COVID-19 VACCINATION IN THREE SITES IN SASKATCHEWAN: A PATIENT-ORIENTED REALIST EVALUATION

A Thesis Submitted to the

College of Graduate and Postdoctoral Studies

In Partial Fulfillment of the Requirements

For the Degree of Master of Science

In the Department of Community Health & Epidemiology

University of Saskatchewan

Saskatoon

By

AMIR REZA AZIZIAN

© Copyright Amir Reza Azizian, February 2023. All rights reserved

Unless otherwise noted, copyright of the material in this thesis belongs to the author.

Permission to Use

In presenting this thesis/dissertation in partial fulfillment of the requirements for a Postgraduate degree from the University of Saskatchewan, I agree that the Libraries of this University may make it freely available for inspection. I further agree that permission for copying of this thesis/dissertation in any manner, in whole or in part, for scholarly purposes may be granted by the professor or professors who supervised my thesis/dissertation work or, in their absence, by the Head of the Department or the Dean of the College in which my thesis work was done. It is understood that any copying or publication or use of this thesis/dissertation or parts thereof for financial gain shall not be allowed without my written permission. It is also understood that due recognition shall be given to me and to the University of Saskatchewan in any scholarly use which may be made of any material in my thesis/dissertation.

Disclaimer

The views and opinions of the author expressed herein do not state or reflect those of the University of Saskatchewan and shall not be used for advertising or product endorsement purposes.

Requests for permission to copy or to make other uses of materials in this thesis/dissertation in whole or part should be addressed to:

Head of the Department of Community Health & Epidemiology
Box 7, Health Science Building, 107 Wiggins Road
University of Saskatchewan
Saskatoon, Saskatchewan S7N 5E5 Canada

OR

Dean
College of Graduate and Postdoctoral Studies
University of Saskatchewan
116 Thorvaldson Building, 110 Science Place
Saskatoon, Saskatchewan S7N 5C9 Canada

Abstract

The purposes of this research were to evaluate the COVID-19 vaccination campaign in three pilot sites (Regina, Saskatoon, Prince Albert) in Saskatchewan and construct program theories for vaccine uptake among the recipients and vaccine delivery by the Saskatchewan Health Authority (SHA) stakeholders who were involved in the planning and delivery of the vaccines. The program theories contain contextual factors and causal mechanisms that influenced vaccine uptake and delivery.

Traditional evaluations oversimplify characteristics of interventions and the environment surrounding them (1). Finding solutions to complex problems needs a through understanding of the nature of the problem, interventions, and the implementation contexts (2). Problems operate at various levels (individual, local, organizational, societal) which makes the relevant interventions complex (2). Literature has shown that targeted efforts are needed to increase vaccine uptake (3). In a theory-driven realist evaluation, evaluators raise the question of "for whom, under what circumstances, how and why do interventions work or not work?", and build program theories to answer the question (2,4,5). Realist evaluation requires considerable researcher reflection, creativity, judgment, and inferences (6,7).

By using a novel combination of patient-oriented research (POR) strategy and the realist evaluation, three and six initial program theories (IPTs) for the vaccine recipients and the SHA stakeholders, respectively, were developed collaboratively with three patient and family partners (PFPs). We refined and finalized the IPTs into seven program theories (PTs) by collecting insights from six vaccine recipients and six SHA stakeholders via realist evaluation interviews. We identified salient contextual factors that evoked mechanism chains resulting in intermediate outcome of vaccine hesitancy or willingness among the recipients. These contextual factors and causal mechanisms demonstrate the complex reality of Saskatchewan's COVID-19 vaccination campaign, show causal pathways for vaccine strategies, and help policymakers to enhance vaccination programs for other jurisdictions.

Acknowledgements

I would like to thank Dr. Gary Groot for his continuous support, never-ending caring, and inspiring supervision. Dr. Groot coached me to learn about realist evaluation, provided me with mental and resources support, and motived me throughout my studies journey.

I would like to thank Dr. Tracey Carr for her enthusiastic mentorship and immersive knowledge. Dr. Carr helped me to pass the hurdles I met during my research study, kept me focused on important tasks, and encouraged me to be positive.

I would like to thank the study's patient and family partners (Brenda Andreas, Candace Skrapek, and Gerry Farthing) for their invaluable engagement and experience. Without them, I would not be able to finish this study.

I would like to thank my committee, Dr. Nazeem Muhajarine and Dr. Tanya Verrall, as well as my external examiner, Dr. Karen Lawson, for their insights and feedback at crucial points in my research.

I would like to thank all the people, including Maryam Yasinian, Collin Hartness, Robert Parker, Dr. Jason Vanstone, Dr. Vivian Ramsden, Dr. Roslyn M. Compton, and Stephanie Kehrig, who supported me during the course of this research study.

I would like to thank my spouse, Ladan, for her patience and belief in me.

Table of Contents

1 List of Tables 4

2 List of Abbreviations 5

3 Introduction 7

3.1 Rationale 8

3.2 Research Questions 8

3.3 Research Objectives 8

4 Literature Review 10

4.1 COVID-19 10

4.2 Saskatchewan Vaccination Program 10

4.3 Vaccination Program Implementation 11

5 Methods 13

5.1 Research Teams 13

5.1.1 Research Team for Vaccine Recipients 13

5.1.2 Research Team for Stakeholders Involved in Planning and Delivery of Vaccines 14

5.2 Methods Overview 14

5.3 Study Phases 16

5.3.1 Phase I: Developing Initial Program Theories (IPTs) 16

5.3.2 Phase II: Testing Initial Program Theories (IPTs) 17

5.3.3 Phase III: Developing Final Program Theories (PTs) 18

5.4 Data analysis 18

5.5 Ethics Exempt 21

6 Results 22

6.1 Vaccine Recipients 22
6.1.1 Phase 1: Developing Initial Program Theories (IPTs) for Vaccine Recipients 22
6.1.2 Phase 2: Testing Initial Program Theories (Interviews) for Vaccine Recipients 26
6.1.3 Phase 3: Developing Final Program Theories for Vaccine Recipients 26
6.2 SHA Stakeholders Involved in Planning and Delivery of Vaccines 36
6.2.1 Phase 1: Developing Initial Program Theories (IPTs) for Stakeholders 36
6.2.2 Phase 2: Testing Initial Program Theories (Interviews) for Stakeholders 40
6.2.3 Phase 3: Developing Final Program Theories for Stakeholders 40
7 Discussion 72
7.1 Summary of Findings 72
7.2 Vaccine Recipients' Program Theories 73
7.2.1 Trust as a Key Mechanism 74
7.2.2 Actors' Diversity within Each Category 75
7.2.3 Resource Discrepancy in LTC Facilities 76
7.3 SHA Stakeholders' Program Theories 76
7.3.1 Desire to Achieve Fidelity as a Key Mechanism 77
7.3.2 Cultural Responsiveness for Northern Communities 78
7.4 Comparing Vaccine Recipients' and SHA Stakeholders' Program Theories 78
7.5 Comparison with Existing Literature 79
7.6 Strengths, Limitations, and Future Directions 80
7.6.1 Strengths 80
7.6.2 Limitations 80
7.6.3 Future Directions 83
8 Conclusion and Recommendations 85
9 Funding 86

Appendix A : Memo Template Adapted from Gilmore 87

Appendix B : Letter of Ethics Exemption..... 88

Appendix C : Screenshot of Mural Board Used for Study 89

Appendix D : Interview Guide..... 90

Appendix E : Plain Language Version of Initial Program Theories for Vaccine Recipients 92

Appendix F : Initial Program Theories for Vaccine Recipients..... 95

Appendix G : Sample Invitation Letter 97

Appendix H : Sample Consent Form 98

Appendix I : Final Program Theories for Vaccine Recipients 102

Appendix J : Initial Program Theories for SHA Stakeholders 104

Appendix K : Final Program Theories for SHA Stakeholders..... 108

Appendix L : Screenshot of NVivo for Data Analysis 111

10 References..... 112

1 List of Tables

Table 5.1. Outline of the study phases 15
Table 6.1 Summary of meetings held with the study's Patient and Family Partners (PFPs). 23
Table 6.2. List of confirmed contextual factors and causal mechanisms within IPTs for the vaccine recipients 27
Table 6.3. List of new contextual factors and causal mechanisms to IPTs for the vaccine recipients 32
Table 6.4. List of refined contextual factors and causal mechanisms within IPTs for the vaccine recipients 34
Table 6.5. List of confirmed contextual factors and causal mechanisms within IPTs for the SHA stakeholders 41
Table 6.6. List of new contextual factors and causal mechanisms to IPTs for the SHA stakeholders 56
Table 6.7. List of refined contextual factors and causal mechanisms within IPTs for the SHA stakeholders 67

2 List of Abbreviations

CBC	Canadian Broadcasting Corporation
CFIR	Consolidated Framework for Implementation Research
CMO	Context-Mechanism-Outcome
CMOCs	CMO Configurations
CoMRAD	College of Medicine Research Award
COVID-19	Coronavirus disease of 2019
DNA	Deoxyribonucleic acid
EDs	Emergency Departments
EOC	Emergency Operating Centre
HCWs	Health Care Workers
ICRT	Indigenous Cultural Responsiveness Theory
ICUs	Intensive Care Units
IHICC	Integrated Health Incident Command Centre
IPTs	Initial Program Theories
LTC	Long-term Care
MoH	Ministry of Health
mRNA	Messenger RNA
NEJM	New England Journal of Medicine
PARiHS	Promoting Action on Research Implementation in Health Services
PFPs	Patient and Family Partners
PHAC	Public Health Agency of Canada
PHN	Public Health Nurse
POR	Patient-Oriented Research
PORLET	Patient-Oriented Research Level of Engagement
PPE	Personal Protective Equipment
PTs	Program Theories
RAMESES II	Realist And Meta-narrative Evidence Synthesis: Evolving Standards II
RE	Realist Evaluation
RE-AIM	Reach Effectiveness Adoption Implementation Maintenance
RNA	Ribonucleic acid

SARS-CoV	Severe Acute Respiratory Syndrome Coronavirus
SCPOR	Saskatchewan Center for Patient-Oriented Research
SES	Socioeconomic Status
SHA	Saskatchewan Health Authority
TDF	Theoretical Domains Framework

3 Introduction

The spread of the coronavirus disease of 2019 (COVID-19) has substantially strained health care systems around the globe (8–11). Although the public health measures including hand washing, mask wearing, and physical distancing reduce the spread of the disease, the only available tool to prevent the disease is vaccination (12). At the time of our study's initial proposal, more than 150 potential COVID-19 vaccines were at different stages of development, and two of them (Pfizer-BioNTech and Moderna) were approved by Health Canada (13–15).

Distribution, prioritization, and administration of the COVID-19 vaccines warrant implementation plans and integration of various sectors in health care systems. To learn about best interventions and programs in health systems and to be accountable to the general public, evaluation of health programs (e.g., vaccination) is essential (16). The type of program evaluation should match appropriately with the development level of the program (17). For example, formative evaluation (needs assessment) is conducted during the development of a new program while process evaluation happens as soon as program implementation begins (17). Process evaluation shows how well a program works and whether it is accessible and acceptable to its target population. Understanding how programs work for whom in the context in which they will be used facilitate and sustain their implementation (18). However, rapid dissemination of evidence into routine care or health system planning generally does not happen quickly (19), and it takes 17 years on average to transition research evidence to clinical practice (20). Hence, health systems are looking to evolve into learning health systems in which continuous learning is part of the organizations' culture to improve effectiveness and efficiency of care (21).

As the COVID-19 vaccination was becoming available in Saskatchewan, there was limited evidence about the effectiveness of implementation processes used in COVID-19 vaccination strategies originating from inside and outside of the Saskatchewan Health Authority (SHA). In this study, we aimed to examine the implementation of the Saskatchewan COVID-19 vaccination program to understand the contextual factors and underlying mechanisms of vaccine uptake among the recipients and vaccine delivery by the SHA stakeholders. The study findings can be used to modify the implementation of the COVID-19 vaccination in Saskatchewan and in line

with the concept of learning health systems. They also provide a template for how vaccination programs might be effectively carried out in future pandemics.

3.1 Rationale

COVID-19 has made a profound impact on various sectors in health care systems, and vaccination may be the best available tool to prevent the disease. While Saskatchewan started vaccinating high risk populations, we did not know if the processes (e.g., safe delivery to sites, target population prioritization, communication plans, and compliance) embedded in the COVID-19 vaccination delivery plan in Regina, Saskatoon, and Prince Albert would work in other contexts in Saskatchewan. There was a need to establish a theory-driven evaluation that could be used to guide further vaccine roll-out in the province.

3.2 Research Questions

The research questions of this study are as follows:

- What are the experiences of vaccine recipients and SHA stakeholders (people who were involved in the planning and delivery of the COVID-19 vaccine) with the Saskatchewan COVID-19 vaccination program in the three pilot sites? Specifically:
- Who did or did not participate?
- What circumstances increased uptake?
- How and why was vaccine uptake higher in some circumstances (to understand how the vaccine rollout was implemented)?

3.3 Research Objectives

- To document the COVID-19 vaccination plan and implementation in Regina, Saskatoon, and Prince Albert.
- To understand how, for whom, in what context, and why the implementation plan of the COVID-19 vaccination led to vaccine uptake from vaccine recipients' and the SHA stakeholders' perspectives.

- To establish a program theory (based on the COVID-19 vaccination strategies in Regina, Saskatoon, and Prince Albert) that can be tested in multiple contexts across Saskatchewan.

4 Literature Review

4.1 COVID-19

After a cluster of severe pneumonia cases of unknown cause in Wuhan, China, in late 2019, the severe acute respiratory syndrome coronavirus (SARS-CoV)-2 was identified in early 2020 (22,23). The spread of the virus across the globe resulted in a pandemic declaration by the World Health Organization (WHO) on March 11, 2020, and the novel coronavirus was named COVID-19 (22,23).

As of November 2022, the total count of COVID-19 cases in Canada was more than 4,408,000 people, of which more than 47,000 died because of the disease (24). COVID-19 spreads mainly via respiratory droplets and aerosols of an infected person when the person coughs, sneezes, sings, shouts, or speaks (25). Public health measures such as proper hygiene practices (hand washing or sanitizing), face masking, and physical distancing as well as limitations on non-essential travel and self-isolation help reduce the spread of the disease (26,27). Vaccination is considered to be an effective method to prevent a variety of infectious diseases including COVID-19 (28,29). Since the identification of the COVID-19 genome sequence and its structural and non-structural proteins, various types of COVID-19 vaccines including RNA-, DNA-, peptide-based, and attenuated viral vaccines were under development (30). At the time of the study, there were two authorized mRNA vaccines available in Canada: Pfizer-BioNTech and Moderna (14), and they had been distributed to the provinces including Saskatchewan (31).

4.2 Saskatchewan Vaccination Program

Health Canada authorized Pfizer-BioNTech and Moderna vaccines on December 9th and 23rd, 2020, respectively (32,33). The Government of Saskatchewan in partnership with Saskatchewan Health Authority (SHA) and Public Health Agency of Canada (PHAC) developed a COVID-19 Vaccine Delivery Plan in which Saskatchewan's phased approach in delivering the COVID-19 vaccination to residents is outlined (31). As per the Delivery Plan, the first COVID-19 vaccination in Saskatchewan was conducted in Regina on December 15th followed by Saskatoon on December 22nd, 2020 and Prince Albert on January 7th, 2021 (34–36).

According to the Government of Saskatchewan website, in the first phase (targeted immunization) of the Delivery Plan, the recipients of the vaccines were health care workers in intensive care units (ICUs), Emergency Departments (EDs), COVID Units, staff at testing and assessment centers, elderly residents in care homes, seniors over 80, and residents in northern remote communities (31). In the second phase (widespread access) of the Delivery Plan, priority population immunization was continued while the general population had access to the vaccine at public health clinics or other vaccination delivery sites such as physician clinics or pharmacies (31).

4.3 Vaccination Program Implementation

It has been shown that the challenges in program implementation and therefore impact are related to a lack of theoretical understanding of how successful implementation occurs (37). Programs that are theoretically based allow researchers to test hypotheses and demonstrate program effectiveness and impact since the theory depicts the essential processes that cause behavior change (37,38).

There are many and often overlapping theories addressing the implementation of clinical practice that affect public health practices (39). Some of the common ones are Diffusion of Innovations, Promoting Action on Research Implementation in Health Services (PARiHS), Reach Effectiveness Adoption Implementation Maintenance (RE-AIM), Consolidated Framework for Implementation Research (CFIR) , and Theoretical Domains Framework (TDF) (37,39). These theories act as substantive theories and can guide the development of program specific theories (40). Substantive theories are theories of action for a specific context (unlike grand theories that have abstract concepts and broad scope), but unlike program theories, they do not attend to causal mechanisms and context (40). For example, TDF is based on 33 behavior change theories (128 constructs) and consists of 14 domains including knowledge, skills, beliefs about capabilities, optimism, beliefs about consequences, reinforcement, intentions, goals, memory, attention and decision process, emotions, behavioral regulation, social/professional role and identity, environmental context and resources, and social influences (39,41). This framework is used when behavioral change or compliance is the desired outcome, and a program theory is

required to test the relationship between constructs such as social/professional role and identity, environmental context and resources, beliefs about consequences, or social influences (42).

5 Methods

On November 23, 2021, the study protocol was published in the Canadian Medical Association Journal (CMJA) Open (DOI: 10.9778/cmajo.20210041). I used some contents from the manuscript within this chapter and referenced them accordingly. The manuscript is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY-NC-ND 4.0) licence.

5.1 Research Teams

Two research teams were developed: a team for the vaccine recipients and a team for SHA stakeholders involved in planning and delivery of vaccines. I oversaw the two teams as the lead researcher. This allowed me to gain broader perspectives from multiple people and limit my bias as a researcher.

5.1.1 Research Team for Vaccine Recipients

This arm of the research was guided by a transdisciplinary team consisted of myself (Amir Azizian [AA]) as the student researcher, three patient and family partners (Candace Skrapek [CS], Brenda Andreas [BA], and Gerry Farthing [GF]), my supervisor (Dr. Gary Groot), a research associate (Dr. Tracey Carr [TC]) with realist evaluation experience, and a research assistant (Maryam Yasinian [MY]) working under Dr. Groot's supervision.

The patient and family partners (PFPs) had a considerable amount of experience and engagement in a variety of health research studies but lacked experience with using a realist approach. The PFPs lived in Saskatoon and Maple Creek, and they had background in health sciences, nursing, and psychology. They brought perspectives of social workers, health educators, cancer survivors, and family members and caregivers of long-term care residents to the team. We utilized the Saskatchewan Center for Patient-Oriented Research (SCPOR) Patient-Oriented Research Level of Engagement (PORLET) (43,44) to engage with the three PFPs.

Patient-oriented research is a model shift in health care research since engagement with patients and family partners influences the research topics, improves the quality of the studies, and adds patients' perspectives (45). To prepare the PFPs for their roles, TC and I introduced the realist

evaluation in the first meeting, and we practiced a context-mechanism-outcome (CMO) extraction from a Canadian Broadcasting Corporation (CBC) interview during the second meeting with the PFPs.

The study's research assistant (MY) coordinated meetings with PFPs, sent invitation emails to potential participants, scheduled interview sessions with the participants, and arranged honoraria for the PFPs and potential participants. She also created a USASK email account (covid-19vac.research@usask.ca) to centralize communications with participants.

5.1.2 Research Team for Stakeholders Involved in Planning and Delivery of Vaccines

The research team for the SHA stakeholders' group included myself as the student researcher, my supervisor (Dr. Gary Groot), the Director of Clinical Excellence (Collin Hartness [CH]) at the SHA, the research associate (Dr. Tracey Carr [TC]), and the research assistant (Maryam Yasinian [MY]). The Director of Clinical Excellence (CH) was heavily involved in the planning and delivery of the vaccines from the beginning of the rollout in Regina and throughout the implementation of the vaccination to other sites. He was part of the team that built the first COVID-19 vaccination clinic in Regina and developed resources and tools used at the Saskatoon and Prince Albert clinics.

5.2 Methods Overview

This study used realist evaluation (RE) to assess the COVID-19 vaccination implementation in Regina, Saskatoon, and Prince Albert. The Realist And Meta-narrative Evidence Synthesis: Evolving Standards II (RAMESES II) were applied to this evaluation (2). The study comprised three iterative phases for each category of potential participants (i.e., vaccine recipients and people involved in planning and delivery of vaccines [SHA stakeholders]) outlined in Table 5.1. The Government of Saskatchewan's COVID-19 Dashboard (46) was monitored to track the number of vaccines administered. I also confirmed the vaccine administration with the SHA stakeholders to monitor if the pilot phase progressed as planned.

Table 5.1. Outline of the study phases

Evaluation Phase [Timeframe]	**Activities**	**Research Team Members Involved (Initials)**
Phase I: Developing Initial Program Theory (IPT) [January – May 2021]	Review of provincial COVID-19 vaccines implementation documents and presentations in Saskatchewan	PFPs/TC/MY/AA
	Review of literature about implementation of COVID-19 vaccines or general vaccines	PFPs/TC/MY/AA
	Development of Initial Program Theory (IPT) for each group of participants	PFPs/TC/MY/GG/CH/AA
	Development of an interview guide	PFPs/TC/MY/AA
Phase II: Testing of IPT (interviews with participants) [June – December 2021]	Conducting realist interviews with 6 vaccine recipients and 8 SHA stakeholders	PFPs/AA for vaccine recipients AA for SHA stakeholders
	Analyses of interview transcripts	PFPs/TC/MY/AA for vaccine recipients AA/TC for SHA stakeholders
Phase III: Developing Final Program Theory (PT) [October – December 2021]	Extraction of demi-regularities from context-mechanism-outcome configurations (CMOCs) emerged in Phase II	PFPs/TC/MY/AA for vaccine recipients TC/AA for SHA stakeholders
	Meetings with PFPs to finalize the PT	PFPs/TC/MY/AA

5.3 Study Phases

5.3.1 Phase I: Developing Initial Program Theories (IPTs)

Developing an initial program theory (IPT) forms the basis of a realist evaluation, narrows the focus of the evaluation activities, and guides the selection of study methods (18). The first step in this phase was to review the documents and presentations related to the COVID-19 vaccination program in Regina (the first pilot site in Saskatchewan). The intent was to uncover the rationale, components, and protocols of the COVID-19 vaccination program. This step identified the program's underlying assumptions, outcomes of interest, proposed mechanisms of achieving targeted outcomes, and planned activities. For example, on December 13, 2020, the Director of Clinical Excellence at the SHA (CH) presented the "7 Flows of Medicine" framework for the pilot implementation of COVID-19 vaccination in Regina to a group of representatives from Saskatoon's COVID-19 clinic, Human Resources, Transportation Services, and Protection Services, as well as representatives from the SHA leadership team and the Ministry of Health. The purpose of the presentation was to help Saskatoon stakeholders replicate the Regina pilot while modifying the components of the pilot to their local requirements and needs.

Another step in this phase was to review literature on vaccination implementation, including journal articles and grey sources (SHA documents and presentations, SHA COVID-19 news webpage, the Government of Saskatchewan COVID-19 vaccination plan documentations, field notes, and observations), with a realist lens. The goal was to find theories from similar contexts (e.g., theories on COVID-19 or non-COVID-19 vaccination implementation). I alongside the PFPs (CS, BA, GF), the research associate (TC), and the research assistant (MY) reviewed the provincial implementation documents and existing literature. MY and I established a group in Mendeley reference management software to facilitate the process of manuscript sharing.

To equip the PFPs with the realist evaluation skills, I shared the study's proposal prior to the first meeting and demonstrated realist evaluation analysis on a sample grey literature using an online shared platform (Mural). For the later meetings, MY and I were distributing the agenda and pertaining materials prior to each meeting.

I performed the initial analyses on each source (journal articles or grey sources) to develop the IPTs for vaccine recipients and the SHA stakeholders. Then, the PFPs, GG, TC, MY, and I co-

refined the IPTs for vaccine recipients. GG, TC, CH, and I revised the IPTs for SHA stakeholders.

At the end of Phase I, the research team prepared two realist interview guides based on identified contexts and mechanisms for a) vaccine recipients and b) people involved in planning and delivery of the vaccines. The interview guides consisted of a series of open-ended questions asking interviewees to confirm, refute, and refine the elements in the IPTs (47) that impacted the COVID-19 vaccine uptake among vaccine recipients and the vaccine delivery in the three sites.

5.3.2 Phase II: Testing Initial Program Theories (IPTs)

Realist evaluation is about theory testing and refinement (48). I purposively recruited six vaccine recipients in Regina, Saskatoon, and Prince Albert, as well as eight key SHA stakeholders involved in the planning, development, and implementation of the COVID-19 vaccination program (e.g., one representative from Logistics and Distribution, Security, Human Resources, Communications, vaccine chiefs at the SHA, and clinic managers in Regina, Saskatoon, and Prince Albert). MY sent the invitation emails via the study's email address to the potential participants for 30-minute, semi-structured, online (Webex) interviews (14 interviews). Written informed consent was collected prior to or at the beginning of the interviews. Before conducting the actual interviews with the participants, I performed mock-up interviews with each PFP to ensure that the PFPs were comfortable with the flow of the interviews, and they understood realist-informed interview style.

During an interview, the attending PFP introduced the format of the session, and I co-facilitated the IPTs review and discussion. I illustrated the IPTs in PowerPoint slides (shared my screen), explained the contents to the interviewees, and highlighted the fact that the IPTs were about what works for whom and in what circumstances when we considered COVID-19 vaccination rollout plans. Cognizant of the possibility that interviewees would not be familiar with realist terminology, I occasionally stopped the conversations to provide time to the interviewees to review the contents of the slides. If there was a need to explain an element(s), the attending PFP or I clarified the content and ensured that the interviewees were comfortable with the explanation. In some instances, due to the interviewees' characteristics (e.g., age and disability),

the interview pace had to be adjusted to ensure the interviewees were able to follow the PFPs or myself.

Using the realist interview guide developed in Phase I, interviews were performed in a "teacher-learner" fashion (47,48). For vaccine recipients' interviews, the PFPs and I taught the interviewees the study IPTs about the COVID-19 vaccine uptake in the three sites (Regina, Saskatoon, and Prince Albert). For the SHA stakeholders, I performed the interviews and followed a format the same as the vaccine recipients' interviews. After performing the interviews, MY transcribed the audio recordings of the sessions. PFPs, TC, and I analyzed the qualitative data (described in more detail under the "Data Analysis" section) to build context-mechanism-outcome configurations (CMOCs).

5.3.3 Phase III: Developing Final Program Theories (PTs)

After performing the data analysis, TC and I extracted the demi-regularities from the CMOCs and synthesized them into revised program theories (described in more detail under the "Data Analysis" section). Subsequently, several meetings (depending on the number of changes to the revised PTs) with the PFPs, GG, CH, TC, and MY were held to finalize the program theories (PTs).

5.4 Data analysis

Realist evaluation data analysis is not a set technique, but rather a way to examine program theories with data and use these theories to interpret data patterns. It's a way of uncovering what is effective, for whom, under what circumstances, and to what extent, among other factors (2)(2). In realist evaluation, it is ideal to have an iterative data analysis process. The analysis follows a retroductive approach, considers and verifies the researcher's assumptions or hunches, and aims to provide the most accurate explanation for limited data. The techniques used for data analysis and integrating the data into program theories should align with the central principle of realism, which is generative causation (2).

Rooted in the three realist ontological levels of stratified reality (empirical, actual, and real), retroduction is a method of reasoning that involves taking a close look at specific phenomena,

analyzing them, and then using this information to reconstruct the underlying conditions that make these phenomena what they are. This is done through a combination of mental operations and hypothetical thinking to determine the potential causes for these phenomena (49). As Eastwood et al. have alluded, typical retroductive questions constitute of "How is X possible? What properties must exist for X to be what X is? [And] what causal mechanisms are related to X?" (49). Retroductive reasoning is not based on logic per se but is instead characterized by intuition and creativity (researcher's hunches) (50).

In this study, all the interviews were conducted using Webex, audio-recorded, transcribed verbatim, and imported to Microsoft Word 365 (vaccine recipients' transcriptions) or NVivo v.12 Plus (key SHA stakeholders' transcriptions). The qualitative data was analyzed using the retroductive approach (2,51–53).

For the vaccine recipients' arm, the analysis was performed by selecting segments of transcribed texts in Word documents and coding them into the explanatory pathways of context-mechanism-outcome configurations (CMOCs). We used Dalkin et al.'s CMOC framework to code the segments and identify the CMOCs in the transcriptions (6). Dalkin et al. explain that resources (the component introduced in a context) and reasoning (responses of the participants) are integral to the concept of a mechanism and breaking them down into separate elements helps distinguish a mechanism from a context (6). As an expansion of the original heuristic developed by Pawson and Tilley (4) Dalkin et al's new framework separates resources and reasoning with context in between and emphasizes that it is crucial to remember that resources and reasoning must always be used together, not just resources or reasoning on their own (6). The determination of the resource depends on the purpose of the study (in our case, evaluation of Saskatchewan vaccination program in three pilot sites), and specifying the reasoning (in our case, vaccine recipients and key SHA stakeholders' responses to the vaccination program) helps prevent confusion between program strategy (resource) and mechanism (6).

Each coded segment was then tested against the IPTs to identify which elements of the IPTs were confirmed, refuted, or refined. This process was iterative (moved between inductive and deductive processes), therefore PFPs and I sometimes went back to the previously tested segments to ensure that we correctly (based on emergent findings) developed, confirmed, refuted, or refined the IPT elements.

For the key SHA stakeholders, the following iterative steps were adapted from Gilmore's approach in NVivo (51):

- Each piece of data was saved as a unique "source" (one interview transcript = one unique source).
- "Nodes" (or "codes") were created to contain confirmed, new, revised, and refuted contexts and mechanisms. I reviewed the stakeholders' transcripts, selected segments of texts, and coded them into the predefined nodes.
- "Child nodes" were created if the parent node needed detailed coding, e.g., under a revised context node, there were multiple child nodes with revisions.
- A "memo" was linked to each node (and any new child nodes) to capture decision-making processes and rationales for theories refinements (CMOCs were mostly extracted here). All CMOCs in each memo were reviewed using a memo template (Appendix A) (51).
- From various sources, similar CMOCs in memos were combined and used to support, refute, or refine the IPTs. The refinement of the IPTs occurred at the same time and continued throughout the data analysis (51).
- Within a source, if there were sufficient contexts or mechanisms to refine the IPTs, a new child node was created to document the refinement processes throughout the analysis. Subsequent contexts and mechanisms from new sources were then coded directly to the most relevant child nodes of former sources (51). The refined nodes (i.e., refined contexts and mechanisms) and the new child nodes were called program theories (PTs) and collated if they looked similar or overlap, aiming to identify final PTs (51).

In Phase III, I used three methods to finalize the IPTs refined in Phase II:

- First, TC and I extracted the demi-regularities identified from the CMOCs.
- Second, GG, TC, and I conducted an online meeting with the Director of Clinical Excellence (CH) to review the demi-regularities related to the SHA stakeholders' CMOCs and developed PTs for the SHA stakeholders.
- Lastly, I met with the PFPs, TC, and MY to synthesize the refined IPTs and demi-regularities extracted from the vaccine recipients' interviews into final PTs for the vaccine recipients.

5.5 Ethics Exempt

This study received an ethics exemption (Appendix B). However, we obtained a formal consent prior to the interviews.

6 Results

This chapter details the results of program theories development for vaccine recipients and the SHA stakeholders who were involved in the planning and delivery of COVID-19 vaccines in the three pilot sites (Regina, Saskatoon, and Prince Albert). For each group (vaccine recipients and SHA stakeholders), the contextual factors and causal mechanisms of initial program theories (Appendix F for vaccine recipients and Appendix J for SHA stakeholders), refined contexts and mechanisms, and the final program theories (Appendix I for vaccine recipients and Appendix K for SHA stakeholders) are presented.

This study was presented at the 2022 Life and Health Sciences Research Expo, University of Saskatchewan and awarded first place under the COVID-19 Pandemic Research, Response, and/or Outreach category and second place under the Social & Population Health category (54).

6.1 Vaccine Recipients

6.1.1 Phase 1: Developing Initial Program Theories (IPTs) for Vaccine Recipients

At the time of the IPTs development, there was little published literature on COVID-19 vaccine uptake and hesitancy. Therefore, I used a snowballing approach in which I reviewed the references of the articles found in early stages. One of the main sources of peer-reviewed papers and expert interviews was the New England Journal of Medicine (NEJM). After the CMOs extractions, I performed follow-up iterative discussions with GG, TC, and MY to identify the outcome of interest. We selected the **vaccine uptake among vaccine recipients** as the outcome of interest.

MY and I attended the three sites (Regina, Saskatoon, and Prince Albert) implementation teams, the Emergency Operating Centre (EOC), and the Integrated Health Incident Command Centre (IHICC) teams' daily meetings held at 8 AM, 12:00 PM, and 4:00 PM every day since December 2020 to take observation and meeting notes. I also took field notes and observations by attending the opening day of the Saskatoon vaccination clinic at Merlis Belsher Place. The meeting notes, field notes, and observations then formed part of the data collection for this phase.

The research team for the vaccine recipients arm of the study held nine meetings to discuss the contextual factors and causal mechanisms that were relevant to the vaccine uptake among

vaccine recipients, developed the IPTs, deliberated ethics and participants consent form, prepared an interview guide, and created a plain language version of IPTs to elaborate on the elements of the IPTs (Table 6.1). The team used a Mural board to show related contextual factors and causal mechanisms (Appendix C).

Table 6.1 Summary of meetings held with the study's Patient and Family Partners (PFPs).

Count of meetings	Phase of the study	Purpose of meetings
9	Phase I	Develop the IPTs, participants consent form, an interview guide, and a plain language version of IPTs
3	Phase II	Run mock-up interviews with each PFP
3	Phase III	Review preliminary analysis results with each PFP
1	Phase III	Final research team meeting to finalize the IPTs

During the meetings, the team determined a need to include a separate IPT for Indigenous communities. However, the team decided to remove reference to Indigenous communities since we did not involve representatives from the communities in our research team.

Along with other members of the research team, the PFPs articulated the contents of the interview guide (Appendix D) and used the realist informed interview approach to incorporate teacher-learner style into the guide. The interview guide contained an introduction of the attending PFP at the interview and me, brief explanation of the study, two rapport making questions, a section to teach the interviewee the pertaining IPT, and four realist style questions seeking for interviewees' comments and ideas about the elements (contextual factors, causal mechanisms) of the presented IPT. The research team also created the plain language version of the IPTs (Appendix E).

In the pilot phase, the vaccine recipients were health care workers (HCWs) in intensive care units (ICUs), Emergency Departments (EDs), COVID Units, staff at testing and assessment centers, elderly residents in care homes, seniors over 80, and residents in northern remote communities. As a result, the research team developed three categories of IPTs for the vaccine recipients:

- ICU/ED physicians, nurses, and HCWs,
- Long-term care (LTC) managers and HCWs, and
- LTC residents

6.1.1.1 IPT for ICU/ED Physicians, Nurses, and Health Care Workers (HCWs)

In the IPT for ICU/ED physicians, nurses, and HCWs, there are five contextual factors as follows (Appendix F):

- Demographics (age, gender, socioeconomic status [e.g., education, income], immigrants, and childbearing and breastfeeding women),
- Religion / worldview,
- Location (urban, acute care settings, non-LTC facilities),
- Communication (social media, misinformation, physician town halls, SHA daily news updates), and
- Health literacy

For the causal mechanisms, the research team realized that the interconnections between the mechanisms are complex. Hence, we proposed a mechanism chain to stand for the collection of causal mechanisms. We grouped the causal mechanisms into two categories: reasoning mechanisms and cognitive/emotional mechanisms. Under the reasoning mechanisms, we identified "understanding of transmission and prevention (meaning of vaccine work, science speed)" as the only relevant mechanism. Under the cognitive / emotional mechanisms, we found the following mechanisms:

- Trust, including trust in vaccine efficacy and safety, trust in healthcare institutions, including medical professionals, and trust in leadership,
- Anxiety (re: disease and vaccination) / fear of death,
- Perception of transparency from source,
- Perception of personal vulnerability,
- Perception of risk to side effects,
- Sense of community versus individual / responsibility, and
- Physical exhaustion / perception of competing priorities

The reasoning and the cognitive / emotional mechanisms result in the intermediate outcome of "willingness / hesitancy" among the recipients of the vaccines. This intermediate outcome will then generate the vaccine uptake, which is our study's outcome of interest.

6.1.1.2 IPT for Long-Term Care (LTC) Managers and Health Care Workers (HCWs)

In the IPT for LTC managers and HCWs, six contextual factors were identified as follows (Appendix F):

- Demographics (age, gender, socioeconomic status [e.g., education, income], immigrants, and childbearing and breastfeeding women),
- Religion / worldview,
- Working in multiple places / precarious employment,
- Communication (language)
- Location (private sector versus SHA), and
- Lack of appropriate staff ratio

The mechanism chain for this group of actors was the same as the previously mentioned mechanism chain.

6.1.1.3 IPT for Long-Term Care (LTC) Residents

In the IPT for LTC residents, six contextual factors were identified as follows (Appendix F):

- Demographics (age, gender, socioeconomic status [e.g., education, income], immigrants),
- Religion / worldview,
- Policy: Denied from visiting family members in LTC facilities
- Decision making capacity,
- Family presence and need for family support
- Communication (information about the vaccine via media and social media)

The mechanism chain for this group of actors was the same as the previously mentioned mechanism chain.

6.1.2 Phase 2: Testing Initial Program Theories (Interviews) for Vaccine Recipients

The research assistant (MY) sent the invitation emails along with a letter of invitation (Appendix G) and a consent form (Appendix H) via the study's email account (covid-19vac.research@usask.ca). Interviews were conducted over three months (June to September 2021). I performed six interviews (two interviews with each PFP), including interviews with two ICU physicians (with CS), two LTC managers (with BA), and two family members and caregivers of LTC residents (with GF). The two ICU physicians were from Regina and Saskatoon and were the early recipients of the vaccines. One of the LTC nurse managers was from Prince Albert and was identified by one of the PFPs. The other LTC manager and the two family members and caregivers of LTC residents were recruited through the Saskatchewan Care Network (Dr. Roslyn M. Compton) and resided in Saskatoon.

I conducted the interviews virtually using my USASK Webex account and audio-recorded after receiving consent and permission from the interviewees. The interviews lasted from 30 to 45 (mean: 38) minutes. MY transcribed the recordings and saved the transcriptions on my USASK Jade drive, which is part of GG's Datastore storage space.

The interviewees' reference to the IPTs varied during the sessions, and either the PFPs or I had to maintain the focus of the discussion around the IPTs and the pilot phase. Nevertheless, when new ideas were uncovered, either the PFPs or I asked impromptu questions to explore the idea. For example, when an interviewee mentioned "*I'm actually a committee member in the senior group in the clinic, so you know, we were briefed on this, …*", then the PFP asked "*ok, when you say briefed, could you elaborate just a little bit like what were you told in the briefing about it [vaccination]?*". In this way, the interviewers verified their understandings with the interviewees.

6.1.3 Phase 3: Developing Final Program Theories for Vaccine Recipients

The research associate (TC) and I performed the preliminary analysis of the qualitative data for the development of the final program theories. The findings of the preliminary analysis of each interview were then reviewed with each PFP who co-conducted the corresponding interview (I

held three one-hour sessions with the three PFPs to review the preliminary analysis results). Microsoft Word 365 was used to analyze and comment on the transcriptions. There was high coding agreement between the PFPs, TC, and me. In case there was discrepancy in codes, all codes were kept and considered to be discussed in a final meeting where all research team members took part.

I summarized the coded quotes from the interviews into four categories of analysis codes including confirmed, new, refined, and refuted contextual factors or causal mechanisms. If an interviewee refuted a contextual factor or a causal mechanism but other interviewees confirmed or refined the element, we then deemed the element relevant to the IPTs. For instance, one interviewee said that "*demographic, believe it or not, was not in my mind",* but this comment was not refuted or reinforced by other interviewees. Therefore, this element was retained in the IPTs. The confirmed, new, and refined elements are summarized in the following sections.

6.1.3.1 Confirmed Contexts and Mechanisms

Interviewees confirmed all contextual factors and causal mechanisms (Table 6.2). Of confirmed contextual factors, interviewees highly emphasized communications (e.g., social media and its impact). Of causal mechanisms, trust, sense of community versus individual, and understanding of transmission were underscored.

Table 6.2. List of confirmed contextual factors and causal mechanisms within IPTs for the vaccine recipients

Confirmed Element	**Context or Mechanism**	**Quote Examples**
Health literacy	Context	*"I'm very much about immunizations."*
Communication	Context	*"The media wasn't always helpful …"*

		"… things came out very quickly for us."
		"I think social media is insanely important, almost as important as worldview because you often times form your worldview based on social media."
		"I think the pilot project was horribly advertised."
		"Information about the vaccines from other media, I take the Globe and Mail, and I think that the coverage was really excellent …"
		"I think we were communicated fairly well from the nursing home"
Religion / world view	Context	*"I do think that the world view is certainly a major aspect in this."*
		"… so I come from the Protestant Evangelical Christian background up and, if you look at a lot of the vaccine hesitancy, it seems to originate in that people group because of a lot of misconceptions about the vaccine …"

Location	Context	*"So, you know, people who were in nursing homes people are in long term care facilities, etc., they're obviously more likely to take it because they knew that the price to not taking it."*
Demographics	Context	*"Obviously, research would be interesting to see whether it did, but in my view, it really boils down to worldview, demographic, and social media."* *"She's a woman, may have different views. Caucasian may have different views…"*
Decision making capacity	Context	*"She was not competent to make the decision for herself as to whether she should have the vaccination or not, and I'm assuming that I was asked about this."*
Policy: Denied from visiting family members in LTC facilities	Context	*"Now, again, I don't know, but I think I am part of very small minority of visitors that is taking up this option* [getting tested once a week]*"* *"… I wasn't sure then when being settled down for visiting purposes, how that was all going to work."* *"I think it's great for the policy where you have denied from visiting family members in long term care. That was the most frustrating part, so I think that's very important to have that there."*

Family presence and need for family support	Context	*"... you know, family presence is really needed ..."* *"But it went on far too long and greatly to the detriment of our residents, as well as family members who were better able to, you know, adapt to the situation that I know."*
Sense of community versus individual / responsibility	Mechanism	*"... you are protecting yourself and others ..."* *"...well, we're all in this together. We need a high rate of vaccination to protect the community."*
Trust • Trust in vaccine efficacy and safety • Trust in healthcare institutions / medical professionals • Trust in leadership	Mechanism	*"I was very confident. I'm always very confident that they have done the research, they've done the work and generally it's all been well prepared and thought out and that nobody would ever impose any harm if they knew."* *"I think the trust that was important and that was there for us."* *"... I also believe in the systems that our country has, and our province has ..."*

Understanding of transmission and prevention	Mechanism	*"I think I'm pretty well informed."* *"… you know you did some research on your own and talked to other people and other professionals about their opinion on that …"*
Perception of risk to side effects	Mechanism	*"I was a little bit concerned about perhaps what were the side effects, …"*
Perception of transparency from source	Mechanism	*"…there were a number of sessions where we could go over lunch hour and actually listen to people talk about each of the vaccines and what the risks were with the side effects, what the benefits were …"* *"… it was a little bit confusing at the beginning conflicting views from different scientists …"*
Perception of personal vulnerability	Mechanism	*"… I worked so closely with the COVID patients …"*
Anxiety (re: disease and the vaccination) / fear of death	Mechanism	*"… they would rather take it than to risk dying"*
Physical exhaustion / perception of competing priorities	Mechanism	*"… I think staff you know were physically exhausted because they had to do more than that they did before because caregivers were not coming in."* *"… . I'm not putting 4 hours at age of 23 into getting a vaccine that most likely blah blah blah."*

6.1.3.2 New Contexts and Mechanisms

Multiple elements (contextual factors or causal mechanisms) either emerged as new or needed refinement. Three and four new contextual factors and causal mechanisms were added to the IPTs, respectively (Table 6.3). The new contextual factors include “pre-existing medical conditions”, “open non-judgmental relationships”, and “availability of resources / ease of access”. The new causal mechanisms include “perceptions of being the first”, “desire for high or early uptake”, “eagerness to provide positive leadership / being champion”, and “concerns that side-effects of one’s experience will deter others”.

Table 6.3. List of new contextual factors and causal mechanisms to IPTs for the vaccine recipients

New Element	**Context or Mechanism**	**Quote Examples**
Pre-existing medical conditions	Context	*“… they had mentioned that not everyone, like as far as a resident, would receive the vaccine because of immune compromission.”*
Open non-judgmental relationships	Context	*“And I think that if people are hesitant, we have to be open to having that conversation with them in a very trusting, nonjudgmental way to hear their fears, to hear what's making them hesitant so that we can then move past that by validating those feelings and emotions and helping them to understand that things are safe, that things are going to be OK, and that yes there may be side effects, but they're just a normal body reaction but they don't last forever”*

Availability of resources; Ease of access	Context	*"... I also believe that having that right on site for us was a huge reason we were able to reach such high rates."* *"I didn't have to sign up for anything and then everything else just kind of fell together and it happened very quickly."*
Perception of being the first	Mechanism	*"I felt very fortunate to be one of the first people in Saskatchewan to have received the vaccine."* *"... I did feel quite also excited and really wanted to be the first ..."*
Desire for high or early uptake	Mechanism	*"... I was hoping that it was going to be efficient or also would be good uptake ..."*
Eagerness to provide positive leadership / being champion	Mechanism	*"... I felt that If I was to take the vaccine, potentially, I may influence a lot of people to believe in the message that I have ..."*
Concern that side-effects or one's experience will deter others	Mechanism	*"... I was worried that I would be the one that would have a reaction and then people would be like look even this guy had that reaction ..."*

6.1.3.3 Refined Contexts and Mechanisms

One contextual factor and two causal mechanisms were refined (Table 6.4). The contextual factor of communication was refined to "communication via person's preferred or trusted source". The causal mechanism of anxiety (re: disease and the vaccination) / fear of death was

refined to two sub mechanisms: “Anxiety (re: disease and the vaccination): 1. fear of getting a needle and 2. fear of death”. The causal mechanism of sense of community versus individual / responsibility was refined to “sense of community versus individual / perception of freedom / personal choice / responsibility”.

Table 6.4. List of refined contextual factors and causal mechanisms within IPTs for the vaccine recipients

Refined Element **(Refinement in bold)**	**Context or Mechanism**	**Quote Examples**
Communication to Communication **via person’s preferred or trusted source**	Context	*“… Like the side effects and all that kind of stuff that you got information about or some help from the general practitioner.”*

Anxiety (re: disease and the vaccination) / fear of death to two sub-mechanisms Anxiety (re: disease and the vaccination) **1. fear of getting a needle** **2. fear of death**	Mechanism	*"I think anxiety is something that is actually bigger than what we had anticipated that people actually have a fear of getting a needle."* *"... they now have therapy dogs ..."*
Sense of community versus individual / responsibility to Sense of community versus individual / **Perception of freedom / personal choice/** responsibility	Mechanism	*"... They don't believe in the government rules in dictating what they need to do ..."* *"... I'm also a member of a health authority committee ... and advise the health authority about it [COVID]. "* *"... we're all in this together ..."*

A final meeting with the PFPs was held to review all comments and modifications for final refinement. During the discussion, I presented the analysis results concluded from the individual

PFP discussions, and all research team members achieved consensus about the final program theories. As a result, three final program theories for each category of actors (i.e., ICU/ED physicians, nurses, and HCWs, LTC managers and HCWs, and LTC residents) were developed (Appendix I).

6.2 SHA Stakeholders Involved in Planning and Delivery of Vaccines

6.2.1 Phase 1: Developing Initial Program Theories (IPTs) for Stakeholders

The research team for the SHA stakeholders' arm of the study used peer reviewed and grey literature as well as contents of onboarding presentations done by the Director of Clinical Excellence (CH) to the Saskatoon's and Prince Albert's vaccination teams to extract the contextual factors, causal mechanisms, and outcomes related to the vaccine rollout. The vaccination rollout was designed based on the "7 Flows of Medicine" framework. In this framework, flows of patients, family, providers, medications (vaccines), supplies, information, and equipment are considered to design for implementation.

In multiple iterative discussions, the research associate (TC), GG, and I determined **vaccine delivery** as the outcome of interest for the SHA stakeholders' group. We considered vaccine delivery because it was the outcome of interest for SHA stakeholders who were planning for the vaccine delivery. This outcome acted as an intermediate mechanism, which then led to vaccine uptake among vaccine recipients.

In August 2021, I held a meeting with GG, CH, and TC to confirm the elements of the IPTs for stakeholders. It was recommended that the IPTs should include elements at individual, management, union, and organizational levels. As such, unlike mechanism chain for vaccine recipients, I could not generate an overarching mechanism chain applicable to all levels of vaccination rollout and implementation. I had to tailor the mechanism chain for each level or group of actors involved in the vaccine delivery. As a result, I developed six categories of IPTs for the SHA stakeholders:

- Clinic managers,
- Security workstream,
- Logistics and Distribution (L&D) workstream,

- Communication workstream,
- Human Resources workstream, and
- Vaccine campaign chiefs

6.2.1.1 IPT for Clinic Managers

In the IPT for clinic managers, there are six contextual factors as follows (Appendix J):

- Union / regulatory body engagement
- Job / standards of practice requirements
- Communication (social media, misinformation, SHA daily news updates)
- Logistical challenges
- Security issues
- Inspirational leadership / champions

For the causal mechanisms triggered by the contextual factors for clinic managers, GG, TC, and I concluded that various mechanisms interact, resulting in the intermediate outcome of vaccine delivery. Therefore, we proposed a mechanism chain to illustrate the collection of causal mechanisms for clinic managers. We grouped the causal mechanisms into two categories: a) reasoning and b) resources mechanisms. Under the reasoning mechanisms, we identified the following mechanisms:

- Perception of commitment
- Desire to achieve fidelity
- Confidence in their ability
- Capacity to do the task
- Anxiety of the new task
- Understanding the need to shift person's scope of practice / to adapt usual practice
- Perception of leader's vision
- Triggering internal values
- Sense of values (personal and professional)
- Sense of social connectivity / meaning

- Perception of urgency to act
- Perception of a priority for organization / union
- Perception of significance of pandemic and no prior schema
- Concerns about vaccine recipients' privacy
- Feeling of importance / accomplishment

Under the resources mechanisms, we identified the following mechanisms:

- SHA's policy mandate for staff allocation in emergency conditions
- Limited number of immunizers
- Non-traditional immunizers
- Pandemic emergency legislation

6.2.1.2 IPT for Security Workstream

In the IPT for the Security workstream, the contextual factors are the same as for the clinic managers IPTs (Appendix J). In addition to the causal mechanisms included in the IPT for clinic managers, the "fear of theft" was added under the reasoning mechanisms, the "need to secure resources" and "availability of security resources" were added under the resources mechanisms, and the "limited number of immunizers" and "non-traditional immunizers" were removed for the mechanism chain for security workstream.

6.2.1.3 IPT for Logistics and Distribution (L&D) Workstream

In the IPT for the Logistics and Distribution (L&D) workstream, the contextual factors are identical to the ones for the Security workstream and clinic managers (Appendix J). The mechanism chain for the L&D workstream is almost the same as for the Security workstream. The only difference is the "need to secure IT resources" in the L&D workstream resources mechanisms versus the "need to secure resources" in the security workstream resources mechanisms.

6.2.1.4 IPT for Communications Workstream

In the IPT for the Communications workstream, there are four contextual factors as follows (Appendix J):

- Union / regulatory body engagement
- Communication (social media, misinformation, physician town halls, SHA daily news updates)
- Inspirational leadership / champions
- Ministry of Health

Compared to the mechanism chain for the L&D workstream, that of the Communications workstream does not include “availability of security resources” and “fear of theft”.

6.2.1.5 IPT for Human Resources Workstream

In the IPT for the Human Resources workstream, there are five contextual factors as follows (Appendix J):

- Demographics (occupation, training [public health nurses (PHN)] / traditional immunizers vs non-PHN / non-traditional immunizers])
- Union / regulatory body engagement
- Job / standards of practice requirements
- Communication (social media, misinformation, physician town halls, SHA daily news updates)
- Inspirational leadership / champions

In addition to the reasoning and resources mechanisms for the Communications workstream, the “limited number of immunizers” and “non-traditional immunizers” were added to the mechanism chain for the Human Resources workstream.

6.2.1.6 IPT for Vaccine Campaign Chiefs

In the IPT for vaccine campaign chiefs, all seven contextual factors listed for other actors were included (Appendix J). One reasoning mechanism (perception of unions authority) was supplemented to the list of all other mechanisms in the other stakeholders IPTs.

6.2.2 Phase 2: Testing Initial Program Theories (Interviews) for Stakeholders

Invitation emails were sent via GG's email account and contained a letter of invitation and a consent form (Appendix G and Appendix H). Interviews were conducted over three months (October to December 2021). I interviewed six SHA stakeholders, including clinics managers of the three sites (Regina, Saskatoon, and Prince Albert), Logistics and Distribution, Human Resources, and Communications leads. However, I was not able to interview the Security lead and the vaccine chief.

I conducted interviews virtually using my USASK Webex account and audio-recorded after receiving consent and permission from the interviewees. The interviews lasted from 30 to 90 (mean: 54) minutes. MY transcribed the recordings and saved the transcriptions on my USASK Jade drive, which is part of GG's Datastore storage space. I followed the sequence of the interview guide components, except for the PFP introduction, in all interviews.

6.2.3 Phase 3: Developing Final Program Theories for Stakeholders

I performed the preliminary analysis of the SHA stakeholders' interview transcriptions in an analogous way to the recipients' transcripts analysis. I coded the responses as to whether the interviewees confirmed, refuted, or refined the contextual factors or causal mechanisms in the IPTs. I then met with the research associate (TC) in multiple iterative sessions to discuss the findings. Since the amount of interview materials was substantial, and only TC and I were involved in the data analysis, I used NVivo v.12 Plus software to code the transcriptions (a screenshot of NVivo is provided in Appendix L). Interviewees did not refute any of the elements in the IPTs. The confirmed, new, and refined elements are summarized in the following sections.

6.2.3.1 Confirmed Contexts and Mechanisms

Interviewees confirmed all contextual factors and causal mechanisms (Table 6.5). Of confirmed contextual factors, logistical challenges (e.g., timing, number of recipients [demand], availability of vaccines, and scope of stakeholders' involvement) and communications (although it was later refined), and union / regulatory body engagement were highly stressed. Of confirmed causal mechanisms, the SHA stakeholders more emphasized on perception of commitment, sense of social connectivity / meaning, and need to secure resources, including IT resources. Desire to achieve fidelity was identified as a core mechanism that increases the intermediate outcome of vaccine delivery.

Table 6.5. List of confirmed contextual factors and causal mechanisms within IPTs for the SHA stakeholders

Confirmed Element	**Context or Mechanism**	**Quote Examples**
Demographics (occupation, training [public health nurses [PHN] / traditional immunizers vs non PHN / non-traditional immunizers])	Context	*"… so the reason why I got involved was because occupational health is to immunize health care workers and public health couldn't do it on their own, and occupational health had like a card in this game."*
Union / regulatory body engagement	Context	*"We had even as we move past the pilot and into the next stages when we continued to have more demand than we had supply, we had to make decisions about who would stage one of our employees and physicians and who's phase two of our employees and physicians in*

		phase three? And that's where some of that union involvement definitely came into play." *"I want to bring occupational health and continuing care and Primary Health care together. I want to bring three of us together because I think that we're not going to be able to do this alone. We're going to have to be able to figure out how to work together."* *"and then bringing some of those stakeholders together and some key go-to people that we are able to help you execute this and empowering them to do the tasks that they needed to do to build this and help frame this."* *"There was a recognition at that point in time that this was in the early phases of very confidential piece so getting people engaged without telling people what getting them involved in, you know, it is always a challenge"*
Job / standards of practice requirements	Context	*"... that's because in Regina we had a structure in place already that had pharmacists immunizing, had RTs immunizing, it was only influenza, but we had the confidence and I think that's often why we let out in Regina..."*
Logistical challenges	Context	*"... one of the huge challenges was scheduling. The scheduling is that, you would get a whole new team every single day like you would get 50 new nurses coming, and we're a large center, 50 new nurses coming*

every day, and you then had to review everything every day, and then the next shift again. And then you start again the next day …"

"Logistical challenges, for sure, I think, yeah, logistical would be the equipment and supply would fit in there as well as vaccine. I do not know if you have it like the context in here, not only like the provider like how we train them and everything, but then also like what we would consider patients or clients so that people receiving vaccine and in January we were also immunizing 80 plus. So, then you have family involved as well because there's lots of challenges with getting those individuals to the clinic as well as getting them upstairs and being able to hear and consent to vaccines … like having wheelchairs accessible at the front door because people can't walk as far or upstairs."

"What is the parameters on the time frame of when is the first doses of vaccine arriving? What's the parameters around how fast we have to have that group at first, second arms and stuff like that to things such as funding for this location all of those sorts of things."

"The execution of the needle in the arm wasn't the biggest thing. It was the handling of the product and some of the other rules around that, the documentation

		needs. And you know, the details around adverse responses and properly informed consent"
Security issues	Context	*"Organizationally, that was less clear because this was a secretive operation, so to speak, from a security perspective. in the early stages of it, you know we couldn't just go say this is what we're doing."*
Ministry of Health	Context	*"So what we would do now or the fact that the Ministry would announce and none of us would knew effective immediately X is going to happen and all of a sudden we had people showing up and none of us knew like and none of our teams knew and we couldn't prepare our teams"* *"And sometimes the goals that were in objectives that were set out by the Ministry or even by ourselves were unrealistic. And there was that moment of we're never going to be able to do that. And then it's like, screw that we're going to exceed this expectation and you know some of that clarity. There was a little bit of lack of clarity."*
Perception of leader's vision	Mechanism	*"…it's really important this perception about leaders' vision."* *"So I think that perception of a leader's vision I think what is really important is that in the early days that person who is going to be leading it on behalf of the province is going to surround themselves with people who can also, and you know, I did have other colleagues*

		as part of this team that struggled with this perceptive leaders' vision." *"Again, [vaccine chief] and I can challenge each other but I still follow her vision like nothing else and I will challenge her."* *"I didn't understand the provincial oversight and pressure from the government."*
Triggering internal values	Mechanism	*"... all of us were very much the culture responsive piece was in there, which then triggered and aligned with our internal values and sense of values personal, professional got it really big."* *"So, some people had young families at home. I did too. I didn't see my kids for a long time working 16 hours a day, so my value was I'm here, I'm not an immunizer. I don't know your intimate knowledge and in your task but I'm here to support you so I would work way over my 7.5 hours. I would work 16-hour-days, two weeks straight, like no days off."*
Sense of values (personal and professional)	Mechanism	*"... we really talked about safety, but there was that maybe it's related to that sense of values because safety is one of our values…."* *"I think getting the personal values and how like you mentioned trust, like I had to trust people immediately*

		who I had never met before. I think out of the whole clinic there were maybe two people that I worked with prior. And they weren't even there full time. They were just like of the side of their desk, helping me set up a clinic while also managing their own areas."
Sense of social connectivity / meaning	Mechanism	*"It was nice to be involved in something that was positive and, you know really well looked upon"* *"I talked about us working in silos. We can't be successful if we silo our community in our population. If we build to the 80 percent, which is the average middle educated upper white people. We will never be successful in a vaccine campaign."* *"Sense of social connectivity meaning like I think obviously, if I didn't believe in vaccine and how it was going to get us out and the importance of that to our community and Saskatchewan more broadly …"* *"But it was my friend who her brother-in-law is a paramedic and he got in the clinic on the Boxing Day or whatever and so then it was like OK why am I here? I'm here for those people who are out on the streets and working their butts off and need their immunizations how grateful they are, right? They're so grateful for the staff coming in and, so, I think that's kind of what brought me back is like who might hear or, and yes, it sucked that I couldn't spend the time with my family, but*

		just the importance of it is beyond me. And how impactful it is to other people. … So you kind of have to like we get from other people perspective of like yes this sucks for me, but in the grand scheme of things this is better for our community and the people, the paramedics providing care on the streets who are so vulnerable to even take that disease back to their families."
Perception of commitment	Mechanism	*"Perception of commitment yeah, …, well I guess in hindsight for sure those were obviously at play because there was many days where I wanted to quit. So, I don't know what kept me going. It's something I still reflect on."* *"So, we go above and beyond of what's being asked in our, I guess a scope of practice. Because we are committed, but that can also lead to huge burnout, mental health."* *"But then coming in and knowing what people were committed to, so those values did drive commitment, so I sacrificed family and put the SHA work above that."* *"… they were given an opportunity to work on something positive instead of the darkness that had become our life for that period of time, they were ecstatic to be able to be given that opportunity and they were fighting to stay engaged and involved. So, to an individual, the commitment was there."*

		"So that in terms of commitment that was a bit of a challenge for the first few weeks, actually quite frankly. Because of you know the competing interest on a finite resource pool, and the need to have those other pieces continue on while we were building this sort of thing."
Desire to achieve fidelity	Mechanism	*"But as we've seen since then, if you don't have compliance, you don't have regulations, then it run around that pretty quick."*
Understanding the need to shift person's scope of practice / to adapt usual practice	Mechanism	*"I think the piece about the scope of practice I think some areas did that really well. I'd like to think that Regina, for the most part did that really well here. It was a bit challenging but we're also further ahead in network development which is a different way of how we do this. So, we already had some of those like our teams already did immunization for flu. They did all of those, so it allowed us to be able to shift some of that so that was great."* *"You know so then, the understanding to need to shift to person's scope of practice and stuff. … they're focused on number one thing in the system, at that point in time, was contact tracing*
Perception of urgency to act	Mechanism	*"The people who we were vaccinating at that time were working in the emergency departments and in critical care areas of the organization. And they were seeing patients every single day, and so I almost feel like that*

		lived experience resulted in their perception of urgency to act." *"... you know when did I first get called ..., we kicked the meeting off on December at 4:00 o'clock in the afternoon. It was a Friday afternoon at 4:00. And you know, at the time, like I said, we thought we were going to be starting to receive vaccine in early January and then really quickly into it, we have actually heard then that we needed to move that up like you said earlier to December 14th."*
Perception of a priority for organization / union	Mechanism	*"Perception of priority for organization, I think for the organization they did a really good job with that too, like really impressed with how well they did that."* *"Senior leadership, the Emergency Operations Center, you know, number one thing was top priority in the system at that point in time was contact tracing and testing and contact tracing as our #1 offensive strategy. You know, here we were introducing another potential number one priority to the system. But you've already deployed and exhausted all of those resources that have the contents and the expertise, and you know, there was no EOC shift to say a formal shift at that first point in time to say this is the new number one strategy"*
Confidence in their ability	Mechanism	*"... in certain areas we have the confidence that we have those people doing it already, so we're just going to roll it into the next. So again, we had already had*

		past experience that taught us we could be successful. So we weren't afraid to try it." *"Occupational Health historically has only immunized healthcare workers on site on acute care sites. So, setting up a community clinic was a whole new thing for them."*
Capacity to do the task	Mechanism	*"So I think first and foremost, what I thought about the program, not understanding the scope, so I understood the scope but I was kind of naive about the scope."* *"I think the capacity was really tough. There was a lot of us that hadn't immunized for years."* *"So, it was just a huge learning experience of just being thrown kind of directives and a very quick way or quick ask to implement them, and then when we were meeting those targets it was a change and it was like no, you gotta do better. You gotta work harder and you got to roll out actually a day earlier or you got to get these doses out in three days, not a week or two weeks. So yeah, that was my initial kind of introduction. So, I think I was very naive coming into it."*
Anxiety of the new task	Mechanism	*"I think a lot of times our staff, the anxiety was really high because things changed like this and we didn't have the ability to because of the way the structure was to*

		make sure they had what they needed in enough time …" *"… they didn't feel like they had what they needed to be safe. That is no fault of the leadership that is no fault of our senior leadership team that was trying to get vaccines in arms as quickly as we can, which was the right thing to do. But it did create an unsafe environment and created anxiety for our teams at all levels, for sure."* *"… so then I don't think the panic set in until like two days later when I actually realized what the ask was. And at that time, I don't even think I was clear what the ask was. There was actually a week later, so we were given a lot of vaccine."* *"Yeah, the anxiety for all the tasks that were especially new like there was I don't know how much detail you need to get into, but like I had to force feed myself, I couldn't sleep. I slept maybe two to three hours a night for weeks on end because it's all new and the pressure was there …"*
Concerns about vaccine recipients' privacy	Mechanism	*"does the employer you know even the question is from you know how many employees have had the immunizations while we don't know not a right to know sort of thing, but yet to legitimate question, how many*

		health care workers have been immunized? You know deidentify everybody but still a challenge."
Fear of theft	Mechanism	*"It was a really popular commodity at the time, you know to the point that we even had a security services work stream and law enforcement well, mentoring transports of the vaccine between cities, and you know, really worried about the potential of fact and all of those kinds of things."* *"In terms of the fear of theft, obviously we had, you know, we had our procedures and processes in place. We had really good engagement from our security team in house as well as RCMP and our transportation partners in the career system and stuff like that."*
Feeling of importance / accomplishment	Mechanism	*"... I think just thinking back to that first day in December, there was, you know, a tremendous amount of tears and joy and just excitement from people to be able to kind of give some hope..."* *"So, talking about our accomplishments, how many vaccines we got out in a day and overall, and hearing how well we were doing provincially compared nationally, that definitely helped with morale."*
SHA's policy mandate for staff allocation in emergency conditions	Mechanism	*"So eventually, I believe it was immunization regulations were altered to accommodate non-traditional immunizers. But that didn't occur during this pilot phase."*

		"SHA policy mandate for staff allocation and emergency additions to the letter of understanding which empowered certain things."
Limited number of immunizers	Mechanism	*"I think in the pilot phase, we were pretty confident that we had access to staff who can deliver the vaccine, so you did need to have training components that went without specific to define your vaccine, but like you've got suggested in your slide here we did have public health nurses and other traditional immunizers like occupational health nurses and licensed to administer the vaccine and be reconstituted with a specific role or somebody to play in the delivery of the vaccine. So, we had good confidence that we had enough people with the right skill set to get through the pilot from the immunizer perspective."* *"… their own local context, either the facilities that they were going to have, the people that they are going to have available and those sorts of things."*
Non-traditional immunizers	Mechanism	*"You can't just take a whole bunch of staff because they're available and say going to immunize. There's still be training that needs to happen, and there is still credential that needs to occur, and onboarding and inventorship for some of those stuff."*
Need to secure (IT) resources	Mechanism	*"Well, what I had heard in the initial stages of the vaccine work was that it was quite a popular choice of working destination for people, right?! So, when we*

look at the resources, we did not struggle to fill shifts on vaccine clinics because it was so positive because you'd like to see people dance when they get their vaccine, and the stickers were a really big deal and that kind of thing."

"So eventually, I believe it was immunization regulations were altered to accommodate non-traditional immunizers. But that didn't occur during this pilot phase."

"... did we have the capacity and the infrastructure required to administer the vaccine that we were receiving and being a new vaccine with new cold chain requirements and when Pfizer first came out of the vaccine that was very specific transportation requirements, dry ice and other things, to keep it at ultra low temperatures. And then we had to have the infrastructure to transport it from the airports to the site to store it into the ultra low freezers. We needed to have some of those physical infrastructure pieces."

"... we used bedside like hospital bedside tables because that's what we had to work with right so we used hospital bedside tables and put computers on them and wheeled the hospital bedsides around"

		"That program [Panorama] that I mean, occupational health didn't use that program. They couldn't do direct entry into that program, 'cause they've never trained on it, even though that's the national database registry for immunizations from an occupational health perspective. It's not sort of thing" *"The IT resources, IT was literally slammed in every direction during pandemic to providing the physical resources for all these people to work remotely and get them all, then provide data support to pull information from all of these all these data sources that previously didn't exist"*
Availability of security resources	Mechanism	*"So, you know some of our requests around ensuring security or not, you know that the information didn't necessarily translate through 100% accurate. And therefore some of the transition points had some hiccups associated with them. We didn't have any point where there was any reaches from a theft perspective or anything like that that was it's not totally over uncovered that I heard sort of thing."*
Pandemic emergency legislation	Mechanism	*"But I have to say from our team, the most important things have been their emergency legislation, and those mandates, and the public health orders. Those facilitate the work that we are going to do we get lots of people …. But they certainly facilitate and are supportive and, and the team certainly found that the vaccine mandates were incredibly important …"*

	"Then pandemic emergency legislation so relying on the provincial level of understandings and those sorts of things, the information that was coming from the Ministry around the vaccine information, so they had to produce their documents in order for us to produce our documents and they couldn't fully produce their documents until it was a Health Canada approved vaccine and then so the turnaround time for them had to be really tight didn't even tighter for us to get that into a live document to be able to share. And then making the resources available on a provincial scale as well."

6.2.3.2 New Contexts and Mechanisms

Several contextual factors and causal mechanisms emerged as new elements (Table 6.6). The four new contextual factors include "actor's experience and knowledge", "cultural responsiveness", "partnership and engagement (recipients, family, and community)", and "rapid evolving regulations and policies". The seven new causal mechanisms encompassed reasoning mechanisms of "sense of being partnered and supported", "adaptability of approach to community needs", and "sense of uncertainty" as well as resources mechanisms of "need to acknowledge cultural responsiveness", "need to not waste vaccines", "need to prioritize recipients", and "need to protect workforce".

Table 6.6. List of new contextual factors and causal mechanisms to IPTs for the SHA stakeholders

New Element	Context or Mechanism	Quote Examples

Actor's experience and knowledge	Context	*"... in terms of the planning, I think some of the work that I've done over the years in terms of process planning, patient flow and the seven flows and understanding all of those pieces and things like that and as a system the work that was done the previous all or during that fall around the flu campaign. There was there's some information and learning done and from the flu campaign, it was valuable and relevant."*
Cultural responsiveness	Context	*"... the understanding of impact on First Nations and Métis and cultural responsiveness. The lack of cultural responsiveness in the context impacts our mechanism and it impacts our outcome."* *"... the absence of that [cultural responsiveness] in this entire program is unacceptable and it's unacceptable even we look at our 5 to 11 year rollout and the new mandate that came down about parental consent and how we deliver it in schools is unacceptable."* *"It is the foundation before all other pieces are looked at that is your foundation of what you need to build on. How are you going to be culturally responsive? And it's not just First Nations and Métis, but it's our new immigrants. It is our new to Canada residents. It is those who have language and cultural barriers …."* *"The community context, socioeconomic barriers people face, history (ie – residential school and potential*

		distrust of the system), social determinants of health should all play and important part in how an immunization campaign (planning and implementation) should be created."
Partnership and engagement (recipient, family, and community)	Context	*" I feel strongly that the campaign had far greater impact with the help and collaboration of our key partnerships- for us in Prince Albert I would say our FN partners (PAGC specifically) increased our weekly capacity to immunize (doubled or tripled our capacity), provided important insight to reaching our shared FN client population during our joint planning, was able to reach people that perhaps had distrust (past history) of the healthcare system, provided much needed outreach. This was an example of true partnership for the overall good of the whole population in our city."* *"And then we got lots of questions from other cities and rural areas or on well when are we going to get vaccine? Why is it only focused on the three cities and not the rural areas or the other cities in the province? So lots of competition, I would call it and advocacy going on for all areas in the province to have some access to vaccine."* *"You have to be able to engage leaders of those communities so that you can learn and understand if you're not from that community yourself."*

"And then that was another whole shift to engage the long-term care as well, right? … so getting their leadership engaged in this work while at the same time they were addressing outbreaks, critical outbreak in long term care at the same time, right?"

"But being able to bring people to the table and kind of get them started in on that common vision on what we're going to do here was the big beast."

"… in January we were also immunizing 80 plus. So, then you have family involved as well because there's lots of challenges with getting those individuals to the clinic as well as getting them upstairs and being able to hear and consent to vaccines. So definitely the second family supports."

"I think in hindsight, obviously having a patient family advisor to support the work at the clinic, right from the get-go."

"Yeah, so we would huddle. We would huddle and we would go through like what are your patient flow issues? What are your vaccine medication issues? What are your equipment issues? So those they were a part of our seven flows that we would reflect on. But we didn't have a specific individual advocating right? We were bringing our own health care worker biases and

		advocating for the clients without actually having them present. So, I would say that's definitely a gap."
Rapid evolving regulations and policies	Context	*"... we were trying to do constantly every single day because directives were changing every single day"* *"So in Prince Albert, the other thing that changed a bit as we got some new direction, I believe it was in the Prince Albert pilot where we got new direction around the ability to transport the Pfizer vaccine between locations to the point that if we did move it away from the ultra little freezer, but we got it over to a facility where we administered it on site that same day, we were able to move the Pfizer vaccine around with more confidence than we did in Regina and Saskatoon."* *"... recognizing that there was many things, even from the scope of the pilot like 975 doses OK, so is that 975 first doses or is it 481 first doses. ... and then all of a sudden we were at 1800. And we thought it was 1800 1st and 2nd doses. But then all of a sudden it was 1800 first doses. So we went from 475 to 1800 as a pilot in Regina"* *"I think something knows that the vaccine availability I think caught everybody off guard a little bit in terms of how soon it came like, I don't really think that a lot of people were overly optimistic that we would have had*

		anything prior to say April of 2021. Here we were December planning for first doses by the mid December"
Sense of being partnered and supported	Mechanism	*"Even early on, I did recognize that this was going to be a real collaborative way of doing business. And so I did, I brought the team together between Christmas and New Year's and said, OK, what do you need from us? What do we need? How do we how do we work together so that we can, none of us have enough supports to do this. How do we work together and support it?"* *"... when we're setting up in the early days and again this was with [vaccination chiefs] really set us up to have these really strong teams local teams like they did recognize very early on with this and so they helped us or empowered us to be able to set up these teams .... and allowed us to be able to build teams around ourselves to be able to do this"* *"... the ability to have that she [vaccination chief] developed structure for us so that we could have those back and forth so we were safe to be really vocal about what we disagreed with. And she was really clear on what we had control and not control over."* *"...it fell on somebody elses' hands and I didn't want to inflict this pain on somebody else 'cause it both pain like*

		mentally and physically, It was pain. So resourcing up front for knowing what was coming I think would be obviously the best, but I did I got through it with those provincial supports."
Adaptability of the approach to community needs	Mechanism	*"Although there are important elements of standardization the approach needs to be flexible enough to meet the needs of the community and populations within it."*
Sense of uncertainty	Mechanism	*"Well, certainly that the initial you know piece was understanding the scope"* *"we're going to exceed this expectation and you know some of that clarity. There was a little bit of lack of clarity."* *"I think if I try to go back to that time, there was a lot of uncertainty. I think a lot of excitement, mostly about what was going to happen, but a lot of uncertainty, you know, very specifically around when the vaccine was going to arrive and how we were going to ensure that it gets to the right place."*
Need to acknowledge cultural responsiveness	Mechanism	*"So I think you have a really strong understanding of colonization and the impacts of residential schools. I'll use the example of July 1st. So July first we had been mandated to provide vaccines on the legislation and this is right after they had found the 215 graves at British Columbia and then shortly thereafter found them at Cowessess First Nations, which is in our own*

community and within the Regina area SHA. We sought advice from our elders on whether it was appropriate or not for us to be vaccinating at the legislative grounds on July 1st that the answer to them was no and so you need to understand why the answer was no. And the answer was no, because on July 1st every year, the Northwest Mounted Police at the time, which is now RCMP, would ground up our First Nations communities, bring them to a location, and forcibly immunize them on July 1st. So to run an immunization campaign on the grounds of the legislature on July 1st, they had just discovered all these unmarked mass graves was incredibly disrespectful and reinforced the colonization and the fact that they can't trust us."

"And to know that we need to seek out the advice, the guidance and the support from our First Nations and Métis colleagues and staff as well. Again, we need to understand our history."

"we work with lots of refugees and newcomers as well, as if they've been in refugee camps. The violence, the trauma, in particular for children, children who have experienced violence and trauma and now all of a sudden, you're doing something to them that hurts them, or you're restraining them so that they can be safely administered you're recreating trauma. And so you have to understand when you are working being culturally responsive."

		"So when you talk about mechanisms for cultural responsiveness, I think what you're needing is knowledge, so how do we make our staff knowledgeable and our leaders knowledgeable so that they understand, how do we engage our community leaders and our knowledge keepers for that guidance"
Need to not waste vaccines	Mechanism	*"There was also this, we had a very strict approach to vaccine wastage right. So, in the pilot phases it was extremely important and especially on that first day we thought that we were getting 5 doses out of the vial and we ended up getting 7 and we ran downstairs to find two more people that qualified so they could get the shot in there because we absolutely could not waste any right?! And that's not a challenge that we have now. Like the amount there is definitely wastage that occurs in the system, but at that time it was such a precious resource that we had to use every last drop of it. And it was treated that way."* *"You will remember the importance that was placed on not wasting any doses of vaccine that was a huge focus of ours was to make sure that we need to maximize everything."* *"… making sure that no drop goes to waste and you know so how do we prioritize using up of extra doses at the end of the day 'cause we had certain builds cracked*

		and a certain number of vials cracked open and needed to be used"
Need to prioritize recipients	Mechanism	*"So along with delivering the vaccine was you know who was going to get it in our workplace, and certainly there was a perspective of occupational health and safety looking at who are the most at risk of getting COVID during their workday and looking at vaccines is an opportunity to minimize that risk. There was a lot of work that went into it prioritizing which people in the workplace and which employees in the workplace and physicians in the workplace would be the first eligible people if you want to call it, capturing the pilot phase."* *"We also knew that we had a significant number of employees that would be anxious for wanting to get the vaccine and be the first one to get it far more people interested in getting vaccinated than we had for vaccines so we had to make some strategic choices about which departments go first, and that's where we talked about emergency departments and ICU departments and those COVID units and the hospitals."* *" There's the challenges associated with how we are immunizing the right people first. You know, even the immunizers themselves, because the immunizers weren't immunized at the early phases like they had to kind of wait until their appropriate sequence came into being"*

Need to protect workforce	Mechanism	*"One thing I thought about adding was that perspective of occupational health and safety and protecting our workforce and using the vaccine to do that. I know that was a big perspective. We had even as we move past the pilot and into the next stages when we continued to have more demand than we had supply, we had to make decisions about who would be stage one of our employees and physicians and who's phase two of our employees and physicians in phase three? And that's where some of that Union involvement definitely came into play."* *"But then having to have conversations around mitigating the risk and like, we were coming into places knowing that there is COVID right and how do we mitigate that occupational hazard and help support people. Just constantly going through how do I keep myself safe and my family safe and don't bring that back so."*

6.2.3.3 Refined Contexts and Mechanisms

Two contextual factors and one causal mechanism were refined (Table 6.7). The "communication" was refined to "communication (social media, media attention, public narrative, misinformation, SHA daily news updates)". The "inspirational leadership or champions" was refined to "supportive and inspirational leadership / champions". The "perception of significance of pandemic and no prior schema" was separated into a refined mechanism of "lived experience of significance of pandemic" and a new context of "prior experience with pandemics".

Table 6.7. List of refined contextual factors and causal mechanisms within IPTs for the SHA stakeholders

Refined Element **(Refinement in bold)**	**Context or Mechanism**	**Quote Examples**
Communication to Communication (social media, **media attention**, **public narrative**, misinformation, SHA daily news updates)	Context	*"We often think about communications in terms of differentiating internal communication versus external communication, right? So, the things that you have listed here are things that, primarily we communicate outwardly to staff and physicians using those types of channels. I guess what's missing for me here is that influence of what's going on externally in the world, and particularly the dialogue that's happening in the news media related to the vaccine because in the early days, I think it played significantly into how would things were received at that time."* *"There was also a lot of media attention at the time. And you know, a keen level of interest to track the flight that the vaccine was coming in or the bus that it was being shipped through and that sort of thing."* *"Because that's what led to that uptake being so positive. We actually didn't need to do much in terms of communication because it traveled so quickly"*

"And so, I guess what the other thing I might add here is that word of mouth itself moves in tremendously quickly as it did at this time, that finally when it's here then the calls started ringing off the hook"

"So, I think that's probably the one gap for me within the context is, I do believe that there was kind of a public narrative that was taking place that was helping to convey the fact that the vaccine was a good thing and that it was actually going to cut through some of that negativity that had been experienced previously."

"... they communicated that clearly in the directives. All that made it very clear for me when I was going to other areas or teams or Regina IHICC to be able to say we're in this and this is our vision and this is what we've been working on. So that again, you know I talked about cultural competency being number one or responsiveness, this is number 2."

"I didn't understand the media attention that this would have, which I'm very grateful for because what I had to deal with in those days above all of that was enough for me to handle like mentally."

"I think communication also like within the clinic and then provincially and then back down again, right? It's like very focused, broad, and focused so that we were

		trying to do constantly every single day because directives were changing every single day, so we had to take what was coming either from the Ministry or SHA and then communicate that. We'll understand it with the leadership team, operationally how can we make that work for us and then communicate it to our immunizers and our local stakeholders…. So, I think that internal communication as well. So, every morning we huddled with provincial leaders. Then I had a huddle with the immunizers at 8:30. …Then at the end of the day we would huddle with our local stakeholders and then we would start all over the next day. So, we had a very tight cascading huddle for that information flow that I think is very invaluable because we had to have what are our barriers and what are the learnings" *"… and then those provincial supports and how it made sense like we really had to make it meaningful for what that meant to our clinic operations."*
Inspirational leadership / champions to **Supportive** and inspirational leadership / champions	Context	*"I empowered our teams and I have great leadership around me that supported me empowered our teams to be able to make sure that we could build that piece in. I think it is probably the piece that we're most proud of, what our teams in Regina have done is that in the absence of having cultural responsiveness built into this, we did everything we could to be culturally responsive."* *"You know, obviously, like I said pulling a number of those clinicians from their areas of expertise and you*

		know, identifying to them but you know I'm not here to scare you. You're all brought here because you have been identified as a knowledge expert and expertise that you bring to the table and the passion and all those sorts of things to be significant players in the various components." *"I kind of kept them focused on the small tasks in front of them so that they didn't get overwhelmed. And then my responsibility was to kind of look at that data and the next steps and the next steps, and the next steps and bigger than who's where are we going from here? How do we make that transition easy and so framing that up and bringing very clear, intense touch points at the start couple times a day to make sure we're on track and we're covering everything collectively as a team."* *"I'm very grateful for the provincial supports that were kind of already in line to help support the clinic rollout."*
Perception of significance of pandemic and no prior schema to **Lived experience of** significance of pandemic	Mechanism	*"... maybe it's this perception of the significance of the pandemic. I don't know if it's perception so much as reality, right?! I mean they weren't perceiving it, they were living it every single day."* *"... in my previous role I was aware of some of those plans and participated in some of that planning process for SARS and the flow of patients through the system*

		related to that and as well as the COVID pathway. So, I mean, everybody was recognizing that pandemic itself was significant"
Perception of significance of pandemic and no prior schema to **Prior experience with pandemics**	Context	*"this is our whole life has been public health nursing has been outbreak management …. This is what we have trained to do. …They have they contributed to our planning. They contributed to helping us get ourselves organized. They contributed OK, what do we need to do? They buddied they've mentored, they have overseen staff to help build that confidence and to really get people to where they need to be and so we really relied on those frontline public health nurses to work really long hours in the beginning up until we could get those people trained because we didn't have the modules set up the way we do now."*

Since no interviews were conducted with the security lead and the vaccine campaign chief, the corresponding IPTs were excluded from the list of final program theories. As a result, we developed four final program theories for each category of actors (i.e., clinical managers, Logistics and Distribution, Human Resources, and Communication) (Appendix K).

7 Discussion

7.1 Summary of Findings

In this study, we used a novel combination of patient-oriented research (POR) strategy and a theory driven realist evaluation (RE) to answer the question "how, why, for whom, and under what circumstances did the COVID-19 vaccination program lead to vaccine uptake in three Saskatchewan sites (i.e., Regina, Saskatoon, and Prince Albert)?"

I oversaw the development of three program theories for the COVID-19 vaccine recipients (i.e., ICU / ED physicians, nurses, and health care workers; long-term care managers and health care workers; and long-term care residents). The program theories have twelve (12) contextual factors and a mechanism chain, containing seventeen (17) causal mechanisms. The intermediate and final outcomes of interest are willingness / hesitancy and vaccine uptake among the recipients, respectively. Prominent contextual factors include demographic characteristics, religion or worldview, location of residence, and communication channels. Major causal mechanisms encompass trust, anxiety, perception of personal vulnerability, eagerness to provide positive leadership, and understanding of transmission and prevention. I discussed the relationships between the contextual factors and the causal mechanisms leading to vaccine uptake (outcome) in the "vaccine recipients" section.

I also oversaw the development of four program theories for the SHA stakeholders with vaccine delivery as an intermediate outcome that led to vaccine uptake among vaccine recipients. These program theories hold thirteen (13) contextual factors and a mechanism chain, containing thirty (30) causal mechanisms, for four categories of actors (i.e., clinic managers, Logistics and Distribution, Human Resources, and Communication work streams). Prominent contextual factors include inspirational leadership, union and regulatory body engagement, communication, and logistical challenges. These contextual factors triggered causal mechanisms, including desire to achieve fidelity, sense of values and social connectivity, perception of urgency to act, perception of commitment, sense of being supported, SHA's policy mandate, need to not waste vaccines, and need to acknowledge cultural responsiveness. I discussed the relationships between the contextual factors and the causal mechanisms in the "SHA stakeholders involved in planning and delivery of vaccines" section.

The vaccine recipients and the SHA stakeholders underscored a few common elements. For example, both groups highlighted perception of freedom and personal choice, burnout, and exhaustion mechanisms. I will compare the vaccine recipients' and the SHA stakeholder's theories in the "comparing vaccine recipients' and SHA stakeholders' program theories" section below.

7.2 Vaccine Recipients' Program Theories

The IPTs for the vaccine recipients were complex. They needed to be inclusive of various levels (personal, local, regional, and provincial) in which the vaccination campaign occurred. These levels resulted in multiple context-mechanism relationships that included the idea of "child" mechanisms within a chain of mechanisms. Mechanisms at personal level became intermediate outcomes (willingness or hesitancy to receive a vaccine) for other levels (local or regional), which in turn became mechanisms for the outcome of interest (vaccine uptake at the provincial level).

Related to the concept of mechanisms chain, John Mingers in his book entitled "Systems Thinking, Critical Realism and Philosophy: A Confluence of Ideas" discusses "circular causality" or "feedback" (50). He explains that a fundamental idea in the science of communications and control (cybernetics) is a chain of causal connections in which "a change in one element eventually feeds back to either balance or reinforce the initial change" (50). He further explains that circular (as opposed to linear) causality is a characteristic of self-influencing systems. Jagosh et al. have used the concept of the ripple effect to expound how the outcome of one phase of a project becomes an aspect of context for the next phase (55). This phenomenon indicates a systems approach to realist evaluation. Traditionally, errors in health care (or vaccine unwillingness or hesitancy in our case) are attributed to individual providers' insufficient knowledge or skills (in our case, SHA stakeholders involved in the planning and distribution of vaccines in Saskatchewan) (56). A systems approach contrasts this point of view and bases the errors in poorly designed systems. In systems thinking, characteristics of systems depend on the relationship compositions of systems' elements rather than the elements themselves (50). A systems approach identifies the underlying system elements that can create human error, rather than a focus on the human error alone (56). James Reason in his book entitled "Human Error"

exemplifies the systems flaws as the holes in Swiss cheese where flawed systems allow errors made by people to penetrate through different levels of the systems and to result in unwanted consequences (57). Literature has also shown that human factors systems approaches are important for healthcare quality improvement and patient safety (58). From my perspective, we can connect the concept of ripple effect to the Swiss Cheese model. I believe that the identification of underlying systems factors warrants realist evaluation in which the systems factors and peoples' actions (or errors) be considered as contextual factors, underlying mechanisms or intermediate outcomes, depending on at what level the realist evaluation is happening.

All vaccine recipient interviewees highlighted the importance of communication (context) that started multitude of mechanisms, including trust, understanding of transmission and prevention of the disease, and sense of community versus individual. We found that there are internal and external sources of communication for the vaccine recipients. Internal communication sources consisted of SHA's daily news updates and physician town halls. External communication sources included SHA's messages via social media to the public. How to communicate messages from health care authorities to the public (e.g., frequency, language, and tone of messages) influenced the public's relationship with valid sources of reliable information. Person's preferred sources of communication (e.g., one's regular or trusted channels of communication) increased their understanding of transmission and prevention. Multiple interviewees affirmed the power of social media (external component) and its influence on misinformation and hesitancy among the vaccine recipients. Social media (context) triggered trust and understanding of transmission and prevention (mechanisms) by disseminating information or misinformation about the side effects of the vaccines (e.g., autism or infertility).

7.2.1 Trust as a Key Mechanism

Trust was a by-product of relationships between the public and the communication sources. Transparent communication by public health authorities (e.g., competing information from SHA versus Ministry of Health [MoH] versus social media) strengthened the relationship. This trusting relationship via other mechanisms (e.g., understanding of transmission and prevention of the disease) then led to confident decisions by the public.

We also found that trust in healthcare institutions including medical professionals (mechanism) enhanced the consent taking and vaccine uptake (outcome) among the LTC residents. Trust in medical staff (mechanism) overshadowed and mitigated the concerns from previous vaccination experiences, the perception of risk to side effects, and the perception of vulnerability (mechanisms). Trust in healthcare institutions also resulted in vaccine uptake (outcome) among LTC residents with pre-existing medical conditions (context) who perceived or were anxious about their vulnerability to the vaccines' side effects (mechanisms).

We found that relationships between mechanisms (e.g., trust in medical staff and perception of risk to side effects) were relative, dynamic, and iterative. For example, pre-existing medical conditions (context) evoked the mechanisms of anxiety, perception of personal vulnerability, and perception of risk to side effects. These mechanisms then lowered the positive impact of the trust and understanding of transmission and prevention mechanisms on willingness or hesitancy (intermediate outcome) to receive the vaccines among LTC residents (outcome). However, the trust mechanism overshadowed the perception of risk to side effects or vulnerability (mechanisms) as it became more prominent via transparent communication (context) by public health authorities.

Interviewees emphasized that trust in leadership (mechanism) encouraged the public to receive the vaccines (outcome). They raised that the mistrust in public health leadership by the public may be rooted in racism. People who do not identify themselves with minority groups may not believe in the messaging coming from the public health authorities when authority representatives are from minority groups (e.g., Dr. Theresa Tam, Chief Public Health Officer of Canada, or Dr. Saqib Shahab, Chief Medical Health Officer of Saskatchewan). Inclusion of diverse ethnic groups in public messaging may reduce the impact of this phenomenon.

7.2.2 Actors' Diversity within Each Category

Participants' experiences influenced their responses to the interview questions even though we stratified them within the same category of actors. For example, one of the LTC managers indicated that the fear about the disease (mechanism) was not a causal factor for the nurses in their facility (they put residents ahead of themselves to receive the vaccines). However, the other manager explained that they had to vaccinate their health care workers first (perception of

competing priorities [mechanism]) to be able to vaccinate the LTC residents. Facilities' policy or philosophy of care (e.g., people centred care) (context) affected sense of community versus individual (mechanism) among residents and staff, which increased vaccine uptake (outcome).

7.2.3 Resource Discrepancy in LTC Facilities

SHA affiliated facilities were provided with different resources than private ones. This shows inequity, especially in facilities in rural centers with limited number of immunizers (resource mechanism). The mechanism of limited number of immunizers then increased the mechanism of understanding the need to shift a person's scope of practice and to adapt usual practice (e.g., shift in role from manager to provider). The mechanism of shift in a person's scope of practice could compensate for the mechanism of limited number of immunizers and increased the vaccine uptake (outcome).

7.3 SHA Stakeholders' Program Theories

The SHA stakeholders' program theories were complex as well, and multiple mechanisms were interrelated. The complexity and interconnectedness of the mechanisms warranted the idea of "child" mechanisms within a chain of mechanisms. Although the scales of the SHA stakeholders' program theories were at local, regional, and provincial, the vaccine delivery outcome was the same across them. This differs from what we found in vaccine recipients' program theories in which various scales resulted in various outcomes of interest. Willingness or hesitancy outcome appeared to be at personal scale, which in turn it resulted in vaccine uptake at local, regional, and provincial scales.

The people involved in planning and delivery benefited from Saskatchewan's single healthcare system. Having a single health authority in Saskatchewan facilitated building new structures or teams from different portfolios or departments, enhancing relationships, and deepening the trust between various stakeholders.

7.3.1 Desire to Achieve Fidelity as a Key Mechanism

Proctor et al. propose fidelity (an underlying mechanism and an intermediate outcome in our study) as one of the eight conceptually distinct implementation outcomes, including acceptability, adoption, appropriateness, feasibility, implementation cost, penetration, and sustainability (59). They define fidelity as "the degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers". They mention five dimensions for fidelity including adherence, quality of delivery, program component differentiation, exposure to the intervention, and participant responsiveness or involvement. They claim that fidelity is analyzed at individual provider level, and it is salient in early to mid stages of intervention implementation (59). Lavallée et al. posit fidelity as an indicator for effective behaviour change (60). We considered desire to achieve fidelity as an underlying mechanism to vaccine delivery (an intermediate outcome to vaccine uptake) in our program theories because desire to achieve fidelity is measured at individual level and represent reasoning and behaviour change at this level.

Multiple mechanisms influenced the desire to achieve fidelity mechanism. For example, the SHA stakeholders indicated that rapid evolving regulations and policies (context) compromised the desire to fidelity (mechanism). Regulations were not clear from the MoH during the pilot phase, and the SHA had to set up their own expectation of the mandates from the MoH. Policies needed to be more agile and responsive, especially for LTC residents. Another example was uncertainties about the course of the COVID-19 disease (mechanism). This mechanism alongside the rapid evolving evidence and regulations (context) necessitated the need to prioritize recipients (mechanism). Nevertheless, the need to prioritize recipients challenged the vaccination planners to develop a steady implementation plan, which then affected the desire to achieve fidelity (mechanism), without receiving negative feedback from the SHA staff. Although the Saskatchewan's COVID-19 Vaccine Delivery Plan outlined the recipients of the vaccines, prioritization became a prominent challenge for the vaccination planners because of limited understanding of the vaccination rollout scope (reasoning mechanism) and limited supply (resource mechanism).

In the early phases of the vaccination rollout, there was a shortage of supply (i.e., Pfizer vaccine, personal protective equipment [PPE]). Logistical challenges (context), including reliable supply

chain and sustainability were major challenges for the policymakers in the pilot phase due to the uncertainties (mechanisms) about the timeframe of the pandemic. The sense of uncertainty mechanism triggered other mechanisms, including understanding the need to shift person's scope of practice, perception of commitment, and desire to achieve fidelity. The broad spectrum of logistical challenges (context) also evoked the mechanism of the need to prioritize recipients. Logistical factors such as safety and appropriate workplace environment (context) fired the need to protect workforce (mechanism) and concerns about vaccine recipients' privacy (mechanism). These mechanisms then affected the SHA stakeholders' desire to achieve fidelity (mechanism) and how they delivered the vaccines.

7.3.2 Cultural Responsiveness for Northern Communities

SHA stakeholders underscored the importance of the need to acknowledge cultural responsiveness (mechanism) during vaccination and emphasized that the vaccination rollout had to be adaptable to the unique needs of targeted communities.

7.4 Comparing Vaccine Recipients' and SHA Stakeholders' Program Theories

Both the vaccine recipients and the SHA stakeholders highlighted the importance of partnership and engagement (context) via supportive and inspirational leadership and championship (context). Not only did partnership and engagement built up trust (mechanism), but this also strengthened existing trust.

We found that the elements in the PTs for the vaccine recipients affected various elements in the PTs for the SHA stakeholders and vice versa. For example, ease of access (context) accelerated vaccine uptake (outcome of interest in the vaccine recipients' PTs) among vaccine recipients, but logistical challenges (context) and resource mechanisms (e.g., limited number of immunizers, need to secure IT resources, availability of security resources) introduced barriers for the SHA stakeholders to deliver the vaccines (outcome of interest in the SHA stakeholders' PTs). Logistical challenges such as training (public health nurses [PHN] and traditional immunizers versus non-PHN and non-traditional immunizers) and standards of practice requirements (contexts) evoked the mechanisms of limited number of immunizers and non-traditional

immunizers and reduced the vaccine delivery (outcome of interest in the SHA stakeholders' PTs). This phenomenon then limited the ease of access (context) for the recipients, which then led to lower vaccine uptake (outcome of interest in vaccine recipients' PTs). The interconnection between the PTs shows that program planning and implementation should be adaptive to the contextual factors and causal mechanisms for the actors influenced by a program.

7.5 Comparison with Existing Literature

Other quantitative and qualitative examinations of COVID-19 vaccination have found similar issues with vaccine willingness or hesitancy among the recipients. We found that trust is a key mechanism for the vaccine recipients' willingness or hesitancy to receive the vaccines. This finding was highlighted in other literature (55,61–65). Distrust in the vaccines and the authorities has been noted as a strong and common cause of low uptake by the public (64). However, none of these studies has been able to make causal theoretical statements that our evaluation has put forward.

We found communication (internal or external [social media]) influenced vaccine recipients' willingness or hesitancy by firing or silencing multiple mechanisms (e.g., trust, understanding of transmission and prevention of the disease, anxiety, or fear of death). Literature has shown the negative impact of media attention on vaccine acceptance (66). Low trust and fear of COVID-19 have been shown to be associated with unwillingness or indecision about the vaccination (67). We found that social media did not have significant role in vaccine uptake if they did not evoke a collection of mechanisms (e.g., trust and anxiety) in vaccine recipients. These findings demonstrate the complexity, dynamic, and interconnectedness of contexts and mechanisms.

We found acknowledging cultural responsiveness plays a positive role in vaccine uptake. Literature has shown that cultural responsiveness can enhance trust (mechanism) and mitigate health care disparities (68,69). Organizations' leaders and policies impact cultural responsiveness resources and capabilities as well (70). To equip leaders and policymakers, models and frameworks such as Indigenous Cultural Responsiveness Theory (ICRT) can be used to guide revision of current policies (71).

7.6 Strengths, Limitations, and Future Directions

7.6.1 Strengths

By engaging with PFPs and following the Saskatchewan Center for Patient-Oriented (SCPOR) Patient-Oriented Research Level of Engagement Tool (PORLET) (44) as a guiding framework, we co-created the IPTs that were reflecting the lived experiences of the vaccine recipients. The IPTs were relatively complete and required minimal refinement. We were fortunate to engage with PFPs who were experienced in research and realist methodologies.

Policymakers working in LHS oriented organizations enhance value through optimization of patient and provider experience, population health and health system costs (72). The optimization is achieved via learning cycles where data is converted to knowledge, knowledge is applied in practice, and practice changes are recorded as new data (72). Our findings as new knowledge can have practical applications for policymakers, including MoH, SHA, or PHAC so as to develop implementation plans. We found that communication, religion or worldview, ease of access, and open non-judgmental relationships, among other contexts, evoked a chain of mechanisms (e.g., trust, anxiety, fear of death, understanding of transmission and prevention, sense of community) among the recipients, which in turn increased willingness or decreased hesitancy among them. Reduction in logistical challenges and rapid evolving regulations and policies and increase in partnership and engagement and communication, among other contexts, lowered sense of uncertainty and enhanced understanding the need to shift person's scope of practice, sense of value, and desire to achieve fidelity among the SHA stakeholders, which in turn increased vaccine delivery by them. These findings can then be applied in implementation practices for vaccination campaigns (knowledge to practice) to enhance vaccine uptake among recipients.

7.6.2 Limitations

Our study limitations include a) lack of engagement with Indigenous communities, b) no interviews with people who did not get vaccinated, LTC residents, security work stream, and the vaccination chief, c) transferability of findings to similar contexts but not generalizability to every context, and d) challenges with resources necessary to develop and refine IPTs at various timings of vaccination.

Our study's final program theories do not have elements related to Indigenous communities. In fact, the IPTs for vaccine recipients initially had those elements, but we later removed the elements because representatives from Indigenous communities were not engaged in the IPTs development phases. This limitation reduces the application of the study's program theories in the context of Indigenous communities.

I tried to interview a person with vaccine hesitancy (not an anti-vaccine) referred to our study by one of the PFPs. Despite multiple requests, she did not take part in the study. I had the same challenge with the security work stream lead and the vaccine chief. To mitigate the lack of representatives from anti-vaccine or vaccine hesitant groups, LTC residents, security work stream, and vaccination chiefs, I along with the research team reviewed the literature about anti-vaccine or vaccine hesitant groups' rationale and reasoning and asked pertaining questions from the study's participants (e.g., if you are aware of someone who is hesitant or against the vaccines, could you elaborate or explain what the contextual factors or casual mechanisms were that led to vaccine hesitancy among them?).

Vanstone et al. found that media issues resulted in vaccine hesitancy (73). They also found that mandates, restrictions, having positive attitude toward COVID-19 vaccines, and having access to trustworthy and reputable information sources would accelerate vaccine uptake among the vaccine hesitant individuals (73). In another study, Morales et al. conducted in-depth interviews with COVID-19 vaccine hesitant people and concluded that social pressure to not get vaccinated and lack of trust in the healthcare system influenced vaccine hesitancy (74). They also determined the reasons behind why vaccine-hesitant individuals eventually chose to get the COVID-19 vaccine, such as gaining knowledge, the desire to return to normal, and societal pressure. Lastly, they explored the sources of COVID-19 information, which included traditional media like TV and digital/social media, as well as personal sources like family, friends, and coworkers (74). Demographics (e.g., age, gender, socioeconomic status such as education levels, employment status, and immigrant) are also significantly associated with COVID-19 vaccine hesitancy (3,75,76).

Although the desire to return to normal and societal pressure are not in this study's final program theories, I would argue that demographics (context), sense of community versus individual (mechanism), perception of freedom (mechanism), and personal choice and responsibility

(mechanism) are closely related to the abovementioned factors. Furthermore, the other findings (e.g., having access to trustworthy and reputable information sources, lack of trust in the healthcare system) are in alignment with the results of our study where we identified communication via person's preferred or trusted source (context), open non-judgmental relationships (context), trust in healthcare institutions (mechanism), and trust in vaccine efficacy and safety (mechanism) are crucial elements for vaccine uptake among the recipients. Literature has shown that healthcare advice is still considered to be the most trustworthy when coming from physicians and other healthcare providers (75,77), but also recommends that healthcare providers need to provide support, guidance, and take into account the patient's perspective (77). This validates the contextual factor of open non-judgmental relationships by which several mechanisms such as trust and understanding of transmission and prevention of the COVID-19 disease are evoked, which eventually lead to vaccine uptake (outcome).

We studied the pilot phase of the vaccine campaign. The contextual factors or causal mechanisms found may not be applicable to different timeframes (e.g., mass phase). Nevertheless, if there are similar contexts to the pilot phase, evaluators can use our study results to evaluate vaccine campaigns.

We found that timing of our evaluation study played a role as a contextual factor. Interviews happened 4-6 months after the pilot phase, and many interviewees compared their decision-making processes during pilot phase with the mass immunization phase. This implies the fact that the timing of a given study reveals certain noticeable contexts and underlying mechanisms at the time of the study. However, if the study happens in a different timeframe, the salient contexts and underlying mechanisms may change. In multiple occasions, interviewees brought up contextual factors (e.g., rapid evolving regulations and policies) or underlying mechanisms (e.g., need to not waste vaccines) that directly affected their decision-making processes during pilot phase. However, those contexts and mechanisms became less prominent during the mass phase due to changes in the vaccine campaign landscape. This proves the fact that one size does not fit all and endorses the necessity to understand under which circumstances (e.g., pilot vs mass immunization), for whom (e.g., LTC residents or ED / ICU physicians), why, and how a program works.

In realist methodology, environments are considered dynamic (unlike traditional research in which environment is considered static). However, the methods being used in realist evaluation are inherently static and have limitations in their ability to capture the dynamics between elements of an environment. Realist evaluators should be aware of the limitations of the methods and the possible implications of these limitations for their theories.

7.6.3 Future Directions

Our findings suggest several opportunities for research including the development of program theories for Indigenous communities, refinement of the study's program theories for vaccine hesitant individuals, evaluation of COVID-19 mass vaccination phase via realist understanding of causality, and effective knowledge translation by engaging PFPs in research studies.

Muhajarine et al. have shown that Indigenous status was associated with increased likelihood of vaccine refusal and hesitancy (3). Although Indigenous communities have among the lowest COVID-19 vaccine uptakes across Canada (78), the vaccine uptake among Indigenous elders in Saskatchewan was high (46). To understand contexts and mechanisms to vaccine uptake in Indigenous communities with the goal to develop vaccination related program theories, researchers should consider Indigenous worldview (79,80).

I was not able to interview vaccine hesitant individuals in this study. This then affected the refinement of the identified contextual factors and causal mechanisms in the final PTs. Pawson et al. proposed that contextual factors can be categorized into four levels (four Is): "the individual capacities of the key actors and stakeholders, the interpersonal relationships, the institutional setting, and the infra-structural and welfare system" (81). The four Is framework categorizes contextual factors and provides a useful high-level understanding of context for analyzing the factors that impact CMOs (82). The term causal mechanism refers to the reasoning (cognitive or emotional) and responses of different actors in connection to the resources provided by a program (6,83). In other words, reasoning is the intrinsic quality of actors that is reflected through their thinking and decision-making (agency) and is considered a hidden aspect (6). As such, participants (or actors) involved in a realist evaluation (e.g., this study) influence the development and refinement of contextual factors and causal mechanisms of PTs. Had I

interviewed vaccine hesitant individuals, the final PTs might have been further refined. This could be a valuable resource for future researchers to further refine it.

It was important to clarify between pilot phase and mass phase of vaccination to depict more influential contexts and mechanisms. For example, hesitancy (an intermediate outcome) during pilot phase could be evoked due to mechanisms other than those that led to hesitancy during mass phase. Understanding of transmission and prevention of the disease (mechanism) was playing a key role in increasing or decreasing hesitancy during pilot phase, which might not be the case during the mass immunization. High or low hesitancy during this phase may be prominently due to trust (mechanism). Future studies can explore the contexts and mechanisms evoked during the mass phase of the vaccine campaign.

PFPs engaged in our study made extensive contributions and added value throughout the study by helping to co-identify relevant contextual factors and casual mechanisms, refer potential participants, co-interview participants, co-analyze the interview transcripts, and co-develop the final PTs. In terms of knowledge translation of our studies findings, the study's protocol and its results have been published and presented in CMAJ Open and 2022 Life and Health Sciences Research Expo, USASK. However, the role of PFPs in creation of effective knowledge translation plans such as timely infographics or patient friendly materials is to be explored in future studies.

8 Conclusion and Recommendations

We evaluated the COVID-19 vaccination campaign in three sites (Regina, Saskatoon, and Prince Albert) during the pilot phase. We engaged with PFPs and used realist evaluation to develop program theories for vaccine recipients and SHA stakeholders. Our program theories provide a structure on causal pathways for vaccine uptake and delivery. When health system leaders consider relevant contexts and mechanisms for specific vaccine recipients, vaccine uptake may be enhanced. We recommend that leaders and policymakers adapt our study's findings for other jurisdictions and integrate them in future campaigns to increase the uptake of vaccines in public.

9 Funding

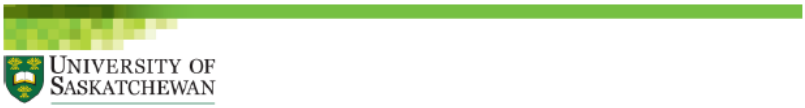
This work was supported by the 2020 College of Medicine Research Awards (CoMRAD) program, University of Saskatchewan.

I received the SCPOR trainee program support for doing the patient-oriented research. I also received the Building Research Relationships with Indigenous Communities (BRRIC) training by SCPOR

Appendix A : Memo Template Adapted from Gilmore

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:

Appendix B : Letter of Ethics Exemption



To: Gary Groot

Date: 20 January 2021

Re: Exemption Request

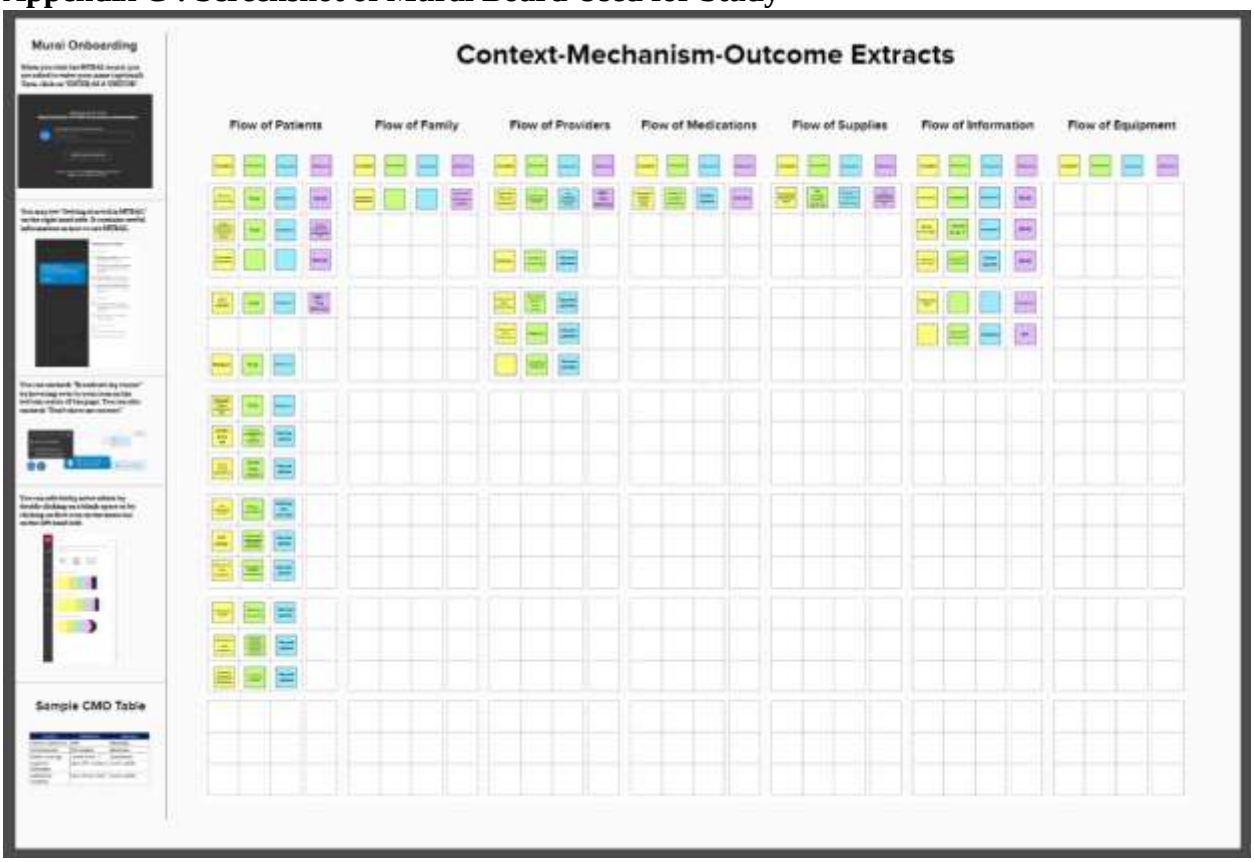
Thank you for submitting your request regarding the project entitled *Realist Evaluation of COVID-19 Evidence Support Team (CEST) and Vaccine Rollout*. The application meets the requirements for exemption status as per **Article 2.5 of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018)**, which states "*Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review*."

It should be noted that though your project is exempt of ethics review, your project should be conducted in an ethical manner (i.e. in accordance with the information that you submitted). It should also be noted that any deviation from the original methodology and/or research question should be brought to the attention of the Behavioural Research Ethics Board for further review.

Please revise the consent form to reflect an exemption from the REB or delete the sections regarding REB approval.

Digitally Approved by Vivian Ramsden, Vice-Chair
Behavioural Research Ethics Board
University of Saskatchewan

Appendix C : Screenshot of Mural Board Used for Study



Appendix D : Interview Guide

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

Interview Guide

Introductory script

Hello Mr./Mrs./Dr. [name of participant or stakeholder],

My name is [INTERVIEWER'S NAME]. I am a patient/family partner collaborating with a team of researchers who want to understand the pilot phase of SHA's COVID-19 vaccination rollout in Regina, Saskatoon, and Prince Albert. We are using a theory-driven approach called realist evaluation to assess the experiences of people who received vaccines or did not receive vaccines. We will also interview people who were involved in the planning and delivery of COVID-19 vaccines in Saskatchewan. Using past research and discussing with patient/family partners, we have developed an initial theory about what works for whom and in what circumstances when we consider vaccination plans. The goal of this research study is to develop a program theory that can be used to improve Saskatchewan's COVID-19 vaccination plans and other vaccination plans in the future.

I am here with Amir (Amir introduces himself [Master's student + SHA employee]).

1. As a first question in this interview, what were your thoughts when you heard about the COVID-19 vaccine rollout in your region?
2. Thank you. What did you think about getting vaccinated?

At this point, we teach the interviewee our initial theory, then ask the following questions:

1. After having seen our ideas, from your experience, what do you think? What about our ideas are accurate?
2. What about them needs to be changed to fit your experience?
3. Is there anything that you would like to add? Are we missing anything?

4. Are there any other comments that you would like to share?

Thank you for your time.

Appendix E : Plain Language Version of Initial Program Theories for Vaccine Recipients

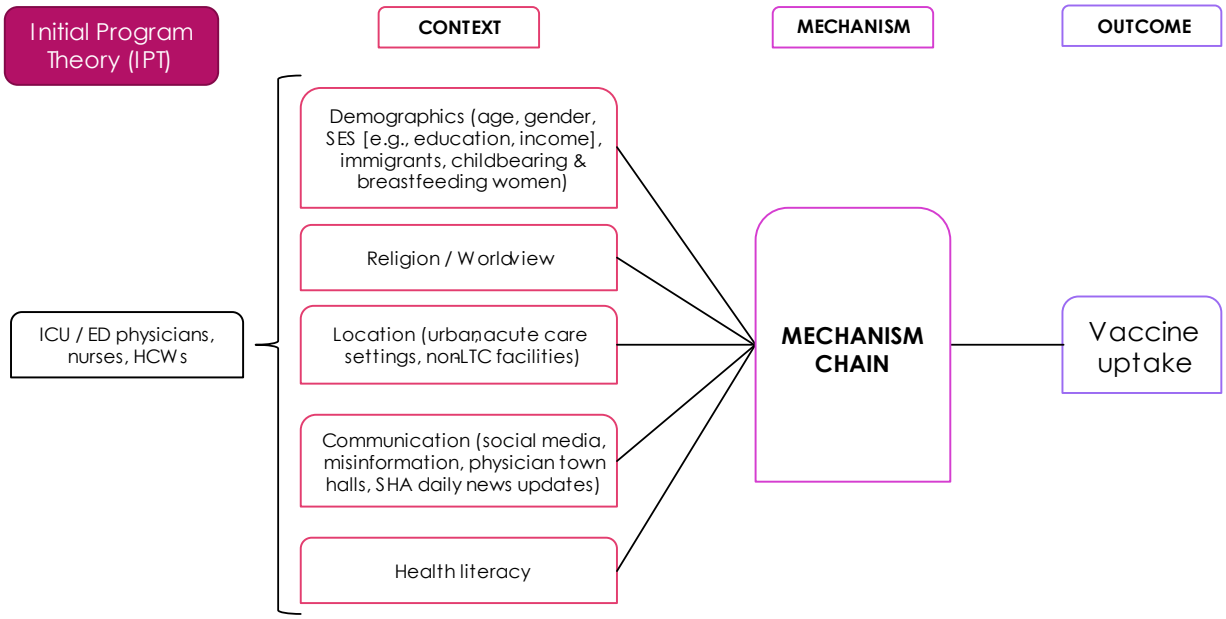
Plain language version of COVID-19 vaccine implementation initial program theory (IPT) for people who received or did not receive the vaccine.

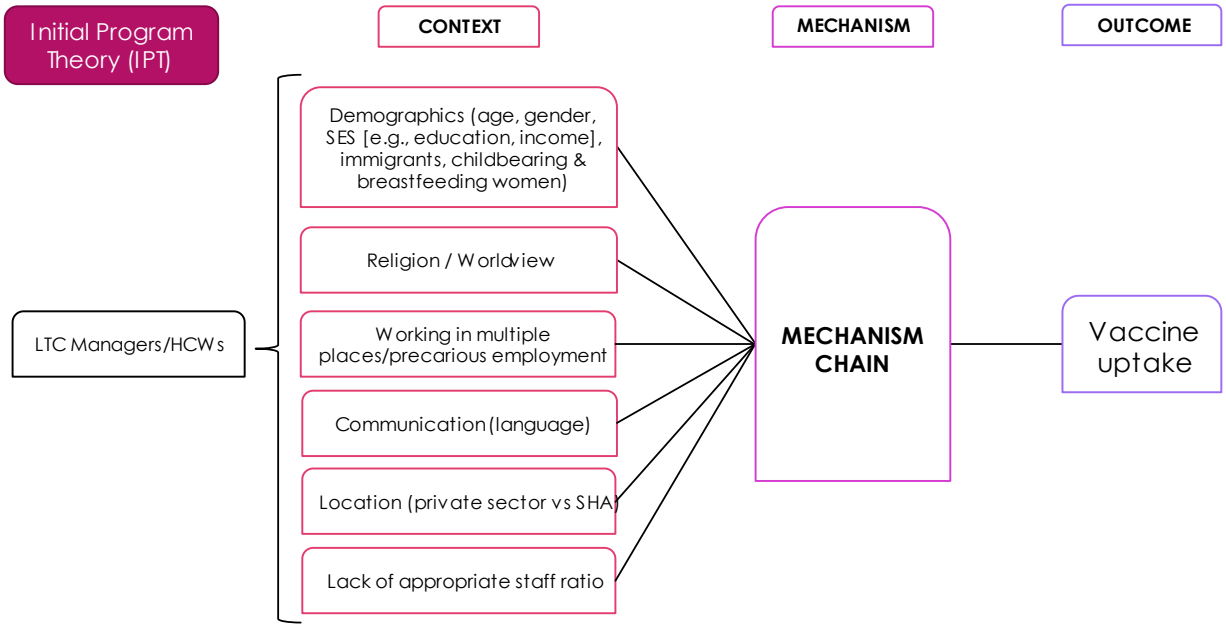
Actor	Context	Attribute	Theory statement
ICU / ED physicians, nurses, HCWs	Demographics	Age	When they are older, people may think that they are more likely to get the disease, and therefore they will be more willing to take the vaccine. When they are younger, people may think that they are less likely to get the disease, and therefore they will be less willing to take the vaccine.
		Gender	When they have multiple life or health responsibilities (e.g., caring for elderly parents), people may think getting vaccinated could interfere with their responsibilities, and therefore they may be less willing to take the vaccine.
		SES [e.g., education, income]	When they have higher income security, people may think they will be less vulnerable, and therefore they are more willing to take the vaccine. When they have higher education, people may realize the disease is more deadly, and

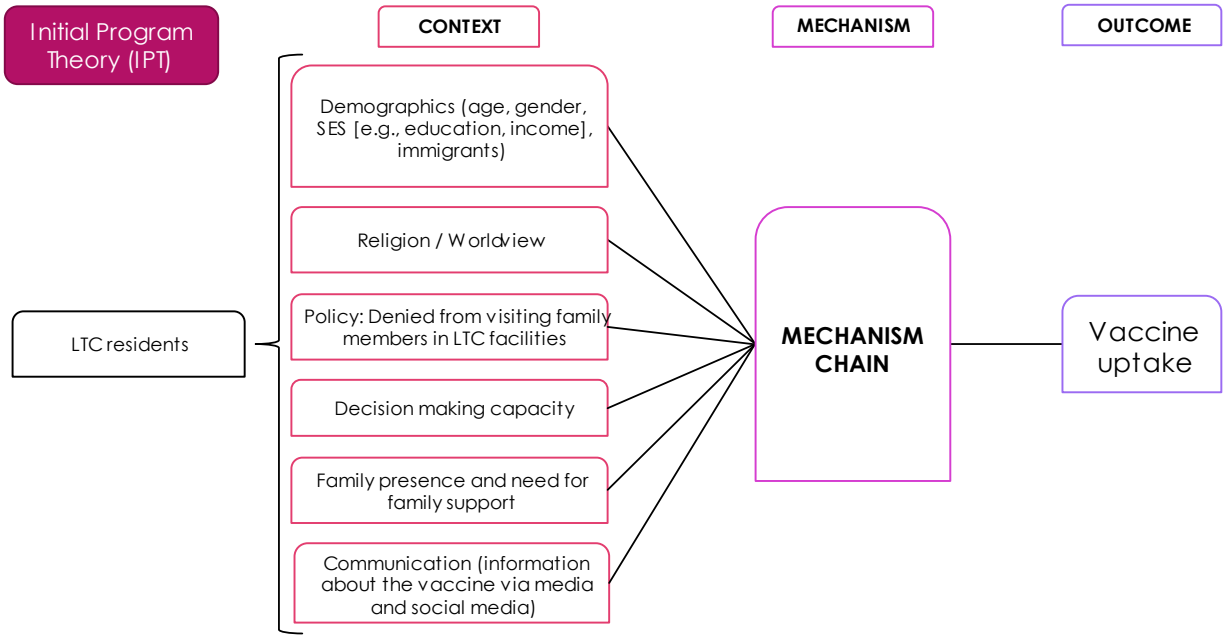
			therefore they are more willing to take the vaccine.
		Immigrants	CONSIDER: immigrant is a multifactorial attribute: personal preferences, level of education, beliefs, language barrier, etc. When they are newcomers/immigrants, people may think that they are more vulnerable (e.g., not having sick leaves benefits or resources availability), and therefore they may be less willing to take the vaccine.
		Childbearing & breastfeeding women	When recipients of vaccines are childbearing and breastfeeding women, they may think that they are more vulnerable and therefore they will be more willing to take the vaccine.
	Religion / World view		When they examine their religion or world view (e.g., trust God, or assess their vulnerability), some people find they have strong religious beliefs or world views they think they may be less vulnerable and therefore are less willing to take the vaccine.
	Location	Urban	When people live in urban locations, they may think they are more vulnerable and feel more sense of responsibility, therefore they will be more willing to receive the vaccine.

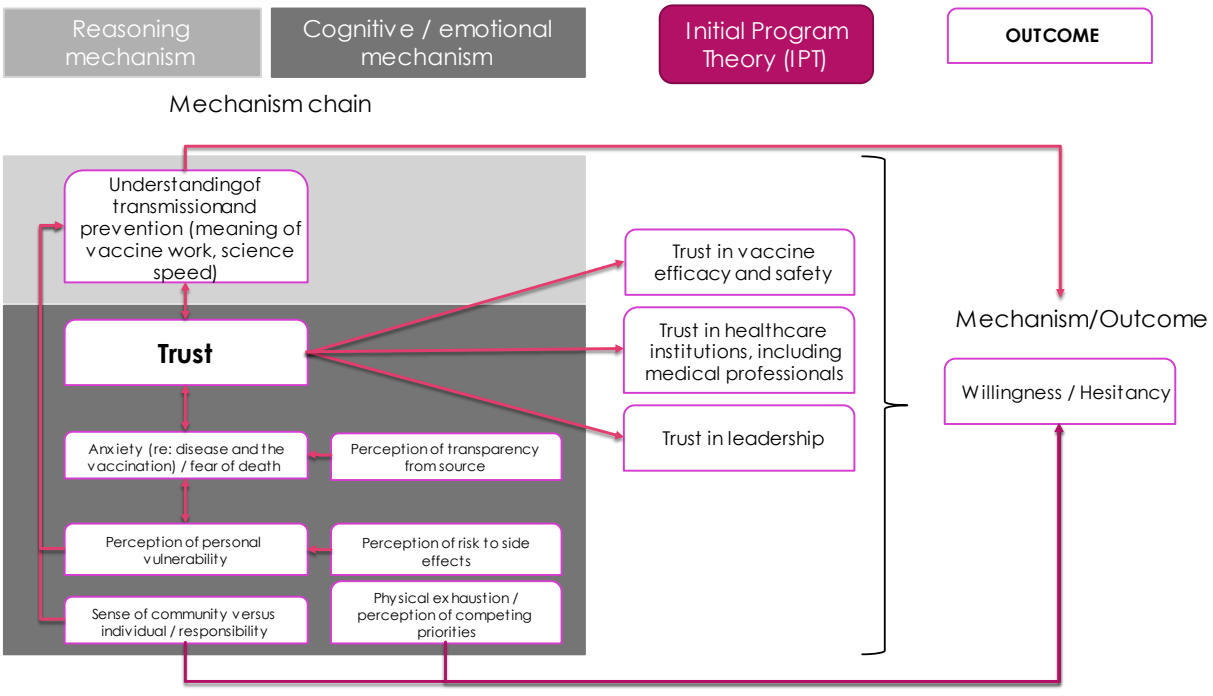
		Acute care settings	When they work in acute care settings, people may think they are more vulnerable, and therefore they will be more willing to take the vaccine.
		Non-LTC facilities	When they are health care providers in non-LTC facilities, people may think they are more vulnerable, and therefore will be more willing to take the vaccine.
	Communication	Social media, misinformation, physician town halls, SHA daily news updates	When they receive information primarily from social media, people may have more doubts about the reliability of the vaccine, and therefore they will be less willing to take the vaccine.
	Health literacy		When they do not have high health literacy, then people may be less likely to trust the vaccine, and therefore they will be more hesitant to take the vaccine.

Appendix F : Initial Program Theories for Vaccine Recipients






Initial Program Theory (IPT)
CONTEXT
MECHANISM
OUTCOME
Demographics (age, gender, SES [e.g., education, income], immigrants)
Religion / Worldview
Policy: Denied from visiting family members in LTC facilities
Decision making capacity
Family presence and need for family support
Communication (information about the vaccine via media and social media)
LTC residents
MECHANISM CHAIN
Vaccine uptake


Reasoning mechanism
Cognitive / emotional mechanism
Initial Program Theory (IPT)
OUTCOME
Mechanism chain
Understandingof transmissionand prevention (meaning of vaccine work, science speed)
Trust
Anxiety (re: disease and the vaccination) / fear of death
Perception of transparency from source
Perception of personal vulnerability
Perception of risk to side effects
Sense of community versus individual / responsibility
Physical exhaustion / perception of competing priorities
Trust in vaccine efficacy and safety
Trust in healthcare institutions, including medical professionals
Trust in leadership
Mechanism/Outcome
Willingness / Hesitancy

Appendix G : Sample Invitation Letter
Pilot Phase of COVID-19 Vaccination in Saskatchewan: A Realist Evaluation

Date: [DATE OF INVITATION]

Dear [PARTICIPANT'S NAME],

We are conducting interviews as part of a research study to understand the pilot phase of COVID-19 vaccination plans in Regina, Saskatoon, and Prince Albert. We are using a research approach called realist evaluation to assess the experiences of people who did or did not receive vaccines or were involved in the planning and delivery of COVID-19 vaccines in Saskatchewan. The goal of the study is to develop a program theory that will be used to improve Saskatchewan's COVID-19 vaccination plans. The interview will be conducted by my master's student Amir Reza Azizian, will take around 30 minutes, and will be done virtually through WebEx. In the interview, you will be asked about your experiences with the vaccination process.

The study team includes representation from patient and family partners (PFPs) with different backgrounds from various locations in Saskatchewan, the Saskatchewan Health Authority, the Saskatchewan Health Quality Council, and the University of Saskatchewan.

The study has received letters of exemption from the Research Ethics Board of the University of Saskatchewan and the Saskatchewan Health Authority. Your responses to the questions will be kept confidential.

If you are willing to participate or want more information, please contact us at covid-19vac.research@usask.ca to arrange a time that is convenient for you. On behalf of the research team, I appreciate your support and look forward to hearing from you.

Sincerely,

Gary Groot

Appendix H : Sample Consent Form

Participant Consent Form

You are invited to participate in a research study entitled:

Pilot phase of COVID-19 Vaccination in Saskatchewan: A Realist Evaluation

Researchers

- **Supervisor:** Dr. Gary Groot, Department of Community Health and Epidemiology, University of Saskatchewan. Phone: (306) 966-1670, **Email: gary.groot@usask.ca**
- **Student:** Amir Reza Azizian, Department of Community Health and Epidemiology, University of Saskatchewan.
- **Patient Family Partners:** Brenda Andreas; Candace Skrapek; Gerald Farthing.
- **Research Associate:** Dr. Tracey Carr, Department of Community Health and Epidemiology, University of Saskatchewan.
- **Research Assistant:** Maryam Yasinian, Department of Community Health and Epidemiology, University of Saskatchewan. **Email: COVID-19vac.research@usask.ca**

Purpose and Objectives of the Research

This research aims to evaluate the COVID-19 vaccination plan and implementation in Regina, Saskatoon, and Prince Albert during the pilot phase of vaccine rollout in Saskatchewan. We intend to capture your perspectives as an individual who received or did not receive or who has been involved in planning, development, or implementation of the COVID-19 vaccination program to identify how, for whom, under which circumstances, and why the Saskatchewan COVID-19 vaccination rollout is successful or not. Your participation will help us to establish a program theory which will inform the COVID-19 vaccine delivery in our province as well as the future similar vaccination programs.

Procedures

You will be invited to participate in an individual interview to share your perspective and experience with receiving or not receiving COVID-19 vaccination or the planning or delivery of COVID-19 vaccination. The individual interview will last approximately 20-30 minutes and will be conducted online using Webex. The interview will be audio-recorded; however, you can request that the audio-recording device be turned off at any time without explanation. In this case, notes may be taken to capture the conversation with your

consent. The interview time will be arranged in advance, at your convenience. Please feel free to ask any questions regarding the procedures and goals of the study or your role.

Potential Risks

You will share your experience and knowledge regarding the COVID-19 vaccination implementation. Due to the scientific and evaluative nature of discussions, we do not anticipate any risks to your participation in this study.

Potential Benefits

While our research does not offer direct benefits to individual participants, the findings could increase our knowledge on COVID-19 vaccine delivery and support ongoing quality improvement within our healthcare system. This improvement could consequently benefit patients, healthcare providers, and policymakers. Our research may also inform Saskatchewan's healthcare responses to unprecedented public emergencies, building up more knowledge to address future similar circumstances.

Confidentiality

Your information and identity will not be revealed to anyone outside of the research team. To protect your confidentiality, no personal identifiers (e.g., name, email address, affiliation) will be linked to the final reports. The research team may use direct quotations from the interviews in publications and presentations. However, we will ensure that quotations have general concepts, and no names will be associated with quotations. The research team will store your Consent Form on a password-protected folder separate from the transcripts and analyzed data, so that it will not be possible to link a name with any given set of responses.

The interviews will be transcribed by the University of Saskatchewan's Canadian Hub for Applied and Social Research (CHASR) which is trained and obligated to the confidentiality of transcriptions. We acknowledge that they sign a confidentiality agreement to safeguard privacy and confidentiality.

Storage of Data

Data and any research materials will be stored and backed up on Dr. Groot's Jade drive and DATASTORE, both of which are secure password-protected storage spaces used by University of Saskatchewan's researchers. Data will be retained for a period of 5 years per University of Saskatchewan's protocol, at which time they will be destroyed.

Right to Withdraw

- Your participation is voluntary, and feel free to answer only those questions that you are comfortable with. You may withdraw from the research project for any reason, at any time without explanation or penalty of any sort.
- Should you wish to withdraw, any data that you have contributed will be deleted from the research project and destroyed.
- Your right to withdraw from the study will apply until data has been pooled for the final report. After this date, it may not be possible to withdraw your data.
- Any new information that could have a bearing on your decision to participate will be clearly stated to you before or during the study. You have the right not to accept new changes.

Follow up

If you request, we will email a report of the findings to you which will be prepared after completion of the research (approximately one year from this date).

Funded by

This research has been funded by the College of Medicine Research Award (CoMRAD).

Questions or Concerns

- If you have any questions and concerns, please contact the research team members using the information at the top of page 1.
- This research project has received an exemption from the University of Saskatchewan Behavioural Research Ethics Board due to its evaluative nature. Any questions regarding your rights as a participant may be addressed to that committee through the Research Ethics Office: ethics.office@usask.ca; 306-966-2975; out of town participants may call toll free 1-888-966-2975.

Written Consent

Your signature below indicates that you have read and understood the description provided.
I have had an opportunity to ask questions and my questions have been answered. I consent to participate in the research project. An electronic copy of this consent form has been given to me for my records.

Name of Participant	*Signature*	*Date*

Researcher's Signature	*Date*

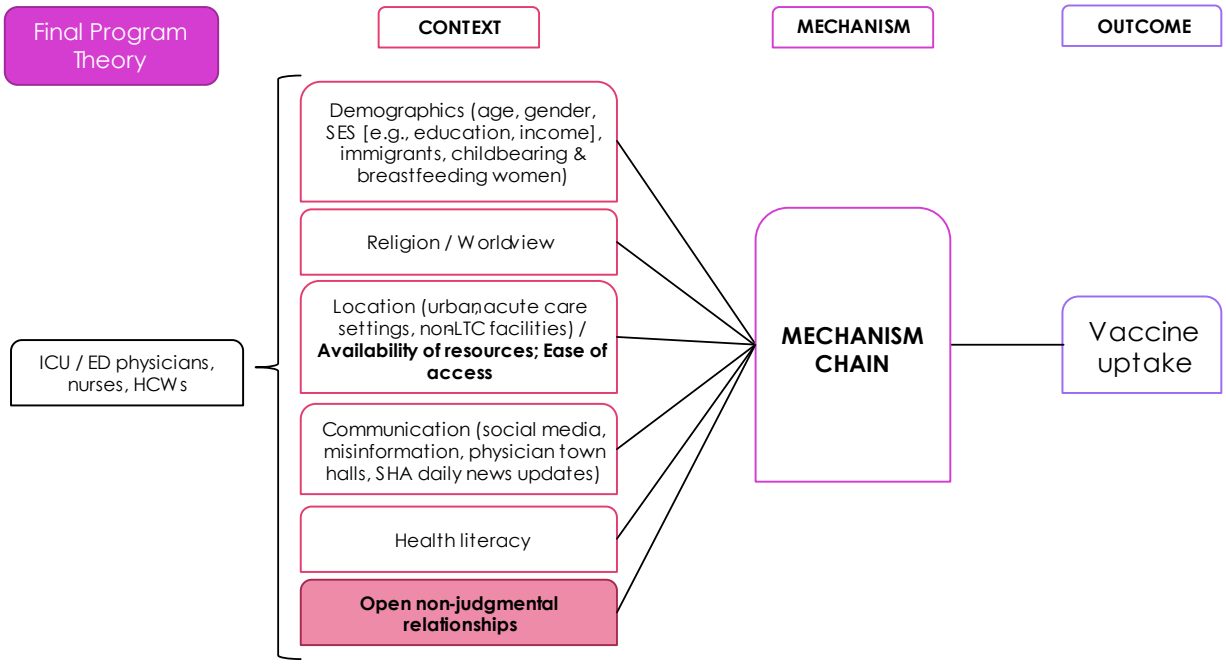
Oral Consent

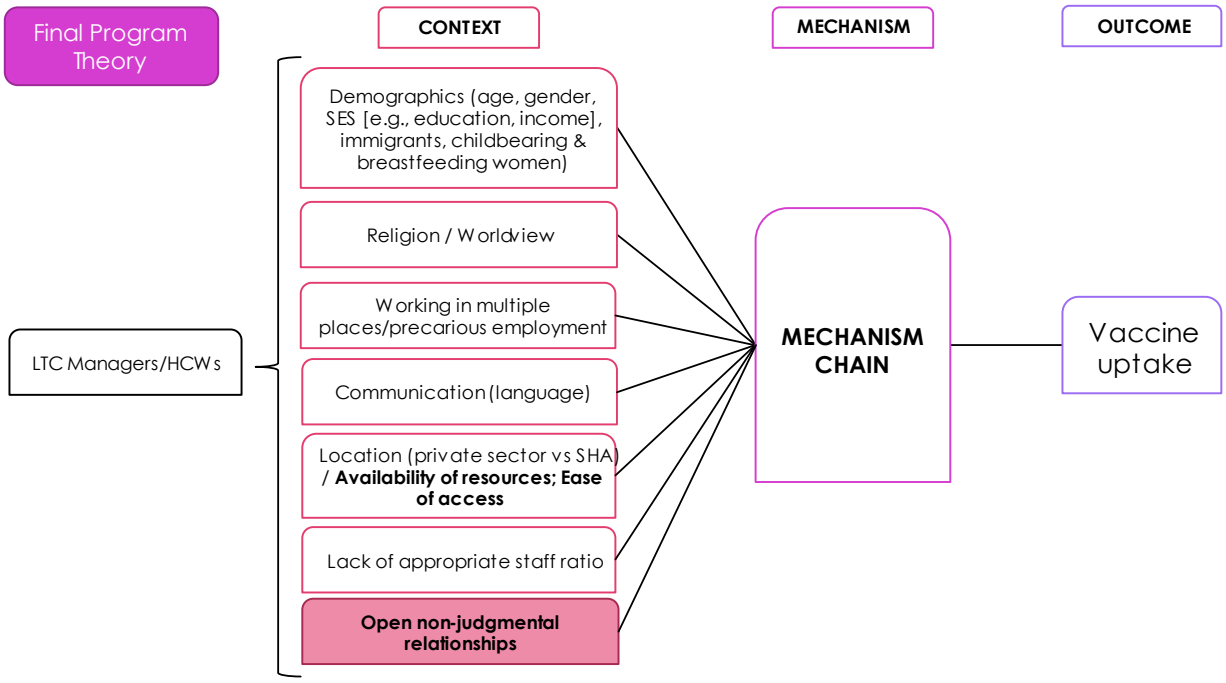
I read and explained this consent form to the participant before receiving the participant's consent, and the participant had knowledged of its contents and appeared to understand it.

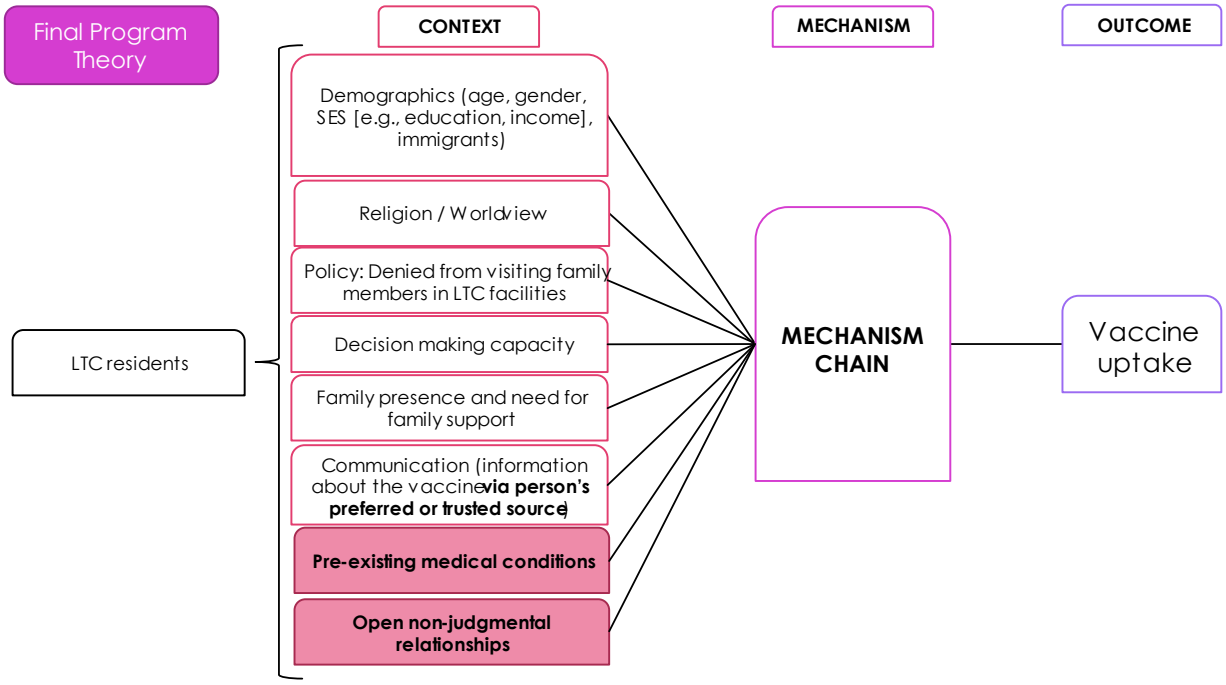
Name of Participant	*Researcher's Signature*	*Date*

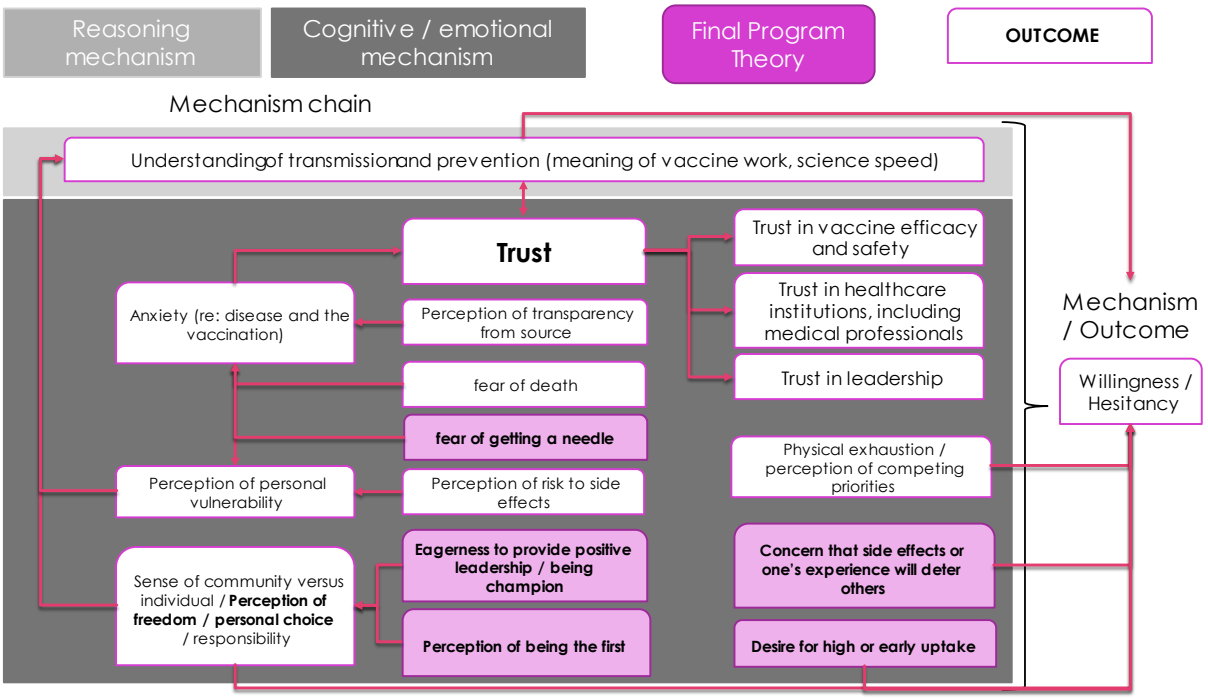
An electronic copy of this consent will be left with you, and a copy will be taken by the researcher.

Appendix I : Final Program Theories for Vaccine Recipients

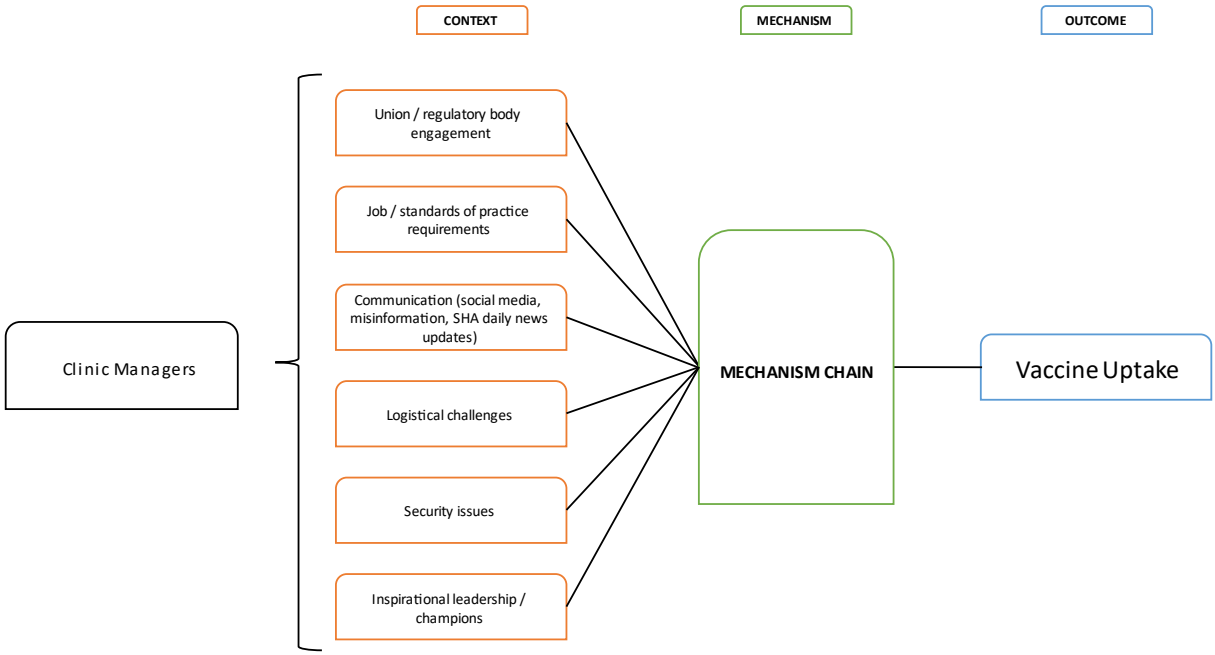


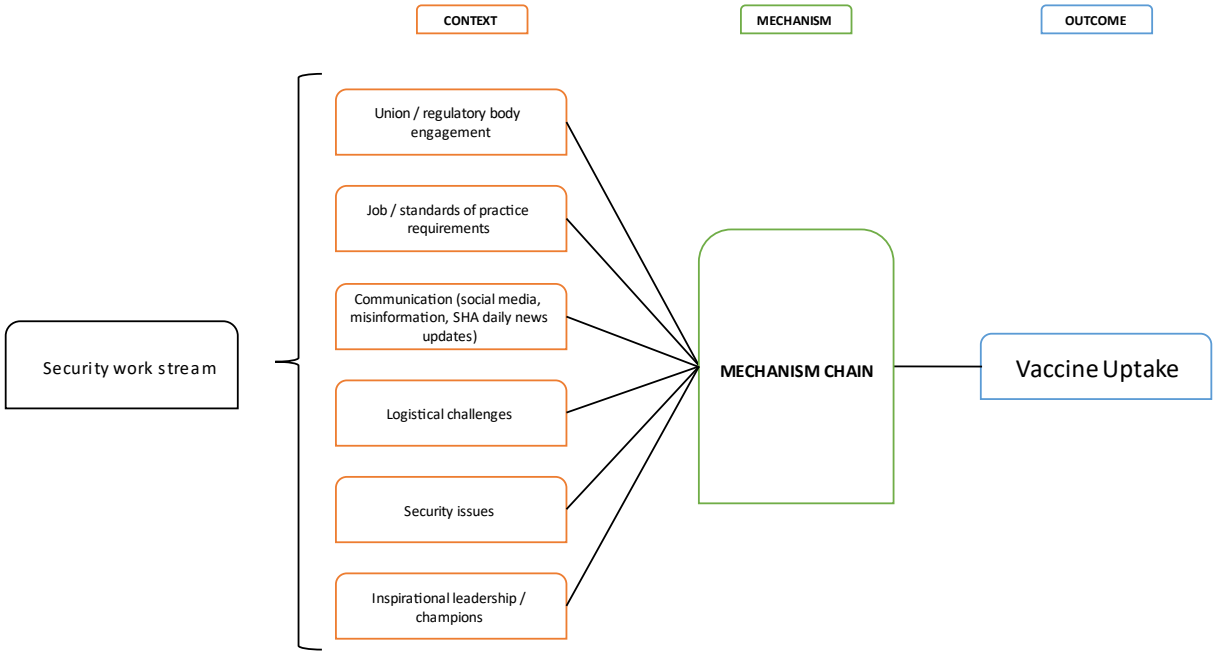


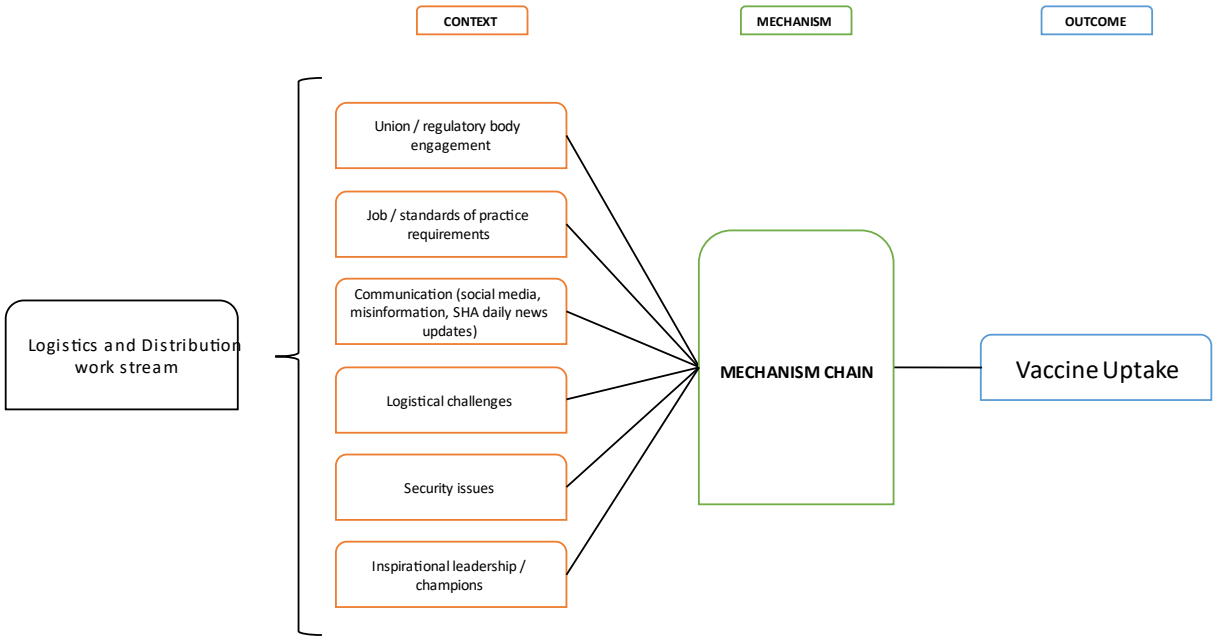

Final Program Theory
CONTEXT
MECHANISM
OUTCOME
LTC residents
Demographics (age, gender, SES [e.g., education, income], immigrants)
Religion / Worldview
Policy: Denied from visiting family members in LTC facilities
Decision making capacity
Family presence and need for family support
Communication (information about the vaccine via person's preferred or trusted source)
Pre-existing medical conditions
Open non-judgmental relationships
MECHANISM CHAIN
Vaccine uptake

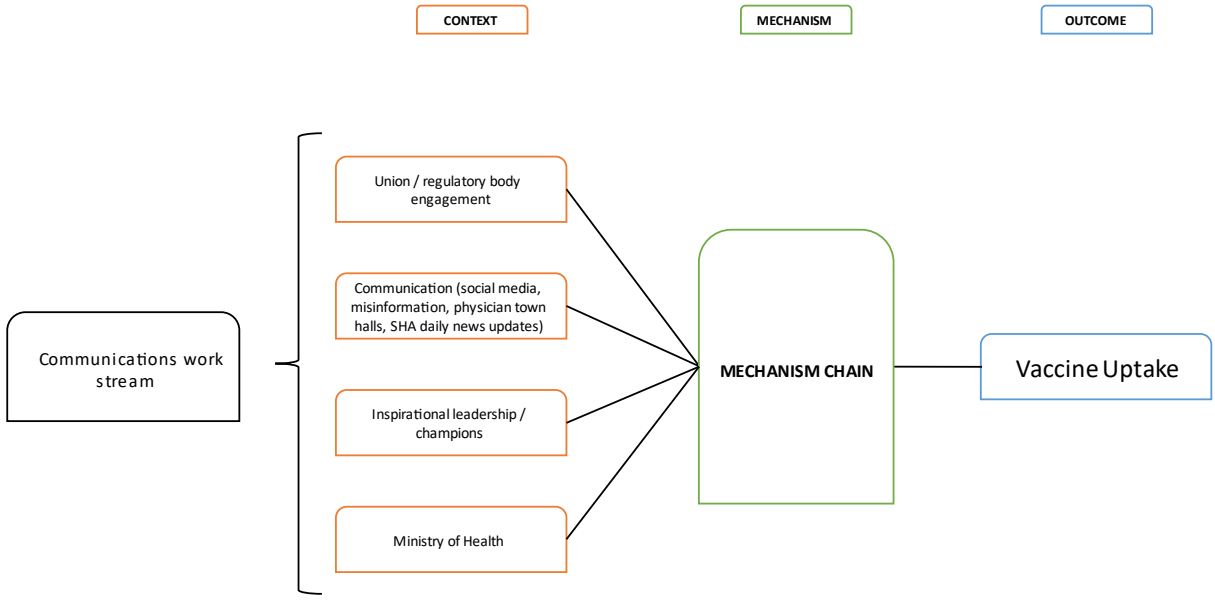

Reasoning mechanism
Cognitive / emotional mechanism
Final Program Theory
OUTCOME
Mechanism chain
Understanding of transmission and prevention (meaning of vaccine work, science speed)
Trust
Trust in vaccine efficacy and safety
Trust in healthcare institutions, including medical professionals
Trust in leadership
Anxiety (re: disease and the vaccination)
Perception of transparency from source
fear of death
fear of getting a needle
Perception of personal vulnerability
Perception of risk to side effects
Physical exhaustion / perception of competing priorities
Sense of community versus individual / Perception of freedom / personal choice / responsibility
Eagerness to provide positive leadership / being champion
Perception of being the first
Concern that side effects or one's experience will deter others
Desire for high or early uptake
Mechanism / Outcome
Willingness / Hesitancy

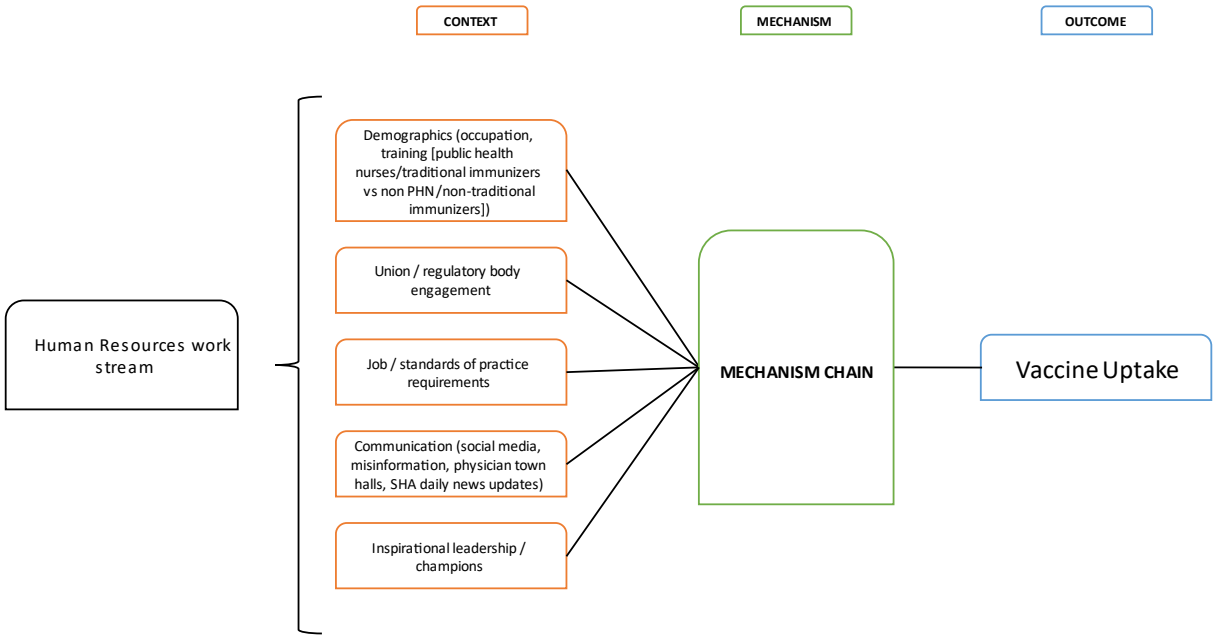
Appendix J : Initial Program Theories for SHA Stakeholders

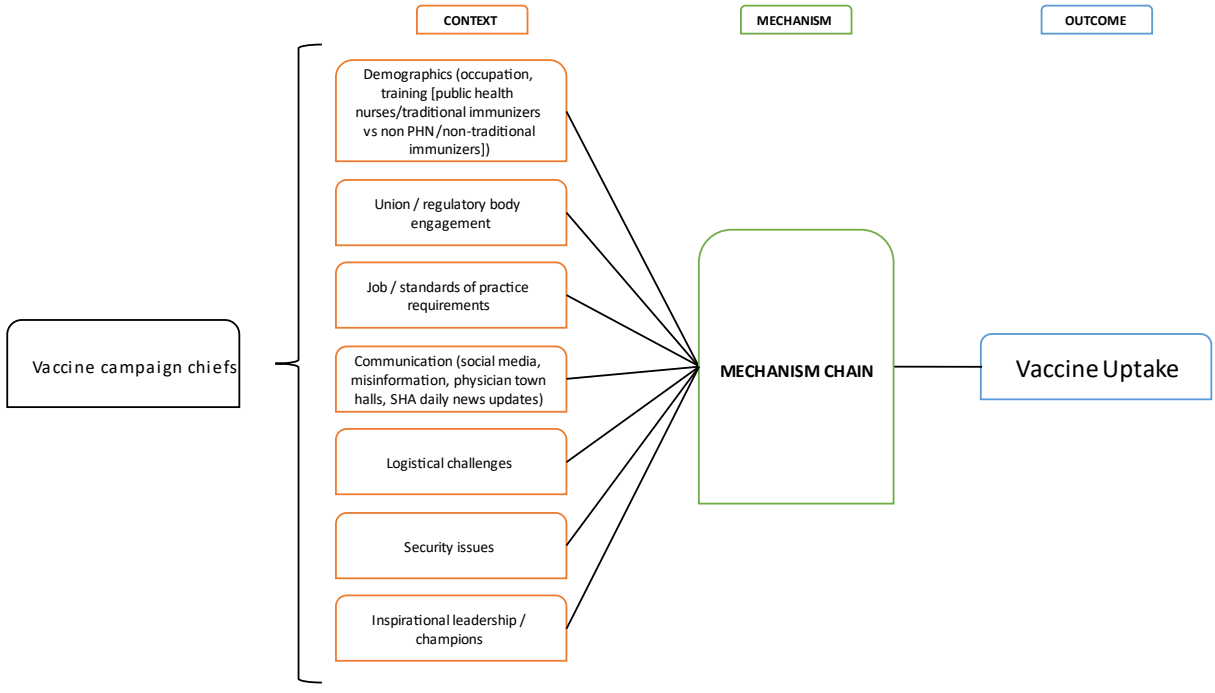


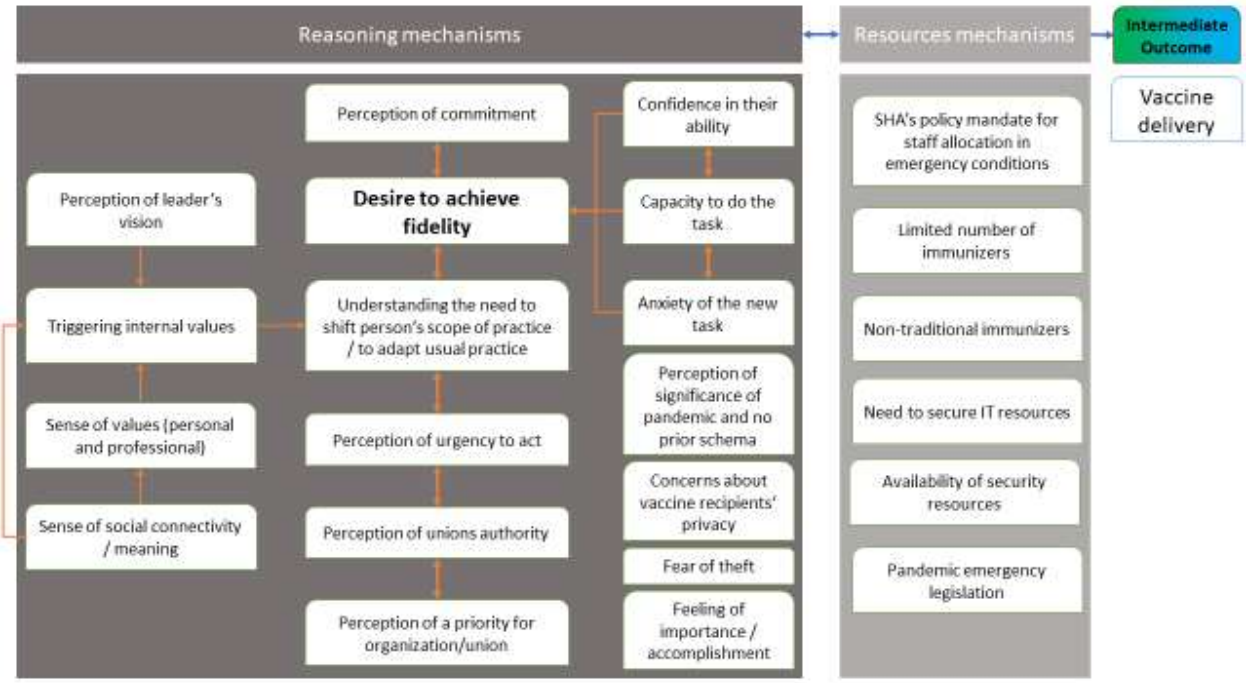



CONTEXT
MECHANISM
OUTCOME
Logistics and Distribution work stream
Union / regulatory body engagement
Job / standards of practice requirements
Communication (social media, misinformation, SHA daily news updates)
Logistical challenges
Security issues
Inspirational leadership / champions
MECHANISM CHAIN
Vaccine Uptake

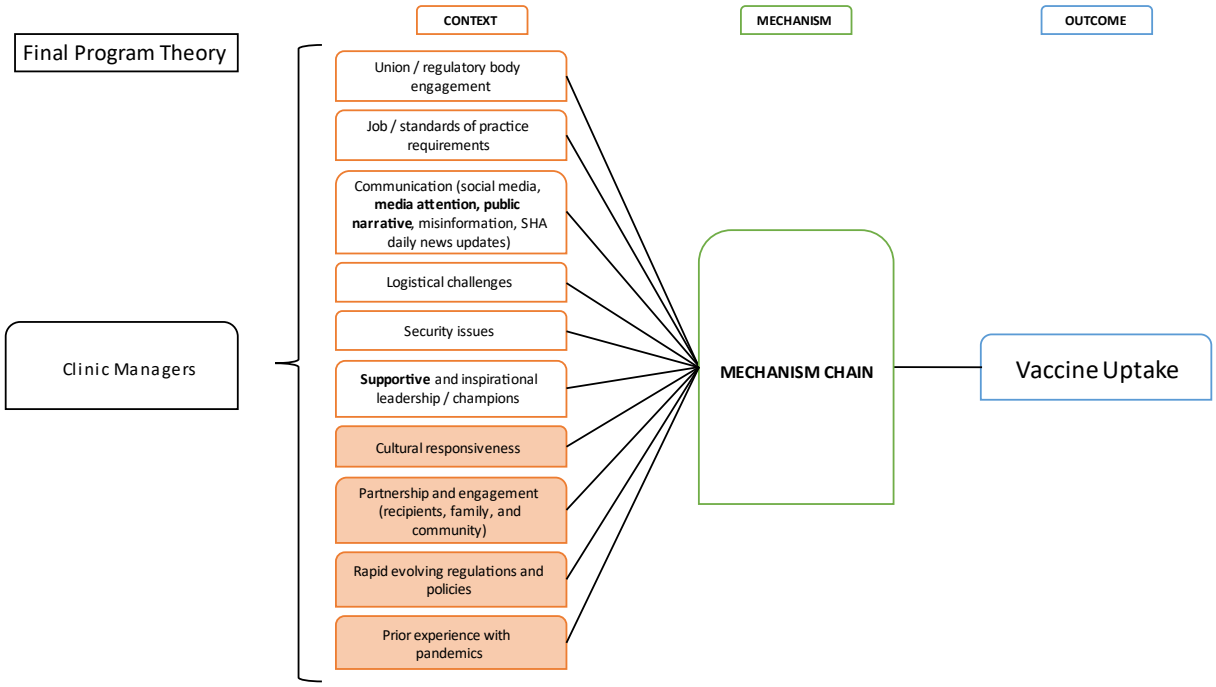

CONTEXT
MECHANISM
OUTCOME
Communications work stream
Union / regulatory body engagement
Communication (social media, misinformation, physician town halls, SHA daily news updates)
Inspirational leadership / champions
Ministry of Health
MECHANISM CHAIN
Vaccine Uptake

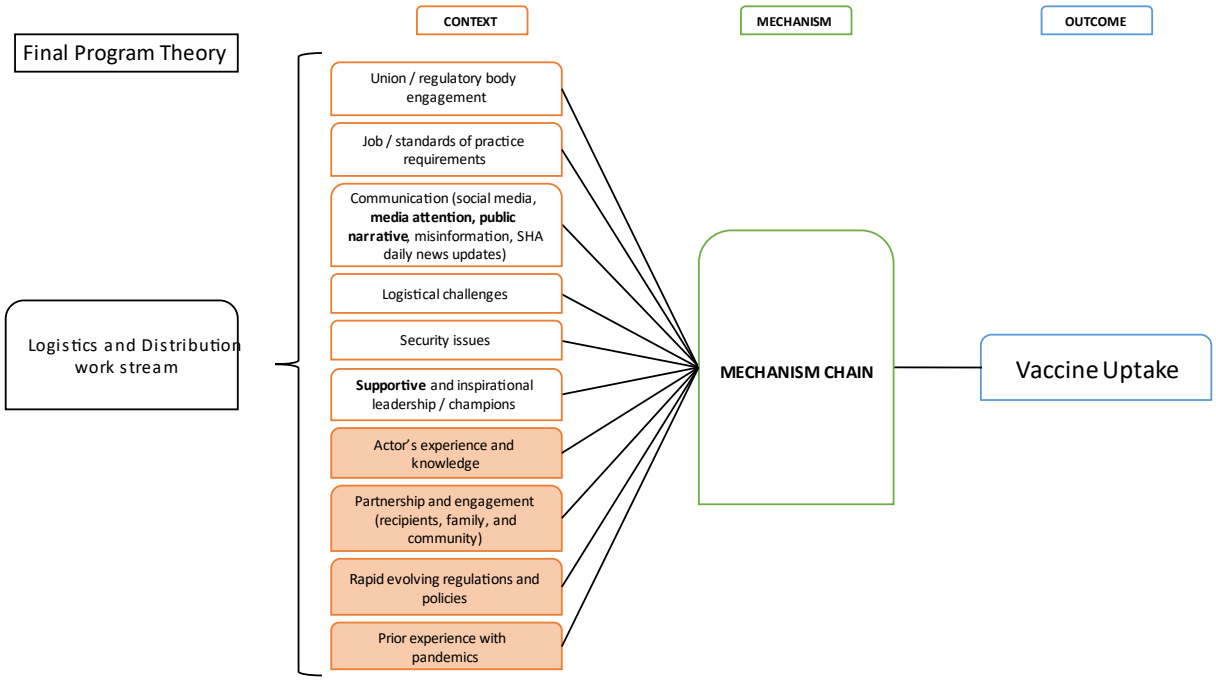

CONTEXT
MECHANISM
OUTCOME
Human Resources work stream
Demographics (occupation, training [public health nurses/traditional immunizers vs non PHN/non-traditional immunizers])
Union / regulatory body engagement
Job / standards of practice requirements
Communication (social media, misinformation, physician town halls, SHA daily news updates)
Inspirational leadership / champions
MECHANISM CHAIN
Vaccine Uptake

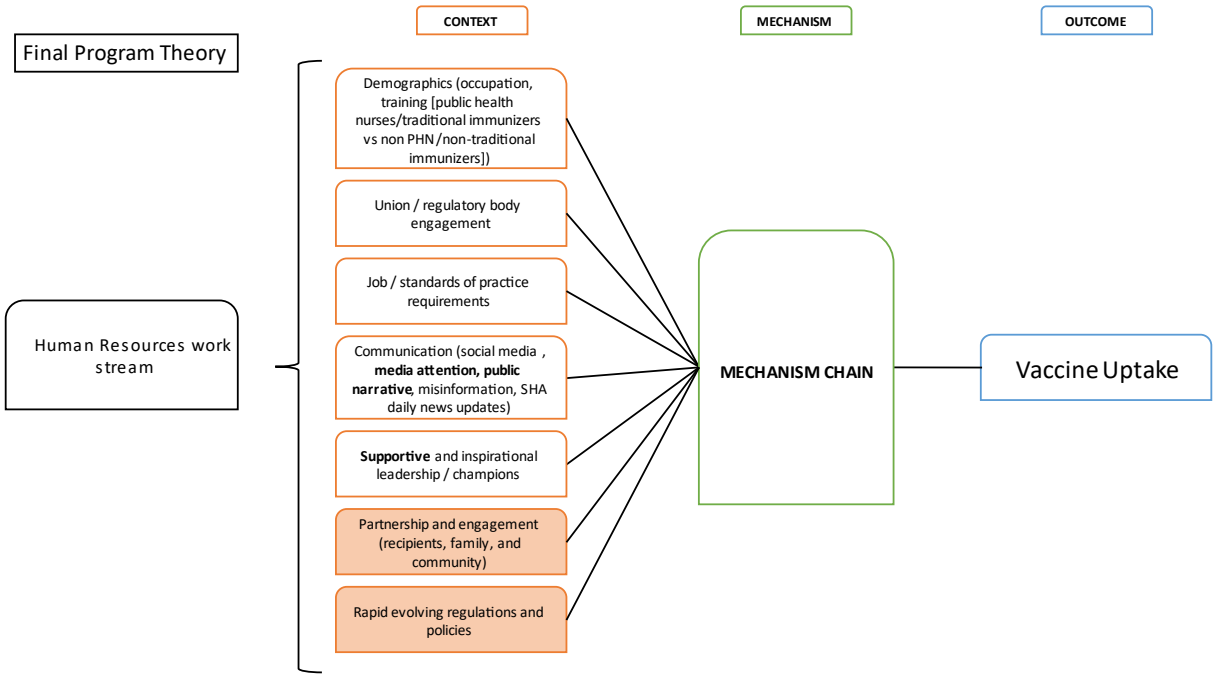

CONTEXT
MECHANISM
OUTCOME
Vaccine campaign chiefs
Demographics (occupation, training [public health nurses/traditional immunizers vs non PHN/non-traditional immunizers])
Union / regulatory body engagement
Job / standards of practice requirements
Communication (social media, misinformation, physician town halls, SHA daily news updates)
Logistical challenges
Security issues
Inspirational leadership / champions
MECHANISM CHAIN
Vaccine Uptake

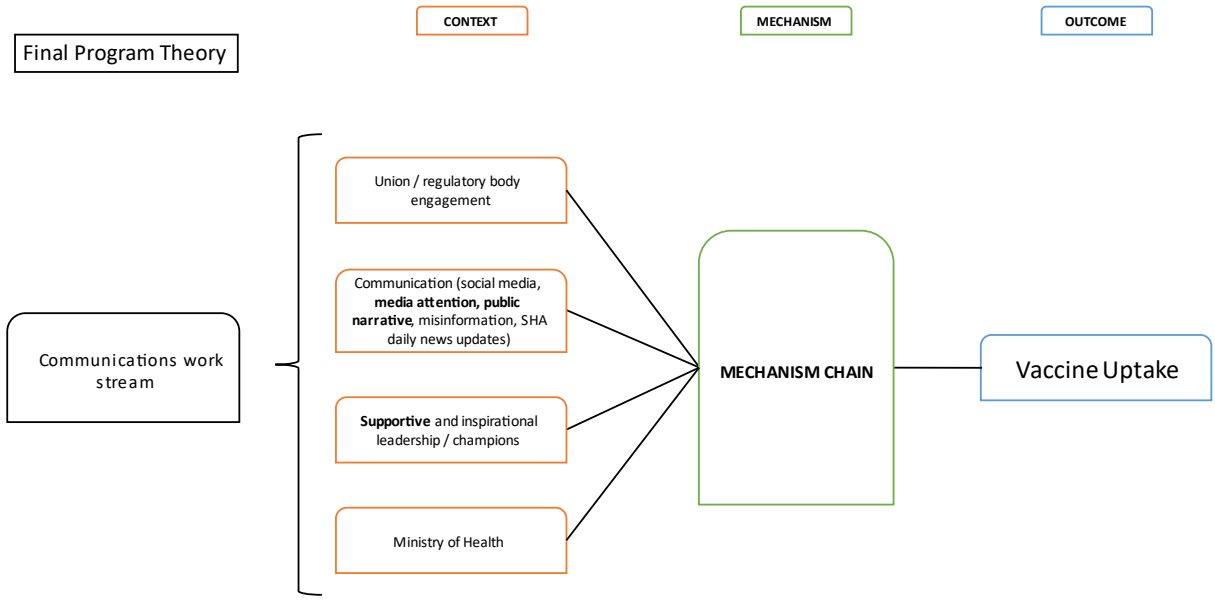

Reasoning mechanisms
Resources mechanisms
Intermediate Outcome
Vaccine delivery
Perception of commitment
Perception of leader's vision
Desire to achieve fidelity
Triggering internal values
Understanding the need to shift person's scope of practice / to adapt usual practice
Sense of values (personal and professional)
Perception of urgency to act
Sense of social connectivity / meaning
Perception of unions authority
Perception of a priority for organization/union
Confidence in their ability
Capacity to do the task
Anxiety of the new task
Perception of significance of pandemic and no prior schema
Concerns about vaccine recipients' privacy
Fear of theft
Feeling of importance / accomplishment
SHA's policy mandate for staff allocation in emergency conditions
Limited number of immunizers
Non-traditional immunizers
Need to secure IT resources
Availability of security resources
Pandemic emergency legislation

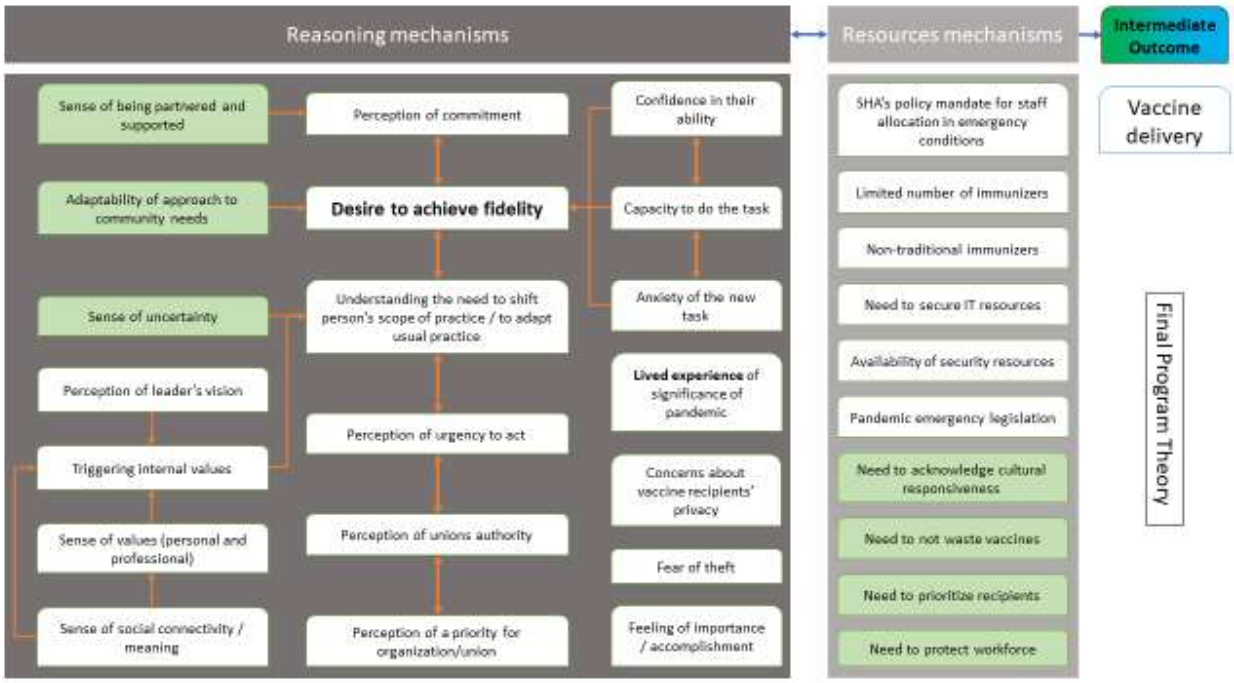
Appendix K : Final Program Theories for SHA Stakeholders



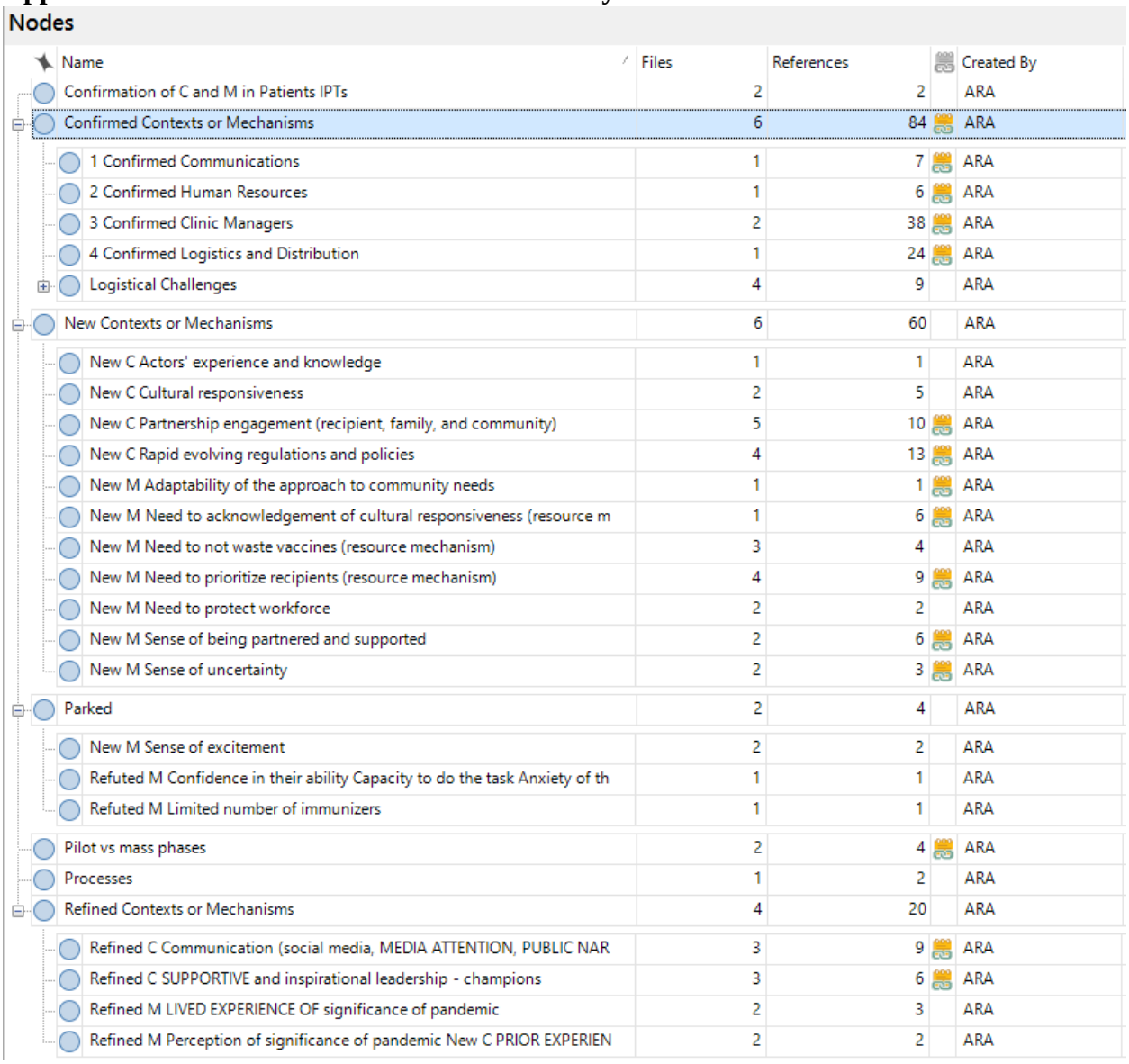



Final Program Theory
CONTEXT
MECHANISM
OUTCOME
Human Resources work stream
Demographics (occupation, training [public health nurses/traditional immunizers vs non PHN/non-traditional immunizers])
Union / regulatory body engagement
Job / standards of practice requirements
Communication (social media , **media attention, public narrative**, misinformation, SHA daily news updates)
Supportive and inspirational leadership / champions
Partnership and engagement (recipients, family, and community)
Rapid evolving regulations and policies
MECHANISM CHAIN
Vaccine Uptake


Final Program Theory
CONTEXT
MECHANISM
OUTCOME
Communications work stream
Union / regulatory body engagement
Communication (social media, **media attention, public narrative**, misinformation, SHA daily news updates)
Supportive and inspirational leadership / champions
Ministry of Health
MECHANISM CHAIN
Vaccine Uptake


Reasoning mechanisms
Resources mechanisms
Intermediate Outcome
Sense of being partnered and supported
Perception of commitment
Confidence in their ability
SHA's policy mandate for staff allocation in emergency conditions
Vaccine delivery
Adaptability of approach to community needs
Desire to achieve fidelity
Capacity to do the task
Limited number of immunizers
Non-traditional immunizers
Sense of uncertainty
Understanding the need to shift person's scope of practice / to adapt usual practice
Anxiety of the new task
Need to secure IT resources
Final Program Theory
Perception of leader's vision
Lived experience of significance of pandemic
Availability of security resources
Triggering internal values
Perception of urgency to act
Pandemic emergency legislation
Concerns about vaccine recipients' privacy
Need to acknowledge cultural responsiveness
Sense of values (personal and professional)
Perception of unions authority
Need to not waste vaccines
Fear of theft
Need to prioritize recipients
Sense of social connectivity / meaning
Perception of a priority for organization/union
Feeling of importance / accomplishment
Need to protect workforce

Appendix L : Screenshot of NVivo for Data Analysis



Nodes

Name	Files	References	Created By
Confirmation of C and M in Patients IPTs	2	2	ARA
Confirmed Contexts or Mechanisms	6	84	ARA
1 Confirmed Communications	1	7	ARA
2 Confirmed Human Resources	1	6	ARA
3 Confirmed Clinic Managers	2	38	ARA
4 Confirmed Logistics and Distribution	1	24	ARA
Logistical Challenges	4	9	ARA
New Contexts or Mechanisms	6	60	ARA
New C Actors' experience and knowledge	1	1	ARA
New C Cultural responsiveness	2	5	ARA
New C Partnership engagement (recipient, family, and community)	5	10	ARA
New C Rapid evolving regulations and policies	4	13	ARA
New M Adaptability of the approach to community needs	1	1	ARA
New M Need to acknowledgement of cultural responsiveness (resource m	1	6	ARA
New M Need to not waste vaccines (resource mechanism)	3	4	ARA
New M Need to prioritize recipients (resource mechanism)	4	9	ARA
New M Need to protect workforce	2	2	ARA
New M Sense of being partnered and supported	2	6	ARA
New M Sense of uncertainty	2	3	ARA
Parked	2	4	ARA
New M Sense of excitement	2	2	ARA
Refuted M Confidence in their ability Capacity to do the task Anxiety of th	1	1	ARA
Refuted M Limited number of immunizers	1	1	ARA
Pilot vs mass phases	2	4	ARA
Processes	1	2	ARA
Refined Contexts or Mechanisms	4	20	ARA
Refined C Communication (social media, MEDIA ATTENTION, PUBLIC NAR	3	9	ARA
Refined C SUPPORTIVE and inspirational leadership - champions	3	6	ARA
Refined M LIVED EXPERIENCE OF significance of pandemic	2	3	ARA
Refined M Perception of significance of pandemic New C PRIOR EXPERIEN	2	2	ARA

10 References

1. Salter KL, Kothari A. Using realist evaluation to open the black box of knowledge translation: A state-of-the-art review. Implement Sci. 2014;9(1):1–14.

2. Wong G, Westhorp G, Greenhalgh J, Manzano A, Jagosh J, Greenhalgh T. Quality and reporting standards, resources, training materials and information for realist evaluation: the RAMESES II project. Heal Serv Deliv Res [Internet]. 2017;5(28):1–108. Available from: https://www.journalslibrary.nihr.ac.uk/hsdr/hsdr05280

3. Muhajarine N, Adeyinka DA, McCutcheon J, Green KL, Fahlman M, Kallio N. COVID-19 vaccine hesitancy and refusal and associated factors in an adult population in Saskatchewan, Canada: Evidence from predictive modelling. PLoS One [Internet]. 2021;16(11 November):1–18. Available from: http://dx.doi.org/10.1371/journal.pone.0259513

4. Pawson R, Tilley N. Realistic Evaluation. London: SAGE; 1997.

5. De Weger E, Van Vooren NJE, Wong G, Dalkin S, Marchal B, Drewes HW, et al. What's in a Realist Configuration? Deciding Which Causal Configurations to Use, How, and Why. Int J Qual Methods. 2020;19:1–8.

6. Dalkin SM, Greenhalgh J, Jones D, Cunningham B, Lhussier M. What's in a mechanism? Development of a key concept in realist evaluation. Implement Sci. 2015;10(1):1–7.

7. Wong G, Westhorp G, Manzano A, Greenhalgh J, Jagosh J, Greenhalgh T. RAMESES II reporting standards for realist evaluations. BMC Med [Internet]. 2016;14(1):1–18. Available from: http://dx.doi.org/10.1186/s12916-016-0643-1

8. Barrett K, Khan YA, Mac S, Ximenes R, Naimark DMJ, Sander B. Estimation of COVID-19–induced depletion of hospital resources in Ontario, Canada. Can Med Assoc J [Internet]. 2020 Jun 15;192(24):E640–6. Available from: http://www.cmaj.ca/lookup/doi/10.1503/cmaj.200715

9. Butler CR, Wong SPY, Wightman AG, O'Hare AM. US Clinicians' Experiences and Perspectives on Resource Limitation and Patient Care During the COVID-19 Pandemic. JAMA Netw Open [Internet]. 2020 Nov 6;3(11):e2027315. Available from: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2772567

10. Cammarota G, Ragazzoni L, Capuzzi F, Pulvirenti S, De Vita N, Santangelo E, et al. Critical Care Surge Capacity to Respond to the COVID-19 Pandemic in Italy: A Rapid and Affordable Solution in the Novara Hospital. Prehosp Disaster Med [Internet]. 2020 Aug 19;35(4):431–3. Available from: https://www.cambridge.org/core/product/identifier/S1049023X20000692/type/journal_article

11. Coghlan N, Archard D, Sipanoun P, Hayes T, Baharlo B. COVID-19: legal implications for critical care. Anaesthesia [Internet]. 2020 Nov 11;75(11):1517–28. Available from: https://onlinelibrary.wiley.com/doi/10.1111/anae.15147

12. Coronavirus disease (COVID-19): Prevention and risks [Internet]. Government of Canada.

2020 [cited 2020 Dec 25]. Available from: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks.html?utm_campaign=gc-hc-sc-coronavirus2021-ao-2021-0005-396055227&utm_medium=search&utm_source=bing-ads-1242448631827600&utm_content=text-en-&utm_te

13. Vaccines and treatments for COVID-19: Progress [Internet]. Government of Canada. 2020 [cited 2020 Dec 25]. Available from: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks/covid-19-vaccine-treatment.html

14. COVID-19 Vaccines [Internet]. Government of Canada. 2020 [cited 2020 Dec 25]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines.html

15. COVID-19 Studies from the World Health Organization Database [Internet]. ClinicalTrials.gov. 2020 [cited 2020 Dec 25]. Available from: https://clinicaltrials.gov/ct2/who_table

16. Raifman J, Lam F, Madan Keller J, Radunsky A, Savedoff W. How well are aid agencies evaluating programs? An assessment of the quality of global health evaluations. J Dev Eff [Internet]. 2018 Apr 3;10(2):277–89. Available from: https://www.tandfonline.com/doi/full/10.1080/19439342.2018.1452779

17. CDC. Types of Evaluation [Internet]. 2017 [cited 2020 Dec 24]. Available from: https://www.cdc.gov/std/Program/pupestd/Types of Evaluation.pdf

18. Nurjono M, Shrestha P, Lee A, Lim XY, Shiraz F, Tan S, et al. Realist evaluation of a complex integrated care programme: protocol for a mixed methods study. BMJ Open [Internet]. 2018 Mar;8(3):e017111. Available from: https://bmjopen.bmj.com/lookup/doi/10.1136/bmjopen-2017-017111

19. Nevedal AL, Reardon CM, Jackson GL, Cutrona SL, White B, Gifford AL, et al. Implementation and sustainment of diverse practices in a large integrated health system: a mixed methods study. Implement Sci Commun. 2020;1(1):1–14.

20. Morris ZS, Wooding S, Grant J. The answer is 17 years, what is the question: Understanding time lags in translational research. J R Soc Med. 2011;104(12):510–20.

21. Morain SR, Majumder MA, McGuire AL. Learning Health System — Moving from Ethical Frameworks to Practical Implementation. J Law, Med Ethics. 2019;47(3):454–8.

22. Cucinotta D, Vanelli M. WHO declares COVID-19 a pandemic. Acta Biomed. 2020;91(1):157–60.

23. Pascarella G, Strumia A, Piliego C, Bruno F, Del Buono R, Costa F, et al. COVID-19 diagnosis and management: a comprehensive review. J Intern Med. 2020;288(2):192–206.

24. Coronavirus disease (COVID-19): Outbreak update [Internet]. Government of Canada. 2020 [cited 2022 Dec 3]. Available from: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection.html#a1

25. Coronavirus disease (COVID-19): Prevention and risks [Internet]. Government of Canada. 2020 [cited 2020 Dec 28]. Available from: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks.html#h

26. Coronavirus disease (COVID-19): Measures to reduce COVID-19 in your community [Internet]. Government of Canada. 2020 [cited 2020 Dec 28]. Available from: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks/measures-reduce-community.html

27. Klompas M, Morris CA, Sinclair J, Pearson M, Shenoy ES. Universal Masking in Hospitals in the Covid-19 Era. N Engl J Med [Internet]. 2020 May 21;382(21):e63. Available from: nejm.org

28. Checcucci E, Piramide F, Pecoraro A, Amparore D, Campi R, Fiori C, et al. The vaccine journey for COVID-19: a comprehensive systematic review of current clinical trials in humans. Panminerva Med [Internet]. 2020; Available from: http://www.ncbi.nlm.nih.gov/pubmed/32456404

29. Kaur SP, Gupta V. COVID-19 Vaccine: A comprehensive status report. Virus Res [Internet]. 2020 Oct;288(January):198114. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0168170220310212

30. Marian AJ. Current state of vaccine development and targeted therapies for COVID-19: impact of basic science discoveries. Cardiovasc Pathol [Internet]. 2021 Jan;50:107278. Available from: https://linkinghub.elsevier.com/retrieve/pii/S105488072030082X

31. Saskatchewan Releases COVID-19 Vaccine Delivery Plan [Internet]. Government of Saskatchewan. 2020 [cited 2020 Dec 28]. Available from: https://www.saskatchewan.ca/government/news-and-media/2020/december/09/saskatchewan-releases-covid-19-vaccine-delivery-plan

32. Pfizer-BioNTech COVID-19 vaccine: What you should know [Internet]. Government of Canada. 2020 [cited 2020 Dec 28]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/pfizer-biontech.html

33. Moderna COVID-19 vaccine: What you should know [Internet]. Government of Canada. 2020 [cited 2020 Dec 28]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/moderna.html

34. COVID-19 Vaccine Pilot Launch - CEO Message [Internet]. Saskatchewan Health Authority. 2020 [cited 2020 Dec 25]. Available from: https://www.saskhealthauthority.ca/news/releases/Pages/2020/December/COVID-19-Vaccine-Pilot-Launch---CEO-Message.aspx

35. First health-care workers in Saskatoon vaccinated for COVID-19 [Internet]. Canadian Broadcasting Corporation (CBC). 2020 [cited 2020 Dec 25]. Available from: https://www.cbc.ca/news/canada/saskatoon/saskatoon-first-covid-vaccines-1.5852045

36. Hicks G. First COVID vaccines given in Prince Albert [Internet]. Prince Albert.RIGHT

NOW! 2021 [cited 2021 Jan 14]. Available from: https://panow.com/2021/01/07/first-covid-vaccines-given-in-prince-albert/

37. Raine R, Fitzpatrick R, Barratt H, Bevan G, Black N, Boaden R, et al. Challenges, solutions and future directions in the evaluation of service innovations in health care and public health. Heal Serv Deliv Res [Internet]. 2016 May;4(16):1–136. Available from: https://www.journalslibrary.nihr.ac.uk/hsdr/hsdr04160/

38. Eccles M, Grimshaw J, Walker A, Johnston M, Pitts N. Changing the behavior of healthcare professionals: the use of theory in promoting the uptake of research findings. J Clin Epidemiol [Internet]. 2005 Feb;58(2):107–12. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0895435604002562

39. Birken SA, Powell BJ, Shea CM, Haines ER, Alexis Kirk M, Leeman J, et al. Criteria for selecting implementation science theories and frameworks: Results from an international survey. Implement Sci. 2017;12(1):1–9.

40. Shearn K, Allmark P, Piercy H, Hirst J. Building Realist Program Theory for Large Complex and Messy Interventions. Int J Qual Methods. 2017;16(1).

41. Lynch EA, Mudge A, Knowles S, Kitson AL, Hunter SC, Harvey G. "there is nothing so practical as a good theory": A pragmatic guide for selecting theoretical approaches for implementation projects. BMC Health Serv Res. 2018;18(1):1–11.

42. Nilsen P, Bernhardsson S. Context matters in implementation science: A scoping review of determinant frameworks that describe contextual determinants for implementation outcomes. BMC Health Serv Res. 2019;19(1):1–21.

43. Canadian Institutes of Health Research. What is the Strategy for Patient-Oriented Research? [Internet]. [cited 2019 Oct 23]. Available from: http://www.cihr-irsc.gc.ca/e/documents/spor_infographic-en.pdf

44. PORLET & IRLET - Saskatchewan Center for Patient-Oriented Research [Internet]. [cited 2022 Dec 29]. Available from: https://www.scpor.ca/porlet20

45. Zibrowski E, Carr T, McDonald S, Thiessen H, van Dusen R, Goodridge D, et al. A rapid realist review of patient engagement in patient-oriented research and health care system impacts: part one. Res Involv Engagem. 2021;7(1):1–13.

46. Government of Saskatchewan. Saskatchewan's Dashboard - Total Doses [Internet]. [cited 2022 Jun 19]. Available from: https://dashboard.saskatchewan.ca/health-wellness/covid-19-vaccines/vaccines

47. Manzano A. The craft of interviewing in realist evaluation. Evaluation. 2016;22(3):342–60.

48. Pawson R, Tilley N. Realist Evaluation [Internet]. 2004 [cited 2020 Dec 25]. p. 36. Available from: http://www.communitymatters.com.au/RE_chapter.pdf

49. Eastwood JG, Jalaludin BB, Kemp LA. Realist explanatory theory building method for social epidemiology:A protocol for a mixed method multilevel study of neighbourhood context and postnatal depression. Springerplus. 2014;3(1):1–12.

50. Mingers J. Systems Thinking, Critical Realism and Philosophy: A Confluence of Ideas. 1st editio. Routledge; 268 p.

51. Gilmore B, McAuliffe E, Power J, Vallières F. Data Analysis and Synthesis Within a Realist Evaluation: Toward More Transparent Methodological Approaches. Int J Qual Methods. 2019;18:1–11.

52. Mukumbang FC, Marchal B, Van Belle S, Van Wyk B. Unearthing how, why, for whom and under what health system conditions the antiretroviral treatment adherence club intervention in South Africa works: A realist theory refining approach. BMC Health Serv Res. 2018;18(1):1–15.

53. Smeets RGM, Hertroijs DFL, Mukumbang FC, Kroese MEAL, Ruwaard D, Elissen AMJ. First Things First: How to Elicit the Initial Program Theory for a Realist Evaluation of Complex Integrated Care Programs. Milbank Q. 2021;0(0):1–39.

54. 2022 Life and Health Sciences Research Expo - University of Saskatchewan [Internet]. [cited 2022 Dec 3]. Available from: https://healthsciences.usask.ca/documents/research-expo/award-recipients--2022-usask-life-and-health-sciences-research-expo-2022-05-09.pdf

55. Jagosh J, Bush PL, Salsberg J, Macaulay AC, Greenhalgh T, Wong G, et al. A realist evaluation of community-based participatory research: Partnership synergy, trust building and related ripple effects. BMC Public Health. 2015;15(1):1–11.

56. Systems Approach | Patient Safety Network [Internet]. Agency for Healthcare Research and Quality. 2019 [cited 2022 Jul 12]. Available from: https://psnet.ahrq.gov/primer/systems-approach#:~:text=Rather than focusing corrective efforts,minimize their impact on patients.

57. Reason JT. Human Error. Cambridge, UK: Cambridge University Press; 1990.

58. Carayon P, Wetterneck TB, Rivera-Rodriguez AJ, Hundt AS, Hoonakker P, Holden R, et al. Human factors systems approach to healthcare quality and patient safety. Appl Ergon [Internet]. 2014;45(1):14–25. Available from: http://dx.doi.org/10.1016/j.apergo.2013.04.023

59. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Heal Ment Heal Serv Res. 2011;38(2):65–76.

60. Lavallée JF, Gray TA, Dumville J, Russell W, Cullum N. The effects of care bundles on patient outcomes: A systematic review and meta-analysis. Implement Sci. 2017;12(1):1–13.

61. Gregory ME, MacEwan SR, Gaughan AA, Rush LJ, Powell JR, Kurth JD, et al. Closing the Gap on COVID-19 Vaccinations in First Responders and Beyond: Increasing Trust. Int J Environ Res Public Health [Internet]. 2022 Jan 6;19(2):644. Available from: https://www.mdpi.com/1660-4601/19/2/644

62. Kibongani Volet A, Scavone C, Catalán-Matamoros D, Capuano A. Vaccine Hesitancy Among Religious Groups: Reasons Underlying This Phenomenon and Communication

Strategies to Rebuild Trust. Front Public Heal [Internet]. 2022 Feb 7;10(February):1–3. Available from: https://www.frontiersin.org/articles/10.3389/fpubh.2022.824560/full

63. Trent M, Seale H, Chughtai AA, Salmon D, MacIntyre CR. Trust in government, intention to vaccinate and COVID-19 vaccine hesitancy: A comparative survey of five large cities in the United States, United Kingdom, and Australia. Vaccine [Internet]. 2022 Apr;40(17):2498–505. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0264410X21007982

64. Schernhammer E, Weitzer J, Laubichler MD, Birmann BM, Bertau M, Zenk L, et al. Correlates of COVID-19 vaccine hesitancy in Austria: trust and the government. J Public Health (Bangkok) [Internet]. 2022 Mar 7;44(1):e106–16. Available from: https://academic.oup.com/jpubhealth/article/44/1/e106/6263399

65. Marchal B, Dedzo M, Kegels G. A realist evaluation of the management of a well-performing regional hospital in Ghana. BMC Health Serv Res [Internet]. 2010 Dec 25;10(1):24. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2828434&tool=pmcentrez&rendertype=abstract

66. Zhou L, Ampon-Wireko S, Xu X, Quansah PE, Larnyo E. Media attention and Vaccine Hesitancy: Examining the mediating effects of Fear of COVID-19 and the moderating role of Trust in leadership. PLoS One [Internet]. 2022;17(2 February):1–16. Available from: http://dx.doi.org/10.1371/journal.pone.0263610

67. Sekizawa Y, Hashimoto S, Denda K, Ochi S, So M. Association between COVID-19 vaccine hesitancy and generalized trust, depression, generalized anxiety, and fear of COVID-19. BMC Public Health [Internet]. 2022;22(1):1–17. Available from: https://doi.org/10.1186/s12889-021-12479-w

68. Patneaude A, Kett J. Cultural Responsiveness and Palliative Care during the COVID-19 Pandemic. Palliat Med Reports. 2020;1(1):171–3.

69. Flaskerud JH, Nyamathi AM. Attaining gender and ethnic diversity in health intervention research: Cultural responsiveness versus resource provision. Adv Nurs Sci. 2000;22(4):1–15.

70. Roberts D, Moussa M, Sherrod D. Foster cultural responsiveness on your unit. Nurs Manage. 2011;42(9):52–4.

71. Sasakamoose JL, Bellegarde T, Sutherland W, Pete S, McKay-McNabb K. Miỳo-pimatisiwin developing indigenous cultural responsiveness theory (ICRT): Improving indigenous health and well-being. Int Indig Policy J. 2017;8(4).

72. Menear M, Blanchette MA, Demers-Payette O, Roy D. A framework for value-creating learning health systems. Heal Res Policy Syst. 2019;17(1):1–13.

73. Vanstone JR, Azizian AR, Berry W, Carr T, Falastein P, Mise T-R, et al. Identifying Barriers and Enablers to Vaccine uptake from Immunizers and Individuals Receiving a COVID-19 Vaccine in Saskatchewan. Open Public Health J. 2022;15(1):1–11.

74. Morales GI, Lee S, Bradford A, De Camp A, Tandoc EC. Exploring vaccine hesitancy

determinants during the COVID-19 pandemic: An in-depth interview study. SSM - Qual Res Heal [Internet]. 2022 Dec;2(January):100045. Available from: https://linkinghub.elsevier.com/retrieve/pii/S2667321522000075

75. Marzo RR, Sami W, Alam MZ, Acharya S, Jermsittiparsert K, Songwathana K, et al. Hesitancy in COVID-19 vaccine uptake and its associated factors among the general adult population: a cross-sectional study in six Southeast Asian countries. Trop Med Health [Internet]. 2022;50(1):1–10. Available from: https://doi.org/10.1186/s41182-021-00393-1

76. Razai MS, Osama T, McKechnie DGJ, Majeed A. Covid-19 vaccine hesitancy among ethnic minority groups. Vol. 372, The BMJ. BMJ Publishing Group; 2021.

77. Larson HJ, Gakidou E, Murray CJL. The Vaccine-Hesitant Moment. N Engl J Med. 2022;387(1):58–65.

78. Issa O. How Indigenous communities are working to boost COVID-19 vaccine rates [Internet]. Canadian Broadcasting Corporation (CBC). [cited 2022 Jun 11]. Available from: https://www.cbc.ca/news/canada/saskatoon/indigenous-covid19-vaccination-saskatchewan-1.6220497

79. Kovach M. Indigenous Methodologies: Characteristics, Conversations, and Contexts, Second Edition. University of Toronto Press; 2021. 328 p.

80. Hart MA. Indigenous Worldviews, Knowledge, and Research: The Development of an Indigenous Research Paradigm. J Indig Voices Soc Work. 1(1):1–16.

81. Pawson R, Walshe K, Greenhalgh T. Realist synthesis : an introduction [Internet]. ESRC Research Methods Programs. University of Manchester, RMP Methods Paper 2/2004; Available from: https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.432.7999&rep=rep1&type=pdf

82. Nielsen SB, Lemire S, Tangsig S. Unpacking context in realist evaluations: Findings from a comprehensive review. Evaluation [Internet]. 2022 Jan 25;28(1):91–112. Available from: http://journals.sagepub.com/doi/10.1177/13563890211053032

83. Jagosh J, Pluye P, Wong G, Cargo M, Salsberg J, Bush PL, et al. Critical reflections on realist review: insights from customizing the methodology to the needs of participatory research assessment. Res Synth Methods. 2014 Jun;5(2):131–41.