Protocol Paper

COVID-19 Vaccine Implementation in Three Sites in Saskatchewan: Protocol for a Patient-Oriented Realist Evaluation

Authors:

Amir Reza Azizian MD, Tracey Carr PhD, Nazeem Muhajarine PhD, Tanya Verrall PhD, Collin Hartness MAL, Jason Vanstone PhD, Maryam Yasinian MEd, Candace Skrapek BN, Brenda Andreas BSW, Gerald Farthing PhD, Gary Groot PhD MD

Corresponding author:

Gary Groot

Gary.groot@usask.ca

Competing interests:

None declared.

Affiliations:

Department of Community Health and Epidemiology (Azizian, Carr, Muhajarine, Yasinian, Groot), University of Saskatchewan; Patient partner (Skrapek), Saskatoon, SK; Patient partner (Andreas), Maple Creek, SK; Family partner (Farthing), Saskatoon, SK; College of Medicine (Groot), University of Saskatchewan; Saskatchewan Health Authority (Groot, Hartness, Vanstone), Regina, SK; Saskatchewan Health Quality Council (Verrall), Saskatoon, SK.

Contributors:

Amir Reza Azizian contributed to conceptualization, methodology, project administration, writing the original draft and reviewing and editing the final version. Tracey Carr contributed to conceptualization, funding acquisition, methodology, project administration, writing-review and editing the final version. Nazeem Muhajarine, Tanya Verrall, Collin Hartness, and Jason Vanstone contributed to conceptualization, methodology and writing-review of the final version. Maryam Yasinian contributed to funding acquisition, project administration, writing-review of the final version. Candace Skrapek, Brenda Andreas, and Gerald Farthing contributed to conceptualization and writing-review of the final version. Gary Groot contributed to conceptualization, funding acquisition, methodology, project administration, supervision and writing-review of the final version. All authors revised the article critically for important intellectual content, approved the final version to be published and agreed to be accountable for all aspects of the work.

Funding:

2020 College of Medicine Research Awards (CoMRAD) program, University of Saskatchewan

Data sharing:

No data are associated with this protocol. It is anticipated that data generated from the realist evaluation will be made available in response to a reasonable request sent to the corresponding author.

Ethics Exemption

The study has received a letter of exemption from the Research Ethics Board (REB) at the University of Saskatchewan. The study consent forms will be distributed to potential participants prior to their interview and will reflect the exemption status from the REB.

Supplemental information:

Appendix: Memo template for initial program theory in a site (e.g., Regina)

Abstract

Background

As COVID-19 vaccines are implemented, there is limited evidence about the effectiveness of implementation processes around the world. Understanding how and why models and programs work for whom in the context in which they will be used facilitate and sustain their implementation. In this manuscript, we outline the protocol for a patient-oriented realist evaluation of COVID-19 vaccine implementation in Saskatchewan, Canada to understand the underlying mechanisms and contexts of successful implementation.

Methods

Using a patient-oriented, realist, mixed-method evaluation design to assess COVID-19 vaccine implementation in Regina, Saskatoon, and Prince Albert, Saskatchewan, Canada, the study will comprise three iterative phases guided by Realist And Meta-narrative Evidence Synthesis: Evolving Standards II (RAMESES II). Phase I will develop the initial program theory (IPT), Phase II will test and refine the IPT, and Phase III will establish the final program theory (PT). Patient family partners (PFPs) with different backgrounds were selected purposively from various locations in Saskatchewan (urban and rural) to engage collaboratively in the evaluation.

Interpretation

The goal of this realist evaluation is to co-produce a program theory with PFPs that will be used to enhance COVID-19 vaccine implementation in Saskatchewan. With PFP engagement, the evaluation findings will be shared with the Saskatchewan Health Authority and provincial government's policy

makers and communications departments, published in peer-reviewed journals, presented at provincial or national conferences, and disseminated through any additional media identified by the PFPs.

Plain language summary

COVID-19 has impacted many lives of individuals, families, communities, and countries around the world. Hand washing, face masking, and physical distancing help reduce the spread of the disease, but vaccination is an effective method to prevent the disease, lower the risk of severe infections, and reduce deaths. Vaccination programs need thoughtful planning and cooperation between multiple groups in health care systems as well as across sectors. In the planned study described here, we will try to understand why COVID-19 vaccination plans used in three different sites were successful. The study team includes patient and family partners (PFPs) with different backgrounds from various locations in Saskatchewan, health care policy makers at the Saskatchewan Health Authority, a research director from Saskatchewan Health Quality Council, and epidemiologists and patient-oriented health researchers from the University of Saskatchewan. We will use a realist evaluation, a theory-driven approach, to assess the experiences of people who received vaccines or not or were involved in the planning and delivery of COVID-19 vaccines in Saskatchewan. We will explore who did or did not participate, in what circumstances and how the COVID-19 vaccination program was or was not implemented, and why the COVID-19 vaccination program was successful. With PFP engagement, we will develop a program theory that will be used to improve Saskatchewan's COVID-19 vaccination plans.

Introduction

More than a year into the COVID-19 pandemic, countries are now implementing the largest vaccination program in history to prevent further spread of the disease. Vaccines are now being administered daily in Canada. However, accelerated vaccine development has left little time to ground the implementation plans in evidence-based practices, contributing to many logistical and ethical challenges (1). Because vaccine development is typically a lengthy and complex process (2), the cost to moving quickly can result in mistrust towards vaccine safety and effectiveness (3,4), access and equity issues (4,5), lack of community engagement (6), insufficient supplies (7), and delays in delivery (8), among other challenges.

While COVID-19 vaccine programs required implementation plans involving integration of various sectors in the health care system and across sectors, we do not know whether the current COVID-19 vaccination processes in three urban areas (Regina, Saskatoon, and Prince Albert) have been effective, and whether they will work in other Saskatchewan contexts. Given that there is an urgent need for evidence to inform decision-making and safe delivery of vaccines in a timely manner, this report outlines the protocol for a patient-oriented, realist evaluation to develop a program theory of the underlying contexts and mechanisms of successful and unsuccessful implementation.

Research questions and objectives

Through engaging those with lived experience of the health care system (also known as patient/family partners, PFPs) and using key stakeholder perspectives, we will establish a program theory of vaccine implementation that can be adapted to multiple contexts across Saskatchewan and other jurisdictions. The questions are as follows: What are the experiences of key stakeholders (people who receive the

vaccine or not or are involved in the delivery of COVID-19 vaccines) with the Saskatchewan COVID-19 vaccination program in the three sites? Specifically, who does or does not participate; how and in what circumstances is the COVID-19 vaccination program implemented or not implemented; and why is the COVID-19 vaccination program successful or unsuccessful?

Methods

Study design

A relatively new approach in health care research used to explain why relationships exist in complex systems and interventions is patient-oriented, realist research and evaluation (9–11). Since theories depict the essential processes that cause behavior and system change, programs that are theoretically based allow researchers to test hypotheses and demonstrate program impact and effectiveness (12,13). In developing, testing and refining a program theory, realist evaluators establish explanatory pathways linking how certain contexts (C) evoke underlying mechanisms (M) to generate outcomes (O) (14,15). These causal relationships are referred to as CMO configurations, or CMOCs, and are the building blocks of the program theory (16).

This realist evaluation will assess COVID-19 vaccine implementation in Regina, Saskatoon, and Prince Albert, Saskatchewan using a multi-level sequential exploratory strategy to capture the perspectives of the people who receive the vaccine or not or are involved in the delivery of the vaccines. We will employ

the Realist And Meta-narrative Evidence Synthesis: Evolving Standards II (RAMESES II) to outline our reporting of the methods and data analysis (17).

Vaccine Implementation in Saskatchewan

As of February 2021, two Health Canada authorized mRNA vaccines, produced by Pfizer-BioNTech and Moderna (18), have been distributed to the provinces, including Saskatchewan (19). The provincial government, in partnership with the Saskatchewan Health Authority (SHA) and Public Health Agency of Canada (PHAC), has developed a COVID-19 Vaccine Delivery Plan in which a phased approach to delivering the COVID-19 vaccines to residents is outlined (19). As per the Delivery Plan, the first COVID-19 vaccination in Saskatchewan was delivered in Regina on December 15th, followed by Saskatoon (December 22nd, 2020), and Prince Albert (January 7th, 2021), and targeted health care workers in intensive care units, emergency departments, hospital COVID units, staff at testing and assessment centers, elderly residents in care homes, seniors over 80, and residents in northern remote communities (20–22).

Our study comprises three iterative phases and engages PFPs at each step (Figure 1).

Placeholder (Figure 1 Patient and Family Partners (PFPs) Activities by Realist Evaluation Phases)

Phase I: Development of Initial Program Theory (IPT)

An initial program theory (IPT) forms the basis for a realist evaluation, narrows the focus of the evaluation activities, and guides the selection of study methods (16). The goal of this phase is to identify

the program's underlying assumptions, outcomes of interest, proposed mechanisms of achieving targeted outcomes, and planned activities. The first step in this phase will be to review the documents and communications related to the COVID vaccination program at each site. Two members of the research team, who are also SHA employees (CH, AA), have attended implementation meetings at each site, therefore, their field notes and observations will comprise part of the data collection for this phase.

The second step in this phase is to review literature on vaccine implementation, including journal articles and grey literature sources to find resources from similar contexts (e.g., theories on COVID-19 or non-COVID-19 vaccine implementation). For example, the "Social Contours and COVID-19: Using metrics and data to guide the reopening and reintegration process in Saskatchewan survey" (23), "White Coat, Black Art - Some health-care workers still hesitant to get COVID-19 vaccine" (24), and "Planning for the SARS-CoV-2 Vaccine Rollout" (25) are reviewed using a realist lens to understand why there is hesitancy or resistance to getting vaccinated.

The PFPs will be actively engaged in reviewing provincial implementation documents and existing literature, including presentations, field notes, and observations. In two to three virtual meetings with PFPs, we will use Mural (a digital workspace for visual collaboration) (26) to identify CMOCs in each source and analyze and synthesize these into the IPT(s) (see "Data Analysis and Synthesis" for details).

Based on the aggregated IPT at the end of Phase I, the PFPs and researchers will prepare a realist interview guide (27) consisting of a series of open-ended questions asking interviewees to confirm, refute, and refine the elements in the IPT. We estimate Phase I will be completed in approximately one month.

Phase II: Testing Initial Program Theory (IPT)

To test and refine the IPT, interviews will be conducted with eight key stakeholders from the SHA who were involved in the planning, development, and implementation of the COVID-19 vaccination program (e.g., one representative from Clinical Excellence, Public Health, Protective Services, Human Resources, Communications, as well as clinic managers from each site), and six eligible and actual vaccine recipients, two from each site (i.e., a vaccine recipient and someone who did not receive the vaccine but was eligible to be vaccinated at each site). Recruitment will be purposive, and semi-structured online or remote interviews are expected to be 20-30 minutes in duration. The researchers will conduct the interviews with planning and implementation personnel, while PFPs will lead the vaccine recipient interviews. Written, informed consent will be collected prior to the interviews.

Taking a "teacher-learner" stance (14,27), where the interviewers "teach" the interviewees about the IPT, the interviewees will be asked to confirm, refute, or refine the IPT elements. The interviews, performed via Webex or telephone, will be audio-taped, transcribed, and analyzed to build CMOCs, which will be the substance of the program theory for vaccine implementation (16).

Quantitative data, such as number and proportion of vaccinated people per week or number of vaccine doses delivered per week, will be requested from each clinic at the three sites. Data about the number and proportion of vaccinated people are also available from the Government of Saskatchewan (28) or other websites, such as the COVID-19 Vaccination Tracker (29). All data will be aggregated and de-identified. Quantitative data will allow comparisons among the three sites regarding outcomes. For example, if the number of vaccine doses delivered at each site for the first month was less than 100% of projected number or if the proportion of people who received a vaccine did not meet the target, we can compare the context and mechanisms (e.g., damaged or wasted doses, not including groups that may be inappropriate to vaccinate in the target calculation) that led to disparate outcomes. As per the COVID-19

Vaccine Delivery Plan, the provincial target number is 10,825 Pfizer-BioNTech vaccine doses delivered per week, and it is anticipated that 202,052 doses of both available vaccines will be delivered in the first quarter of 2021 (19). However, allocations per site are yet to be explored. We estimate Phase II will be completed in approximately three months.

Phase III: Development of Final Program Theory (PT)

The CMOCs that emerge in Phase II will be synthesized and consolidated to construct a PT (see "Data Analysis and Synthesis" section). Subsequently, in an online meeting with one to two SHA directors who were involved in the strategic planning and implementation of the COVID-19 vaccines in the three sites, the PT will be presented using the Mural platform to receive their final feedback. Following that, several meetings (depending on the number of changes to the revised PT) with the PFPs and research team will be held to finalize the PT. We estimate the Phase III will be completed in approximately two months.

Stakeholders

Our research team includes three PFPs (CS, BA, GF), four experienced Realist evaluators (TC, NM, TV, GG), two SHA employees (AA, JV), one SHA policy maker (CH), and one Research assistant (MY).

Patient Engagement

The PFPs have been engaged in patient-oriented realist research, are considered as high-risk population for contracting severe COVID-19 and have extensive lived experience with the health care system or care for family members with chronic health conditions. All have been identified purposively from

various locations in Saskatchewan (urban and rural). The researchers will collaborate actively with the PFPs throughout the study. To maximize our engagement with the PFPs, we will follow the Saskatchewan Center for Patient-Oriented Research Patient-Oriented Research Level of Engagement (PORLET) to direct our evaluation (30). Specifically, the PFPs will conduct the interviews with vaccine recipients, assist with interpretation of qualitative data, co-develop the CMOCs, and co-produce the PT and knowledge translation plans.

Data Analysis and Synthesis

Qualitative data will be analyzed using a "retroductive" approach common in realist research (31,32). In this approach, both inductive and deductive analyses are used along with researchers' insights to understand generative causation (31). The main stages of inductive analysis are developing a code, identifying initial themes from data sources (e.g., interviews), and coding initial themes. For the deductive analysis, the three broad concepts of context, mechanism, and outcome will be applied to the codes identified in the inductive stage. Two independent researchers (a PFP and a team member who is familiar with realist evaluation) will analyze the data by selecting the appropriate segments of text and coding them.

All interview transcripts will be imported to QSR International's NVivo 12 Plus software (33). Thorough iterative steps to analyzing the interview transcripts in NVivo are described in Gilmore et al. (32). In summary, any CMO in a data source (e.g., an interview transcript) will be recorded as a code, linked to an appropriate IPT (node), and added to the memo that is linked to the IPT. All CMOs in each memo will then be reviewed using a memo template (Appendix) to develop CMOCs and refine the IPT (node). Subsequently, from new sources, CMOCs will be coded directly to the most relevant refined IPTs of

former sources. At the end, the refined IPTs will be collated if they look similar or overlap to synthesize a PT. PFPs along with the researchers will synthesize the PT in a series of team meetings.

Interpretation

With PFP engagement, we will share the PT with SHA and provincial government policy makers and communications departments. By including SHA directors in Phase II and III of this study, we aim to provide them with the IPT and the final PT in real-time. We have met with the co-leads of the COVID-19 vaccination at the Saskatchewan Emergency Operating Center (EOC) to notify them of this study. Depending on how far the COVID-19 vaccination implementation has progressed at the time of Phase II and III of this study, the IPT or PT will be used for the implementation of the current COVID-19 vaccination program or future vaccination programs.

Findings will also be disseminated at provincial or national conferences and articles will be prepared to be published in peer-reviewed journals. The PFPs will provide guidance on dissemination through any additional media, and they will be invited and co-present the findings.

Limitations

Because of the nature of COVID-19 vaccination plans, the documentations or presentations used as data sources may limited as they evolve or change over time. This may affect the development of the IPT. However, the refinement of the IPT in various steps as well as the iterative design of the study may reduce the effect of outdated data sources. Recruiting representatives for the interviews may be

challenging. Implementation of COVID-19 vaccines is consuming much of the time of various key stakeholders targeted in this study. We will schedule interviews with key stakeholders at their convenience. Accessing quantitative data may also be limited. Panorama is an administrative database that captures vaccination information in Saskatchewan. We aim to approach the administrators of this database to explore whether it is accessible for this study. If it is not accessible, we will explore other avenues to obtain this information, including publicly available data. Another option would be requesting de-identified, aggregate data from the three sites' clinic managers.

Conclusion

We will co-develop a COVID-19 vaccination implementation PT with PFPs to demonstrate for whom, under which circumstances, how, and why Saskatchewan's COVID-19 vaccination program is successful or not. We expect the findings will inform various stakeholders about the current processes (e.g., safe delivery to sites, target population prioritization, communication plans, and compliance) embedded in COVID-19 vaccine delivery in Regina, Saskatoon, and Prince Albert, and how these processes can work in other contexts in Saskatchewan to guide further vaccine roll-out.

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Appendix

Memo Template (32)

Memo for Initial Program Theory in a Site (e.g., Regina)
IPT:
Code:
Source:
Context:
Mechanism(s):
Outcome:
CMOC:
Support/Refute/Refine:
How/Why/Decision-Making Processes:
Result/Refined:
Links/Ripple Effects:
Additional Notes:
Other Codes:

Figure 1 Patient and Family Partners (PFPs) Activities by Realist Evaluation Phases