Public Health Agency of Canada | Agence de la santé publique du Canada

Canada

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

PROTECTING AND EMPOWERING CANADIANS
TO IMPROVE THEIR HEALTH

Declaration of Interests- Dr. Shelley Deeks

- Nothing to Declare

OBJECTIVES

- Provide an overview of Canada's National Advisory Committee on Immunization (NACI) and role in COVID-19 vaccine planning, including:
  - NACI's role in the Federal/Provincial/Territorial landscape of bringing vaccines to Canada
  - NACI's process including triggers, membership and evidence
  - NACI's guidance on COVID-19 vaccines
  - NACI's role in creating the Canadian Immunization Guide

Who is involved in bringing vaccines to Canadians?

Health Canada

Authorizes health products for use in Canada, based on evidence of safety, efficacy and quality, and continues to regulate the products after authorization.

Public Health Agency

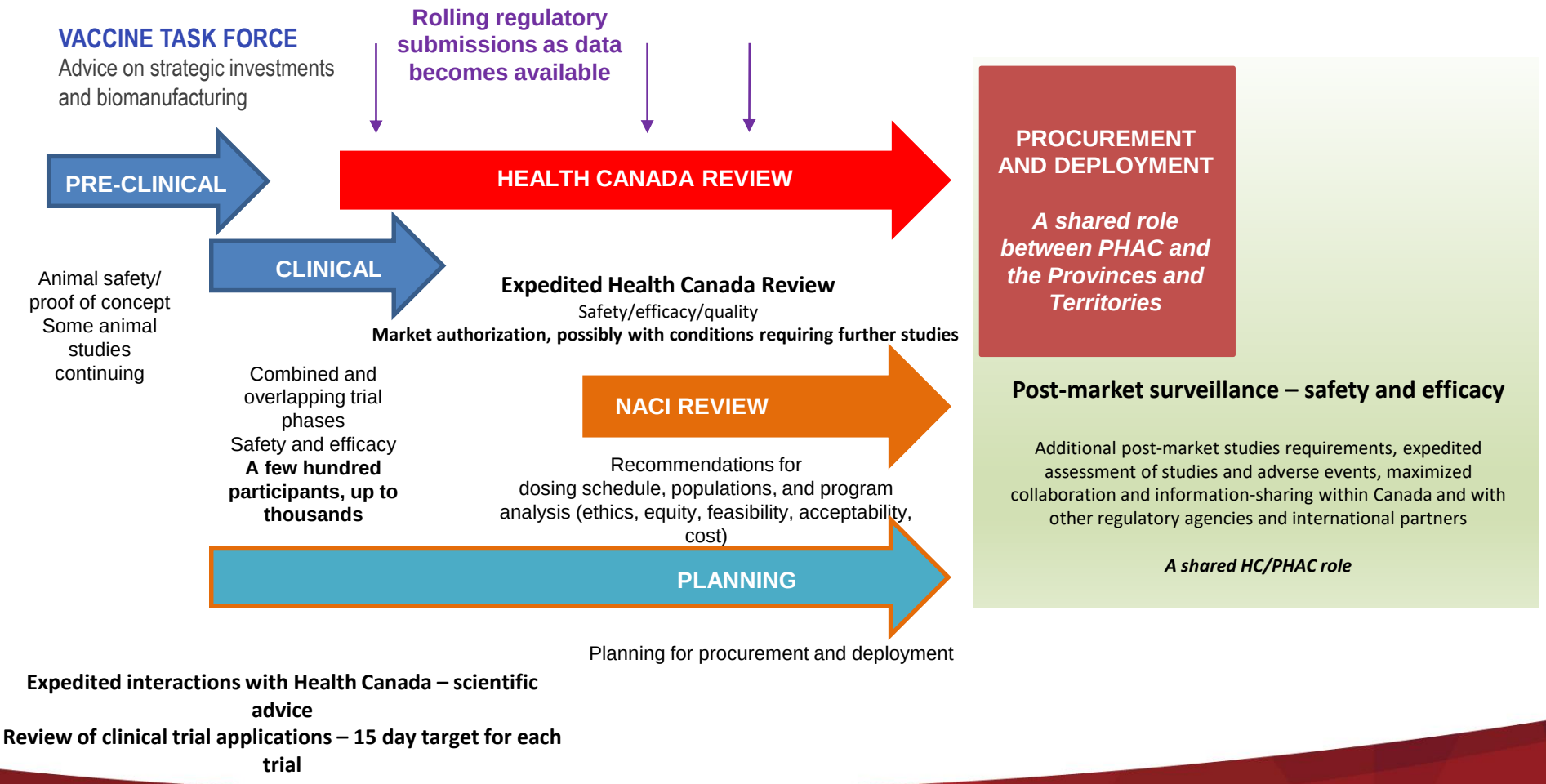
National Advisory Committee on Immunization (NACI) makes recommendations on use of authorized vaccines.

PHAC has a role in vaccine safety surveillance, working with the provinces and territories.

Provinces and Territories

Determine publicly funded vaccination program within their jurisdictions and responsible for vaccine funding, distribution and delivery.

Expedited Vaccine Development/ Authorization/ Deployment



Health Canada vs. NACI

	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 vaccine characteristics, epidemiology and a public health ethics analysis

National Immunization Technical Advisory Groups (NITAG)

- NITAGs are multidisciplinary groups of national experts responsible for providing independent, evidence-informed advice to policy makers and programme managers on policy issues related to immunization and vaccines.

- NITAGs now established in 134 countries and are recommended by the WHO.

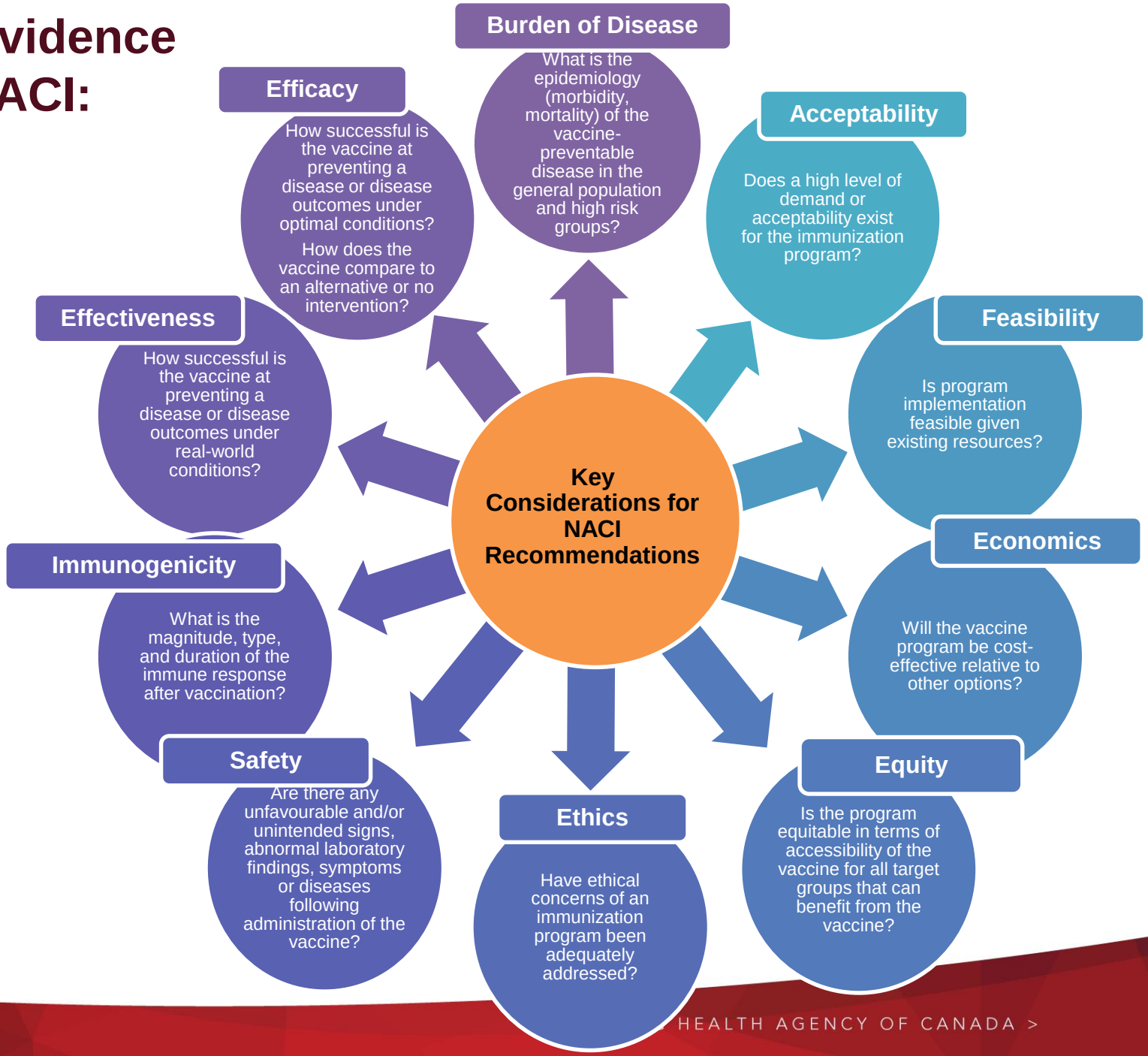
- The National Advisory Committee on Immunization (NACI) is Canada's national NITAG and is one of the longest standing (over 50 years)

- NACI makes recommendations for the use of vaccines currently or newly approved for use in humans in Canada, including the identification of groups at risk for vaccine-preventable diseases for whom vaccination should be targeted.

- In Canada, most jurisdictions also have formal provincial/territorial immunization technical advisory groups (PITAGs)

- In 2019, NACI expanded its mandate to include consideration of ethics, equity, feasibility, acceptability and economics

Types of Evidence Used by NACI:



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), public health 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 and COVID-19 Vaccines

NACI will provide guidance to public health decision makers and clinicians on multiple aspects of COVID-19 vaccines:

Completed:

- Research/clinical trial priorities for COVID-19 vaccines
- Preliminary guidance on key populations for early COVID-19 immunization
- Guidance on prioritization of initial COVID-19 vaccine doses

Ongoing:

- Ongoing vaccine guidance for COVID-19 immunization and specific products
- Updated Guidance on key populations for COVID-19 Immunization

NACI on COVID-19 Vaccines

Updated as of Jan 31 2021

▼ COVID-19

Current vaccine statement

This statement will be updated with recommendations on the use of authorized COVID-19 vaccines as they are approved for use in Canada, and as evidence on these vaccines and COVID-19 evolves. For earlier versions of this document, refer to the Previous versions.

- January 12, 2021: Recommendations on the use of COVID-19 vaccines
- Table of updates

▶ Previous versions

Prioritization statements

- December 2020: Guidance on the prioritization of initial doses of COVID-19 vaccine(s)
- November 2020: Preliminary guidance on key populations for early COVID-19 immunization
  - CMAJ – Key populations for early COVID-19 immunization: preliminary guidance for policy
  - BMJ – Navigating inequities: a roadmap out of the pandemic

Research priorities statement

- Archived: Research priorities for COVID-19 vaccines to support public health decisions [2020-07-15]
  - Refer to the current vaccine statement for research priorities.

Guidance documents

- October 2020: Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic
- September 2020: Guidance on the use of influenza vaccine in the presence of COVID-19
- August 2020: Guidance for influenza vaccine delivery in the presence of COVID-19
- May 2020: Interim guidance on continuity of immunization programs during the COVID-19 pandemic

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

COVID-19 Vaccine Guidance

Updated COVID-19 vaccine guidance will be available through the CIG, including updated information on:

- **Vaccine administration**

- Extended intervals between doses
- Vaccines and Allergies
- Anaphylaxis management
- Offering vaccine during pregnancy and breastfeeding
- Interchangeability between authorized vaccines

Vaccine administration

For additional vaccine product-specific information, consult the product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database. Refer to Vaccine Administration Practices in the Canadian Immunization Guide (CIG), Part 1 - Key Immunization Information for additional general information.

Dose, route of administration, and schedule

Dose

Pfizer-BioNTech COVID-19 vaccine

Each dose is 0.3 mL after dilution, containing 30 mcg of SARS-CoV-2 spike protein mRNA.

The dose for the Pfizer-BioNTech COVID-19 vaccine (0.3 mL) is unique compared to that of most routine vaccinations. Special precaution should be taken to ensure the correct dose is taken from the multi-dose vial.

Moderna COVID-19 vaccine

Each dose is 0.5 mL, containing 100 mcg of SARS-CoV-2 spike protein mRNA.

No dilution is required.

Route of administration

COVID-19 vaccines are given as an intramuscular (IM) injection into the deltoid muscle.

Refer to Vaccine Administration Practices in the CIG, Part 1 - Key Immunization Information for additional information.

Schedule

Refer to Table 2 for a summary of immunization schedules for authorized COVID-19 vaccines.

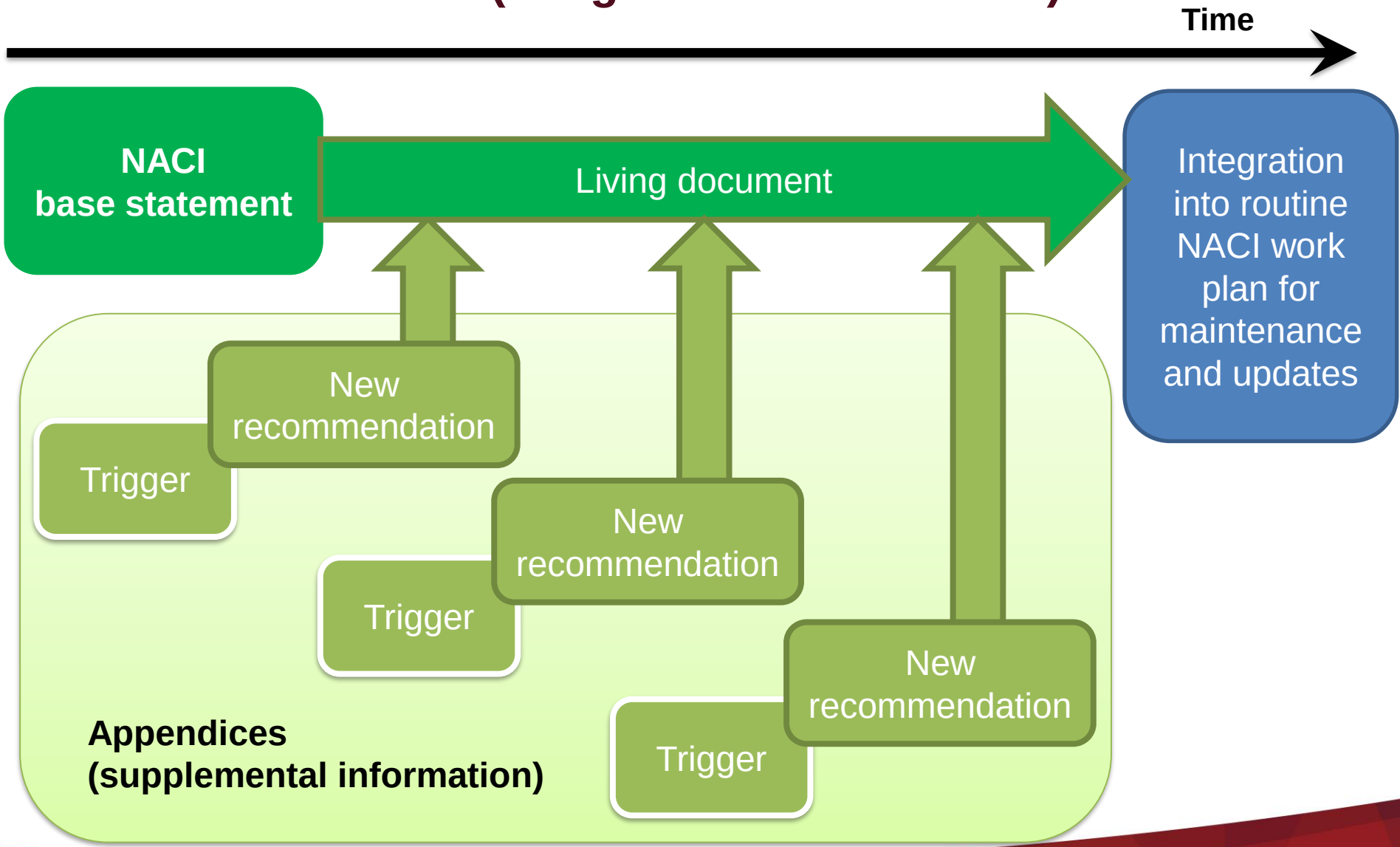
Table 2: Recommended immunization schedule, by COVID-19 vaccine

Vaccine product (manufacturer)	Immunization schedule	Minimum interval	Authorized interval	Alternate interval
Pfizer-BioNTech COVID-19 (Pfizer-BioNTech)	2-dose schedule	19 days	21 days	28 days
Moderna COVID-19 (Moderna)	2-dose schedule	21 days	28 days	None

Refer to Timing of Vaccine Administration in the CIG, Part 1 - Key Immunization Information for additional general information.

https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#b4

Framework for the development of NACI's COVID-19 vaccine statements (integrates CIG elements)



Canadian Immunization Guide

- Canadian Immunization Guide (CIG) 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)

- CIG is intended for:
  - Health professionals
  - Vaccine program decision makers
  - Other Canadian stakeholders

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

SUPPLEMENTAL SLIDES

Recommendations on the use of COVID-19 vaccines

Publication date: January 12, 2021

On this page

Disease Context

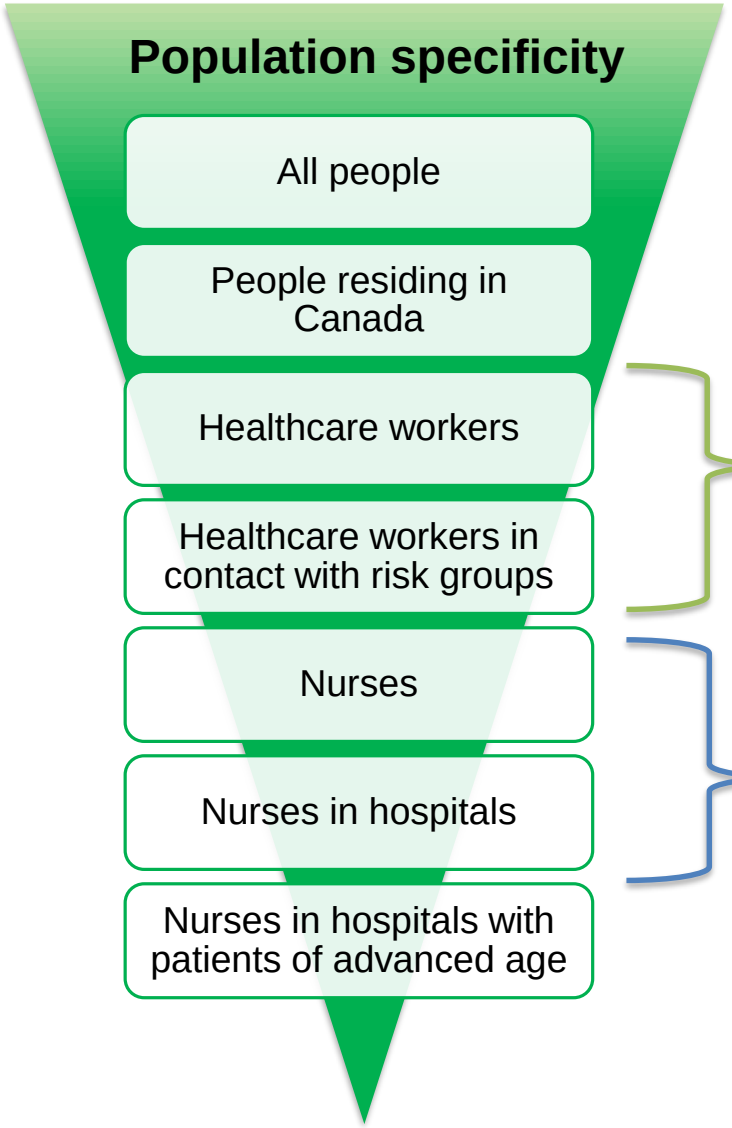
COVID-19 Vaccine Guidance

Guidance for Public Health

Vaccine-Specific Information

https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html

NACI's role in COVID-19 vaccine prioritization



Level of prioritization	Committee	Considerations
"Strategic" (sequencing of key populations)	NACI	• **Epidemiology** • **Vaccine characteristics as available** • **EEFA***
"Operational" (sub-prioritization within key populations and allocation/ distribution)	F/P/T	• **EEFA*** • Politics • Conformity of programs • Ability to evaluate

* Informed by EEFA tools populated in NACI's preliminary guidance (ethics, equity, feasibility, acceptability)

NACI Operations

- NACI face-to-face meetings (3 annually) are closed to the public (but summary minutes produced/posted)
  - Now meeting virtually once per month, with Working Group meeting every two weeks

- Expert Working Groups develop draft products for NACI consideration and voting
  - Established as needed to support NACI workplan
  - Working Groups include NACI members and external experts
  - Chaired by NACI members

- PHAC identifies the workplan and key questions for which NACI advice is sought

- PHAC provides scientific, project management, and logistical support

- NACI Executive Committee (Chair, Vice Chair, Executive Secretary, Secretariat Manager) provides oversight on meeting agendas, methods, work plan items and priorities

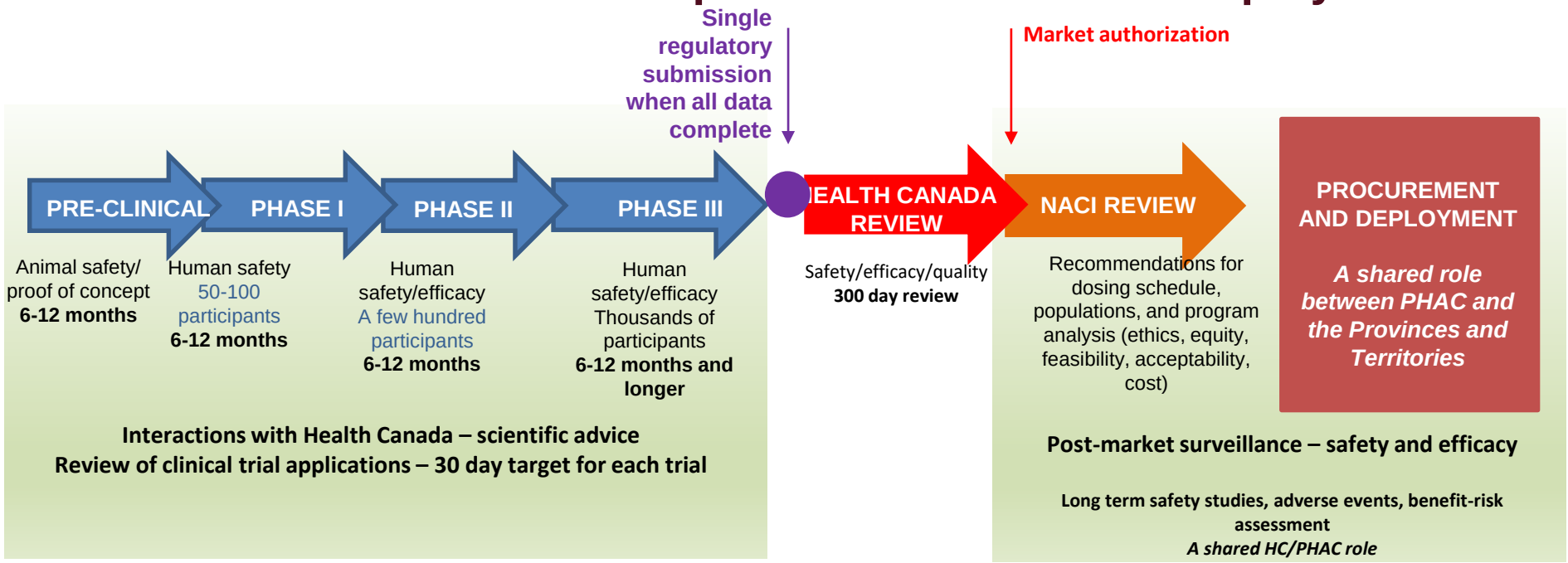
- NACI reports to the Vice President, Infectious Disease Prevention and Control Branch, who approves all NACI statements prior to public release

NACI Liaison and Ex Officio Representatives

- 9 liaison representatives (non-voting) from organizations with an interest/role in immunization
  - Association of Medical Microbiology and Infectious Disease Canada
  - Canadian Association for Immunization Research and Evaluation
  - Council of Chief Medical Officers of Health
  - Canadian Immunization Committee
  - Canadian Pediatric Society
  - Canadian Public Health Association
  - Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices (CDC-ACIP)
  - College of Family Physicians of Canada
  - Society of Obstetricians & Gynecologists of Canada

- 7 ex-officio (non-voting) federal representatives
  - PHAC: Immunization program areas represented, including National Microbiology Lab
  - Health Canada: Marketed Health Products Directorate, Biologic and Radiopharmaceutical Drugs Directorate
  - Indigenous Services Canada
  - National Defence and the Canadian Armed Forces
  - Public Health Ethics Consultative Group

Traditional Vaccine Development/ Authorization/ Deployment



Entire Process takes several years