allotted as absent resources with respect to CARD implementation: "The challenge is also that we're trying to do so much right now with so few resources" (P2). Training for the COVID-19 vaccination in general, as well as training for the CARD intervention, was left to the staff themselves to learn and navigate. As a result of poor training, COVID-19 vaccination was at risk of not being executed well and with an absence of CARD: "I was trying to train myself for COVax, and it was literally, okay, here you go, here's the information, now train yourself. So, I didn't have anybody to train me on it, so that was stressful . . . " (P6). Participants also mentioned possible barriers for the future implementation of CARD, because of the complexity, availability, and costs of receiving topical anesthetics for future use: "It could be done, only if the government were to cover the cost" (P6).

Characteristics of Individuals

Knowledge and Beliefs. Individuals' attitudes and values placed on the intervention and familiarity with facts related to the intervention positively affected CARD implementation. Within this facility, most staff believed that there was value to CARD:

I think it could help the families as well, to be more prepared. . . . If they had questions and stuff like that, . . . I think [CARD pamphlets and handouts] would have

been good for lots of the family members too, as well as some of the residents that are cognitively aware. (P3)

As noted earlier, CARD was believed to be consistent with staff and organizational values, especially aspects aligned to the person's needs, based on their intimate knowledge of the person:

Some residents tend to be more anxious, more alert and unable to verbalize the discomfort they have with the injection, their responses to pain. We know that some residents have a high or a lower pain threshold, so I do have the topical anesthetic still available with my immunizations now. The nursing team do feel that it's more specific to a certain person and they would evaluate that, so they did appreciate having it. (P1)

Staff attitudes were positive toward CARD-based interventions such as omitting alcohol skin antisepsis, due to evidence-based outcomes. Staff also realized that topical anesthetics (something they had not used before) were very beneficial and appreciated learning this new practice. "We were wondering whether there was a benefit for that topical anesthetic ... the nurses did feel that there was more discomfort expressed with the injection itself without the topical anesthetic" (P1).

Topical anesthetic administration was tailored over time. Importantly, staff fine-tuned implementation to meet the needs and preferences of individuals through trial and error. This helped staff more fully support CARD. Staff continued to apply topical anesthetics to residents with cognitive impairment due to perceptions of benefit.:

We went around and we made sure that all the residents had their anesthetics ... for the first dose. The second dose ... we made sure that the residents with dementia had it for sure, and then we asked the residents who were cognitively able to tell us if they wanted it or not, and the majority did—did want it. . . . (P6)

Staff believed that they were already familiar with aspects of CARD through their own work experience and had implemented the principles of CARD prior to it being introduced in their facility: "lots of [components within CARD], I was kind of already doing just with my nursing skills" (P6). There was familiarity with CARD and past interventions for pain and fear:

"Oh, Mrs. Smith, you know what, vaccinations, they use these needles that are so tiny now you don't even feel them.' I said, 'A mosquito will bite you and hurt more than the vaccine.' I do believe that pain and fear during vaccination can lead to negative effects if it's done and other people are watching." (P5)

Staff believed that CARD helped improve the vaccination process:

We're always looking at quality initiatives and looking on how to improve, you know, processes, policies, so I really feel that that's a big part of who we are and that the CARD system is going to make things better for this vaccination process. It's something that we will definitely take and roll with it. (P4)

The use of distractions (D in CARD) was aligned with values that staff had internalized and practices they already had utilized. One nurse describes her approach:

I made sure to dress up as a distraction, so that the residents wouldn't be fearful from the vaccine, so I dressed up in purple pants, I had a scrub top that had flowers, I had bee earrings. So that it would flap in the wind free much whenever I was bending down and every time I would bend down to go and give them their vaccine, I made sure I was placing myself in front of them and not beside them, and I would go around and tell them, "I'm here to sting you." I was just being a fool, but I think the residents enjoyed it. (P6)

CARD provided reminders of proper vaccination procedures, and for less experienced staff, it was perceived as more important. "I think probably what struck me is that there's some really great reminders in there, too, for people who are more experienced. So, I think it will say different things to different people, depending on their level of experience" (P2).

Some participants stated that vaccine information sessions had a positive influence on vaccination decision making:

I think having the sessions, before getting the third shot of the booster, really helped some of the residents who may have been sitting on the fence deciding whether or not they wanted the booster shot to get it. So, they did make reference to the study . . . the things that we talked to the doctor about on the computer. (P5)

Individual Identification with Organization. How individuals perceived the organization and their relationship and degree of commitment to the organization was a facilitator for CARD implementation. Participants repeatedly stressed the importance of viewing residents as a whole and an emphasis on optimal quality of life, which was aligned with the organization's values and supported the values behind CARD:

"Our mission statement is dignity, excellence, service, and integrity, and—and pretty much what's written in the CARD system is pretty much all those, and if you think about it, the values of the CARD system would reflect our values, our mission statement." (P6)

Quantitative Findings

Staff responses to survey questions about vaccination and CARD are shown in Table 3. Staff held positive attitudes about educating and supporting residents during vaccination. They believed that CARD was compatible with their setting and led to more positive vaccination experiences. Some were unsure whether CARD use was ongoing; there

Table 3. Staff attitudes toward vaccination and CARD (n = 6).

Domain and item(s)	Median (range)
General attitudes (5-point Likert scale, range 1 = strongly disagree to 5 = strongly agree)	
Residents and caregivers should be given information about vaccinations to address their concerns	5 (5, 5)
l am confident in my ability to answer questions about vaccination from residents and caregivers	5 (4, 5) ^a
Residents and caregivers should be given information about how to make vaccinations more comfortable	5 (5, 5)
l am confident in my ability to reduce pain and fear in residents during vaccinations	5 (4, 5) ^a
I believe that pain and fear during vaccination can have a negative impact on residents	5 (4, 5)
I am willing to try new ways to deliver vaccinations	4.5 (4, 5) ^b
I experience good collaboration with residents and caregivers	4 (4, 5) ^a
I experience good collaboration with staff and managers	4 (4, 5)
The staff and managers on my team work together as a well-coordinated team	4 (1, 5)
Attitudes about CARD (5-point Likert scale, range 1 = strongly disagree to 5 = strongly agree)	
Acceptability	
I understand the individual components of the CARD system	4.5 (4, 5)
I am willing to try all components of the CARD system	5 (4, 5)
I would recommend the CARD system to reduce pain and fear during vaccinations	4 (4, 5)
I am likely to continue to use the CARD system in the future	4 (4, 5)
Appropriateness	
The CARD system is aligned with our organizational goals	5 (4, 5)
Feasibility	
Management supports my daily efforts in implementing the CARD system	4 (3, 5) ^b
I have the support I need from other personnel to implement the CARD system	4 (3, 5)
I believe the documentation involved in the CARD system is too time-consuming	2.5 (2, 3)
I think it is realistic to continue to use the CARD system in our setting	4 (4, 5)
Fidelity (compliance and quality of implementation) ^a	
I am confident in my ability to use the CARD system	4.5 (4, 5)
I believe the CARD system is being used in my unit	2 (1, 5)
I believe that the CARD system improves the resident experience during vaccinations	4 (3, 5)

 $a_n = 5$.

 $^{^{\}rm b}n = 4.$



Table 4. Adverse events occurring in LTC residents over the first 14 days after Pfizer-BioNTech COVID-19 vaccination (n = 90).^a

	Dose 1	Dose 2
No. with local reactions (e.g., swelling, redness, pain) (%)	7 (7.8)	14 (15.6)
Duration of reaction in days, median (range)	1 (1, 1)	1 (1, 4)
No. with systemic reactions (e.g., fever, muscle ache, headache) (%)	7 (7.8)	1 (1.1)
Duration of reaction in days, median (range)	1 (1, 1)	1 (n/a)
No. with behavior changes (e.g., delirium, aggression) (%)	10 (11.1)	7 (7.8)
Duration of reaction in days, median (range)	1 (1, 2)	1 (1, 1)

^aData abstracted from medical charts; only residents who received vaccination and did not opt out of data

was a preference for continued use going forward. Results are in alignment with the themes identified during one-on -one interviews.

The medical charts of 93 residents were reviewed to examine safety outcomes for vaccination, representing approximately 70% of the population. Mean age was 85 years (SD 11 years) and 67% were female. Altogether, 83% and 82% received acetaminophen after the first and second COVID-19 vaccine doses, respectively. The rate of adverse events observed was low (Table 4). There were no cases of cellulitis or infectious abscess and no adverse events persisted beyond 4 days.

Discussion

Older adults who are residents of LTC facilities are at high risk for severe complications from COVID-19 disease, including accelerating age-related deterioration in physical performance and frailty.^{7,8} Vaccination has been demonstrated to be effective in preventing serious disease.¹⁷ CARD was introduced in this setting to improve the vaccination experience for individuals and staff and promote high rates of COVID-19 vaccine uptake. CARD is a person-centered vaccine delivery framework designed to address sources of anxiety, fear, and pain.⁴ This study examined the experience of CARD implementation during COVID-19 vaccinations in one LTC facility in northern Ontario. The results revealed that public health-led COVID-19 vaccine delivery at the facility and prioritized efficiency over person-centeredness. This prevented some CARD interventions from being used, such as private vaccination spaces. In addition, there was inadequate communication between managers and staff and many staff were unaware of CARD. CARD was aligned with institutional and staff values, and many CARD interventions were consistent what they were already doing (e.g., distractions, comfort). CARD introduced new practices, including information sessions to address vaccination concerns, topical anesthetic administration to reduce needle puncture pain, and omission of alcohol swab skin cleansing prior to injection. Staff perceived these interventions to be helpful by increasing vaccine acceptance and making vaccinations more comfortable. Perceptions of COVID-19 vaccine and CARD intervention safety were corroborated by chart reviews that identified a low rate of adverse events and no cases of cellulitis in vaccinated residents. Staff questioned the practicality of having topical anesthetics available for future vaccinations beyond COVID-19 due to financial constraints.

Importantly, the implementation context was demonstrated to include constraints imposed by external organizations (i.e., public health) as well as internal processes of the LTC facility. This real-world implementation approach revealed that there is the potential for considerable variation in the interventions selected to be used from the CARD framework and how they are integrated. Effectiveness may be affected by a lack of implementation fidelity. It was not possible to ascertain implementation fidelity with the current study design. Topical anesthetic administration details, for instance, were not documented in the medical charts. Opportunities for refinement were nevertheless identified. For example, some staff comments suggest that interactional aspects of CARD may not be fully understood. This included the use of dismissive language (e.g., "You won't even feel them") or fear-provoking phrases (e.g., "I'm here to sting you"). 18 It is reasonable to expect that there would similarly be variations in selected interventions and fidelity of implementation across LTC settings because of comparable overarching drivers of implementation. We additionally note that some interventions were facilitated by the study, such as vaccine educational sessions and topical anesthetics. Going forward, additional resources would have to be allocated to be able to continue to provide these interventions. We recommend that more attention and support be given to LTC facilities for implementation of evidence-based health innovations, such as CARD, and including evaluation of implementation, to achieve higher quality of care delivery across this health care setting.

Care provision in LTC facilities should consider the care recipient's perspective and typically take place during interactions between providers and residents.¹⁹ In this study, there was little to no evidence of resident involvement in organization and delivery of COVID-19 vaccinations to suit their needs and preferences. After the study, researchers were informed by facility staff that participating in the study empowered some residents to advocate for more comfortable vaccination spaces to institutional leaders, which was subsequently agreed to. Inviting residents and caregivers to provide more formal feedback on care practices is recommended as part of regular practice to allow their preferences for comfort to inform policies and procedures.

Safety data were collected because of limited published clinical trial data with the COVID-19 vaccine in addition to lack of documentation of the effect of CARD interventions (e.g., administering topical anesthetics and acetaminophen, omitting alcohol skin cleansing) on adverse events in this population. A recent meta-analysis concluded that available evidence demonstrates COVID-19 vaccines to have short-term safety among older adults.²⁰ The present study provides additional reassurance of the safety of the vaccine and concomitant CARD interventions. Importantly, data provided reassurance to local implementers during the time the study was undertaken.

It is also important to note that since this study was undertaken, we have accrued additional evidence of the effectiveness and feasibility of CARD for reducing ISRRs in diverse populations and settings. This includes children and adults receiving COVID-19 vaccinations in pharmacies and mass vaccination clinics. 21-23 Together with the results of this study and our foundational work with CARD in children undergoing vaccinations at school,^{5,6} CARD appears to be a promising general framework for vaccination delivery in individuals across the life span.

The results must be interpreted in the context of the COVID-19 pandemic. Though LTC settings have longstanding challenges related to understaffing and limited resources for education,^{24,25} the pandemic introduced additional implementation challenges (e.g., COVID-19 disease outbreaks, increased staff shortages, unpredictable vaccine supplies and delivery, low vaccination uptake for certain staff groups) above usual nonpandemic circumstances, which reduced the priority for CARD implementation. In addition, at the time the study was planned, LTC facilities were expecting to have independence over the delivery of COVID-19 vaccinations and that all LTC residents, staff, and essential caregivers affiliated with their facilities would be offered vaccination. It was subsequently announced by the local public health unit that public health staff would attend the sites to oversee vaccine distribution while qualified facility staff administered the vaccine and that access to vaccination was limited to LTC residents. Our study was thus limited to the experiences of staff and residents with resident COVID-19 vaccinations. Results are limited to one site, and

researchers were not allowed to access the site for the interview portion because of pandemic restrictions. This limited the ability to recruit individuals for interviews from all of the targeted groups, leading to lack of representation of essential caregivers. Virtual consenting and interview procedures were used, which may have been a deterrent to participation. As a result of these factors, it is possible that not all perspectives were captured. The pandemic processes did not include documentation of administration of topical anesthetics in the medical charts of residents and the exact number of individuals who received them could not be determined. In addition, the adverse event data collected from medical charts are limited by the quality of documentation. Though it is possible that adverse events were underreported, the novelty of the COVID-19 vaccine and lack of published studies in this population may have led to higher vigilance on the part of staff with respect to monitoring for vaccine administration-related complications. Finally, the overall vaccination rate achieved for residents in the LTC facility is not known because researchers were only provided with access to the charts of residents who were vaccinated and did not opt out of the study.

Strengths of the study included participation of individuals leading vaccination services, staff, and residents, allowing for the perspectives of important stakeholder groups. Themes appeared saturated due to the presence of redundancy across participants. Online interviews may have improved feasibility and flexibility for some participants. Implementation precluded involvement of the research team, leading to a pragmatic approach to implementation and evaluation. In addition, we used a rigorous analysis methodology, including two coders and validation of coding by a third researcher. Triangulation of qualitative data was carried out with a quantitative attitude survey and chart review of documented adverse events experienced by residents.

In summary, this study explored how one LTC facility incorporated CARD into COVID-19 vaccinations among older adults. There was openness to and uptake of some CARD components; however, staff were limited in their ability to engage with available resources and build confidence and competence with CARD due to lack of time and resources. More systematic and adequately resourced implementation efforts are recommended to ensure optimal translation of research evidence into routine practice, including participation of residents, to achieve a more person-centered approach to vaccination delivery and overall care.

Acknowledgments

We thank Dr. Janet McElhaney, geriatrician and vaccine scientist, for her contributions, which included introducing CARD



to the participating centre, assisting with development of the study protocol, obtaining project approval, and leading information sessions for staff, residents, and essential caregivers. Dr. McElhaney was passionate about providing quality care to the LTC population and died during the conduct of the study. We also thank all of the individuals that participated.

Authors' Contributions

AT, KSM, NEM, and MKA made substantial contributions to the conception and design of work. AT, BL, and JSTF contributed to acquisition of data. NZ, LY, KSM, and AT contributed to data analysis. CPV provided administrative support. All authors contributed to interpretation of data. The first draft of the article was written by AT and KSM; all authors provided comments and have read and approved the submitted version.

Conflicts of Interest

AT declares the University of Toronto holds a Section 9 Trademark No. 924835 for CARD. MKA reports unrelated grants and payments from Sanofi, GSK, Pfizer, and Segirus. KSM, NEM, BL, JSTF, NZ, LY and CPV have no conflicts of interest to report.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Funding

Funding was provided to AT by the Public Health Agency of Canada Immunization Partnership Fund (2021-HQ-000220) and to MKA by the Maria and Walter Schroeder Institute for Brain Innovation and Recovery. There is no fund number associated with this award.

ORCID

Anna Taddio (D) http://orcid.org/0000-0003-4432-8975

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