WEBINAR SERIES

PHAC: Revaccination with COVID-19 vaccines after anaphylaxis

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Canada

November 15, 2021

National Advisory Committee on Immunization (NACI) updated recommendations on vaccination of people with severe immediate allergic reactions (e.g. anaphylaxis) following COVID-19 vaccines or to their components

Speaker: Elissa Abrams, MD, MPH, FRCPC
Moderator: Stephanie Elliott, MPH, CPH

PROTECTING AND EMPOWERING CANADIANS TO IMPROVE THEIR HEALTH

Conflict of Interest/Disclosures:

Dr. Elissa Abrams:

- Chair of the Anaphylaxis Section of the Canadian Society of Allergy and Clinical Immunology (CSACI)
- President of the Allergy Section of the Canadian Pediatric Society (CPS)
- Co-author or lead author on some of the studies related to anaphylaxis/ allergic reactions following COVID-19 vaccines
- Co-author on the CSACI recommendations regarding anaphylaxis following COVID-19 vaccines

Stephanie Elliott: None to declare

Objectives

- Explain the **October 22nd, 2021** guidance from the National Advisory Committee on Immunization regarding revaccination of people with previous **severe immediate allergic reactions** (e.g. anaphylaxis) following **COVID-19 vaccines** or **to their components.**
- Examine the evidence and rationale behind the recommendations.
- Locate resources to facilitate safe vaccination or revaccination of people with severe immediate allergic reactions (e.g. anaphylaxis) following COVID-19 vaccines or to their components.

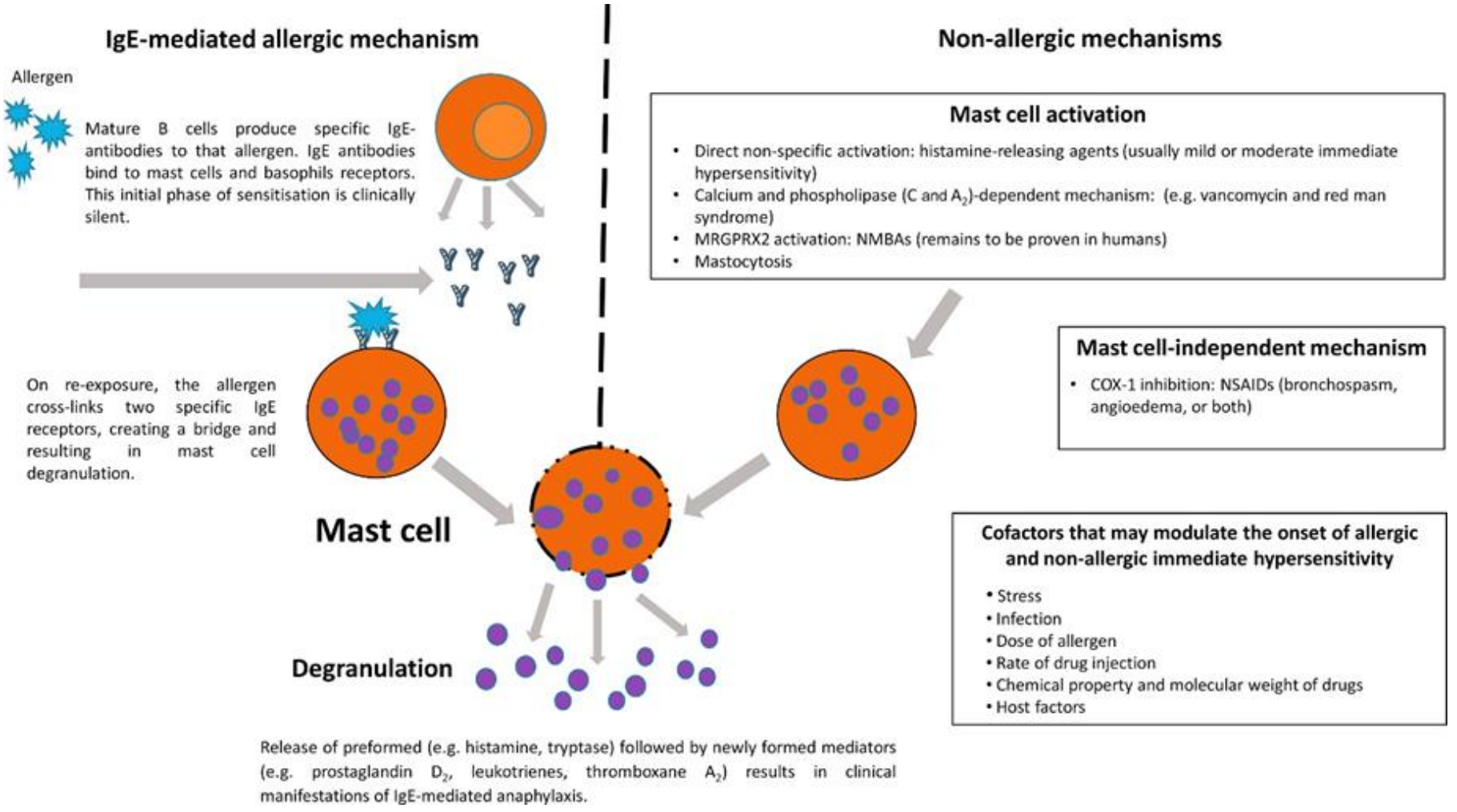
Overview of Anaphylaxis

Signs of anaphylaxis may include but are not limited to:

- Skin symptoms (hives, swelling)
- Respiratory symptoms (wheezing, difficulty breathing)
- Gastrointestinal symptoms (vomiting)
- Cardiovascular symptoms (decreased level of consciousness, shock)

Most severe immediate allergic reactions occur within 30 minutes of vaccination

Pathophysiological Mechanisms



- There are different mechanisms of action for anaphylaxis (IgE mediated versus non-IgE mediated)
- Emerging evidence suggests that many of the severe reactions following COVID-19 vaccines are likely not IgE mediated
- Non-IgE mediated reactions can be **less likely to recur** with subsequent exposure

Image from : P Dewachter, L Savic (2019) PMC7807982 // DOI: 10.1016/j.bjae.2019.06.002

Incidence of anaphylaxis after COVID-19 vaccines is higher than for non-COVID-19 vaccines but remains very rare

- Rates of anaphylaxis are dependent on which diagnostic criteria are used.
- Incidence rate of severe allergic reactions to mRNA vaccines is estimated to be approximately 2-10 cases per million doses of vaccine administered.
  - Incidence rate for viral vector vaccines is estimated at ~4.7 cases per million doses).
  - Incidence for other vaccines is lower than for mRNA and viral vector vaccines (1.3 cases per million doses).

Anaphylaxis rates for COVID-19 vaccines in Canada are similar to those reported around the world

Severe immediate reactions meeting Brighton criteria 1-3 for anaphylaxis following COVID-19 Vaccines reported to Canadian adverse event following immunization surveillance system (CAEFISS) per million doses as of October 29, 2021

Vaccine	Rate per 1,000,000 doses
Pfizer BioNTech Cominarty	10.0
Moderna Spikevax	7.8
AstraZeneca Vaxzevria /Covishield	7.5
Total rate	9.3

As of October 29, 2021, there have been:

- 539 anaphylaxis cases (total) reported in Canada
- 0 fatalities identified in Canada in association with anaphylactic reactions following COVID-19 vaccines

Some vaccine components in COVID-19 vaccines have been identified as potential allergens

Vaccine / packaging contents	Vaccine	Components found in
Polyethylene glycol (PEG)	mRNA vaccines	cosmetics, drugs such as cough syrups, medical bowel preparations, such as those used for colonoscopy, or ultrasound gels
Tromethamine	Moderna Spikevax vaccine	contrast media and some oral and parenteral medications
Polysorbate 80	Viral vector vaccines	cosmetics and some medical preparations, such as tablets, oils and vitamins

Skin testing of those who experienced immediate severe allergic reactions to mRNA vaccines suggest the reactions may not be IgE mediated.

Several small studies show that **people with severe allergic reactions to a previous dose of an mRNA vaccine can safely be revaccinated** with another mRNA vaccine

Study	Sample size	Study design	Findings

Krantz MS, Kwah JG, et al. *JAMA Internal Medicine* (DOI: 10.1001/jamainternmed.2021.3779)	n=189
	32 met criteria for anaphylaxis
	159 revaccinated
		retrospective	• All 159 revaccinated participants tolerated a second dose
			  • 19 of those had previous reactions that met anaphylaxis criteria
			  • 20% reported mild allergic symptoms following revaccination that were self-limiting or resolved with antihistamines

Kessel A, Bamberger E, et al. *Allergy* (DOI: 10.1111/all.15038)	n=18 36.8% met criteria for anaphylaxis	prospective	• Skin testing with vaccine in 15; skin prick and intradermal tests to PEG in 16 • All 18 were revaccinated with Pfizer-BioNTech • 14 had no reaction; 4 had an immediate reaction-milder than their initial reaction, none required epinephrine or ED visit
Krantz MS, Bruusgaard-Mouritsen MA et al *Allergy* (DOI: 10.1111/all.14958)	n=47 39 mild reactions 8 met criteria for anaphylaxis	prospective	• PEG allergies were ruled out in those who experienced anaphylactic reactions (skin testing, challenge, or tolerance history) • All 8 tolerated second dose with no or significantly milder reaction
Kelso JM, *Ann Allergy Asthma Immunol* (DOI:10.1016/j.anai.2021.03.024)	n=4	case series	• All cases had a systemic allergic reaction to mRNA vaccines • Skin prick and intradermal tests negative • 3 of 4 received a subsequent dose with no or mild symptoms

PEG: polyethylene glycol

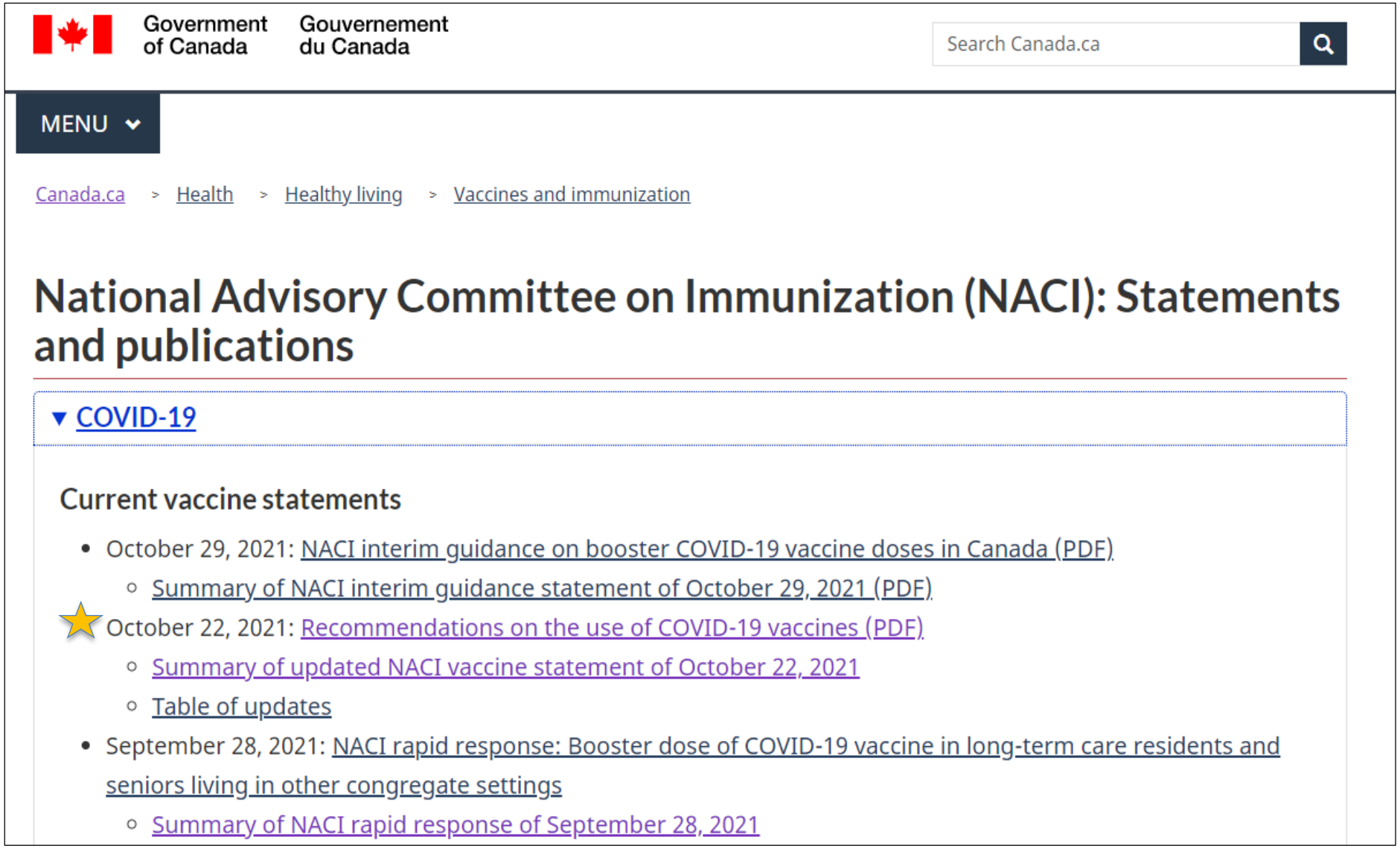
Previous NACI Recommendation
September 28, 2021

- An authorized COVID-19 vaccine should not be offered routinely to individuals with a history of severe allergic reaction (e.g., anaphylaxis) after previous administration of a COVID-19 vaccine using a similar platform (mRNA or viral vector).

- If a risk assessment deems that the benefits outweigh the potential risks for the individual; and if informed consent is provided, an authorized COVID-19 vaccine using a different platform may be considered for re-immunization (i.e., individuals with anaphylaxis post mRNA vaccine may be offered a viral vector vaccine and individuals with anaphylaxis post viral vector vaccine may be offered a mRNA vaccine).

- An authorized COVID-19 vaccine should not be routinely offered to individuals who are allergic to any component of the specific COVID-19 vaccine or its container.

NACI recommendation updated October 22, 2021



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National Advisory Committee on Immunization (NACI): Statements and publications

▼ COVID-19

Current vaccine statements

- October 29, 2021: NACI interim guidance on booster COVID-19 vaccine doses in Canada (PDF)
  - Summary of NACI interim guidance statement of October 29, 2021 (PDF)
- October 22, 2021: Recommendations on the use of COVID-19 vaccines (PDF)
  - Summary of updated NACI vaccine statement of October 22, 2021
  - Table of updates
- September 28, 2021: NACI rapid response: Booster dose of COVID-19 vaccine in long-term care residents and seniors living in other congregate settings
  - Summary of NACI rapid response of September 28, 2021

Visit Recommendations on the use of COVID-19 Vaccines (published October 22, 2021)

Current NACI Recommendations, October 22, 2021

mRNA vaccines

- In individuals with a history of a severe, immediate (≤4h following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of **an mRNA COVID-19 vaccine**:
  - revaccination may be offered with the same vaccine or the same mRNA platform if:
    - risk assessment deems that the benefits outweigh the potential risks for the individual
    - informed consent is provided
- Consultation with an allergist or other appropriate physician should be sought prior to revaccination.

Current NACI Recommendations
mRNA vaccines (cont'd)

- If revaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis.

- Individuals should be observed for **at least** 30 minutes after re-vaccination.
  - A longer period of observation is warranted for individuals exhibiting any symptom suggestive of an evolving AEFI at the end of the 30 minute observation period.

Current NACI Recommendations

Viral Vector Vaccines

In individuals with a history of a severe, immediate (≤4h following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of a **viral vector COVID-19 vaccine**:

- revaccination may be offered with an mRNA platform if:
  - a risk assessment deems that the benefits outweigh the potential risks for the individual and
  - informed consent is provided.

- if revaccinated, individuals should be observed for **at least** 30 minutes after re-vaccination.

Current NACI Recommendations

Components of the vaccine or its container

Individuals with a confirmed severe, immediate (≤ 4h following exposure) allergy (e.g., anaphylaxis) to a **component of a specific COVID-19 vaccine or its container** (e.g., PEG):

- consultation with an allergist is recommended before receiving the specific COVID-19 vaccine.
- Individuals who are allergic to tromethamine (found in the Moderna product) should be offered the Pfizer-BioNTech vaccine which does not contain this excipient
- Individuals who are allergic to polysorbates (found in viral vector vaccines), should be offered an mRNA vaccine.

Other COVID-19 vaccine precautions related to allergies:

- ✓ People with **previous mild to moderate allergic reactions to COVID-19 vaccines***
- ✓ People with **suspected but unproven allergies to a COVID-19 vaccine ingredient** (e.g. PEG)
- ✓ People with **severe allergies to injectable therapies such as other vaccines**

Can be vaccinated and **observed for at least 30 minutes** following vaccination

No precautions are needed for people with food, environmental or other drug allergies

*Consultation with a physician or nurse with expertise in immunization may be warranted

Key takeaways for health care professionals

- Due to emerging evidence that individuals can be safely vaccinated following severe immediate allergic reactions to COVID-19 vaccines or their components, NACI has revised their statement on contraindications.
- In order to proceed with revaccinating someone with a previous severe immediate reaction to a COVID-19 vaccine, providers should:
  - Weigh the risks of vaccination and allergic reaction with the benefits of vaccination
  - Provide the patient with informed choice.
  - Refer to an allergist or physician with experience with anaphylaxis.
- When vaccinated, the patient should be in a controlled setting with expertise and equipment to manage anaphylaxis.
- They should be observed for 30 minutes or more, longer if they demonstrate any signs of evolving adverse reaction within the 30-minute period.

Resources on revaccination

The Canadian Society of Allergy and Clinical Immunology

For up-to-date information on COVID-19 vaccines and allergies

COVID-19 vaccine testing & administration guidance for allergists/ immunologists from the Canadian Society of Allergy and Clinical Immunology (CSACI)

April 2021 guidance and background information on COVID-19 vaccine administration for individuals with allergies

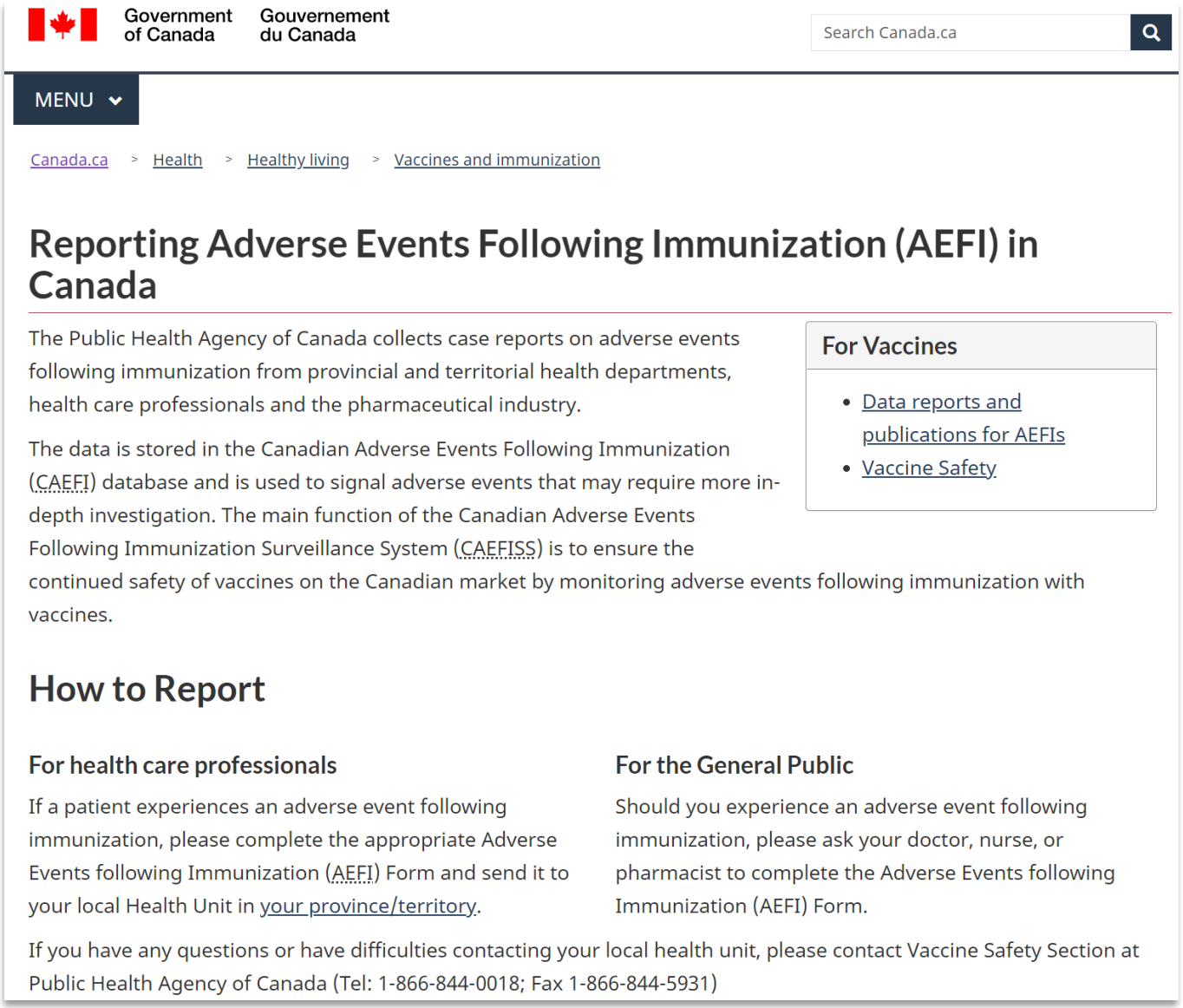
Special Immunization Clinic Network

SIC provides standardized assessments of patients with previous AEFIs and assesses risk of recurrence following immunization, conducts research, and supports a network of expert physicians for referral across Canada

Reporting AEFIs

- **How to report an AEFI:**
  Reporting Adverse Events Following Immunization (AEFI) in Canada
- **Submission of AEFI reports:**
  User guide to completion and submission of the AEFI reports

Processes may vary depending on the province or territory.



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Reporting Adverse Events Following Immunization (AEFI) in Canada

The Public Health Agency of Canada collects case reports on adverse events following immunization from provincial and territorial health departments, health care professionals and the pharmaceutical industry.

The data is stored in the Canadian Adverse Events Following Immunization (CAEFI) database and is used to signal adverse events that may require more in-depth investigation. The main function of the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) is to ensure the continued safety of vaccines on the Canadian market by monitoring adverse events following immunization with vaccines.

For Vaccines

- Data reports and publications for AEFIs
- Vaccine Safety

How to Report

For health care professionals

If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events following Immunization (AEFI) Form and send it to your local Health Unit in your province/territory.

For the General Public

Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events following Immunization (AEFI) Form.

If you have any questions or have difficulties contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada (Tel: 1-866-844-0018; Fax 1-866-844-5931)

Vaccine injury support program (VISP)

https://vaccineinjurysupport.ca/en

- Financial support to individuals who:
  - Experience a **serious** and **permanent** injury from a Health Canada-authorized vaccine or immunoglobulin administered in Canada*;
  - Received the vaccine on or after December 8, 2020; and,
  - Submitted a claim within three years after the date of vaccination, date of death or date when an injury first becomes apparent (when a serious and permanent injury becomes apparent gradually, the time limit will run only from the day the injury first becomes apparent).

- Serious and permanent injury
  - severe, life-threatening or life-altering injury that may require in-person hospitalization, or a prolongation of existing hospitalization, and
  - results in persistent or significant disability or incapacity, or where the outcome is a congenital malformation or death

* Members of the Canadian Armed Forces, Government of Canada officials, and their dependents who are deployed or posted outside of Canada are deemed people in Canada for the purposes of this pan-Canadian Program.

QUESTION & ANSWER PERIOD

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SUPPLEMENT

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