WEBINAR SERIES

PHAC: Revaccination with COVID-19 vaccines after anaphylaxis

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2. Please take our post-webinar survey.

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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
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 22\textsuperscript{nd}, 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
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
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

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Rate per 1,000,000 doses</th>
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<tbody>
<tr>
<td>Pfizer BioNTech Cominarty</td>
<td>10.0</td>
</tr>
<tr>
<td>Moderna Spikevax</td>
<td>7.8</td>
</tr>
<tr>
<td>AstraZeneca Vaxzevria /Covishield</td>
<td>7.5</td>
</tr>
<tr>
<td>Total rate</td>
<td>9.3</td>
</tr>
</tbody>
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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

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

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.

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample size</th>
<th>Study design</th>
<th>Findings</th>
</tr>
</thead>
</table>
| 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
• 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.
National Advisory Committee on Immunization (NACI): Statements and publications

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)
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.
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 AEFIIs 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.
Vaccine injury support program (VISP)

- 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.

https://vaccineinjurysupport.ca/en
QUESTION & ANSWER PERIOD

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SUPPLEMENT
<table>
<thead>
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<tbody>
<tr>
<td>Krantz MS, Bruusgaard-Mouritsen MA et al.</td>
<td>Anaphylaxis to the first dose of mRNA SARS-CoV-2 vaccines: Don’t give up on the second dose!</td>
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<tr>
<td>Krantz MS, Kwah JH et al.</td>
<td>Safety evaluation of the second dose of mRNA COVID-19 vaccines in patients with immediate reactions to the first dose. JAMA Internal Medicine 2021; epub ahead of print</td>
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<td>Kessel A, Bamberger E et al.</td>
<td>Safe administration of the Pfizer-BioNTech COVID-19 vaccine following an immediate reaction to the first dose. Allergy 2021 [epub ahead of print],</td>
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<tr>
<td>Shimabukuro T.</td>
<td>COVID-19 vaccine safety update. Advisory Committee on Immunization Practices (ACIP)</td>
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