

Guidance on the prioritization of initial doses of COVID-19 vaccine(s)

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Introduction

In November 2020, NACI released comprehensive and evidence-informed [Preliminary guidance on key populations for early COVID-19 immunization](#) to inform planning for the efficient, effective, and equitable allocation of COVID-19 vaccine(s) once authorized for use in Canada when limited initial vaccine supply will necessitate the prioritization of immunization in some populations earlier than others. The key populations identified by NACI for early COVID-19 immunization include: those at high risk for severe illness and death, those most likely to transmit to those at high-risk and workers essential to COVID-19 response, essential services for the functioning of society, and those in living or working conditions with elevated risk for infection or disproportionate consequences, including Indigenous communities. NACI also recommends the integration of elements to guide ethical decision-making involving equity, feasibility, and acceptability considerations across all key populations. NACI's preliminary guidance on key populations for early COVID-19 immunization is summarized in [Figure 1](#) of its evidence-informed guidance document.

NACI noted in this recent guidance on key populations for early immunization that a sequential approach cannot be determined until vaccine characteristics, results of clinical trials, and the number of available doses are known. **As additional information on these factors has become available, NACI is providing urgent guidance on the efficient and equitable prioritization of initial doses of COVID-19 vaccines, (further sequencing key populations identified in its recent guidance), to assist with planning for allocation of the first COVID-19 immunization programs.**

NACI will continue to carefully monitor the evidence related to COVID-19 and COVID-19 vaccine(s) and will update recommendations as evidence evolves. NACI will conduct a comprehensive, transparent review of authorized COVID-19 vaccines, including evidence on efficacy and safety in clinical trial populations once available, and provide timely evidence-informed recommendations on the use of COVID-19 vaccines as soon as possible.

Under the [Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19](#). Health Canada could make regulatory decisions for COVID-19 vaccines that have completed Phase 3 clinical trials (i.e., Moderna and Pfizer/BioNTech) for potential authorized use in Canada very soon. Through advanced purchase agreements, Canada will initially receive a combined total of 6 million doses of the Moderna and Pfizer/BioNTech COVID-19 vaccines, if authorized, for distribution and allocation in the first quarter of 2021.

While complete or peer-reviewed evidence from Phase 3 clinical trials is not yet available, press releases by Pfizer/BioNTech ¹ and Moderna ² suggest favourable efficacy and safety of their COVID-19 vaccines. In their final analysis of 170 COVID-19 cases in a trial of 43,998 participants 12–85 years of age, Pfizer/BioNTech reported 95% efficacy 7 days after the second dose of their vaccine with 94% efficacy in adults 65 years of age and older. In their interim analysis of 95 COVID-19 cases in a trial of 30,000 participants 18 years of age and older, Moderna reported an efficacy of 94.5% 2 weeks after the second dose of their vaccine. Neither manufacturer reported serious safety concerns however, both reported that any adverse events were mainly transient and mild to moderate in severity.

NACI will not make specific recommendations on the clinical use of these COVID-19 vaccines until evidence from these Phase 3 clinical trials is available for committee review and synthesis according to NACI's evidence-informed process ^{3 4}.

NACI developed the following recommendations based on the evidence and extensive stakeholder consultations synthesized and presented in the NACI [Preliminary guidance on key populations for early COVID-19 immunization](#), the most recent information available at the time of deliberation on vaccine supply, and preliminary information suggesting comparable efficacy and safety of the Moderna and Pfizer/BioNTech COVID-19 vaccines.

Recommendations

The following recommendations are meant to help plan for the efficient and equitable allocation of initial doses of authorized COVID-19 vaccines when limited initial vaccine supply will necessitate the immunization of certain groups earlier than others. These recommendations further sequence the key populations identified in NACI's recent evidence-informed guidance on [Key populations for early COVID-19 immunization](#). The sequencing of these populations may change as more evidence on COVID-19 vaccines becomes available. Once initial supplies of authorized vaccines are available, the following populations should be offered vaccines according to the authorized immunization schedule (with efforts to ensure completion of the immunization schedule with the same vaccine). NACI does not provide further prioritization within the groups listed below.

Stage 1

NACI recommends that initial doses of authorized COVID-19 vaccine(s) should be offered to individuals without contraindications in the following populations:

- Residents and staff of congregate living settings that provide care for seniors
- Adults 70 years of age and older, beginning with adults 80 years of age and older, then decreasing the age limit by 5-year increments to age 70 years as supply becomes available
- Health care workers (including all those who work in health care settings and personal support workers whose work involves direct contact with patients)
- Adults in Indigenous communities where infection can have disproportionate consequences

Rationale

All residents and all staff of congregate living settings that provide care for seniors (i.e., long term care, assisted living, retirement homes, and chronic care hospitals) should be prioritized for the first COVID-19 vaccine doses as these settings in Canada have experienced a large number of outbreaks associated with a high number of fatalities⁵. Residents of these facilities are primarily of advanced age, further increasing their risk of severe outcomes, including hospitalization and death, due to COVID-19⁶.

All adults of advanced age should be prioritized for initial doses of authorized COVID-19 vaccines, beginning with adults 80 years of age and older, then decreasing the age limit in 5-year increments to age 70 years as supply becomes available. There is a large independent association of severe COVID-19 with increasing age and moderate certainty of evidence for a very large association of hospitalization and mortality particularly in those over 70 years of age. Studies

treating age on a continuum or across small increments have consistently found that risks for hospitalization and mortality increase with increasing age (e.g., approximately 2–6% and 5–10% relative increase in risk per year, respectively) ⁶.

All **health care workers** should be prioritized to receive the COVID-19 vaccine, since health care workers providing frontline care to patients are differentially exposed to SARS-CoV-2, and are needed to protect healthcare capacity. Health care workers are defined as including hospital employees, other staff who work or study in hospitals (e.g., students in health care disciplines, contract workers, volunteers) and other health care personnel (e.g., those working in clinical laboratories, nursing homes, home care agencies and community settings). In addition, immunizing health care workers and other workers functioning in a healthcare capacity (e.g., personal support workers) minimizes the disproportionate burden of those taking on additional risks to protect the public, thereby upholding the ethical principle of reciprocity. Among workers in a healthcare setting, those whose work puts them at increased risk due to direct contact with patients (e.g., physical contact with patients, sustained time in patients' room), particularly those who are in direct contact with COVID-19 patients, should be prioritized during the initial vaccine availability. This can be expanded to other health care workers based on subsequent supply availability.

NACI acknowledges that people of reproductive age constitute a substantial proportion of healthcare workers. Currently, no data on the use of COVID-19 vaccines in pregnancy is available. NACI continues to recommend the safe inclusion of pregnant individuals in clinical trials of candidate COVID-19 vaccines to ensure that this population has equitable access to COVID-19 vaccine options informed by robust safety, immunogenicity, and efficacy data ⁷. NACI also encourages additional research and surveillance of COVID-19 vaccination in pregnancy. Immunization during pregnancy will be further discussed by NACI in its forthcoming recommendations on the use of COVID-19 vaccine(s).

Adults living in Indigenous communities, which include First Nations, Métis, and Inuit communities, where infection can have disproportionate consequences such as those living in remote or isolated areas where access to health care may be limited, should be prioritized to receive initial doses of COVID-19 vaccines. Indigenous communities have been disproportionately impacted by past pandemics (e.g., 2009 H1N1 influenza pandemic). Remote or isolated communities, for example, may not have ready access to sufficient health care infrastructure. Therefore, their risk for severe outcomes, including death, and societal disruption is proportionally greater than in other communities. The risk of transmission is high in 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. Although there have been relatively few cases and outbreaks in these communities to date in Canada, the number of cases in these communities is increasing ⁸.

NACI acknowledges that racialized and marginalized populations in Canada have been disproportionately affected by COVID-19, and that systemic barriers to accessing necessary supportive care for COVID-19 also exist in urban settings related to factors such as poverty, systemic racism and homelessness. These populations may be considered for immunization concurrent with remote and isolated Indigenous communities if feasibly identified within jurisdictions, understanding that these are traditionally hardly reached populations for immunization programs.

NACI is committed to undertaking a comprehensive analysis to inform further program expansion with recommendations that are ethical, equitable, feasible, and acceptable. Through NACI's Ethics, Equity, Feasibility, and Acceptability framework ⁴, NACI is committed to exploring how systemically marginalized and racialized populations have been differentially impacted by COVID-19 and how to reduce these inequities through increased access to vaccines.

Stage 2

NACI recommends that as additional COVID-19 vaccine supplies become available with sufficient supply to vaccinate the above populations, authorized COVID-19 vaccine(s) should be offered to individuals without contraindications in the following populations:

- Health care workers not included in the initial rollout
- Residents and staff of all other congregate settings (e.g., quarters for migrant workers, correctional facilities, homeless shelters)
- Essential workers

Rationale

The risk of infection with SARS-CoV-2 is high in **congregate 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. Furthermore, many residents in these settings have inequitable access to health care.

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 ⁹ beyond those that have occurred in long-term care facilities.

Many **essential services** (e.g., police, firefighters, food production) cannot be provided virtually, potentially leading to an increased risk of exposure to SARS-CoV-2. Immunizing essential workers minimizes the disproportionate burden of those taking on additional risks to maintain services essential for the functioning of society. In addition, racialized populations and recent immigrants are over-represented in jobs providing essential services (e.g., food production, healthcare settings), and have been disproportionately affected by COVID-19 ¹⁰. Therefore, immunization of these workers has the potential to reduce, or prevent the exacerbation of health inequities related to COVID-19. 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.

Attempts should be made to plan for the efficient and equitable use of vaccines among the above recommended groups in the order prioritized (i.e., Stage 1 versus Stage 2), with minimization of risk of vaccine wastage. However, due to restrictive storage and handling requirements, there is a risk of dose wastage if excess doses remain after complete immunization in a particular setting. If doses of COVID-19 vaccine(s) have been delivered to an immunization setting and have been used for a group recommended in Stage 1 but cannot be re-located to another setting for other groups recommended in Stage 1, remaining doses on-site may be provided to individuals in the groups recommended in Stage 2 in order to minimize the risk of vaccine wastage and maximize the benefits of vaccination.

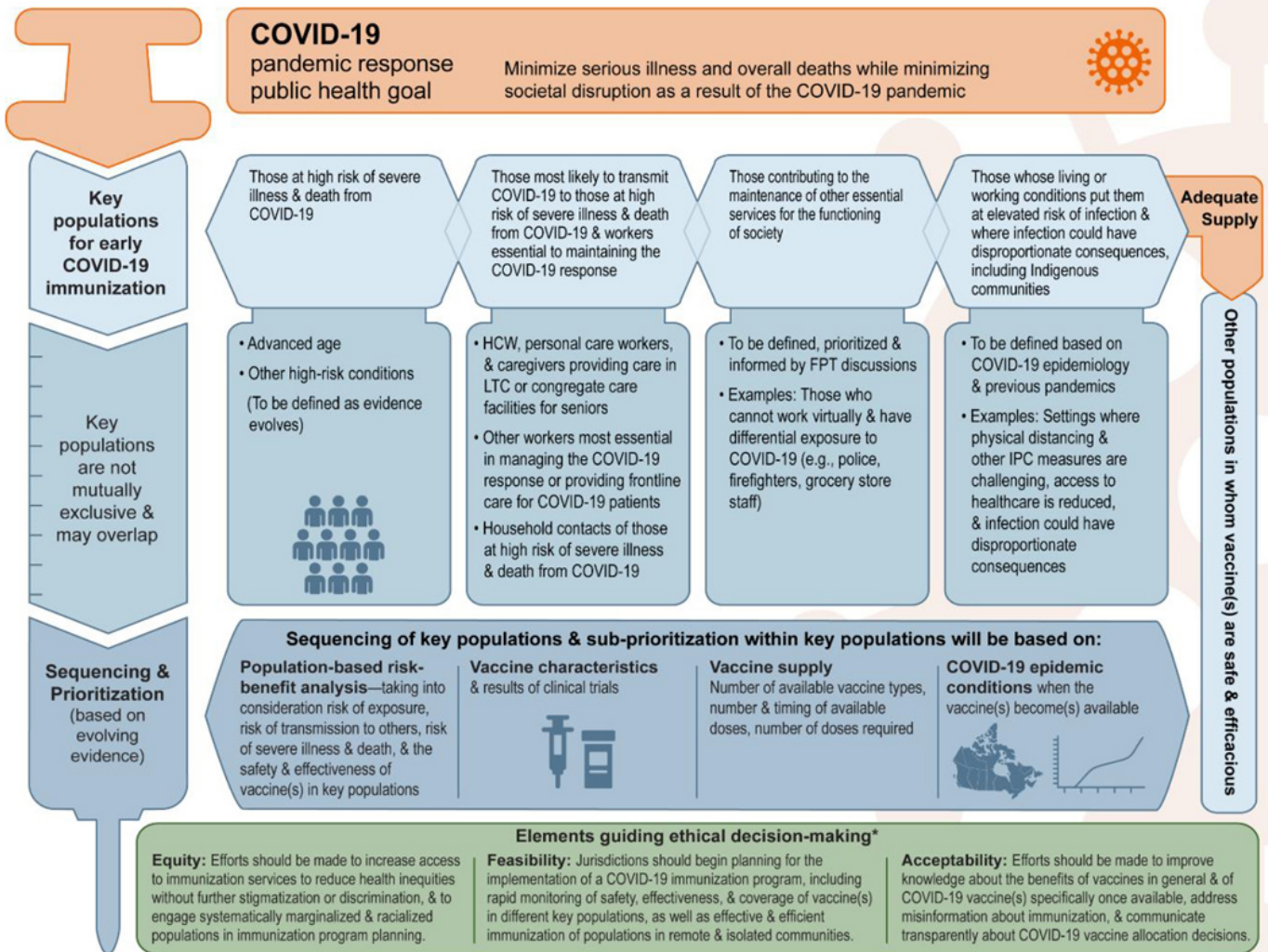
NACI continues to recommend the following elements to guide ethical decision-making:

- 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.

NACI will provide further guidance on the use of COVID-19 vaccine(s) upon further review of the evidence.

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



*based on the systematic assessment of ethics, equity, feasibility and acceptability using an evidence-informed framework, available at: <https://doi.org/10.1016/j.vaccine.2020.05.051>

Abbreviations:

- LTC: long-term care
- HCW: health care worker
- FPT: federal, provincial, territorial
- IPC: infection prevention and control

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NACI

Members: Dr. C Quach (Chair), Dr. S Deeks (Vice-Chair), Dr. J Bettinger, Dr. N Dayneka, Dr. P De Wals, Dr. E Dubé, 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).

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