



Role of the National Advisory Committee on Immunization (NACI) in COVID-19 Vaccine Planning

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December 2020



Declaration of Interests- Dr. Caroline Quach

- Nothing to Declare

OBJECTIVE

- Provide an overview of Canada's National Advisory Committee on Immunization (NACI) and role in COVID-19 vaccine planning
 - International context
 - NACI mandate for COVID-19
 - Preliminary guidance on key populations for early COVID-19 immunization
 - COVID-19 vaccine workplan for NACI

Presentation Recorded on December 12th 2020

Every attempt has been made to present the most current information however information about COVID-19 vaccines is rapidly evolving and the information presented here may be out of date.

Please check the Public Health Agency of Canada website for the most up to date information.

<https://www.canada.ca/en/public-health.html>

WHO Recommends National Immunization Technical Advisory Groups (NITAG)

- NITAGs now established in 134 countries and is the standard of care.
- Recently formed Global NITAG Network (GNN) to increase international collaboration (currently chaired by Canada)
- NACI has been Canada's NITAG for over 50 years, one of the oldest in the world
- We routinely review guidance from key NITAGs when framing issues for NACI and considering proposed recommendations:
 - **WHO** (SAGE) (COVID-19 vaccine working group underway, interim guidance published in September)
 - **USA** (ACIP)– CDC (COVID-19 vaccine working group underway)
 - **UK** (JCVI)– PHE (COVID-19 vaccine work underway, published interim guidance on priority groups in spring, updated in fall)
 - **Australia** (ATAGI)– Department of Health (COVID-19 vaccine work underway)
 - **Germany** (STIKO)– RKI (COVID-19 vaccine work underway)
- In Canada, most jurisdictions also have formal provincial/territorial immunization technical advisory groups (PITAGs)
 - E.g. Comité sur l'immunisation du Québec (CIQ)
 - E.g. Alberta Advisory Committee on Immunization

Health Canada vs. NACI

A NITAG is both a technical resource and a deliberative body to empower the national authorities and policy makers to make evidence-based decisions. Such a resource is particularly important in view of the complex and vast bodies of evidence and the global interdependence and integration of health systems. – *Duclos, Vaccine, 2010*

	Regulator Review	NACI Vaccine Advice
Purpose	Authorize specific indications for use that are expected to be safe, immunogenic, efficacious, and of suitable quality for individuals	Recommend vaccination strategies to promote health, prevent and control infectious diseases, and prepare for or respond to public health emergencies
Focus	Individual use of product	Use of product for public programs and population health and individual recommendations.
Data reviewed	Pre-clinical and clinical trial data and manufacturing information submitted by manufacturers, and post-marketing monitoring	All relevant/available evidence for specific vaccines and similar vaccine formulations in the context of public health considerations, including existing vaccine programs and schedules, disease burden and distribution, and outbreak management
Authority	Minister of Health / Federal Government	

- NACI can make off-label vaccine recommendations when there is a clear need supported by a public health ethics analysis



NACI Structure and Scope

- Established in 1964 by the Government of Canada (Health Canada)
- Provides public health advice relating to immunizing agents used for the prevention of disease in humans
- Scope has traditionally included recommendations based on safety, efficacy, immunogenicity, effectiveness and burden of illness
 - Since 2016, NACI mandate has been gradually expanded to include programmatic factors, such as program feasibility and cost-effectiveness where relevant
- Operates as an External Advisory Body (EAB) to PHAC (delivering advice to the Vice President of the Infectious Disease Prevention and Control Branch)
- Information can be found at: <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html>

The Canadian Immunization Guide (CIG)

- NACI develops evidence-based advice on vaccines approved for use in Canada based on all evidence available for any vaccine evidence.
- This advice is published to the public in the form of NACI statements.
- All of NACI's statements are synthesized into the Canadian Immunization Guide (CIG).

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Canadian Immunization Guide

Important Notice:
Interim guidance on continuity of immunization programs during the COVID-19 pandemic is now available

From [Public Health Agency of Canada](#)

Overview

The Canadian Immunization Guide is a comprehensive resource on immunization. It was developed based on recommendations and statements of expert advisory committees, including the:

- [National Advisory Committee on Immunization \(NACI\)](#)
- [Committee to Advise on Tropical Medicine and Travel \(CATMAT\)](#)

Who this guide is for

This guide was developed for those with an interest in immunization, including:

- health professionals
- vaccine program decision makers
- other Canadian stakeholders

In this guide

This guide consists of 54 chapters organized into 5 parts. Chapters are updated as new evidence becomes available, and NACI and CATMAT statements are completed. Email updates are available through our mailing list.

Related Services

- [Immunization schedules](#)

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NACI Membership

- PHAC appoints voting members, Chair and Vice Chair
 - Members: 4-year term with option of one renewal
 - Chair / Vice Chair: 2-year term two 1-year optional extensions (total 4 years)
- Voting members (Chair + 15) members appointed based on their expertise
 - Canadian experts in pediatric ID (2), adult ID (2), allergy/immunology (1), pharmacy (1), nursing (1), pharmacoeconomics (2), public health and preventive medicine (4), epidemiology (1), social sciences (1)
- 9 non-voting liaison representatives with an interest/role in immunization
 - E.g. Canadian Public Health Association, The Council of Chief Medical Officers of Health (CCMOH), Canadian Pediatric Society, College of Family Physicians of Canada
- 6 non-voting ex-officio federal representatives
 - PHAC, Health Canada, Indigenous Services Canada, National Defence and Canadian Armed Forces

NACI approach to conflicts of interest

- Members declare relevant interests at the beginning of each NACI meeting, and each WG meeting.
- Members declare any new relevant interests to NACI Secretariat when they emerge.
- Members complete annual Declaration of Interest Statements
- Member declarations are assessed for potential conflicts by NACI Executive Committee using an established PHAC tool.
- If COIs are identified, management strategies are applied (e.g. may not lead certain Working Groups, may not vote on some topics).

NACI COVID-19 vaccine workplan activities

NACI High Consequence Infectious Diseases Working Group (HCID WG) will lead NACI work on COVID-19 vaccines

COVID-19 vaccine activities

- Research/clinical trial priorities for COVID-19 vaccines
(July 2020 - completed)
- Preliminary guidance on key populations for early COVID-19 immunization
(November 2020 - completed)
- Guidance on prioritization of initial COVID-19 vaccine doses
(December 2020 – completed)
- Ongoing vaccine guidance for COVID-19 immunization and specific products
(In development)
- Convalescent plasma and mAb for prophylaxis
(PENDING: if trials progress)
- Other vaccines (e.g. BCG vaccine) for potential use as interim measures to protect against COVID-19 through off-target effects
(PENDING: if trials progress)

Guidance on key populations for early vaccines

NACI and Federal/Provincial/Territorial partners will define target groups in two phases:

1. Preliminary Guidance on priority immunization strategies with associated target groups to best achieve pandemic response public health goals

Issued before a vaccine candidate has been identified on November 3, 2020

2. Ongoing Guidance on vaccine strategies for COVID-19 vaccines as they become authorized in Canada

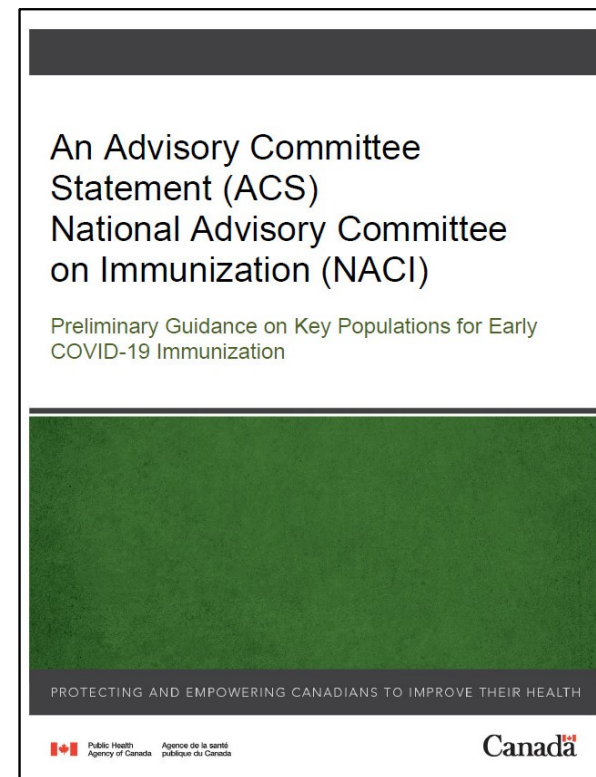
Issued on a rolling basis once vaccine candidates have completed advanced clinical trials starting December 2020 onwards

- NACI will refine and recalibrate initial guidance on target groups based on critical data that are currently not available:
 - Clinical trial outcomes for safety and efficacy in different populations (e.g. older adults, pregnancy)
 - Supply situation (e.g. number of doses available and delivery schedule)
 - Epidemic situation at the time of vaccine availability (e.g. where the epidemic waves are having greatest impact or potential impact)

NACI preliminary guidance on key populations for early COVID-19 immunization

Evidence base reviewed by NACI:

- Systematic review on risk factors for COVID-19 severe disease
- Canadian epidemiological data
- Feasibility assessments from F/P/T committees
- Results of a stakeholder survey on priority immunization strategies
- Canadian public opinion survey data
- Recommended strategies from other jurisdictions and groups (UK, France, US, Johns Hopkins University)
- *Modelling underway to inform final strategy once vaccines are selected*



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

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

Additional Resources

Canadian Immunization Guide

<https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html>

National Advisory Committee on Immunization Statements

<https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html>

Public Health Agency of Canada

<https://www.canada.ca/en/public-health.html>