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

• Provide an overview of Canada’s National Advisory Committee on Immunization (NACI) and role in COVID-19 vaccine planning
COVID-19 vaccine planning
WHO Recommends National Immunization Technical Advisory Groups (NITAG)

• NITAGs now established in 134 countries
• 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)
  – USA (ACIP) – CDC (COVID-19 vaccine working group underway)
  – UK (JCVI) – PHE (COVID-19 vaccine work underway, published interim guidance on priority groups in June)
  – 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. Comite sur l’immunization du Quebec (CIQ)
  – E.g. Alberta Advisory Committee on Immunization
National Advisory Committee on Immunization (NACI)

- NACI is a national advisory committee of experts in the fields of infectious diseases, immunology, pharmacy, nursing, epidemiology, pharmacoeconomics, social science and public health. NACI includes many liaison and ex officio groups with interest in vaccines – including Indigenous Services Canada.

- 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.

- Although vaccine recommendations are made at the federal level, the primary responsibility for matters related to the administration and delivery of health care services, including vaccination programs and who can administer vaccines, falls within provincial/territorial responsibility.

- This is why publicly-funded immunization programs may vary from province or territory.
Regulator (Health Canada) vs. NACI/PHAC

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

<table>
<thead>
<tr>
<th>Regulator Review</th>
<th>NACI Vaccine Advice</th>
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<tr>
<td><strong>Purpose</strong></td>
<td>Authorize specific indications for use that are expected to be safe, immunogenic, efficacious, and of suitable quality for individuals</td>
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<td><strong>Focus</strong></td>
<td>Individual use of product</td>
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<td><strong>Data reviewed</strong></td>
<td>Clinical trial data submitted by manufacturers, and post-marketing monitoring</td>
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<tr>
<td><strong>Authority</strong></td>
<td>Minister of Health / Federal Government</td>
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Recommend vaccination strategies to promote health, prevent and control infectious diseases, and prepare for or respond to public health emergencies

Use of product for public programs and population health

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

- NACI can make off-label vaccine recommendations when there is a clear need supported by a public health ethics analysis
NACI role in F/P/T pandemic vaccine responses

- NACI is identified in the F/P/T pandemic strategy as the authoritative body for advice on vaccine prioritisation and vaccine public health program design

- Canadian Pandemic Influenza Preparedness Guidance: Vaccine annex
  - “...NACI will provide expert advice and guidance for the use of pandemic vaccine, including prioritization. Their recommendations will include dosages and schedules based on pre-pandemic studies of relevant prototype vaccine and, to the extent possible, rapid clinical trials of the new vaccine.”
Key Considerations for NACI Recommendations

- Burden of Disease
- Efficacy
- Acceptability
- Effectiveness
- Feasibility
- Immunogenicity
- Economics
- Safety
- Equity
- Ethics
Key Populations for Early Vaccines

• The traditional influenza pandemic vaccine approach (i.e. to vaccinate everyone immediately) may not be advisable or appropriate for a novel coronavirus vaccine where there is limited trial experience of safety and effectiveness.

• NACI will define target groups in two phases:

  – **Interim Guidance**: before a vaccine candidate has been identified (early October 2020):
    • NACI is reviewing available evidence on the epidemiology and burden of COVID-19 to issue “interim” guidance on priority immunization strategies with associated target groups to best achieve pandemic response public health goals
  
  – **Final Guidance**: once a vaccine candidate has completed advanced clinical trials (fall/winter 2020-2021 if trials progress):
    • NACI will refine and recalibrate initial guidance on target groups, based on: additional safety and efficacy data from advanced clinical trials; availability of supply; one or multi-dose schedules; whether/how to vaccinate children and pregnant women; policy frameworks regarding ethics, equity, economics etc.)
COVID-19 Vaccine Pathway

**Vaccine Candidate**
- Determine R&D investment priorities
- Advise on Canadian investments
- International purchase agreements

**VTF Procurement & Development Advice**
- Determination if vaccine is safe and effective
- Authorization of Canadian clinical trials
- Authorization for sale in Canada

**HC Regulation**
- Program and clinical guidance on the best use of vaccines
- Review safety, efficacy, program equity, acceptability, feasibility, special populations, off-label use if needed

**PHAC/NACI Scientific Guidance on Deployment**
- Deployment considerations
- Logistics and program rollout

**PTs (CIC) PT Program Guidance**
- Reporting and sharing data
- Consider jurisdictional needs
- Ongoing purchase of vaccines and manufacturing

**PTs/ PHAC/ PSPC Implement & Ongoing Supply Mgmt.**
- Impact of vaccination on disease rates
- Vaccine safety profile post-market
- Emerging safety signals & ongoing monitoring

**PHAC/ HC Program Evaluation & Surveillance**

**Market Authorization**

**Public Health Agency of Canada**
PHAC has surveyed stakeholders to prioritize immunization strategies and determine key populations for early vaccine

- optimal strategies may vary depending on where we are in the pandemic curve when vaccine arrives

**Potential immunization strategies**

To minimize serious illness and overall deaths while minimizing societal disruption as a result of the COVID-19 pandemic

**Provide a safe and effective pandemic vaccine and monitor the safety and effectiveness of pandemic vaccine**

**Potential target groups for early COVID-19 vaccination**

For example:
- Adults >60 years of age
- Adults 19-60 years of age with one or more high-risk conditions
- Populations in lower socioeconomic groups
- Individuals with drug and alcohol use disorders
- Indigenous populations
- Pregnant populations and those who are immunocompromised
- Close contacts of the above populations

*These example target groups are based on COVID-19 disease epidemiology and may change as the evidence base for COVID-19 evolves.

**COVID-19 pandemic response public health goals**

- Protect those who are most vulnerable to severe illness and death from COVID-19
- Minimize transmission of COVID-19 disease (i.e., reduce total number of cases)
- Protect critical infrastructure
- Protect healthcare capacity

Canada's National Strategy for Critical Infrastructure classifies critical infrastructure according to the following 10 sectors:
- energy and utilities
- information and communication technologies
- finance
- health
- food
- water
- transportation
- safety
- government
- manufacturing

Healthcare workers and personnel in:
- hospitals
- labs
- pharmacies
- Emergency Medical Services
- public health
- outpatient clinics

For example:
- Institutions where outbreaks occur
- Shelters/group homes/dormitories or overcrowded neighbourhoods
- Homeless populations
- Immigrant or refugee populations and migrant workers
- People with occupations who cannot work virtually and have high social contact

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Feedback so far from Indigenous partners

- Indigenous, remote and isolated communities face unique challenges for COVID-19
- Historical example of H1N1 shows us that transmission can become widespread in small communities
- Multi-generational homes can make it difficult to isolate elderly and other risk groups
- Sequential roll-out of vaccine through multiple immunization campaigns in northern communities may not be feasible to implement
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
1. Research/clinical trial priorities for COVID-19 vaccines (July 2020 - completed)
2. Interim guidance on immunization strategies and target groups for potential COVID-19 vaccines (October 2020)
3. Final vaccine guidance for specific products (PENDING: if trials progress)
4. Convalescent plasma and mAb for prophylaxis (PENDING: if trials progress)
5. Other vaccines (e.g., BCG) for potential use as interim measures to protect against COVID-19 through off-target effects (PENDING: if trials progress)

• NACI Secretariat is closely monitoring the vaccine trial landscape and collating the following evidence:
  - Epidemiological summaries
  - Systematic review on risk factors for severe COVID-19 disease
  - Vaccine acceptability research
  - Clinical trial data
  - Vaccine modeling
Questions
The recommendations in the interim statement 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 vaccination of certain groups earlier than others.

These groups may differ depending on the immunization strategy or strategies to be implemented at the time of initial COVID-19 vaccine availability that can best achieve pandemic response public health goals (see the top section of the figure on slide).

The underlying strategy for all groups will be to provide a safe and effective vaccine with ongoing monitoring of safety and effectiveness.

Potential target groups under each of the pandemic immunization strategies are presented in the figure. This broad list of potential target groups will be refined once vaccine information, such as efficacy and safety in different populations, becomes available.