

An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI)

Preliminary Guidance on Key Populations for Early
COVID-19 Immunization

PROTECTING AND EMPOWERING CANADIANS TO IMPROVE THEIR HEALTH



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INNOVATION AND ACTION IN PUBLIC HEALTH.**

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Également disponible en français sous le titre :
Orientations préliminaires sur les principales populations à immuniser en priorité contre la COVID-19

To obtain additional information, please contact:

Public Health Agency of Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: hc.publications-publications.sc@canada.ca

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PREAMBLE

The National Advisory Committee on Immunization (NACI) is an External Advisory Body that provides the Public Health Agency of Canada (PHAC) with independent, ongoing and timely medical, scientific, and public health advice in response to questions from PHAC relating to immunization.

In addition to burden of disease and vaccine characteristics, PHAC has expanded the mandate of NACI to include the systematic consideration of programmatic factors in developing evidence-based recommendations to facilitate timely decision-making for publicly funded vaccine programs at provincial and territorial levels.

The additional factors to be systematically considered by NACI include: economics, ethics, equity, feasibility, and acceptability. Not all NACI Statements will require in-depth analyses of all programmatic factors. While systematic consideration of programmatic factors will be conducted using evidence-informed tools to identify distinct issues that could impact decision-making for recommendation development, only distinct issues identified as being specific to the vaccine or vaccine-preventable disease will be included.

This statement contains NACI's independent advice and recommendations, which are based upon the best current available scientific knowledge and is disseminating this document for information purposes. People administering the vaccine should also be aware of the contents of the relevant product monograph(s). Recommendations for use and other information set out herein may differ from that set out in the product monograph(s) of the Canadian manufacturer(s) of the vaccine(s). Manufacturer(s) have sought approval of the vaccine(s) and provided evidence as to its safety and efficacy only when it is used in accordance with the product monographs. NACI members and liaison members conduct themselves within the context of PHAC's Policy on Conflict of Interest, including yearly declaration of potential conflict of interest.

TABLE OF CONTENTS

SUMMARY OF INFORMATION CONTAINED IN THIS NACI STATEMENT	5
I. INTRODUCTION.....	8
II. METHODS.....	9
III. VACCINE(S)	10
IV. ETHICS, EQUITY, FEASIBILITY AND ACCEPTABILITY CONSIDERATIONS	11
V. RECOMMENDATIONS	21
VI. RESEARCH PRIORITIES	27
LIST OF ABBREVIATIONS.....	29
ACKNOWLEDGMENTS.....	30
REFERENCES	31
APPENDIX A: ALGORITHM OUTLINING THE PROCESS FOR APPLYING THE EEFA FRAMEWORK	34
APPENDIX B: CORE ETHICAL DIMENSIONS FILTER APPLIED TO COVID-19.....	35
APPENDIX C: ETHICAL PROCEDURAL CONSIDERATIONS FILTER APPLIED TO COVID-19	37
APPENDIX D: EQUITY MATRIX APPLIED TO COVID-19 WITH EVIDENCE TO DATE	39
APPENDIX E: FEASIBILITY MATRIX APPLIED TO COVID-19	44
APPENDIX F: ACCEPTABILITY MATRIX APPLIED TO COVID-19.....	47

SUMMARY OF INFORMATION CONTAINED IN THIS NACI STATEMENT

The objective of this advisory committee statement is to provide preliminary guidance for public health program level decision-making to plan for the efficient, effective, and equitable allocation of a novel coronavirus disease 2019 (COVID-19) vaccine once it is authorized for use in Canada when limited initial vaccine supply will necessitate the prioritization of immunization in some populations earlier than others. These recommendations aim to achieve Canada's pandemic response goal: "To minimize serious illness and overall deaths while minimizing societal disruption as a result of the COVID-19 pandemic." Due to anticipated constraints in supply, these National Advisory Committee on Immunization (NACI) recommendations apply to provincial/territorial publicly-funded immunization programs only and not for individuals wishing to prevent COVID-19 with vaccines not included in such programs.

The recommendations are informed by evidence available at the time of NACI deliberations, including the results of a rapid review of risk factors for severe COVID-19 ⁽¹⁾, an expert stakeholder survey on the relative importance of pandemic immunization strategies ⁽²⁾, and the systematic assessment of ethics, equity, feasibility and acceptability (EEFA) considerations with the peer-reviewed EEFA Framework ⁽³⁾. NACI will continue to carefully monitor the evidence related to COVID-19 and COVID-19 vaccine(s) and will update recommendations as evidence evolves.

Recommendations for public health program level decision-making

Given arrival of vaccine supply is expected to be staggered over several months, NACI recommends that key populations in whom vaccine is deemed safe and effective based on clinical evidence available at the time of vaccine availability should be prioritized for COVID-19 immunization. Vaccination of key populations and the entire at-risk population are not mutually exclusive and timing may overlap. A sequential approach cannot be determined until final vaccine characteristics, results of clinical trials and the number of available doses are known. The specific key populations that are prioritized for vaccination may change as the evidence base for COVID-19 (e.g., epidemiology, transmission dynamics) and vaccine characteristics (e.g., immunogenicity, safety, efficacy, effectiveness in preventing severe illness and interruption of transmission in different populations), as well as information on vaccine supply, evolves.

The sequencing of populations for vaccination and sub-prioritization within these populations will be based on the following:

- A population-based risk-benefit analysis taking into consideration risk of exposure, risk of transmission to others, risk of severe illness and death, and the safety and effectiveness of vaccine(s) in key populations
- Vaccine supply (number of available vaccine types, number and timing of available doses, number of doses required)
- COVID-19 epidemic conditions when the vaccine(s) become(s) available

Key populations include:

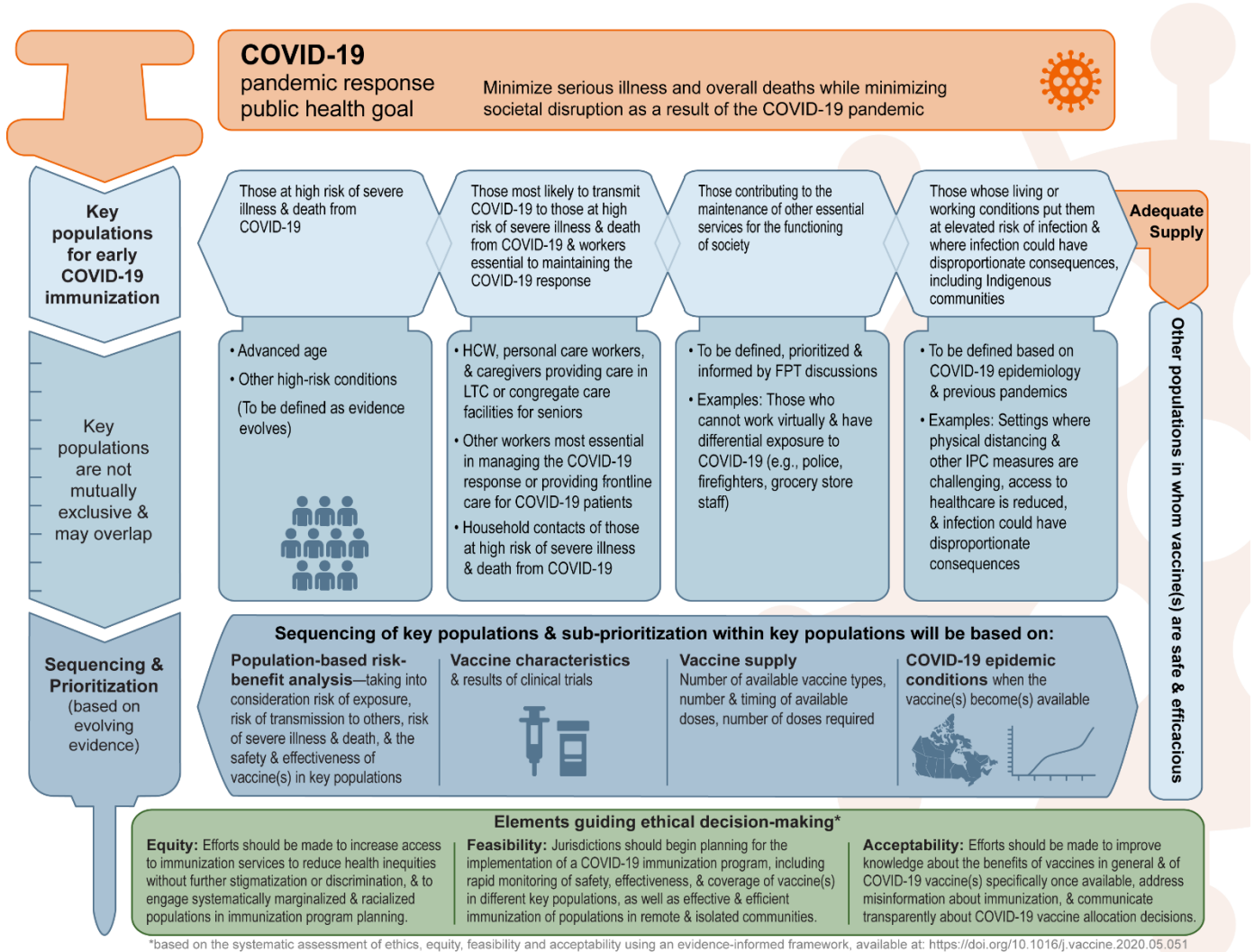
- **Those at high risk of severe illness and death from COVID-19**
 - Advanced age
 - Other high-risk conditions (to be defined as the evidence base evolves)
- **Those most likely to transmit COVID-19 to those at high risk of severe illness and death from COVID-19 and workers essential to maintaining the COVID-19 response**
 - Healthcare workers, personal care workers, and caregivers providing care in long-term care facilities, or other congregate care facilities for seniors
 - Other workers most essential in managing the COVID-19 response or providing frontline care for COVID-19 patients
 - Household contacts of those at high-risk of severe illness and death from COVID-19
- **Those contributing to the maintenance of other essential services for the functioning of society**
 - To be defined, prioritized and informed by federal/provincial/territorial (FPT) discussions
 - Examples: those who cannot work virtually and have differential exposure to COVID-19 (e.g., police, firefighters, grocery store staff)
- **Those whose living or working conditions put them at elevated risk of infection and where infection could have disproportionate consequences, including Indigenous communities**
 - To be defined based on COVID-19 epidemiology and previous pandemic experience
 - Examples: settings where physical distancing and other infection prevention and control measures are challenging, access to healthcare infrastructure is reduced, and infection could have disproportionate consequences

Other considerations for public health program level decision-making

- Efforts should be made to increase access to immunization services to reduce health inequities without further stigmatization or discrimination, and to engage systemically marginalized populations and racialized populations in immunization program planning.
- Jurisdictions should begin planning for the implementation of a COVID-19 immunization program, including close and rapid monitoring of safety, effectiveness, and coverage of the vaccine(s) in different key populations, as well as effective and efficient immunization of populations in remote and isolated communities.
- Efforts should be made to improve knowledge about the benefits of vaccines in general and of COVID-19 vaccine(s) specifically once available, address misinformation about immunization, and communicate transparently about COVID-19 vaccine allocation decisions.

Figure 1 summarizes NACI's interim recommendations on key populations for early COVID-19 immunization for public health program level decision-making.

Figure 1. Summary of the preliminary NACI recommendations on key populations for early COVID-19 immunization



Abbreviations: HCW (healthcare workers), LTC (long-term care), FPT (Federal/Provincial/Territorial), IPC (infection prevention and control)

I. INTRODUCTION

The novel coronavirus disease 2019 (COVID-19) pandemic, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is ongoing. It was declared a pandemic by the World Health Organization (WHO) on March 11, 2020. The pandemic has caused significant morbidity and mortality, as well as social and economic disruption worldwide.

The goal of Canada's pandemic response is to minimize serious illness and overall deaths while minimizing societal disruption as a result of the COVID-19 pandemic.

Clinical trials of candidate COVID-19 vaccines are currently underway. The National Advisory Committee on Immunization (NACI) has developed [guidance on the research priorities for these clinical trials to support public health decisions](#) ⁽⁴⁾. Initial supplies of prospective COVID-19 vaccines are not expected to be sufficient to meet the demand for immunization. Therefore, recommendations are needed on key populations for early immunization.

Guidance objective

The objective of this advisory committee statement is to provide preliminary guidance to plan for the efficient, effective, and equitable allocation of an eventual COVID-19 vaccine when limited initial vaccine supply will necessitate the immunization of some populations earlier than others.

In order to support this objective, the advisory committee statement will:

1. Summarize the current COVID-19 vaccine landscape;
2. Present the results of a rapid review on risk factors for severe COVID-19 ⁽¹⁾;
3. Present the results of an expert stakeholder survey ranking the relative importance of COVID-19 pandemic immunization strategies for different pandemic scenarios ⁽²⁾;
4. Apply the evidence-informed tools (Ethics Integrated Filters, Equity Matrix, Feasibility Matrix, Acceptability Matrix) of NACI's Ethics, Equity, Feasibility and Acceptability (EEFA) Framework ⁽³⁾, and finally;
5. Present key populations prioritized for early COVID-19 immunization to best achieve Canada's pandemic response public health goal when initial vaccine supply is limited, based on the above.

NACI acknowledges that at the time of the development of this statement many uncertainties remain about COVID-19, potential COVID-19 vaccine(s), and therapeutics for COVID-19, as well as what the epidemiology and vaccine supply will be at the time of initial COVID-19 vaccine availability. This guidance is based on the evidence available at the time of NACI deliberations, along with expert and stakeholder opinion. NACI will provide further guidance when additional information on vaccine-specific characteristics (e.g., efficacy, immunogenicity, safety, effectiveness to prevent severe disease or interrupt transmission) in different populations (e.g., age groups, those with underlying medical conditions) becomes available. NACI will continue to monitor the evidence as it evolves.

II. METHODS

This advisory committee statement will aim to address the following policy question:

- Assuming constrained early supply for COVID-19 vaccine(s) in Canada, which populations should be prioritized for early doses of vaccine?

To develop these recommendations over the summer of 2020, NACI reviewed available epidemiological summaries from national analyses of federal/provincial/territorial (FPT) surveillance data reported to the Public Health Agency of Canada (PHAC) ⁽⁵⁾; summaries of the COVID-19 vaccine product landscape from clinical trial registry data; and the Vaccine Annex of the Canadian Pandemic Influenza Preparedness: Planning Guidance for the Health Sector ⁽⁶⁾. In addition:

1. The NACI Secretariat conducted an environmental scan of international guidance on prioritization of key populations for initial COVID-19 immunization.
2. The NACI Secretariat conducted a national survey of expert stakeholders between July 22 and August 14, 2020 to establish a comprehensive perspective on the relative importance of pandemic immunization strategies under four different pandemic scenarios at the time of initial COVID-19 vaccine availability. Full methodological details and results can be found in the preprint ⁽²⁾.
3. The Alberta Research Centre for Health Evidence (ARCHE) was commissioned to conduct a rapid review of risk factors for severe COVID-19 (literature search carried out on June 15, 2020). Full methodological details and results can be found in the preprint ⁽¹⁾. An updated evidence synthesis will be carried out at a later date.
4. The NACI Secretariat applied NACI's EEFA Framework ⁽³⁾ with accompanying evidence-informed tools (Ethics Integrated Filters, Equity Matrix, Feasibility Matrix, Acceptability Matrix) to systematically consider these programmatic factors for the development of clear, comprehensive, appropriate recommendations for timely, transparent decision-making. For details on the development and application of NACI's EEFA Framework and evidence-informed tools (including the Ethics Integrated Filters, Equity Matrix, Feasibility Matrix, and Acceptability Matrix), please see <https://doi.org/10.1016/j.vaccine.2020.05.051>

As per the published process for the application of this Framework (see Appendix A), experts and stakeholder groups (e.g., Public Health Ethics Consultative Group, First Nations and Inuit Health Branch [FNIHB], Indigenous Services Canada, and other [NACI liaison and ex-officio organisations](#)) were consulted. The following FPT committees were consulted during the development of this statement: Canadian Immunization Committee (CIC), the [Pan-Canadian Public Health Network's Special Advisory Committee on COVID-19](#) (SAC), and SAC's Technical Advisory Committee. The Sex and Gender Based Analysis Plus (SGBA+) network with the Social Determinants of Health Division at PHAC also reviewed this guidance. The CIC, FNIHB, and PHAC's vaccine supply manager discussed the feasibility of proposed immunization strategies and validated the Feasibility Matrix. Emerging acceptability data related to COVID-19 vaccines were sought and included in the Acceptability Matrix. See Section IV for further details.

Available evidence was presented to the NACI High Consequence Infectious Disease Working Group (HCID WG) on July 24, 2020, and to NACI on August 13, 2020. NACI deliberated on the cumulative evidence and proposed recommendations on August 20, 2020, provided feedback through to September 1, 2020, and approved the revised recommendations on September 16, 2020.

Further information on NACI's process and procedures can be found elsewhere ⁽⁷⁾.

III. VACCINE(S)

III.1 Current COVID-19 vaccine landscape

Global efforts are underway to develop a COVID-19 vaccine and work is progressing at an unprecedented pace. The Government of Canada is reviewing regulatory pathways to help expedite access to safe and effective vaccine for Canadians.

As of August 5, 2020, there are over 130 candidate COVID-19 vaccines at different stages of development by academia and industry. Many candidates have shown promise to enter into human clinical trials, 15 Phase 1 clinical trials have been registered, 23 Phase 2 clinical trials have been registered, and five Phase 3 clinical trials are underway or planned to start. Phase 3 clinical trials have been started in the United Kingdom (UK), the United States (US), Brazil, and the United Arab Emirates with results expected in late 2020 or in early 2021 (e.g., University of Oxford/AstraZeneca, Moderna, Sinopharm, Sinovac). More than one vaccine developer plans to start clinical trials in Canada. As of September 4, 2020, one vaccine developer has already begun Phase 1 clinical trials and several others are expected to advance to that stage in the coming months.

The current landscape of candidate COVID-19 vaccines in clinical evaluation can be found at: <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>

III.2 Summary of vaccine clinical development

Most of the trials in Phase 1 of clinical development are assessing the safety of vaccines in healthy adults 18 to 49 years of age without underlying health conditions. Due to the high burden of COVID-19 in older adult populations, some Phase 1 studies have expanded age ranges to include older adult populations. In later stages of clinical development (Phases 2 and 3), some vulnerable and at-risk populations (including people who are HIV+ and adults over 65 years of age) are included in study recruitment. Both established and experimental vaccine technologies, including nucleic acid (mRNA and DNA), vectored (viral and bacterial vectors), subunit (protein and glycan), particles (nanoparticles and virus-like-particles), inactivated virus vaccines, and prophylactic immune products (antibodies and sera) are being explored. Vaccine candidates are administered via different routes of administration, including intramuscular, intradermal (and electroporation), oral, and subcutaneous. Schedules of candidate vaccines range between one and three doses.

III.3 Canadian vaccine access

The unprecedented nature of this pandemic and vaccine development efforts has led to a highly competitive global landscape of vaccine access. As of October 27, 2020, seven suppliers of promising vaccine candidates have committed to supply Canada with vaccine to cover a portion of or the entire Canadian population. Three of these have submitted for regulatory authorisation by Health Canada under a rolling submission. It is still to be determined if these vaccines will be safe, efficacious, authorized in Canada, or be recommended by NACI.

IV. ETHICS, EQUITY, FEASIBILITY AND ACCEPTABILITY CONSIDERATIONS

The EEFA Framework ⁽³⁾ facilitates the systematic consideration of factors critical for comprehensive immunization program decision-making and successful implementation of recommendations. The use of the EEFA Framework empowers the committee to review and balance all of the available evidence and transparently summarize their rationale for appropriate, timely recommendations. The evidence informed tools associated with the framework (Ethics Integrated Filters, Equity Matrix, Feasibility Matrix, Acceptability Matrix; see Appendices B–F) ensure that issues related to EEFA of expert committee guidance are adequately integrated. NACI followed the process outlined in the algorithm for applying the EEFA Framework (Appendix A) to this guidance.

IV.1 Ethics considerations

NACI used the [Public health ethics framework: A guide for use in response to the COVID-19 pandemic in Canada](#) ⁽⁶⁾ to support ethics deliberation and decision-making. NACI's Ethics Integrated Filters for core ethical dimensions (respect for persons and communities, beneficence and non-maleficence, justice, trust) and procedural ethical dimensions (accountability, inclusiveness, responsibility, responsiveness, transparency) were applied to this guidance document, and are summarized in Appendices B and C. An in-depth ethics analysis was conducted to analyse and weigh relative considerations and assess options for prioritization of COVID-19 immunization in the face of an uncertain pandemic vaccine supply.

NACI upheld the following core ethical principles:

1. Respect for persons and communities

In order to respect the right to exercise informed choice, NACI has reviewed the evidence to date and summarized it for stakeholders throughout this guidance document. The values and preferences of persons and communities have been considered through the national expert stakeholder survey ranking the relative importance of pandemic immunization strategies ⁽²⁾, as well as evidence available to date on the acceptability of COVID-19 vaccines in various populations in Canada (summarized in Section IV.4). Extensive consultations were conducted in the development of this guidance (summarized in Section II).

2. Beneficence and non-maleficence

NACI considered evidence for minimizing the risk of harm and maximizing benefits for all potential key populations in their deliberations. As information about vaccine characteristics (including safety and efficacy in different populations) becomes available, the principles of **proportionality**

(measures should be proportionate to the level of risk and benefits gained), **effectiveness** (reasonable likelihood that the action will achieve the goals and will be feasible), and **precaution** (take prudent action in the face of scientific uncertainty) will be applied. NACI has previously recommended that individuals with potential biological, social, and occupational vulnerabilities to COVID-19 be included in vaccine clinical trial groups ⁽⁴⁾. However, in the absence of direct data in populations at high risk of severe illness and death due to COVID-19 (e.g., due to age or underlying medical conditions), NACI will consider the principles of proportionality, effectiveness, and precaution, and conduct an in-depth ethics analysis before making specific recommendations. Immunization strategies aimed at protecting healthcare capacity and other services essential for the functioning of society uphold the principle of **reciprocity**, as they aim to minimize the disproportionate burden faced by those taking on additional risks to protect the public. The public also benefits from the ongoing work of those who provide these services and could potentially benefit from reduced transmission from frontline workers, which aligns with the principle of beneficence.

3. Justice

Treating people and groups with equal concern and respect entails setting and applying prioritization criteria fairly, considering the needs of those most at risk of exposure or of severe disease, and weighing risks of furthering inequities, stigmatization, and discrimination. NACI reviewed special considerations for vulnerability of those most at risk through its application of the Equity Matrix (Appendix D), a rapid review of risk factors for severe COVID-19 ⁽¹⁾, as well as a review of disease epidemiology in Canada ⁽⁵⁾. NACI also considered evidence concerning other factors, such as systemic marginalization of groups with differential disease severity and differential access to healthcare, as well as the demonstrated potential for reduced exposure among healthcare workers with increased training in and access to personal protective equipment (PPE) and other infection prevention and control (IPC) measures ^(9,10). In the face of uncertainties about the disease and vaccine with resulting challenges in program planning for an eventual COVID-19 vaccine, and in consultation with jurisdictions and vaccine supply experts, NACI considered the principle of distributive justice with the application of the Feasibility Matrix (Appendix E). The systematic assessment of all of these factors informed NACI's recommendations for the fair and equitable allocation of limited COVID-19 vaccine supply.

4. Trust

Reliability and integrity of guidance must be maintained for trust in this and other immunization programs. Expedited regulatory reviews of COVID-19 vaccines and evolving evidence about the disease may have an impact on the trust of the public in this immunization program and their perception of risks associated with these vaccines. NACI followed its established methodology, standard operating procedures (SOP), and conflict of interest guidelines ⁽⁷⁾ in the context of this expedited review to ensure a robust analysis of evidence and to maintain stakeholder trust. This guidance is based on the best, current evidence available for all groups at risk of COVID-19, with transparency about knowns and unknowns, as well as certainty of evidence. NACI will monitor the evidence with revision of guidance as necessary. To maintain trust among stakeholders, NACI has upheld ethical procedural considerations (accountability, inclusiveness, responsibility, responsiveness, and transparency) with the tools and procedures as summarized in Appendix C.

NACI acknowledges the risk that there could be a perception of conflict of interest, and a resulting loss of trust, when expert groups of healthcare professionals are making recommendations on the prioritization of immunization strategies involving health care workers and personnel. NACI also acknowledges that trust may be eroded if healthcare professionals are not included in a

priority group for earlier immunization with a novel vaccine. To maintain trust, reliability, integrity, and a mutually fair relationship with individuals and communities, NACI applied the Ethics Integrated Filters described above (Appendices B and C), made recommendations based on the evidence transparently summarized in this document, and considered a wide range of stakeholder views (including patient and community advocates) through an expert stakeholder survey ⁽²⁾, as well as the views of the general public through public opinion research ⁽¹¹⁾ when developing this guidance.

IV.2 Equity considerations

NACI reviewed the epidemiology of COVID-19 in Canada ⁽⁵⁾ and the results of the rapid review of risk factors for severe COVID-19 ⁽¹⁾ (summarized in Section IV.2.1) to identify distinct inequities associated with COVID-19, potential reasons for these inequities, and suggested interventions to reduce inequities and improve access to vaccine when it becomes available. The results of this analysis are summarized in the Equity Matrix (Appendix D).

IV.2.1 Factors contributing to severe COVID-19: results of a rapid review of risk factors

A rapid review was conducted by ARCHE to examine the magnitude of association between factors that may contribute to health inequity (summarized by the acronym “P²ROGRESS And Other Factors” in NACI’s Equity Matrix, Appendix D) and severe COVID-19. The HCID WG decided on the primary outcomes, settings, and populations of interest and the protocol was registered in PROSPERO (CRD42020198001). Full details of the rapid review methodology and findings can be found in the preprint ⁽¹⁾.

Literature searches were conducted on June 15, 2020 in the following bibliographic databases: Medline, Epistimonikos COVID-19 in LOVE Platform, and McMaster COVID-19 Evidence Alerts. The following inclusion criteria were used: studies from the Organisation for Economic Co-operation and Development (OECD) countries, published (vs. preprints), and using multivariate analysis to report on the independent contribution of each risk factor while accounting for confounders such as age, sex, race/ethnicity, socioeconomic status, and comorbidities. Populations included a general/community sample, people with confirmed COVID-19, and people hospitalized with COVID-19 (studies were excluded if all patients were in the intensive care unit (ICU) or were in a treatment study). Outcomes of interest included hospitalization and length of stay, severe disease (as defined by study authors) and mortality. The risk of bias/quality of each study was assessed, accounting for the extent of adjustment, follow-up duration/extent of censorship for length of stay and mortality, and inappropriate or large exclusions from the study and/or analysis.

No meta-analysis was conducted. For each risk factor and outcome, findings were assessed across studies in terms of the estimated magnitude of associations (i.e., “not important/not large” [e.g., odds ratio (OR) <1.7], moderate [OR ≥1.7 to 1.99], important/large [OR ≥2.0], very large [OR ≥5.0], and the review team’s confidence in the magnitude of association based on the number, size and consistency between studies and the risk of bias. Varying confidence in the associations is referred to using the terms “uncertain” (no/very low), “may” (low/some), and “probably” (moderate).

A total of 34 published studies were included, although three from the UK had overlapping populations and another UK study is likely to overlap but the degree of overlap is unknown.

Studies were conducted in the US (n=17), Italy (n=9), the UK (n=7 using 5 populations), and across multiple countries (n=1). Sample sizes ranged from 44 to 418,794 (median 596) and mean age in most studies was 54 to 71 years. The majority of studies (n=19; 56%) were rated low risk of bias.

None of the associations had a high level of certainty of evidence. There was low or moderate certainty of evidence for large/important associations (OR or risk ratio [RR]) with increased risk of hospitalization in people having confirmed COVID-19 for the following risk factors: obesity class III (body mass index [BMI] ≥ 40 kg/m²), heart failure, diabetes, chronic kidney disease, dementia, age (particularly over 70 years vs. 45 years or younger), male sex, Black race/ethnicity (vs. non-Hispanic white), homelessness, and low income (<25th vs. >50th percentile). Evidence that age over 70 years may be associated with important increases in the rate of severe disease was considered to be of moderate certainty. Risk factors that have large/important and very large important associations with hospitalization and mortality are presented in Table 1.

Table 1. Risk factors identified through a rapid review that have large/important (++) or very large/important (+++) associations with severe COVID-19 outcomes and the corresponding level of confidence in the association

Risk factor	Outcome of interest	Magnitude of risk * (confidence in association **)
Age		
>80 vs. ≤ 45 years	Hospitalization	+++ (low)
	Mortality	+++ (low)
>70 vs. ≤ 45 years	Hospitalization	+++ (moderate)
	Mortality	+++ (moderate)
>60 vs. ≤ 45 years	Hospitalization	++/+++ (moderate/low)
	Mortality	++/+++ (moderate/low)
50–64 vs. ≤ 45 years	Hospitalization	++ (moderate)
	Mortality	++ (moderate)
45–54 vs. ≤ 45 years	Hospitalization	++ (moderate)
	Mortality	++ (low)
Pre-existing conditions		
Obesity (BMI ≥ 40)	Hospitalization	++ (low)
Heart failure	Hospitalization	++ (low)
Diabetes	Hospitalization	++ (low)
Liver disease	Mortality	++ (low)
Chronic kidney disease	Hospitalization	++ (low)
Alzheimer disease or dementia	Hospitalization	++ (low)
Sex		
Male vs. female	Hospitalization	++ (moderate)
Race/ethnicity		
Black vs. non-Hispanic white	Hospitalization	++ (low)
Asian (Bangladeshi) vs. British white	Mortality	++ (low)
Place of residence		
Homeless vs. has a home	Hospitalization	++ (low)
Socioeconomic status		

Income $\leq 25^{\text{th}}$ vs. $> 50^{\text{th}}$ or 75^{th} percentile	Hospitalization	++ (low)
------------------------------------------------------------------------------------	-----------------	----------

* Magnitude of associations are shown as large/important (++; OR or RR ≥ 2.00) or very large important association (+++; OR or RR ≥ 5.00).

** A formal assessment of the quality/confidence of the evidence was not performed but was informed by the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) approach. Confidence in the magnitude of the associations was determined by considering primarily study limitations (risk of bias), consistency in findings across studies, and precision (sample size). Low confidence indicates that there may be an association and moderate means that the evidence indicates that there probably is an association.

For mortality, important associations with increased risk may exist for liver disease, Bangladeshi ethnicity (vs. British white), and age particularly if over 70 years (vs. < 45 years). The data were somewhat inconsistent for sex, with most studies showing moderate certainty of no important effect. One study directly compared subgroups of older adults, showing that compared to those aged 65–69 years, there may be no important increased risk of mortality among hospitalized adults aged 70–79 years, but risk may increase about 2-fold for those 80 years and older. Studies treating age on a continuum or across small increments consistently found that risks for hospitalization and mortality increased with increasing age (e.g., approximately 2–6% and 5–10% relative increase in risk per year).

Moderate association with low level of confidence may exist for increased risk of hospitalization with obesity (BMI ≥ 30 or 40 kg/m^2); severe disease with heart failure; mortality with hematological malignancy; and hospitalization with social deprivation (lowest vs. highest quintile).

There was moderate certainty evidence for no important increase in risk of hospitalization with chronic respiratory conditions, cardiovascular disease (i.e., coronary artery disease, hypertension, hyperlipidaemia) apart from heart failure, non-specific cancer, Asian race/ethnicity other than Bangladeshi (vs. non-Hispanic white), and current or former smoking. Additionally, there was moderate certainty evidence for no important increase in severe disease (as defined by each study) with chronic respiratory conditions, chronic kidney disease, nonspecific cancer, and Black race/ethnicity (vs. non-Hispanic white) and no important increase in risk of mortality with obesity (BMI $\geq 30 \text{ kg/m}^2$), chronic respiratory conditions, diabetes, chronic kidney disease, nonspecific cancer, male sex, Black or Asian race/ethnicity (vs. non-Hispanic white), and social deprivation (lowest vs. highest quintile).

In the rapid review, data for immunocompromised patients (specifically rheumatic disease and HIV) were limited by small studies and no conclusions could be drawn about the magnitude and certainty of the associations. Further, no studies on pregnancy met the publication date and eligibility criteria.

Generalization of findings from other countries to Canada should be made with caution, as high-risk groups may differ by population. Furthermore, because of differences in methodology, the list of important risk factors identified in this rapid review may differ from other sources. Updated evidence syntheses will inform future NACI decisions.

IV.3 Feasibility considerations

NACI recognizes that there are a number of challenges to the feasible implementation of a COVID-19 immunization program due, in part, to the uncertainties around vaccine characteristics

(e.g., indications, adverse events) and supply, as well as the novel nature of the disease and vaccine(s). Issues around the vaccine and the immunization program with respect to resources (e.g., vaccine and immunization supplies including storage and dissemination of new vaccine technologies in different vaccine delivery venues; human resources for administration of vaccine, communication, training, data entry, screening for COVID-19, operational planning, etc.) as well as integration with existing programs (e.g., registries, surveillance, adverse event following immunization (AEFI) reporting) abound. Close and rapid monitoring of safety, effectiveness, and coverage of the vaccine(s) in potentially different key populations will be critical.

To assist jurisdictions with the planning of a potential COVID-19 immunization program, jurisdictions may refer to the Feasibility Matrix (Appendix E), summarizing potential issues with implementing a COVID-19 immunization program. These issues apply to immunization in any population. Jurisdictions may also wish to refer to the [Interim guidance on continuity of immunization programs during the COVID-19 pandemic](#) ⁽¹²⁾ to minimize disruption to existing immunization programs.

The feasibility of immunizing different populations will vary with the size of the population to be immunized, vaccine characteristics in the population, and vaccine supply, among other considerations. Sub-prioritization or sequencing within key populations may be necessary, either initially and/or gradually.

In some Indigenous communities, crowded multi-generational living makes segregation of at-risk groups challenging, and precarious supply chain, infrastructure, and health systems are vulnerable to critical disruption. In these cases, there may be value in implementing multiple strategies concurrently and completely immunizing entire communities where relatively small quantities of vaccine are needed to achieve the pandemic response goal.

IV.4 Acceptability considerations

In alignment with the ethical principle of respect for persons and communities, the values and preferences of a range of stakeholders, including experts, patient/community advocates, and the general public were considered. Factors influencing acceptability of a COVID-19 vaccine are summarized using the Acceptability Matrix (Appendix E).

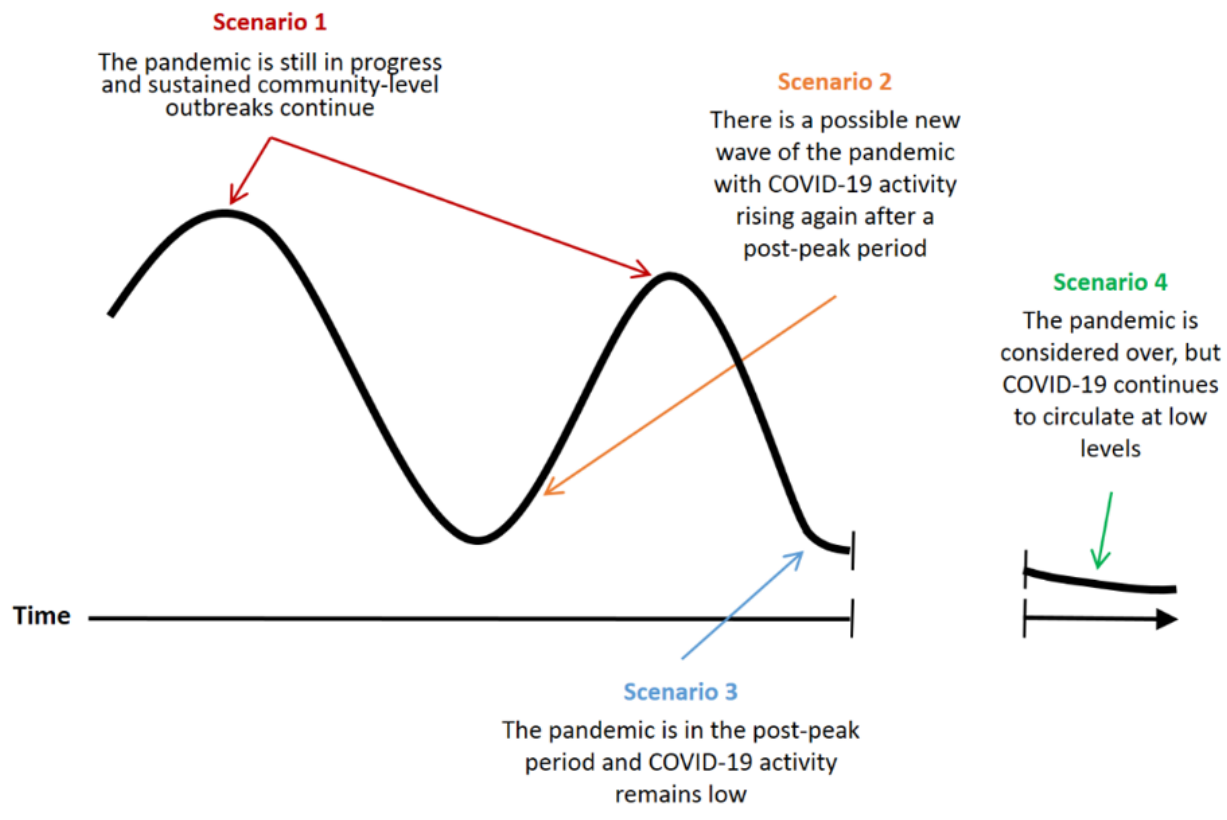
IV.4.1 Results of an expert stakeholder survey on COVID-19 immunization strategies

A PHAC-led survey was conducted to establish a preliminary expert stakeholder perspective on the relative importance of pandemic immunization strategies for different COVID-19 pandemic scenarios at the time of initial COVID-19 vaccine availability. These pandemic scenarios are visualized along a hypothetical pandemic curve in Figure 2. Scenario 4 was further delineated in the survey into two sub-scenarios where the vaccine or previous infection provides or does not provide long-term protection against COVID-19. Full methodology and results of the survey can be found in the preprint ⁽²⁾.

The survey was comprised of five questions that asked the respondent to rank, in order of importance with a rank of “1” being the most important, four COVID-19 pandemic immunization strategies (proposed by PHAC staff with input from the HCID WG) plus an optional respondent-specified strategy for each pandemic scenario. The respondents were asked to assume that the

COVID-19 vaccine is in limited supply for each scenario and that the COVID-19 vaccine is safe and efficacious for all populations for the purposes of the survey.

Figure 2. Pandemic scenarios at the time of initial COVID-19 vaccine availability plotted along a hypothetical pandemic curve



Expert stakeholders were identified through consultations within PHAC and with the HCID WG. These stakeholders included members of clinical and public health expert groups involved with PHAC, members of provincial and territorial committees and representatives from national Indigenous groups, patient and community advocacy representatives and experts from the CanCOVID network (<https://cancovid.ca/>), executives of Canadian health professional associations, and representatives of other federal government departments. An invitation to complete the survey, which was provided as a Word document in English and French, was sent by email to stakeholders in a format that facilitated shared review and discussion within their respective organisations. Members of expert groups (e.g., NACI) each provided individual expert responses, whereas organisational or provincial/territorial representatives each provided a single response on behalf of their organisation or jurisdiction.

The survey was conducted between July 22 and August 14, 2020. Survey results were analyzed using descriptive statistics across all respondents to identify overall trends and by stakeholder group to assess for any differences in prioritization among stakeholder groups. Trends in the

rankings for each pandemic scenario were assessed by descriptive analysis in two ways: taking the average (mean, median, and mode) ranking and comparing the percentage of each ranking contributing to the total for COVID-19 pandemic immunization strategies for different pandemic scenarios at the time of initial COVID-19 vaccine availability.

Of 156 stakeholders contacted, 74 surveys were completed for a participation rate of 47.4%. A total of 22 (29.7%) respondents were members of clinical or public health expert groups involved with PHAC, 19 (25.7%) were patient or community advocacy representatives or experts from the CanCOVID network, 16 (21.6%) were executives of Canadian health professional associations, nine (12.2%) were members of provincial and territorial committees or national Indigenous groups, and eight (10.8%) were representatives of federal government departments.

For all pandemic scenarios, both descriptive analysis approaches showed that stakeholders generally ranked the strategies in the following order from most to least important:

1. Protect those who are most vulnerable to severe illness and death from COVID-19
2. Protect healthcare capacity
3. Minimize transmission of COVID-19
4. Protect critical infrastructure

In subgroup analysis by stakeholder group, the trends were less clear due to smaller sample sizes, but the strategy to protect those who are most vulnerable to severe illness and death from COVID-19 remained the most important in all groups and scenarios.

IV.4.2 Results of surveys of the general Canadian public on COVID-19 immunization

Canada's COVID-19 Snapshot Monitoring Study (COSMO Canada) is a longitudinal study led by Impact Canada in collaboration with the Public Opinion Research Team within the Privy Council Office that began in April 2020 and continued through September 2020 in eight waves ⁽¹¹⁾. This online survey leverages a tool developed by the WHO to monitor knowledge, risk perceptions, and behaviour related to COVID-19, is adapted wave-to-wave in consultation with an external academic advisory committee, and collects data from a representative sample of approximately 2000 Canadians. NACI considered the most up-to-date results of this survey (up to wave 7, conducted between August 13 and 17, 2020) ^(13,14) and populated the Acceptability Matrix (Appendix F) to inform its guidance.

NACI acknowledges that survey data on intent to receive a vaccine can fluctuate, especially in the context of uncertainty about possible COVID-19 vaccines. NACI will continue to monitor data from the remaining wave of the COSMO study, as well as another study assessing acceptability of COVID-19 and other vaccines among Canadians, planned in the coming months.

Which immunization strategies do Canadians prioritize if COVID-19 vaccine supply is limited?

Wave 7 of the COSMO Canada survey asked respondents to prioritize the same immunization strategies that expert stakeholders were asked to rank in order of importance in the context of limited initial COVID-19 vaccine supply (see Section IV.4.1). A majority of these respondents prioritized protecting those most vulnerable (51%), followed by protecting healthcare capacity (28%), minimizing the spread (15%), and protecting critical infrastructure (5%) ⁽¹⁴⁾. The opinions

of respondents from the general public on priority immunization strategies are consistent with those of expert stakeholders surveyed.

Which populations do Canadians prioritize to receive COVID-19 vaccine if supply is limited?

Three-quarters of COSMO Canada respondents (76% in wave 6 and 78% in wave 7) agree that specific groups should be first to get a safe and effective COVID-19 vaccine in the context of limited initial supplies^(13,14). In response to an open ended question in wave 6 asking which group should get the vaccine first, the most commonly identified populations for priority immunization included those with underlying medical conditions (57%), the elderly (53%), healthcare workers (22%), and frontline/essential workers^a (18%). Although endorsed less frequently, respondents also identified children (9%), long-term care/nursing homes (3%), and hospitalized/ill individuals (2%), as other populations that should receive the vaccine first should there be a shortage⁽¹³⁾. When asked to rank a pre-determined list of groups to be prioritized to receive a COVID-19 vaccine before others in wave 7 of the survey, the most commonly identified group for priority immunization was healthcare workers (40%), followed by individuals with high risk medical conditions (19%), frontline workers (16%), seniors (12%), long-term care/nursing homes (10%), and children (2%)⁽¹⁴⁾.

The majority of respondents (87%) to an Angus Reid Institute online survey about COVID-19 in July 2020 of a representative sample of 1,519 Canadian adults agreed that “it is vital that people with chronic health conditions, such as asthma or diabetes, get vaccinated”⁽¹⁵⁾.

Does a high level of acceptability for a COVID-19 vaccine exist?

Almost two-thirds of COSMO Canada respondents (61%) in August 2020 were willing to get an effective recommended COVID-19 vaccine⁽¹⁴⁾. This has decreased from 71% in April. While willingness to get an effective recommended vaccine has decreased among all age groups surveyed, older Canadian respondents (aged 55 years of age and older) are significantly more willing to get immunized than younger Canadian respondents (72% in >54 year olds vs. 57% in 35–54 year olds and 51% in 18–34 year olds; $p < 0.05$). Respondents 35 years and older with a “serious, long-term illness” are somewhat more willing to get an effective recommended vaccine compared to those without (68% vs. 62%). This was not observed in younger individuals 18 to 34 years old with a “serious, long-term illness” compared to those without (43% vs 57%). Non-visible minorities are more willing than visible minorities or Indigenous respondents to get an effective recommended vaccine (63% vs. 53% vs. 43%, respectively; $p < 0.05$). About half of workers in frontline occupations such as grocery and gas station staff (51% vs. 63% for non-frontline workers; $p < 0.05$) and healthcare providers (55% vs. 62% for non-healthcare workers; $p > 0.05$) would get an effective recommended vaccine. Willingness to receive an effective COVID-19 vaccine does not seem to be significantly influenced by socioeconomic status or sex⁽¹⁴⁾.

The findings from the COSMO Canada study are similar to results from other Canadian surveys. The Canadian Perspectives Survey Series 3 (CPSS3) in June 2020 (survey sample is

^a Open ended responses including: frontline workers, first/ emergency responders (police, firefighters, paramedics), essential workers, teachers, service field workers who deal with the general public, grocery store and transit workers, people who keep lights on, those at high risk of exposure due to their job (restaurant servers), airline cabin staff, long haul truckers and those involved in maintaining the supply chain

representative of the Canadian population living in the ten provinces) found that approximately three-quarters of Canadians were either very likely (57.5%) or somewhat likely (19.0%) to get a COVID-19 vaccine when it becomes available ⁽¹⁶⁾. The largest differences in intent to get a COVID-19 vaccine were observed across age groups and education levels. Significantly more Canadians 65 years and older reported being very likely to get a COVID-19 vaccine than those aged 15–64 (70% vs. 52–58%; $p < 0.05$). Respondents with a university degree higher than a bachelor's degree were significantly more likely to report being very likely to get a COVID-19 vaccine (73% vs. 53% of those with a trades or university certificate below a bachelor's degree; $p < 0.05$). The Angus Reid Institute online survey in July 2020 found that 46% of respondents would get a coronavirus vaccine as soon as one became available, but 32% would wait a while first ⁽¹⁵⁾.

What factors affect acceptability of immunization with a COVID-19 vaccine?

The most reported reasons for unwillingness to get a COVID-19 vaccine in wave 7 of the COSMO Canada survey included insufficient research or testing of the vaccine (32%), concerns about vaccine safety or effectiveness (26%), and a lack of trust in the newness of the vaccine (13%) ⁽¹⁴⁾. The top two reasons selected by respondents to the CPSS3 survey who were hesitant to get a COVID-19 vaccine also related to concerns about safety (54% cited a lack of confidence in the safety of the vaccine and 52% were concerned about its risks and side effects; respondents could select more than one response) ⁽¹⁶⁾. Similarly, the majority of respondents to the Angus Reid Institute survey who would wait to get a COVID-19 vaccine reported that they are worried about side effects (76%), and 61% of respondents overall shared concerns about vaccine safety ⁽¹⁵⁾.

Results from the Angus Reid Institute survey reveal that key factors for those willing to be immunized include trust in doctors (84% agree that “we should listen to doctors who recommend vaccines”), and a desire to protect their families (82% agree that they would “get a vaccine to protect my family”) ⁽¹⁵⁾. Only 23% were concerned about getting infected with the coronavirus from a vaccine and only 23% believe a coronavirus vaccine will not be effective. Only a small minority (9%) agree that they will not have time to get a COVID-19 vaccine.

According to this poll, the majority of Canadians support mandatory immunization for healthcare workers (76%), extended care homes (76%), schools (63%), and workplaces such as offices and restaurants (52%) ⁽¹⁵⁾.

What factors affect acceptability of immunization in general?

Research conducted to validate NACI's Acceptability Matrix prior to the COVID-19 pandemic revealed multiple factors that affect the acceptability of immunization in general ⁽³⁾. Consistent with what has been found in recent surveys on a potential COVID-19 vaccine, concern about vaccine safety is the main reason for reluctance to vaccinate among Canadians ⁽¹⁷⁾. However, vaccine effectiveness has the largest influence on choice of vaccine between two provided options ⁽¹⁸⁾. Likewise, among high risk groups, perceived safety and effectiveness of a vaccine are linked to increased vaccine acceptability ⁽¹⁷⁾. Perceived risk of disease and a desire to protect oneself and others are also linked to increased vaccine acceptability, as are low cost of vaccine, low time required to be vaccinated, and access to vaccine or a vaccine provider ^(17,18).

In general, receiving a recommendation from, or being in contact with, a healthcare provider is linked to increased vaccine acceptability ⁽¹⁷⁾. However, a lack of familiarity with a vaccine plays a role in reluctance by healthcare providers to recommend it ^(17,18). A recommendation by an expert committee is a notable factor for healthcare providers to recommend a vaccine ⁽¹⁸⁾.

V. RECOMMENDATIONS

The following recommendations are meant to help plan for the efficient, effective, and equitable allocation of an eventual COVID-19 vaccine(s) when limited initial vaccine supply will necessitate recommendations for the immunization of certain groups earlier than others. These recommendations aim to achieve Canada's pandemic response goal: "To minimize serious illness and overall deaths while minimizing societal disruption as a result of the COVID-19 pandemic." Due to anticipated constraints in supply, these NACI recommendations apply to provincial/territorial publicly-funded immunization programs only and not for individuals wishing to prevent COVID-19 with vaccines not included in immunization programs.

The recommendations are informed by evidence available at the time of NACI deliberations summarized in this document, including the results of a rapid review of risk factors for severe COVID-19 ⁽¹⁾, an expert stakeholder survey on the relative importance of pandemic immunization strategies ⁽²⁾, and the systematic assessment of EEFA considerations with the peer-reviewed EEFA Framework ⁽³⁾.

NACI has reviewed the available international guidance on priority groups for COVID-19 immunization at the time of deliberation. The key populations for early COVID-19 immunization identified by NACI have been similarly identified by other national immunization technical advisory groups ^(19,20) and academic groups ^(21,22) in their vaccine prioritization frameworks.

NACI will continue to carefully monitor the evidence related to COVID-19 and COVID-19 vaccine(s) and will update recommendations as evidence evolves.

V.1 Recommendations for public health program level decision-making

Due to anticipated challenges with sufficient supply to meet vaccine demand initially, NACI recommends that key populations in whom vaccine is deemed safe and effective based on evidence available at the time of vaccine availability should be prioritized for COVID-19 immunization. These groups are not mutually exclusive and may overlap. A sequential approach cannot be determined until vaccine characteristics, results of clinical trials, and the number of available doses are known. Key populations may change as the evidence base for COVID-19 and vaccine characteristics, as well as information on vaccine supply, evolves.

Sequencing of key populations and sub-prioritization within key populations will be based on:

- A population-based risk-benefit analysis taking into consideration risk of exposure, risk of transmission to others, risk of severe illness and death, and the safety and effectiveness of vaccine(s) in key populations
- Vaccine supply (number of available vaccine types, number and timing of available doses, number of doses required)
- COVID-19 epidemic conditions when the vaccine(s) become(s) available

Key populations include:➤ **Those at high risk of severe illness and death from COVID-19**

- **Advanced age**
- **Other high-risk conditions (to be determined as the evidence base evolves)**

Summary and rationale with current evidence:

- There are large/important independent associations of severe COVID-19 with increasing age and for certain high-risk health conditions ⁽¹⁾. There is moderate certainty of evidence for a very large/important association of hospitalization and mortality particularly in those over 70 years of age (vs. ≤ 45 years of age) and low certainty of evidence for a large/important association of hospitalization or mortality with certain high risk conditions (see Table 1).
- Current surveillance data in Canada have shown that hospitalization, ICU admission, and death rates from COVID-19 in Canada increase with age, and that persons with certain underlying health conditions are at highest risk of developing more severe illness from COVID-19 ⁽⁵⁾.
- Expert stakeholder groups and patient/community advocates ⁽²⁾, as well as the general Canadian public ⁽¹⁴⁾, rank the relative importance of an immunization strategy to protect those who are most vulnerable to severe illness and death from COVID-19 as #1 in the context of limited vaccine supply.
- Canadians prioritize those with underlying medical conditions (57%) and the elderly (53%) for early immunization if supply of COVID-19 vaccine is limited ⁽¹³⁾.
- Older Canadians are significantly more willing than younger Canadians to get an effective recommended COVID-19 vaccine ^(13,14,16), and those 35 years and older with a “serious long-term illness” are somewhat more willing to get an effective recommended COVID-19 vaccine ^(13,14).

➤ **Those most likely to transmit COVID-19 to those at high risk of severe illness and death from COVID-19 and workers essential to maintaining the COVID-19 response**

- **Healthcare workers, personal care workers, and caregivers providing care in long-term care facilities or other congregate care facilities for seniors**
- **Other workers most essential in managing the COVID-19 response or providing frontline care for COVID-19 patients**
- **Household contacts of those at high-risk of severe illness and death from COVID-19**

Summary and rationale with current evidence:

- In Canada, long-term care facilities have experienced a large number of outbreaks associated with a high number of fatalities ⁽⁵⁾.

- Immunizing healthcare, personal care, and other workers providing frontline care directly protects them from acquisition of COVID-19 and could indirectly protect their patients and healthcare capacity.
- Though frontline healthcare workers and other workers functioning in a healthcare capacity (e.g., providing medical first response) have differential exposure to COVID-19 with potential transmission to high risk individuals, they may have more access to and training in the use of personal protective equipment and other infection prevention and control measures, and so exposure risk could be significantly reduced compared to other groups. Protection against infection with SARS-CoV-2 has been demonstrated in healthcare workers with the use of personal protective equipment ^(9,10).
- Immunizing healthcare workers and other workers functioning in a healthcare capacity minimizes the disproportionate burden of those taking on additional risks to protect the public.
- Absenteeism due to illness or perceived risk of illness from COVID-19 among healthcare workers and other workers most essential in managing the COVID-19 response (e.g. outbreak management, lab testing, immunization) may compromise healthcare capacity and the management of the COVID-19 response.
- Expert stakeholder groups and patient/community advocates ⁽²⁾, as well as the general Canadian public ⁽¹⁴⁾, rank the relative importance of an immunization strategy to protect healthcare capacity as #2 and an immunization strategy to minimize transmission of COVID-19 as #3 in the context of limited vaccine supply.
- 22% of Canadians identify “healthcare workers” as a key population for priority immunization in the case of COVID-19 vaccine shortage ⁽¹³⁾.
- Immunizing those able to transmit COVID-19 to those at high risk of severe illness and death could indirectly protect those at high risk (if vaccine is effective in interrupting transmission), which could be particularly important if vaccine characteristics are not favourable in these populations.

➤ **Those contributing to the maintenance of other essential services for the functioning of society**

Summary and rationale with current evidence:

- Certain individuals who cannot work virtually may have differential exposure to COVID-19 (e.g., police, firefighters, grocery store staff).
- Designations of essential services in the context of the COVID-19 pandemic vary across jurisdictions within Canada. [Guidance on essential services and functions in Canada during the COVID-19 pandemic](#), including lists published by provinces and territories, is available.
- Provinces and territories have expressed a desire for a harmonized approach to vaccine prioritization for essential services. The appropriate FPT health tables will be consulted to discuss prioritization for the purposes of immunization.
- Immunizing this population minimizes the disproportionate burden of those taking on additional risks to maintain services essential for the functioning of society.
- Absenteeism due to illness or perceived risk of illness from COVID-19 among some workers who cannot work virtually may compromise essential services.
- Expert stakeholder groups and patient/community advocates ⁽²⁾, as well as the general Canadian public ⁽¹⁴⁾, rank the relative importance of an immunization strategy to protect critical infrastructure as #4 in the context of limited vaccine supply.

- 18% of Canadians identify “frontline/essential workers” as a key population for priority immunization in the case of COVID-19 vaccine shortage ⁽¹³⁾.

➤ **Those whose living or working conditions put them at elevated risk of infection and where infection could have disproportionate consequences, including Indigenous communities**

Summary and rationale with current evidence:

- In Canada, a high number of COVID-19 outbreaks/clusters in institutions (e.g., correctional facilities), work settings (e.g., agricultural or meat production/packing facilities), and congregate living settings (e.g., shelters, quarters for migrant workers) have occurred ⁽⁵⁾.
- The risk of transmission is high in these settings where physical distancing and other infection prevention and control measures are challenging and individuals may not be able to exercise sufficient personal actions to adequately protect themselves from infection. This increased risk may expand to other settings as they re-open.
- Remote or isolated populations or those in some congregate living settings may not have ready access to sufficient healthcare infrastructure. Therefore, their risk for death and societal disruption is proportionally greater since the response to any illness within the community might be sub-optimal.
- Indigenous communities have been disproportionately impacted by past pandemics (e.g., 2009 H1N1 influenza pandemic) and require special consideration of issues related to equity, feasibility and acceptability (see Section V.2).

V.2 Principles guiding public health program level decision-making

- **Efforts* should be made to increase access to immunization services to reduce health inequities without further stigmatization or discrimination, and to engage systematically marginalized and racialized populations in immunization program planning (see Equity Matrix, Appendix D).**

Summary and rationale with current evidence:

- Health inequities exist due, in part, to differential access to health care, as well as differential exposure, susceptibility, and severity of infectious diseases (see Equity Matrix, Appendix D). Interventions to reduce these inequities rather than potentiate them with further stigmatization or discrimination should be implemented as part of any immunization program.
- As with any immunization program, efforts should be made to ensure consideration of the needs of diverse population groups, based on health status, ethnicity/culture, ability, and other socioeconomic and demographic factors that may place individuals in vulnerable circumstances (e.g., occupational, social, economic, or biological vulnerabilities). These efforts should include integrating the values and preferences of these populations in vaccine program planning and building capacity to ensure access and convenience of immunization services.
- There is evidence of important/large independent associations of severe COVID-19 with race/ethnicity (low certainty of evidence of hospitalization or mortality), low

- socioeconomic status (low certainty of evidence for hospitalization), homelessness (low certainty of evidence for hospitalization), and male sex (moderate certainty of evidence for hospitalization) ⁽¹⁾.
- Outbreaks involving large numbers of reported cases have occurred in rural and remote communities in Canada ⁽⁵⁾.
 - Outbreaks involving large numbers of reported cases have occurred in agricultural work settings, including those with congregate living for migrant workers ⁽⁵⁾.
 - Visible minorities and Indigenous Canadians appear to be less willing than non-visible minorities to get an effective recommended COVID-19 vaccine ⁽¹³⁾. Reasons for vaccine hesitancy are multifactorial.
 - While significant differences in willingness to get vaccinated with a COVID-19 vaccine haven't been observed by sex or socioeconomic status ^(13,14), immunization coverage rates have tended to be lower among men and those in lower socioeconomic groups for vaccine-preventable diseases where national data are available ⁽²³⁾.
 - Examples of interventions to engage communities and address barriers to accessing vaccine as summarized in the Equity Matrix (Appendix D) could help reduce inequities.
 - This is aligned with the ethical principle of justice, where people and groups are treated with equal concern and respect.

* NACI continues to recommend (as outlined in its guidance on [Research priorities for COVID-19 vaccines to support public health decisions](#) ⁽⁴⁾) that:

- Individuals with potential vulnerabilities to disease related to biological (e.g., increased age, pre-existing medical conditions), social (e.g., lower socioeconomic status, residence in long term care facilities or crowded/remote locations, homelessness, substance use disorder, race/ethnicity, immigration or refugee status), and occupational (e.g., healthcare workers, emergency workers, workers who have a high degree of social contact, international business travellers) factors should be included in clinical trial groups as soon as possible.
- Vaccine outcome results should be disaggregated by potential factors contributing to inequities such as sex, age, race/ethnicity and health status. Trials should endeavour to power their groups to allow analyses by various sociodemographic variables.

- **Jurisdictions should begin planning for the implementation of a COVID-19 immunization program, including close and rapid monitoring of safety, effectiveness, and coverage of vaccine(s) in different key populations, as well as effective and efficient immunization of populations in remote and isolated communities (see Feasibility Matrix, Appendix E).**

Summary and rationale with current evidence:

- Stakeholder reviews of feasibility identified multiple challenges requiring advanced planning and complex combinations of program administration through a variety of vaccine delivery models.
- Planning is required to address issues specific to a potential COVID-19 vaccine program (e.g., storage and dissemination of new vaccine technologies in different vaccine delivery venues; human resources for administration of vaccine, communication, training, data entry, screening for COVID-19, operational planning

- etc.), and integration with or enhancement of existing programs (e.g., registries, surveillance, adverse event following immunization reporting).
 - Close and rapid monitoring of safety, effectiveness, and coverage of the vaccine(s) in potentially different key populations will be critical.
 - The feasibility of sequential immunization of different key populations in remote and isolated communities is challenging. Deploying vaccine to entire communities may be more effective and efficient.
 - Suggestions on planning for these issues are included in Appendix E.
- **Efforts should be made to improve knowledge about the benefits of vaccines in general, and of COVID-19 vaccine(s) specifically, once approved, address misinformation about immunization, and communicate transparently about COVID-19 vaccine allocation decisions (see Acceptability Matrix, Appendix F).**

Summary and rationale with current evidence:

- Willingness to get a safe, effective COVID-19 vaccine has decreased in Canada (from 71% in April to 61% in August 2020) ⁽¹⁴⁾. The most reported reasons for unwillingness to get a COVID-19 vaccine across various Canadian surveys are concerns about safety and a lack of confidence and trust in a new COVID-19 vaccine ⁽¹³⁻¹⁶⁾.
- Deemed one of the top ten major global health threats by WHO in 2019, vaccine hesitancy (the reluctance or refusal to vaccinate despite the availability of vaccines) could lead to the resurgence of deadly, preventable diseases, and limit the success of a COVID-19 immunization program. Key reasons for vaccine hesitancy include complacency, inconvenience in accessing vaccines, and lack of confidence ⁽²⁴⁾.
- Efforts should be made to reduce complacency, improve convenient access to vaccines, and improve confidence in and awareness of immunization in the general public, key populations for early COVID-19 immunization, and health care providers. Transparent, clear communication about vaccine allocation decisions is important to maintain trust, confidence, and improve access to vaccines for key populations.
- In general, receiving a recommendation from, or being in contact with a healthcare provider is linked to increased vaccine acceptability ⁽¹⁷⁾. However, a lack of familiarity with a vaccine plays a role in reluctance by healthcare providers to recommend it ^(17,18). A notable factor for healthcare providers to recommend a vaccine is a recommendation by an expert committee ⁽¹⁸⁾.
- Information on vaccine safety and pharmacovigilance can be found at: <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-2-vaccine-safety/page-2-vaccine-safety.html>

See Figure 1 for a summary of the above recommendations on key populations for early COVID-19 immunization for public health program level decision-making.

V.3 Management options

Specific recommendations for COVID-19 vaccines in key populations will depend on yet unknown factors such as supply and characteristics (e.g., safety, immunogenicity, efficacy and effectiveness in preventing severe illness and interrupting transmission in different populations) of COVID-19 vaccine(s) available to Canadians, evolving evidence on COVID-19, as well as the epidemiological context at the time COVID-19 vaccine(s) become(s) available. When this information is available, NACI will provide additional guidance on management options for COVID-19 immunization.

VI. RESEARCH PRIORITIES

NACI has recently published a focused statement on [Research priorities for COVID-19 vaccines to support public health decisions](#) ⁽⁴⁾, including detailed discussion of clinical trial populations and outputs. In summary, research to address the following outstanding questions is encouraged:

VI.1 New and emerging research priorities

1. How will acceptability of prioritized key populations for early immunization with COVID-19 vaccine(s) evolve in different epidemiological contexts across the country?
2. How can vaccine allocation decisions be communicated to individuals and communities in order to maintain trust in public health authorities?
3. How will acceptability of COVID-19 vaccine(s), and vaccines in general, evolve in the public, key populations, marginalized populations, providers and policy-makers in different epidemiological contexts across the country? What factors will influence acceptability in these groups?
4. What interventions will be effective in reducing health inequities and improving acceptability related to COVID-19 immunization?

VI.2 Standing research priorities

1. How safe and efficacious are candidate vaccines across diverse population groups (e.g., adults >60 years of age, those with high risk medical conditions, individuals with social or occupational vulnerabilities)?
2. How effective will candidate vaccines be in preventing severe illness and death and interrupting transmission of COVID-19 across diverse population groups?
3. Are IgA/IgG/IgM antibodies protective against SARS-CoV-2 and what is the correlate of protection?
4. Is there a cell-mediated immunity correlate of protection against SARS-CoV-2?

5. Is SARS-CoV-2 natural infection (symptomatic or asymptomatic) associated with protection against re-infection or severe disease? What is the duration of natural protection against re-infection or severe disease from SARS-CoV-2?
6. What is the duration of vaccine protection against re-infection or severe disease from SARS-CoV-2?
7. Does vaccination following prior SARS-CoV-2 infection or vaccination of SARS-CoV-2 naïve individuals elicit enhanced disease upon subsequent infection?
8. Are any other vaccines (e.g., BCG) protective against COVID-19 through off-target effects?
9. What is the epidemiological profile of COVID-19 (e.g., communicable period, all risk groups)?
 - a. What is the disease distribution and spectrum of clinical illness for COVID-19, including burden of illness and risk by age, sex and other demographic variables associated with higher risk?
 - b. What are the transmission dynamics of COVID-19, including degree of asymptomatic transmission, role of children in transmission, vertical transmissibility, onset and duration of viral shedding and communicable period, impact of changing weather conditions, and trends over time?
 - c. What are the rates of COVID-19 co-infections with other respiratory pathogens and impact on pathogenesis and clinical outcomes?
 - d. Is there cross-protection or interference from antibodies/exposure to human seasonal coronaviruses when exposed to SARS-CoV-2 or vaccinated against SARS-CoV-2?
10. Are there any emerging safety signals with COVID-19 immunization that are not predicted by the current understanding of the safety profile of similar vaccines?

LIST OF ABBREVIATIONS

Abbreviation	Term
AEFI	Adverse Events Following Immunization
ARCHE	Alberta Research Centre for Health Evidence
BMI	Body mass index
CIC	Canadian Immunization Committee
COSMO Canada	Canada's COVID-19 Snapshot Monitoring Study
COVID-19	Novel coronavirus disease 2019
CPSS3	Canadian Perspectives Survey Series 3
EEFA	Ethics, Equity, Feasibility and Acceptability
FNIHB	First Nations and Inuit Health Branch
FPT	Federal/Provincial/Territorial
GRADE	Grading of Recommendations, Assessment, Development and Evaluations
HCID WG	High Consequence Infectious Disease Working Group
ICU	Intensive Care Unit
IPC	Infection prevention and control
NACI	National Advisory Committee on Immunization
OECD	Organisation for Economic Co-operation and Development
OR	Odds ratio
PHAC	Public Health Agency of Canada
PPE	Personal protective equipment
P ² ROGRESS And Other Factors	Pre-existing condition, Place of residence, Race/ethnicity/culture/language/immigration/refugee status, Occupation, Gender identity/sex, Religion/belief system, Education/literacy level, Socioeconomic status, Social capital, Age, Other factors
RR	Risk ratio
SAC	Special Advisory Committee
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SGBA+	Sex and Gender Based Analysis Plus
SOP	Standard Operating Procedures
UK	United Kingdom
US	United States
WHO	World Health Organization

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NACI High Consequence Infectious Disease Working Group

Members: Dr. C Quach (Chair), Dr. S Deeks (Vice-Chair), Dr. Y-G Bui, Dr. K Dooling, Dr. R Harrison, Dr. K Hildebrand, Dr. M Murti, Dr. J Papenburg, Dr. R Pless, Dr. N Stall, and Dr. S Vaughan.

PHAC Participants: Dr. N Abraham, Ms. P Doyon-Plourde, Ms. V Ferrante, Dr. N Forbes, Dr. SJ Ismail, Dr. A Killikelly, Ms. M Matthieu-Higgins, Dr. A Nam, Mr. M Patel, Ms. A Sinilaite, Dr. MC Tunis, Ms. MW Yeung, and Dr. L Zhao.

NACI

Members: Dr. C Quach (Chair), Dr. S Deeks (Vice-Chair), Dr. JA Bettinger, Dr. N Dayneka, Dr. P De Wals, Dr. E Dube, Dr. V Dubey, Dr. S Gantt, Dr. R Harrison, Dr. K Hildebrand, Dr. K Klein, Dr. J Papenburg, Dr. C Rotstein, Dr. B Sander, Ms. S Smith, and Dr. S Wilson.

Liaison representatives: Dr. LM Bucci (Canadian Public Health Association), Dr. E Castillo (Society of Obstetricians and Gynaecologists of Canada), Dr. A Cohn (Centers for Disease Control and Prevention, United States), Ms. L Dupuis (Canadian Nurses Association), Dr. J Emili (College of Family Physicians of Canada), Dr. D Fell (Canadian Association for Immunization Research and Evaluation), Dr. M Lavoie (Council of Chief Medical Officers of Health), Dr. D Moore (Canadian Paediatric Society), Dr. M Naus (Canadian Immunization Committee), and Dr. A Pham-Huy (Association of Medical Microbiology and Infectious Disease Canada).

Ex-officio representatives: Dr. D Danoff (Marketed Health Products Directorate, HC), Ms. E Henry (Centre for Immunization and Respiratory Infectious Diseases [CIRID], PHAC), Ms. M Lacroix (Public Health Ethics Consultative Group, PHAC), Ms. J Pennock (CIRID, PHAC), Dr. R Pless (Biologics and Genetic Therapies Directorate, Health Canada), Dr. G Poliquin (National Microbiology Laboratory, PHAC), Dr. V Beswick-Escanlar (National Defence and the Canadian Armed Forces), and Dr. T Wong (First Nations and Inuit Health Branch, Indigenous Services Canada).

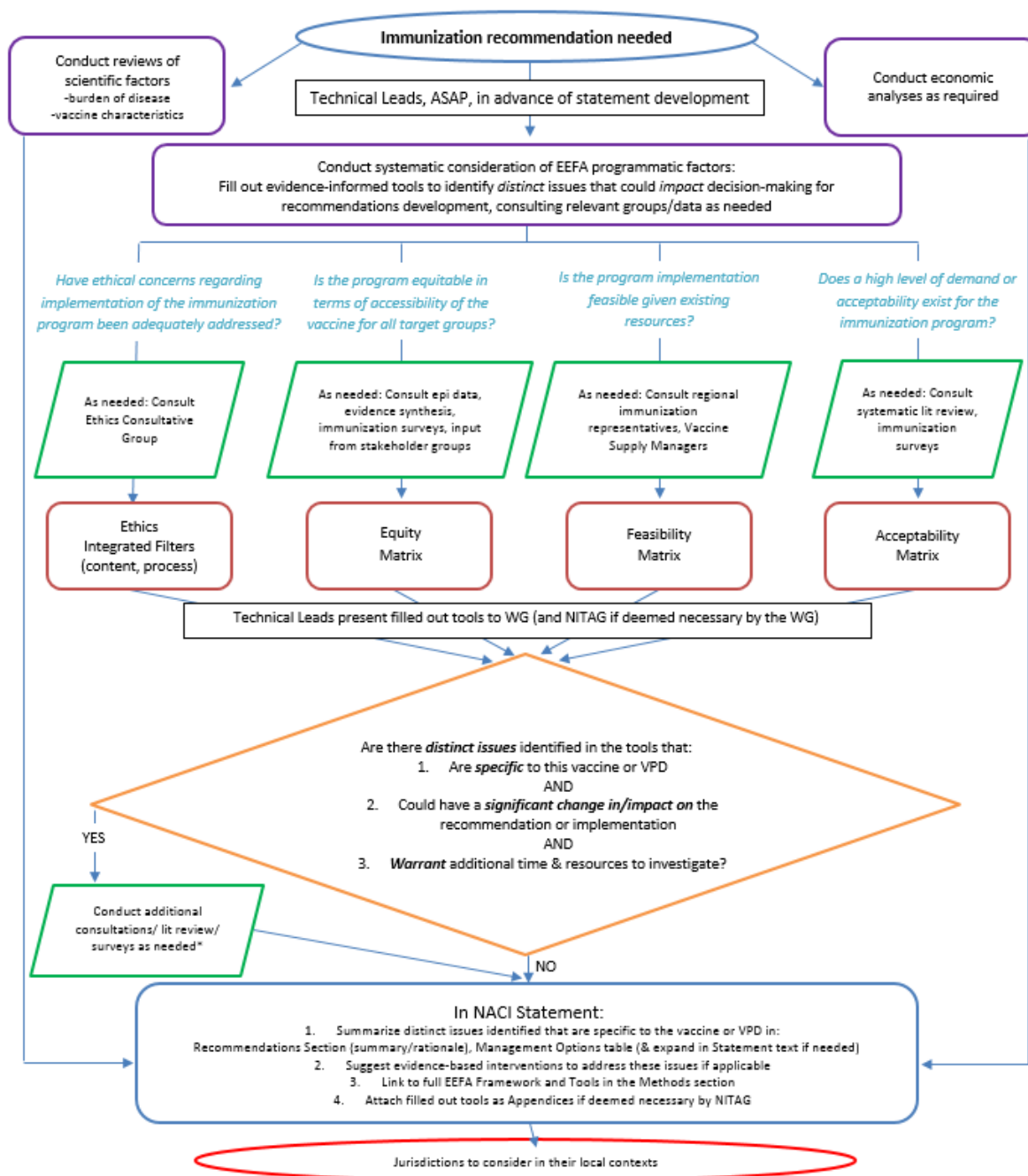
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APPENDIX A: ALGORITHM OUTLINING THE PROCESS FOR APPLYING THE EEFA FRAMEWORK



Source: Ismail SJ, Hardy K, Tunis MC et al., A framework for the systematic consideration of ethics, equity, feasibility, and acceptability in vaccine program recommendations, *Vaccine*, <https://doi.org/10.1016/j.vaccine.2020.05.051>.

* As acceptability is affected by contextual influences where different factors may weigh more or less heavily on vaccine decisions⁽¹⁷⁾, and the COVID-19 pandemic presents distinct issues that could significantly impact the implementation of recommendations, a reliance solely on historical perspectives of acceptability from other vaccine-preventable diseases or vaccine platforms is not sufficient. Therefore, emerging acceptability data related to COVID-19 vaccines was sought.

APPENDIX B: CORE ETHICAL DIMENSIONS FILTER APPLIED TO COVID-19

To ensure NACI's COVID-19 guidance upholds and integrates core ethical dimensions for public health

Core Ethical Dimensions for Public Health	Description	Considerations for integration of core ethical dimensions	Tools to assist with integration of core ethical dimensions
Respect for persons and communities	Right to exercise informed choice based on all available evidence	Has all the evidence been presented in a comprehensive manner? Is the guidance accessible to stakeholders?	<ul style="list-style-type: none"> All evidence (known and unknown) with degree of certainty will be summarized clearly and comprehensively in the advisory committee statement (ACS). Guidance will be web-posted and directly disseminated to stakeholders with early review by experts and stakeholders.
		Have the values and preferences of persons and communities been considered? Does a high level of demand or acceptability exist for the immunization program?	<ul style="list-style-type: none"> See Acceptability Matrix applied in the context of the pandemic (Appendix F) Values and preferences of expert and patient/community advocacy groups and the public (including high risk groups and healthcare providers) have been assessed in the context of the current pandemic as well as in previous research on vaccination in general, and considered in the guidance.
Beneficence and non-maleficence	Promotion of well-being, minimize risk of harm vs benefits	Have the recommendations considered risks and benefits, and do benefits outweigh risks? Has the principle of reciprocity ^a been considered to minimize harm, especially in epidemic contexts?	<ul style="list-style-type: none"> Risks and benefits have been considered in the guidance and summarized in the rationale for each recommendation. The ethical principles of proportionality, effectiveness, precaution and reciprocity have been applied to the guidance and explicitly discussed.
		If major risks are identified, has a risk analysis been conducted?	<ul style="list-style-type: none"> An in-depth Scenario-based Ethics Analysis^b for the risk of prioritization of immunization in key populations has been conducted and considered in the guidance.

^a Societal support to minimize disproportionate risks taken by individuals in their duty to protect the public

^b Steps from Public Health Ethics Consultative Group (PHECG) Framework (available at: <https://www.canada.ca/content/dam/phac-aspc/documents/corporate/transparency/corporate-management-reporting/internal-audits/audit-reports/framework-ethical-deliberation-decision-making/pub-eng.pdf>): 1) identify the issue and context, 2) identify ethical considerations, 3) identify and assess options, 4) select best course of action and implement, 5) evaluate

Core Ethical Dimensions for Public Health	Description	Considerations for integration of core ethical dimensions	Tools to assist with integration of core ethical dimensions
Justice	Treat people and groups with equal concern and respect	Is the recommendation equitable in terms of accessibility of the vaccine for all target groups? Are there special considerations for vulnerability of those most at risk?	<ul style="list-style-type: none"> • See Equity Matrix applied to COVID-19 (Appendix D) • Careful review of surveillance and a rapid review of risk factors was conducted and informed the guidance.
		Distributive justice: Is implementation feasible given existing resources? Do the recommendations result in a fair distribution of resources?	<ul style="list-style-type: none"> • See Feasibility Matrix (Appendix E) applied to a potential COVID-19 immunization program, which has been reviewed and validated by jurisdictions and vaccine supply experts.
Trust	Long term reliability, integrity, sustainable and mutually fair relationship with individuals and communities	Are the recommendations based on the best, current evidence available for all groups at risk of the vaccine-preventable disease (VPD)?	<ul style="list-style-type: none"> • NACI methodology⁽⁷⁾ has been followed despite expedited review to ensure robust analysis of evidence, including additional reviews by experts and stakeholders not usually part of the process. • The guidance is transparent about knowns, unknowns and certainty of evidence. • Evidence will be monitored with revision of guidance as necessary
		Have the Ethics Procedural Considerations been upheld? (see Ethics Procedural Considerations Filter)	<ul style="list-style-type: none"> • The NACI Statement Template, established methodology⁽⁷⁾, Standard Operating Procedures and Conflict of Interest guidelines have been followed in the context of expedited review.

Source: Ismail SJ, Hardy K, Tunis MC et al., A framework for the systematic consideration of ethics, equity, feasibility, and acceptability in vaccine program recommendations, *Vaccine*, <https://doi.org/10.1016/j.vaccine.2020.05.051>.

APPENDIX C: ETHICAL PROCEDURAL CONSIDERATIONS FILTER APPLIED TO COVID-19

To ensure NACI's COVID-19 guidance processes uphold and integrate ethical procedural considerations

Ethical Procedural Considerations	Considerations for integration of ethical procedural considerations	Tools/procedures to assist with integration of ethical procedural considerations
Accountability	Quality and completeness: Was an appropriate review completed on all relevant topics?	<ul style="list-style-type: none"> NACI Methodology⁽⁷⁾ has been followed in the context of expedited review and steps taken for knowledge synthesis have been summarized in the Methodology section of Advisory Committee Statement (ACS) per the Statement Template.
Inclusiveness	Were relevant stakeholders engaged?	<ul style="list-style-type: none"> NACI's Standard Operating Procedures (SOPs) have been followed with a review of membership and inclusion of experts on NACI's High Consequence Infectious Disease Working Group and NACI. Expert stakeholder groups, patient/community experts/advocates, and the general public (including high risk groups and healthcare providers) have been consulted through surveys. Key stakeholder groups hold liaison positions on NACI and are involved in developing the guidance. Early review of the guidance by stakeholder groups and experts was sought.
Responsibility	Did NACI act independently to make decisions (without conflicts of interest, independence from Industry)?	<ul style="list-style-type: none"> NACI's SOPs and Conflict of Interest guidelines were followed in the context of expedited review.
Responsiveness	Did guidance respond to needs of stakeholders?	<ul style="list-style-type: none"> NACI's SOPs for timely guidance and review of feedback from members (inclusive of stakeholder groups and experts) and expert stakeholders were followed in the context of expedited review Early review of the guidance by stakeholders for comment was conducted with issues addressed prior to finalizing Evidence will be monitored and guidance will be revised as necessary
Transparency	Was there a clear and strong rationale for recommendation?	<ul style="list-style-type: none"> NACI Methodology⁽⁷⁾ and ACS template were followed in the context of expedited review and the rationale and evidence for

Ethical Considerations	Procedural Considerations for integration of ethical procedural considerations	Tools/procedures to assist with integration of ethical procedural considerations
		each recommendation (including certainty of evidence and unknowns) is summarized clearly and transparently.

Source: Ismail SJ, Hardy K, Tunis MC et al., A framework for the systematic consideration of ethics, equity, feasibility, and acceptability in vaccine program recommendations, *Vaccine*, <https://doi.org/10.1016/j.vaccine.2020.05.051>.

APPENDIX D: EQUITY MATRIX APPLIED TO COVID-19 WITH EVIDENCE TO DATE

To identify distinct inequities associated with COVID-19, potential reasons for inequities, and suggested interventions to reduce the inequity and improve access to vaccine

Factors that may contribute to health inequity	Why inequity may exist (differential access or differential disease exposure, susceptibility, severity or consequences and <i>their intersections with other factors</i> ^a)	Examples of suggested interventions to reduce inequity and improve access
<p>Pre-existing condition (e.g., chronic disease, immunocompromised, pregnancy, disability)</p>	<ul style="list-style-type: none"> Differential disease severity has been shown to have large independent associations with chronic medical conditions (heart failure, diabetes, chronic kidney disease, dementia, liver disease) and obesity (BMI ≥ 40)⁽¹⁾. Differential disease severity has been shown to have moderate independent associations with obesity (BMI >30), and hematological malignancy.⁽¹⁾ No clear evidence exists for differential disease severity in pregnancy or immunocompromised populations,⁽¹⁾ however, due to the potential for suboptimal immune response related to altered immune systems, the possibility for differential disease severity exists and has been suggested in some studies. <p><i>Multiple possible intersections such as age, SES, place of residence, social capital</i></p>	<ul style="list-style-type: none"> Include these populations in clinical trials to demonstrate efficacy and safety of interventions (following Research Ethics Board [REB] guidelines and First Nations Principles of Ownership, Control, Access and Possession [OCAP®] principles of data collection processes in their communities) Consider these populations as key groups for immunization Facilitate rides to immunization clinics or home visits for those who are immobile to improve access to vaccine and testing for infection Offer immunization at healthcare visits for pre-existing conditions (e.g. medical specialist appointments)
<p>Place of residence (remote, overcrowding, homeless, institutionalization)</p>	<ul style="list-style-type: none"> Differential exposures in institutions exist with evidence of a high number of outbreaks in long-term care facilities (experiencing the majority of outbreaks), hospitals, prisons, shelters.⁽⁵⁾ Outbreaks involving large numbers of reported cases have occurred in rural, remote and Indigenous communities.⁽⁵⁾ Differential disease severity has been shown to have large independent associations with homelessness.⁽¹⁾ Homeless populations and those living in shelters/group homes or in overcrowded neighbourhoods or homes, as well as rural, remote and Indigenous communities have differential exposure and challenges with physical distancing and other IPC measures^b, as well as potentially decreased access to healthcare. 	<ul style="list-style-type: none"> Include these populations in clinical trials of interventions (following REB guidelines and OCAP® principles) Consider these populations as key groups for immunization Consider standing orders in institutions, and mobile clinics in hardly reached populations to improve access to immunization Enable infection prevention and control (IPC) measures^b to reduce exposure Consider immunizing all eligible individuals in remote areas facilitated by community

Factors that may contribute to health inequity	Why inequity may exist (differential access or differential disease exposure, susceptibility, severity or consequences and <i>their intersections with other factors</i> ^a)	Examples of suggested interventions to reduce inequity and improve access
	<p><i>Multiple possible intersections such as pre-existing condition, SES, education/literacy level, social capital</i></p>	<p>members/leaders/advocates for efficient, effective use of resources.</p>
<p>Race/ethnicity/culture/language/immigration/refugee status</p>	<ul style="list-style-type: none"> • Differential disease severity has been shown to have large independent associations with black race/ethnicity and Bangladeshi ethnicity.⁽¹⁾ Evidence of higher rates of COVID-19 and differential disease severity exists in ethno-culturally diverse neighbourhoods.⁽²⁵⁾ • Diverse populations have differential access to healthcare. Lower immunization rates have been observed in immigrant children and seniors.⁽²⁶⁾ Visible minorities or Indigenous Canadians appear to be less willing than non-visible minorities to get an effective recommended COVID-19 vaccine.⁽¹⁴⁾ Reasons for vaccine hesitancy are multifactorial. • Immigrant/refugee populations or migrant workers may have differential exposure due to international travel to visit friends and relatives or due to their occupations, in addition to other intersecting factors listed below: <i>Multiple possible intersections such as SES, place of residence, occupation, pre-existing conditions, social capital, education/literacy level</i> 	<ul style="list-style-type: none"> • Include populations from diverse racial/ethnic/cultural backgrounds in clinical trials (following REB guidelines and <u>OCAP[®] principles</u>) • Improve access to testing and immunization (e.g., mobile clinics, publicly funded interventions) • Engage trusted community leaders/partners/Elders and liaise with relevant organizations (e.g. immigration and refugee departments) in planning for immunization programs and communication materials. • Provide culturally appropriate educational and communication materials with a variety of languages, media platforms, and venues • Have translators and supports (e.g. community members) available in clinics • Enable improved IPC measures^b to reduce exposure
<p>Occupation</p>	<ul style="list-style-type: none"> • Healthcare workers/personnel have differential exposure and transmission to clients at high risk of severe illness. However, this group may have more access to and training in the use of PPE and other IPC measures^b so exposure risk could be significantly reduced compared to other groups.^(9,10) • Essential services workers (e.g., emergency workers, grocery/transit staff, meat/agriculture workers, teachers) and others who cannot work virtually as the economy re-opens and have high social contact (with limited IPC measures^b) have differential exposure. • Outbreaks involving large numbers of reported cases have occurred in agricultural work settings, including those with congregate living for migrant workers.⁽⁵⁾ • Individuals who travel internationally for work may have differential exposure. 	<ul style="list-style-type: none"> • Include these populations in clinical trials (following REB guidelines and <u>OCAP[®] principles</u>) • Consider these populations as key groups for immunization • Offer alternate immunization settings such as mobile, worksite, or after-hours immunization clinics and testing • Enable improved IPC measures^b to reduce exposure

Factors that may contribute to health inequity	Why inequity may exist (differential access or differential disease exposure, susceptibility, severity or consequences and <i>their intersections with other factors</i> ^a)	Examples of suggested interventions to reduce inequity and improve access
	<p><i>Multiple possible intersections such as SES, race/ethnicity/immigration/refugee status, social capital</i></p>	
Gender Identity/Sex	<ul style="list-style-type: none"> Differential disease severity has been shown to have a large independent association with male sex,⁽¹⁾ which may be linked to immunological sex differences or gendered differences in behaviours such as differential access to healthcare before progression of disease. Significantly fewer men than women get vaccinated for vaccine preventable diseases like influenza.⁽²³⁾ Women may be impacted differentially by the pandemic directly and indirectly due to gendered differences in caregiver roles, gender-based violence and socio-economic instability. <p><i>Multiple possible intersections such as occupation, pre-existing conditions, SES, social capital, risk behaviours</i></p>	<ul style="list-style-type: none"> Consider gender/sex-inclusive immunization policies Address gendered barriers to accessing healthcare and immunization programs (e.g. through social influencers) Support sex and gender-based analyses
Religion/Belief system	<ul style="list-style-type: none"> Religious beliefs about immunization may result in differential access to vaccine. Gatherings of faith-based communities may lead to differential exposure. Outbreaks involving large numbers of reported cases have occurred in mass gatherings⁽⁵⁾ and cases linked to religious facilities continue to emerge.^(27,28) <p><i>Multiple possible intersections such as race/ethnicity/culture/immigration/refugee status</i></p>	<ul style="list-style-type: none"> Engage faith-based leaders in education materials and planning for immunization programs Offer alternate immunization settings such as at places of worship Enable improved IPC measures^b to reduce exposure
Education/Literacy level	<ul style="list-style-type: none"> Those with decreased education or literacy levels potentially have decreased access to healthcare. Lower levels of education (or parental education in the case of children) have been associated with lower immunization rates in all age groups for various vaccine preventable diseases.^(23, 26) International students may have differential exposure if they travel internationally, and differential access to healthcare if not insured. <p><i>Multiple possible intersections such as place of residence, occupation, pre-existing conditions, smoking, SES</i></p>	<ul style="list-style-type: none"> Offer alternate immunization and testing settings to improve access (e.g. school-based immunization programs) Provide educational materials at appropriate literacy levels Have translators available in clinics Enlist multilingual family/community members to assist in communication
Socioeconomic status (SES)	<ul style="list-style-type: none"> Differential disease severity has been shown to have large/important independent associations with low socioeconomic status.⁽¹⁾ 	<ul style="list-style-type: none"> Include populations from a variety of SES backgrounds in clinical trials (following REB guidelines and <u>OCAP[®]</u> principles)

Factors that may contribute to health inequity	Why inequity may exist (differential access or differential disease exposure, susceptibility, severity or consequences and <i>their intersections with other factors</i> ^a)	Examples of suggested interventions to reduce inequity and improve access
(including income, and coverage of healthcare and healthcare interventions)	<ul style="list-style-type: none"> Populations with lower income status and inability to pay for IPC resources, higher risk occupations with limited IPC measures^b, job insecurity, and inability to work from home have differential exposure Lack of healthcare insurance or inability to pay for healthcare interventions may result in differential access. Immunization rates tend to be lower in lower socioeconomic groups for various vaccine preventable diseases.^(23, 26) <p><i>Multiple possible intersections such as place of residence, occupation, pre-existing conditions, social capital, education/literacy level, race/ethnicity/immigration/refugee status</i></p>	<ul style="list-style-type: none"> Improve access to testing and immunization (e.g., mobile clinics, publicly funded interventions) Enable improved IPC measures^b to reduce exposure Support programs and policies aimed to assist and empower systemically marginalized populations
Social Capital (social support/networks, trust)	<ul style="list-style-type: none"> Lack of support networks (e.g., to remind or enable individuals and caregivers to attend to immunization and other IPC measures^b), and lack of trust (e.g., in authorities making recommendations) may lead to differential access to healthcare interventions. Non-vaccination^(26, 29) or incomplete vaccination⁽³⁰⁾ has been associated with single-parent families for other vaccine preventable diseases. <p><i>Multiple possible intersections such as SES, place of residence, occupation, age, pre-existing conditions, education/literacy level</i></p>	<ul style="list-style-type: none"> Empower trusted healthcare providers to recommend/provide immunizations during patient visits. Trust in doctors is a key factor in willingness to get a COVID-19 vaccine,⁽²⁰⁾ and receiving a recommendation from a healthcare provider is linked to increased acceptability for immunization in general.⁽⁷⁾ Improve trust in immunization and other healthcare interventions through trusted leaders and social media influencers Implement reminder/recall systems for immunization Offer childcare during immunization visits

Factors that may contribute to health inequity	Why inequity may exist (differential access or differential disease exposure, susceptibility, severity or consequences and <i>their intersections with other factors</i> ^a)	Examples of suggested interventions to reduce inequity and improve access
Age	<ul style="list-style-type: none"> All ages are susceptible to COVID-19, but the rate of diagnosed COVID-19 cases generally increases with age. Recently, however, a significant increase in the proportion of cases in younger adult age groups has been observed as lockdown measures relax.⁽⁵⁾ Differential disease severity has been shown to have a very large independent association with increasing age.⁽¹⁾ Children <10 years of age experience milder or asymptomatic infection but evidence of differential disease severity (i.e. multisystem inflammatory syndrome) is emerging.⁽³¹⁾ <p><i>Multiple possible intersections such as pre-existing conditions, social capital, SES</i></p>	<ul style="list-style-type: none"> Include populations from a variety of age ranges in clinical trials (following REB guidelines and <u>OCAP[®] principles</u>) Consider the evidence of inequities related to age when sequencing groups for early immunization Consider promotion and education activities on platforms that access older adults (e.g. established social media, print media, mail campaigns) Consider immunization programs to protect those in contact with the elderly if vaccine efficacy is impaired due to immune senescence
Other factors (e.g., risk behaviours – substance use disorders, smoking, sex workers)	<ul style="list-style-type: none"> No important increased risk in hospitalization in current or former smokers has been observed to date with limited data for associations with substance use disorders. ⁽¹⁾ However, data continues to evolve. These populations may have differential access to healthcare. <p><i>Multiple possible intersections such as SES, social capital, place of residence, pre-existing conditions, education/literacy level</i></p>	<ul style="list-style-type: none"> Do not exclude these populations in clinical trials (following REB guidelines and <u>OCAP[®] principles</u>) Improve access to testing and immunization (e.g., mobile clinics, at substance use treatment centers) and offer publicly funded interventions Enable improved IPC measures^b to reduce exposure Support programs aimed to assist those with tobacco and substance use disorders

^a Multiple intersections between factors may exist, however only a subset are highlighted in the table

^b Possible IPC measures include: handwashing, disinfecting surfaces, erecting physical barriers, maintaining physical distancing, using appropriate personal protective equipment

Source: Ismail SJ, Hardy K, Tunis MC et al., A framework for the systematic consideration of ethics, equity, feasibility, and acceptability in vaccine program recommendations, *Vaccine*, <https://doi.org/10.1016/j.vaccine.2020.05.051>

APPENDIX E: FEASIBILITY MATRIX APPLIED TO COVID-19

To identify potential, distinct issues with respect to potential COVID-19 vaccine(s) and a COVID-19 immunization program to address the feasibility of implementing recommendations

	Vaccine	Immunization Program	Potential Issues
Resources	Vaccine and Immunization Supplies (short & long term)	Human resources (for administration of vaccine, communication, training, data entry, screening for COVID-19, operational planning, etc.)	<ul style="list-style-type: none"> • Uncertainty and security of short and long term vaccine supply given demand worldwide and uncertainty in doses required, number and timelines of vaccines available, storage and handling requirements etc. are challenges to planning. • Careful monitoring of vaccine supply, allocation, and tracking of doses delivered for potentially multiple vaccines with potentially varied indications and recommendations for use will be important, with minimization of vaccine wastage. • Procurement, management and training in the use of IPC and PPE supplies as well as vaccine administration supplies for potentially different routes of administration for different vaccines, must be considered. • Procurement and management of non-clinical supplies (i.e. tables, chairs, signage) must be considered for different venues. • Procurement, management and maintenance of storage facilities for different vaccines (e.g. refrigerators vs freezers) and packaging must be considered for different venues. • Training in alternative dosing routes may need to be considered for supply constraints (e.g. intradermal administration for dose-sparing). • COVID-19 immunization clinics and a variety of alternate vaccine delivery strategies/venues (e.g. drive-thru, mobile clinics, physician/nurse offices, pharmacies), and demand for vaccine(s) within and outside target groups will require resources for planning, communication, training, as well as <u>precautions to prevent COVID-19 transmission and other VPDs</u> (as a result of possible lower immunization rates and circulating VPDs). • Consider efficient and effective use of resources for in remote/isolated communities
	Funding for vaccine purchase	Funding for human and administrative resources	<ul style="list-style-type: none"> • Cost of vaccine(s) and resources (human and technological) to implement a new program and deliver vaccine to target groups expeditiously with IPC measures to prevent COVID-19 transmission is expected to be high. • Consider plans for human resource shortages due to absenteeism or need to work elsewhere, and additional administrative, surveillance, and training requirements to implement a pandemic immunization program.

	Vaccine	Immunization Program	Potential Issues
			<ul style="list-style-type: none"> Varied procurement and financial approval timelines across the country should be minimized.
Integration with Existing Program	Vaccine coverage	Communication of program (to public, target groups, providers, labs)	<ul style="list-style-type: none"> Clear, transparent communication on eligible groups, vaccine(s), and the vaccine program (with rationale for recommendations) to public, target groups, providers, labs etc. will be required. If more than one vaccine is available, clarity of recommendations for different target groups, schedules, routes of administration etc. will be critical. Immunization records will need to include which vaccine was administered and coverage must be tracked through registries with collection of sociodemographic data on target and marginalized groups. Consider data solutions to enhance existing technologies for real-time and comprehensive coverage reporting and centralized registries among various providers and delivery settings. Potential costs to jurisdictions as registries may require enhancements to meet reporting requirements. Challenges within jurisdictions' registries who have not yet integrated with primary care providers' EMRs (physicians)/Drug Information Systems (pharmacists) must be assessed. Consider strategies to increase coverage for target groups, and risk communication given novel vaccine technologies, expedited regulatory reviews, and disease epidemiology at the time of vaccine availability. Multiple media platforms to counter vaccine misinformation will be required. Consider recall/reminder systems, especially if more than one dose is required for the immunization schedule. Guidance on missed or delayed additional doses if more than one dose is required will be important.
	VPD (sero)types included	Surveillance of VPD	<ul style="list-style-type: none"> Ongoing testing and disease surveillance (with collection of sociodemographic data on target and marginalized groups, as well as immunization status) will be required to evaluate the immunization program and specific vaccine products (e.g., duration of immunity) for longer term immunization strategies.

	Vaccine	Immunization Program	Potential Issues
	Degree of similarity to existing vaccines, co-admin with other vaccines, targeting VPDs with existing programs	Alignment with existing schedule (e.g. with other program targeting same group)	<ul style="list-style-type: none"> Evidence on co-administration with other vaccines is unknown. In the absence of this information, consider reviewing the client's immunization status and scheduling a separate appointment for routine immunizations. To protect healthcare capacity and reduce morbidity and mortality, immunization with seasonal influenza and pneumococcal vaccine in eligible groups, as well as other routine vaccines, is encouraged Consider leveraging established immunization programs (e.g. seasonal influenza) for efficient resource use and improved coverage. Consider strategies to enhance coverage in marginalized and remote/isolated populations included in recommended target groups (see Equity Matrix). Minimize disruption to existing immunization programs with precautions to prevent transmission of COVID-19. Conformity and consistency of COVID-19 immunization programs across jurisdictions in Canada is important.
	Adverse Events	Inclusion in immunization registry, Adverse Event Following Immunization (AEFI) reporting	<ul style="list-style-type: none"> Enhanced capacity and attention to vaccine-specific AEFI surveillance and rapid reporting mechanisms for potentially multiple vaccine types with different doses and schedules, contraindications, precautions and vaccine associated adverse events (VAE) will make AEFI surveillance, integration with other vaccine programs, and staff training more complicated. Strengthening of existing processes, education of providers, and the ability to react quickly with signals to quarantine lots will require strong administrative data by product. Guidance on causality assessment will be required.

Source: Ismail SJ, Hardy K, Tunis MC et al., A framework for the systematic consideration of ethics, equity, feasibility, and acceptability in vaccine program recommendations, *Vaccine*. 2020 June 10. <https://doi.org/10.1016/j.vaccine.2020.05.051>.

APPENDIX F: ACCEPTABILITY MATRIX APPLIED TO COVID-19

To identify potential distinct issues with the acceptability of a recommendation for COVID-19 immunization from the perspective of the public and providers (based on a representative sample of Canadians surveyed through Canada's COVID-19 Snapshot Monitoring Study (COSMO Canada) (11,13,14))

	PUBLIC		PROVIDERS
	General Population	Key Populations at High Risk	
Vaccine (perceptions of): <i>E.g., efficacy, number of injections, route of administration, safety concerns, perceived benefits</i>	<p>Almost two thirds of Canadians surveyed (61%) in August 2020 were willing to get an effective recommended COVID-19 vaccine. This has decreased from 71% in April.</p> <p>Main reasons for vaccine hesitancy were: not enough testing or research has been done (32%), do not believe the vaccine will be safe and/or effective (26%), and lack of trust in the newness of the vaccine (13%).</p>	<p>Older Canadian respondents (aged 55 years and older) are more willing to get vaccinated than younger respondents (72% vs 57% in 35-54 years old and 51% in 18-34 years old; $p < .05$).</p> <p>Respondents 35 years and older with a “serious, long-term illness” are somewhat more willing to get an effective recommended vaccine compared to those without (68% vs 62%; 35-54 years old: 62% vs 59%; 55 years and older: 77% vs 74%). This was not observed in younger individuals 18 to 34 years old with a “serious, long-term illness” (43% vs 57%).</p> <p>Perceived safety (50%) is linked to increased vaccine acceptability compared to vaccine effectiveness (43%) among younger adults with “serious, long-term illness”.</p> <p>Non-visible minorities are more willing than visible minorities or Indigenous Canadians to get an effective recommended vaccine (63% vs 53% vs 43%; $p < .05$).</p> <p>About half of self-identified workers in frontline occupations such as grocery and gas station staff would get an effective recommended vaccine (51% vs 63%, $p < .05$).</p>	<p>Just over half of respondents who self-identified as healthcare providers would get an effective recommended vaccine (55% vs 62% for non-healthcare providers, $p > .05$).</p> <p>Concern about lack of testing or research (39%) and vaccine safety and/or efficacy (22%) are the main factors for vaccine hesitancy among healthcare providers surveyed. Other reasons for hesitancy include newness of the vaccine (19%) and do not believe in vaccines (6%).</p>
Disease (perceptions of): <i>E.g., burden of illness, groups at risk, personal risk,</i>	<p>More respondents believe the worst of the crisis is yet to come than believe that it is behind us (44% vs 33%).</p> <p>Younger respondents are more likely to agree that the worst of the crisis is behind us than older age groups (45% vs 32% and 26%; 18-34 year olds vs 35-54 year olds and 55 years and older, respectively; $p < .05$).</p>	<p>Three quarters of respondents (78%) agree that specific groups should be first to get a safe and effective vaccine in case of a shortage. The most commonly identified group for priority immunization was healthcare workers (40%), followed by individuals with high-risk medical conditions (19%), frontline workers (16%), seniors (12%), long-term care facilities (10%) and children (2%).</p>	<p>The majority of healthcare providers surveyed (83%) agree that specific groups should be first to get a vaccine in case of a shortage. They most often identified themselves (33%) as the priority target group for immunization, followed by individuals with high-risk medical conditions (19%), seniors</p>

	PUBLIC		PROVIDERS
	General Population	Key Populations at High Risk	
<i>severity, outbreak</i>		<p>Half of older adults believe the worst of the crisis is yet to come (50% vs 33% and 45%; 55 years and older vs 18-34 year olds and 35-54 year olds; $p<.05$).</p> <p>Non-visible minorities are more likely to agree that the worst of the crisis is yet to come than visible minorities (45% vs 39%, $p<.05$).</p> <p>People living in small rural areas (<30K population) are more likely to believe the worst is yet to come than those living in medium (30K-999K population) or major (≥ 1 million population) metropolitan areas (47% vs 43% vs 41%, $p<.05$).</p>	<p>(13%), long-term care facilities (13%), frontline workers (12%) and children (7%).</p> <p>Among healthcare providers surveyed, 43% believe the worst of the crisis is yet to come and 28% believe it is behind us.</p> <p>Healthcare providers are more likely than non-healthcare providers to believe we are currently experiencing the worst of the crisis (21% vs 11%, $p<.05$).</p>
<p>Process to get vaccinated <i>E.g., access to vaccine, (opportunity) cost, past vaccine experience</i></p>	<p>Almost half of Canadians surveyed (45%) think that immunization should be mandatory when available.</p> <p>The majority of Canadians surveyed (51%) agreed that in the context of limited initial vaccine supply, the most important strategy should be to protect those who are most vulnerable to severe illness and death from COVID-19; followed by protecting healthcare capacity (28%), minimize spread of COVID-19 (15%) and protect critical infrastructure (5%).</p>	<p>Older adults are more likely to agree to mandatory immunization for COVID-19 (53%) than younger age groups (41% of 18-34 year olds and 40% of 35-54 year olds, $p<.05$).</p> <p>White respondents are less likely to say that minimizing the spread of COVID-19 is the most important strategy in the face of limited initial vaccine supply compared to visible minority and Indigenous respondents (15% vs. 19% and 27% respectively, $p<.05$).</p> <p>A third of workers in frontline occupations like grocery and gas station staff believe immunization against COVID-19 should be mandatory (37% vs 47%, $p<.05$). Less than 10% of these workers believed that protecting critical infrastructure is the most important strategy in the face of limited initial vaccine supply (8% vs. 5%, $p<.05$).</p> <p>Older Canadians are more likely to say that protecting healthcare capacity is the most important strategy in the face of limited initial vaccine supply (33% vs 30% and 19%, $p<.05$).</p>	<p>In August, 37% of healthcare providers surveyed believed immunization against COVID-19 should be mandatory. This has decreased from 44% in July.</p>

	PUBLIC		PROVIDERS
	General Population	Key Populations at High Risk	
<p>Individual factors <i>E.g., beliefs and values, experiences, trust in healthcare providers and healthcare system, trust in vaccine experts and vaccine industry, social norms/pressures and media.</i></p>	<p>Almost half of Canadians surveyed (49%) report that they would get vaccinated in order to return to work, travel or attend a large gathering. This has decreased slightly from 55% in July.</p> <p>Although reported less frequently, lack of belief in vaccines (9%) and lack of trust in the government (7%) were reported as main reason for the vaccine refusal.</p> <p>Nearly all Canadians (84%) think scientific progress in vaccine development is the most needed type of information.</p> <p>Adults less than 55 years old most frequently reported using social media as a source of information on COVID-19 than older Canadians (14% in 18-34 year olds and 10% in 35-54 year olds vs 5% in 55 years and older, p<.05).</p> <p>Women are more likely than men to trust government agencies in their reporting about COVID-19 (55% vs 50%, p<.05) and to use provincial public health leaders to stay informed about COVID-19 (38% vs 33%, p<.05).</p>	<p>Respondents with a “serious, long-term illness” are not more likely to get vaccinated in order to return to work, travel or attend a large gathering (47% vs 50%).</p> <p>Older adults are more likely to report that they don’t believe in vaccines as the main reason for hesitancy compared to younger age groups (17% vs 6% in 18-34 year olds and 8% in 35-54 year olds, p<.05).</p> <p>Visible minorities are more likely to rely on various resources to stay up to date on COVID-19 information (i.e., federal websites [29% vs 23%], conversation with family [21% vs 12%] and colleagues [10% vs 5%], local radio stations [17% vs 12%], weekly newspapers [12% vs 7%], and social media [15% vs 8%]; all p<.05) compared to non-visible minorities who more often use provincial public health officials as a primary source of information (31% visible minorities vs 37% non-visible minorities, p<.05).</p> <p>People with smaller household incomes are more likely to think of social media as a trustworthy source of information compared to those with higher incomes (5% <\$40K vs 3% \$40-100K vs 1% >\$100K, p<.05). Those with high household income rely more often on online news resources to stay up to date on the COVID-19 situation (23% >\$100K vs 19% \$40-100K vs 17% <\$40K, p<.05).</p>	<p>A small proportion of healthcare providers surveyed would refuse to get vaccinated mainly because they believe the virus will naturally disappear (9%), don’t believe in vaccines (6%), fear needles (4%), or do not trust the government (1%).</p> <p>The majority of healthcare providers (76%) think scientific progress in vaccine development is the most needed type of information.</p>

Source: Ismail SJ, Hardy K, Tunis MC et al., A framework for the systematic consideration of ethics, equity, feasibility, and acceptability in vaccine program recommendations, *Vaccine*, <https://doi.org/10.1016/j.vaccine.2020.05.051>. Potential issues with acceptability in policymakers is not included in this matrix.