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Title	COVID-19 vaccine implementation in three sites in Saskatchewan: protocol for a patient-oriented realist evaluation
Authors	Amir Reza Azizian MD, Tracey Carr PhD, Nazeem Muhajarine PhD, Tanya Verrall PhD, Collin Hartness MAL, Jason Vanstone PhD, Maryam Yasinian MEd, Candace Skrapek BN, Brenda Andreas BSW, Gerald Farthing PhD, Gary Groot PhD MD
Reviewer 1	Dr. Sanjay Beesoon
Institution	Alberta Health Services, University of Alberta Faculty of Medicine and Dentistry
General comments (author response in bold)	I suggest waiting for the data that you are currently generating and integrate them in the current manuscript. You will have a much stronger publishable manuscript. **Thank you for your valuable time in reviewing our manuscript. We submitted this manuscript as a protocol paper. We have found the reviewers' comments very helpful for improving the methodology while we are conducting the study. We are planning to report the findings in another manuscript after the data collection and analysis.**
Reviewer 2	Dr. Susan Jelinski
Institution	Alberta Health Services
General comments (author response in bold)	Thank you for the opportunity to review this manuscript submission. The authors describe a rather unique protocol, centering on realist evaluation techniques, to examine the relevant topic of implementation effectiveness of COVID-19 vaccination plans at three Saskatchewan sites. The protocol includes meaningful engagement with patient and family partners throughout the research process. The anticipated outcome of this protocol is the development of a program theory that will inform the successful (or unsuccessful) nature of COVID-19 vaccination programs in Saskatchewan. I highlight the following points for the authors' consideration: The authors refer to the Pfizer and Moderna vaccines, and may want to update their manuscript to include the AstraZeneca vaccine as well. **Thank you for your valuable time in reviewing our manuscript.** **We took your suggestion and indicated that Janssen (Johnson & Johnson) and AstraZeneca/COVISHIELD COVID-19 vaccines got the approval later on after the pilot phase.** **"[Janssen (Johnson & Johnson) and AstraZeneca/COVISHIELD COVID-19 (22) vaccines were granted national approval after the pilot phase]".** **Reference:** **22. Government of Canada. Approved COVID-19 Vaccines. 2021. https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines.html** (p. 6-7) The authors intend to interview six vaccine eligible/actual recipients, where two will be recruited from each of the three sites. This number seems a bit low in order to collect all representative perspectives on the IPT elements. Perhaps the authors could comment on why only six people in this category will be interviewed, with particular attention on their confidence that this will be an adequate number of vaccine eligible interviewees **Thank you for your important questions. We followed the Realist Evaluation sampling strategy and provided six interviews as a proximate plan for data collection (Emmel, 2013; Manzano 2016). According to Emmel (2013), "in realist qualitative research the sample can only be weakly elaborated**

	beforehand" (154) as theory testing is hard to be predicted. As the interviews begin, researchers become more knowledgeable about their evaluations and theory development which assist them to better clarify the approximate number of interviews ((Emmel, 2013; Manzano 2016). In Realist interviews, "the importance is not on 'how many' people we talk to but on 'who', 'why' and 'how'" (Manzano, 2016). **That being said, your comment encouraged us to revise the number of participants and propose 6-12 interviewees as an approximate number for vaccine recipients. We consider six as the minimum number of participants and we will interview more people if we identify the need to collect larger amount of data. Our focus would be on producing substantial amount of data that could explain the Initial program theory comprehensively.** **To address your comment, we added:** **"To test and refine the initial program theory, interviews will be conducted with approximately 14-20 purposively recruited eligible participants. Our inclusion criteria will focus on eight key Saskatchewan Health Authority stakeholders who planned and implemented the COVID-19 vaccination pilot phase (i.e., stakeholder from Clinical Excellence, Public Health, Protective Services, Human Resources, Communications, and each site's clinic managers), and six to twelve eligible vaccine pilot phase recipients, two to four from each site (i.e., a vaccine recipient and someone who did not receive the vaccine but was eligible to be vaccinated). Following Realist sampling strategy (32,33), we will interview a minimum of six participants and increase the number to a maximum of twelve interviewees as we identify the need for further data collection. Purposive participant recruitment will ensure diverse inclusion of healthcare workers and non-healthcare providers".** **References:** **32. Manzano A. The craft of interviewing in realist evaluation. Evaluation. 2016;22(3):342–60.** **33. Emmel N. Sampling and Choosing Cases in Qualitative Research: A Realist Approach. London, England: Sage Publications; 2013.** (p. 9) The authors describe how the vaccination delivery plan in SK initially targeted healthcare workers, as well as seniors and residents of northern communities. It is possible that the vaccine-eligible interviewees may therefore predominantly be healthcare workers. It is plausible that healthcare workers have different perspectives regarding vaccine uptake/adoption which would influence their responses about the IPT. Could the authors comment on their approach to selection of vaccine eligible interviewees to ensure that both healthcare workers and non-healthcare workers are included? **Thank you for your valuable comment. We acknowledge that the majority of vaccine recipients were healthcare workers during the pilot phase because they had the priority for getting the first vaccines. This may impact the representation of healthcare and non-health care populations in our research. Nevertheless, we will address this issue by purposefully selecting participants from both groups. To note your comment in the text, we added: "Purposive participant recruitment will ensure diverse inclusion of healthcare workers and non-healthcare providers".** (p. 9)

	Presumably the quantitative analysis of number of people vaccinated in the three target locations will contribute to the conclusion that the program is/was successful. The authors mention both number of people vaccinated, and number of doses delivered per week. It would be helpful if the authors described why these two numbers may be different in a specific jurisdiction by specifically collecting data on differing second dose strategies that may have been employed. For example, some jurisdictions may be withholding second doses to ensure greater availability of first doses across the population, and some are further identifying sub-populations who receive the second dose sooner than others (older age, immunosuppressed, healthcare workers, etc). **Thank you for your comment. The focus of the development of our program theory relates to the pilot phase only when the first dose was implemented. Therefore, there were no second doses administered.** **The reviewer raises an interesting consideration for the refinement of final theory when it could be tested in a second-dose focused evaluation or first dose roll out in a different context.** (N/A)
Reviewer 3	Dr. Cheryl Barnabe
Institution	University of Calgary
General comments (author response in bold)	This submission is a protocol for a patient-oriented realist evaluation to be conducted in 3 cities in Saskatchewan to link the contexts and mechanisms for the outcome of successful implementation of the COVID-19 vaccination program. As the authors introduce, this evaluation will be important for a systematic assessment of a program that has been reactive and rapidly deployed (and since the submission of this article would have experienced shifts in prioritization of population vaccinated, significant variations of vaccine availability, availability of AstraZeneca vaccine with widespread hesitancy related to potential serious side effects etc.) While this proposed assessment is said to inform real-time vaccine roll-out, I suspect it will primarily inform system-learning for future large scale vaccination program roll-out. **Thank you for your time in reviewing and providing feedback on our manuscript. We appreciate it.** **We are in agreement with your comment. The COVID-19 vaccination program is evolving so fast that the findings of this study may not be able to catch up and inform it in real-time. We adjusted our comment in the text as "By including Saskatchewan Health Authority directors in Phase II and III of this study, we aim to provide them with the initial program theory and final program theory to inform system-learning for the current and future large scale vaccination programs".** (p. 13) As this is a protocol, my review comments are more question/reflections on the methodology described: There is specific consideration of including persons who did not receive vaccines for data collection purposes. While persons opposed to vaccination may be difficult to engage in a research team to understand what makes vaccination programs successful, was there an attempt to include these patients in the research team? How will the potential source of bias of having persons aligned with vacation in the current team composition be managed (as the patients are conducting the interviews and are involved in analysis). Will this limit understanding of the perspectives of people declining vaccination? **Thank you for your important questions. While our patient partners are not**

	opposed to vaccination, they will be a source of lived experiences with people who do not/did not get the vaccine. We believe the PFPs' points of view and experiences will direct us to avoid the potential source of bias that you indicated because we will indirectly hear the opposite perspectives through them. We will also use the grey literature and the media as our second source to hear people who are unwilling to receive vaccination as these platforms have been vocal in reflecting opposite viewpoints towards the COVID-19 vaccination. We strongly agree with you that engaging individuals who do not trust the vaccination is very difficult. Thus, we took your comment and addressed the composition of the research team as a limitation: **"The research team's alignment with the vaccination program may also introduce potential bias. We will intentionally engage patient and family partners who are in contact with individuals unwilling to receive the COVID-19 vaccine to mitigate this bias. The grey literature and media will assist understanding of vaccination opposition".** (p. 13-14) Is the sample size for Phase II (1 vaccine recipient, and 1 eligible non-recipient, per site x 3 sites) 1. sufficient, 2. and reflective of a variety of diversity in gender, age, race/ethnicity, socioeconomic status, education level etc? **Thank you for your valuable comment. As mentioned in previous comments, we followed the Realist Evaluation sampling strategy and provided six interviews as a proximate plan for data collection (Emmel, 2013; Manzano 2016). According to Emmel (2013), "in realist qualitative research the sample can only be weakly elaborated beforehand" (154) as theory testing is hard to be predicted. As the interviews begin, researchers become more knowledgeable about their evaluations and theory development which assist them to better clarify the approximate number of interviews ((Emmel, 2013; Manzano 2016). In Realist interviews, "the importance is not on 'how many' people we talk to but on 'who', 'why' and 'how'" (Manzano, 2016).** **That being said, your comment encouraged us to revise the number of participants and propose 6-12 interviewees as an approximate number for vaccine recipients. We consider six as the minimum number of participants and we will interview more people if we identify the need to collect larger amount of data. Our focus would be on producing substantial amount of data that could explain the initial program theory comprehensively.** **To address your feedback and the second reviewer's comment, we revised and elaborated our sampling strategy** **"To test and refine the initial program theory, interviews will be conducted with approximately 14-20 purposively recruited eligible participants. Our inclusion criteria will focus on eight key Saskatchewan Health Authority stakeholders who planned and implemented the COVID-19 vaccination pilot phase (i.e., stakeholder from Clinical Excellence, Public Health, Protective Services, Human Resources, Communications, and each site's clinic managers), and six to twelve eligible vaccine pilot phase recipients, two to four from each site (i.e., a vaccine recipient and someone who did not receive the vaccine but was eligible to be vaccinated). Following Realist sampling strategy (32,33), we will interview a minimum of six participants**

	and increase the number to a maximum of twelve interviewees as we identify the need for further data collection. Purposive participant recruitment will ensure diverse inclusion of healthcare workers and non-healthcare providers". **References:** **32. Manzano A. The craft of interviewing in realist evaluation. Evaluation. 2016;22(3):342–60.** **33. Emmel N. Sampling and Choosing Cases in Qualitative Research: A Realist Approach. London, England: Sage Publications; 2013.** **With regards to the diversity of interviewees, we will not include gender, race, and ethinicity as criteria for participant recruitment due to the focus of our study. In Realist evaluation, the selection of participants depends on the CMO investigation (Pawson and Tilley, 1997). In other words, "each component – contexts, mechanisms and outcomes – triggers the need for a different kind of respondent" (Manzano, 2016). For this study,** **we will purposefullly select the participants to ensure the balanced representation of health-care and non-healthcare workers.** **the profound consideration of these factors requires multiple resources to avoid a perfunctory and tokenistic practice of inclusion.** **References:** **Pawson R and Tilley N (1997) Realistic Evaluation. London: SAGE.** **Manzano A. The craft of interviewing in realist evaluation. Evaluation. 2016;22(3):342–60.** (p. 9) Why is the literature review on vaccine implementation, hesitancy and resistance limited only to COVID-19 vaccines, and not the broader vaccine literature? I suspect [it is] similar **Thank you, we realized that we may not have been clear in the text about our literature review process because a major part of our research is related to the review of literature on both COVID-19 and non-COVID vaccination programs to develop the initial program theory. We revised the text as:** **"The second step is to review COVID-19 and other vaccine implementation literature to find resources from similar contexts (e.g., theories on COVID-19 or other vaccine implementation, vaccine hesitancy or uptake in various subgroups)".** **"The patient and family partners' activities will encompass review of literature related to COVID-19 and non-COVID vaccination programs, …".** (p. 8, 11) With a significant Indigenous population in Saskatchewan, and knowing that members of the investigative team are also Indigenous health researchers, I found it surprising that this research does not specify any Indigenous inclusion at all. **Thank you for your valuable input. As a side note, the research team members do not have Indigenous background although several of them (e.g., Dr. Tracey Carr, Dr. Gary Groot) have strong academic experiences in Indigenous research. We reflected on the involvement of Indigenous peoples when we began to frame our study, but we decided to postpone it as a future research due to our restricted timelines and resources for the current study. True inclusion of indigenous population requires considerable time and relationship building. Otherwise, there is a risk of misrepresentation or**

	tokenism in our effort. We are planning to conduct another study in the near future to focus on COVID-vaccination and Indigenous population to fill this gap in our findings. (N/A)
Reviewer 3	Dr. Jillian Banfield
Institution	Halifax, NS
General comments (author response in bold)	I think the topic of investigation is important and I appreciate the patient-oriented focus. I appreciate the inclusion of the GRIPP2 checklist. The patient/family partners seem to be meaningfully engaged in the project. I don't have experience with realist evaluations, so I can't competently comment on the methodology. I was surprised that the literature review didn't cover any prior approaches to vaccine roll out. Although the COVID pandemic is unique, the world has experienced other pandemics (e.g. H1N1), so I'd be curious to read about happened during those pandemics. Additionally, vaccines are continually rolled out on broad scales. For example, children receive vaccines for MMR and people of all ages are vaccinated against the flu with varying rates of uptake. Perhaps some acknowledgement of the historical and current diseases and vaccine roll outs is warranted. **Thank you for your time in reviewing our manuscript. We are very happy to read your positive feedback.** **We received the same comment from the third reviewer regarding our literature review. As mentioned above, we realized that we may have been unclear about our literature review because a major part of our research is related to the review of literature on both COVID-19 and non-COVID vaccination programs to develop the initial program theory. We revised the text as:** **"The second step is to review COVID-19 and other vaccine implementation literature to find resources from similar contexts (e.g., theories on COVID-19 or other vaccine implementation, vaccine hesitancy or uptake in various subgroups)".** **"The patient and family partners' activities will encompass review of literature related to COVID-19 and non-COVID vaccination programs, …".** (p. 8, 11) I found the liberal use of abbreviations made it difficult to follow at times. There are quite a few unfamiliar terms in this paper, and it took a lot of effort to read as I tried to keep in mind what all of the abbreviations meant. It is sometimes better to just repeat the terms rather than use abbreviations, if it enhances the reader's ability to follow and comprehend the subject matter. **Thank you for your valuable input regarding the usage of abbreviations. To address your comment, we revised the manuscript and used the whole terms instead of abbreviations for initial program theory, final program theory, Saskatchewan Health Authority, and patient and family partners. The only abbreviation that we kept is "CMOCs" which is a well-known standard abbreviation to maintain the flow of the manuscript.** (Highlighted in red throughout the manuscript)