Manitoba Centre for Health Policy
Community Health Sciences
Max Rady College of Medicine
408-727 McDermot Avenue
Winnipeg, Manitoba
Canada R3E 3P5
info@cpe.umanitoba.ca

Appendix B: Information Letter and Consent Form for Key Informant Interviews

Study Title: Vaccine Distribution Approaches for Underserved and At-Risk Populations during COVID-19: Best Practices and Lessons Learned in Canada

Funder: This study is sponsored by the Canadian Institutes of Health Research

Principal/Lead Investigator:
Monica Aggarwal, PhD
Dalla Lana School of Public Health,
University of Toronto
647-381-5534
Email: monica.aggarwal@utoronto.ca

Project Coordinator:
Carolynn Warnet
Dalla Lana School of Public Health,
University of Toronto

Email: c.warnet@utoronto.ca

Co-Principal Investigators:

Fariba Aghajafari, University of Calgary
Kris Aubrey-Bassler, Memorial University
Mylaine Breton, Universite de Sherbrooke
Alan Katz, University of Manitoba
Noah Ivers, Women's College Hospital
Ruth Martin-Misener, Dalhousie University
Ross Upshur, University of Toronto
Sabrina Wong, University of British Columbia

Co-Principal Decision Makers/ Co-Investigators:

Penny Ballem, Vancouver Coastal Health
Eileen de Villa, Chief Medical Officer, City of Toronto
Catherine Donovan, Advisor, Government of Newfoundland and Labrador
Kristina M Kokorelias, Senior Academic Program Coordinator, Sinai Health Systems, University Health Network
Kavita Mehta, CEO, Association of Family Health Teams of Ontario
Tara Sampalli, Senior Scientific Director at Nova Scotia Health Authority
Carine Sauve, Directrice adjointe a la direction des services professionnels, CISSS de la Monteregie-Centre
Scott Sinclair, Deputy Minister, Government of Manitoba
Gail Tomblin Murphy, Vice-President of Research, Innovation and Discovery and Chief Nurse Executive

Invitation to Participate

You are being invited to participate in the above-mentioned research study led by Dr. Aggarwal and her colleagues. We are inviting you to participate in an interview on the distribution of COVID-19 vaccines. You have been identified as a policymaker or public health official with experience in vaccine distribution strategies during COVID-19. As a participant in this study, we will be asking about your thoughts and experience with vaccine distribution approaches in your jurisdiction, the strengths, weaknesses, and limitations of various approaches, the factors that influenced the uptake of vaccine distribution approaches by the public, and lessons learned.

Purpose of the Research Study

The World Health Organization has stated that one of the serious threats to overcoming COVID-19 is vaccine hesitancy. Vaccine hesitancy amongst underserved and at-risk communities is an ongoing challenge in Canada. Approaches for the effective distribution of vaccines for equity-deserving and at-risk individuals are urgently needed. Equity deserving groups include black, racialized, LGBTQ2S+ and low-income communities, immigrants, persons experiencing housing precarity, and persons with low levels of English/French fluency. At-risk populations include children under the age of 12.

The objective of this pan-Canadian study of British Columbia, Alberta, Manitoba, Ontario, Quebec, Nova Scotia, and Newfoundland is to identify effective vaccine distribution approaches and advance knowledge on how to design and implement these approaches to meet the needs of equity deserving and at-risk communities. “Effective” is defined as approaches that have resulted in high vaccination rates for equity-deserving and at-risk populations. To meet the aims of the study, we will be examining the experiences and perspectives of different stakeholders with vaccine distribution approaches. We will also compare vaccination rates associated with different vaccine delivery channels in each jurisdiction. Your contribution to this study will assist with informing recommendations for policymakers on how to develop and implement effective equitable vaccine distribution strategies for equity deserving and at-risk communities in response to COVID-19 variants and future waves and pandemics.

Participation in the Study

Before agreeing to participate in this study, you must read and understand the explanation of the proposed study procedures. Before agreeing to participate, you should understand enough about its risks and benefits to be able to make an informed decision. Please ask the study coordinator to explain any words that you do not understand. Make sure all your questions have been answered to your satisfaction before signing this consent form.

As a participant in this study, you are being asked to participate in an individual interview, via either telephone, Zoom, or Microsoft Teams (depending on your preference). The interview is anticipated to take 60 minutes and will be conducted at a time and location convenient to you. With your permission, we will audio-record the interview. The use of video is optional and will not be recorded. If you do not consent to the interview being recorded, the interviewer will take notes.

Voluntary Participation and Withdrawal from the Study

Your participation in this study is voluntary. You are under no obligation to participate in this study. You can refuse to answer any questions that make you uncomfortable. If you decide to participate and change your mind and withdraw from the study at any time without consequence. If you decide to withdraw from the

study, you can inform one of the investigators. In addition, you may withdraw your responses from the study within 30 days of participation.

Possible Risks

There are minimal anticipated risks to participating in this study. Participants may experience psychological or emotional discomfort during the interview when disclosing personal and professional experiences with vaccine distribution. You do not need to answer questions that make you uncomfortable or that you do not want to answer. You also have the option to stop the interview or withdraw from the study at any time.

Possible Benefits

You may or may not benefit directly from participating in this study. However, you may find satisfaction in the societal and scholarly benefits of the study. By participating in this study, you will be assisting with identifying effective vaccine distribution approaches and informing the development, implementation, and spread of equity-informed vaccination distribution strategies and programs. By improving the quality and access to these programs for equity-deserving groups and at-risk populations, this research will indirectly prevent the deterioration, morbidity, and mortality of critically ill patients, thereby improving personal health and the health of the underserved populations.

Confidentiality and Anonymity

The information that you share will remain strictly confidential and will be used solely for this research. All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. We will audio-record and transcribe the interview with your consent. Interviews will be recorded using Zoom Cloud or MS Teams (audio only) and securely transferred to the University of Toronto server (password protected Sharepoint) and permanently deleted from the Zoom Cloud or MS Teams. If you are not comfortable with the use of these platforms, we will record the interview using a digital recorder. The recording may be transcribed by a professional transcription service that will be required to complete a confidentiality agreement. Interview audio files and written transcripts will be referred to by participant number and date completed. To maintain confidentiality, names will be replaced with codes in the transcripts. A list linking the number with your name will be kept by the research team on a secure server at the University of Toronto, separate from your file. Therefore, there will be no identifiable information in the written transcripts used for analysis. The only people who will have access to the research data are Dr. Aggarwal and the research team.

Research reports and presentations will include quotations from participants but will not include any personally identifying information. However, participants' identities are sometimes revealed by the experiences that are described. Thus, anonymity cannot be guaranteed. For quotes that might reveal your identity, we will reach out to you and ask for your permission to include the information in any presentation or publication.

Data Storage

All electronic data, documents, audio recordings, and physical records (i.e., hard copies of any notes, consent forms) will be stored electronically on a password-protected secure network at the University of Toronto.

The Principal Investigator will keep any personal information about you in a secure and confidential location for 5 years after study completion and then destroy it according to the University of Toronto policy. This research study may be reviewed for quality assurance to make sure that the required laws and guidelines are followed. If chosen, (a) representative(s) of the Human Research Ethics Program (HREP) may access study-related data and/or consent materials as part of the review. All information accessed by the HREP will be upheld to the same level of confidentiality that has been stated by the research team.

Compensation

Participants will not be compensated for their participation.

Dissemination of Study Results

The research findings will be made available to participants and other interested parties upon completion of the study. The researchers are required by the funder to make the results publicly available. This may include publishing in a peer-reviewed journal, posting to a website, presenting at a conference, or sharing with research participants and other stakeholders. If you wish to receive a summary of the project's results, please reach out to us via email. The results will be sent out to you at the end of the project.

Inquiries and Contact Information

If you have any questions about the study, you may contact Carolynn Warnet, Research Coordinator at the University of Toronto by email at: c.warnet@utoronto.ca. You can also contact Dr. Monica Aggarwal, principal investigator, at: monica.aggarwal@utoronto.ca and 647-381-5534.

If you have questions about your rights as a research participant or any ethical issues related to this study that you wish to discuss with someone not directly involved with the study, you may call the Office of Research Ethics at 416-946-3273 or ethics.review@utoronto.ca.

This study has received ethics approval from the University of Manitoba Bannatyne Health Research Ethics Board and accompanying universities.

DOCUMENTATION OF INFORMED CONSENT

A copy of this consent form will be made available to participants via email and or mail. Participants will be asked to review the consent form in detail before their interview. Participants will be asked to send back a copy of the consent form. Before starting the interview and the recording, verbal consent will also be obtained before commencing the interview (Refer to Section Below).

Project title: An equity-focused evaluation of the COVID-19 vaccine rollout plans proposed by six Canadian provinces

Principal Investigator: Dr. Monica Aggarwal

By signing this form, I confirm that:

Please check the box

1. I confirm that I have read and understand the information in the consent form for the above study. ☐
2. I confirm that I have had the opportunity to ask questions which have been answered to my satisfaction. ☐
3. I have been informed of the risks and benefits of participating in this research study. ☐
4. I understand that my participation is voluntary and that I am free to not answer questions or withdraw at any time, without giving a reason ☐
5. I understand the requirements of participating in the study and agree to take part in the above study. ☐
6. If the interview is taking place on the phone or via Microsoft Teams, or Zoom, I agree to take part in this study, as described in this consent form. ☐
7. I agree with the interview will be audio recorded. ☐
8. I agree with the use of anonymized quotes in publications and presentations. ☐
9. I would like to receive a summary of the study's results. ☐

Please indicate the language of your preference for conducting the interview.

☐ English
☐ French

Please provide an email address if you would like to be sent a summary of the study results.
Email address: _____

_____	_____	_____
Name of Participant	Signature	Date

_____	_____	_____
Name of Interviewer	Signature	Date

VERBAL CONSENT FORM

You have been invited to participate in an interview about vaccine distribution approaches in your jurisdiction.

The World Health Organization has stated that one of the serious threats to overcoming COVID-19 is vaccine hesitancy. Vaccine hesitancy amongst underserved and at-risk communities is an ongoing challenge in Canada. Public confidence in vaccine safety and effectiveness and the principles of equity need to be considered in vaccine distribution since it can result in poorer health outcomes, increased COVID incidence, and less vaccination in underserved communities. Approaches for the effective distribution of vaccines for equity-deserving and at-risk individuals are urgently needed. This pan-Canadian study of British Columbia, Alberta, Manitoba, Ontario, Quebec, Nova Scotia, and Newfoundland will identify effective vaccine distribution approaches and advance knowledge on how to design and implement these approaches to meet the needs of communities and reduce the risk of health and social inequalities during and after COVID-19.

We want to learn more about your thoughts on vaccine distribution approaches. We will ask you about your thoughts and experience with vaccine distribution approaches in your jurisdiction, the strengths, weaknesses, and limitations of various approaches, the factors that influenced the uptake of vaccine distribution approaches by the public, and lessons learned. Your contribution to this study will assist with informing recommendations for policymakers on how to develop and implement effective equitable vaccine distribution strategies for equity deserving and at-risk communities in response to COVID-19 variants and future waves and pandemics.

I would like to review the study information with you before starting the interview.

- You have signed and returned the consent form which authorizes your approval to participate in this study.
- Participation in the study is voluntary, and you may withdraw your responses from the study within 30 days of participation.
- The answers and comments you provide today will remain strictly confidential and will be used only for this study.
- You will be given a unique identifier to maintain anonymity, and all your study data will be stored under this identifier.
- Audio recordings of our interview will be kept on a secure research network server at the University of Toronto.
- You can choose to skip any question you do not feel comfortable answering, and you can stop your participation at any time without having to provide a reason.
- We will be audio recording the session which will only be available to the research team for analysis.
- There are minimal anticipated risks to participating in the study.

Do you have any questions about the study?
☐No ☐Yes

Has the study and its purpose, benefits, and risks been fully explained to you?
☐No ☐Yes

Have all your questions about the study been answered?
☐No ☐Yes

Do we have your consent to begin the recording of the focus group?
☐No ☐Yes

We would like to provide you with a copy of this study information and a verbal consent form. Can we send this to you by email or mail? The security of information sent by e-mail cannot be guaranteed.

☐Mail (Confirm mailing address):

☐Email (Confirm email address):

If you have any questions about the study, you may contact Carolynn Warnet, Research Coordinator at the University of Toronto by email at: c.warnet@utoronto.ca. You can also contact Dr. Monica Aggarwal, principal investigator, at: monica.aggarwal@utoronto.ca and 647 381 5534.

If you have questions about your rights as a research participant or any ethical issues related to this study that you wish to discuss with someone not directly involved with the study, you may call the Office of Research Ethics at 416-946-3273 or ethics.review@utoronto.ca.

Name of Participant	Date of Participant Verbal Consent

Name of interviewer	Signature of interviewer	Date