COVID-19 Vaccine Testing & Administration Guidance for Allergists/Immunologists from the CSACI

Current as of November 14, 2021, and based on available evidence to date

COVID-19 vaccines have demonstrated efficacy and effectiveness against severe COVID-19 outcomes including hospitalizations, intensive care unit admissions, and fatality. They provide the first hope for mitigating the devastating health and economic impacts resulting from the pandemic. Two mRNA vaccines (Pfizer-BioNTech, Moderna), and two adenovirus vector vaccines (AstraZeneca/COVISHIELD, Janssen) are currently approved in Canada.¹

Reports of reactions to COVID-19 vaccines have raised questions about their safety for use in individuals with allergies. In this document, we aim to address these concerns and provide guidance for CSACI members.

Suggested approach to vaccination in individuals with confirmed or suspected allergic conditions:

- Assessment by an allergist is NOT WARRANTED prior to receiving COVID-19 vaccination for individuals with a history of unrelated allergic conditions or adverse reactions, INCLUDING ANAPHYLAXIS, such as:
 - Other vaccines
 - o Foods
 - Insect venom
 - o Environmental allergies
 - Unrelated oral/injected medication
 - o Radiocontrast media (RCM), and
 - o Asthma, allergic rhinitis, or atopic dermatitis

In these individuals, the available COVID-19 vaccines can be administered without any special precautions or investigations. The COVID-19 vaccines available do not contain any food products, antibiotics, latex, or thiomersal.¹ As with the routine administration of all vaccines, the COVID-19 vaccine should be administered in a healthcare setting capable of managing anaphylaxis, and individuals should be observed for a minimum of 15 minutes following vaccination (or 30 minutes if a history of injectable medication allergy or unrelated vaccine allergy).^{1,2}

- Assessment by an allergist is NOT WARRANTED for any individual who has a history of a mild, localized reaction to a prior dose of the COVID-19 vaccine, or to any of its components. The risk of anaphylaxis is low and these individuals can be safely receive a subsequent dose of the same vaccine^{3–5}. A prolonged 30-minute observation period may be considered.
- Assessment by an allergist is WARRANTED for any individual with anaphylaxis following the COVID-19 vaccine or to any of its components. This is strongly preferred over not being vaccinated or withholding vaccination, and includes anyone who has experienced a suspected severe immediate allergic reaction after administration of a

COVID-19 vaccine, or someone with a confirmed allergy to a component of the vaccine.¹ There is increasing evidence that these individuals can safely receive a subsequent dose of the same vaccine with low risk of a systemic reaction under the supervision of an allergist.^{6–10} This recommendation is in keeping with the National Advisory Committee on Immunization (NACI) recommendations, which currently recommend that revaccination with the same vaccine or same mRNA platform may be offered in consultation with an allergist.¹

• These recommendations will be updated as evidence evolves to reflect ongoing best practice.

Summary:

- 1. There is a low risk for allergic reactions associated with vaccines. Non-allergic reactions to vaccines are much more frequent than allergic reactions.
- 2. The nature and cause of the reported allergic reactions to COVID-19 vaccines remain unclear, including what component of the vaccine those individuals may have reacted to.
- 3. The role of allergy testing for COVID-19 vaccines and their excipients is limited and not currently recommended.
- 4. In someone with anaphylaxis following a COVID-19 vaccine for whom an additional dose is required, revaccination with the same platform vaccine has been demonstrated to be safe under the supervision of an allergist. Graded dosing may be considered. A prolonged observation period of at least 30 minutes is recommended.

1. There is a low risk for allergic reactions associated with vaccines. Non-allergic reactions to vaccines are much more frequent than allergic reactions.

Vaccines activate the immune system, which commonly result in minor local and systemic side effects, including fever and local inflammatory reactions (redness, swelling, pain and warmth) at the site of the injection. As with other vaccines, local cutaneous reactions after vaccination with COVID-19 vaccines are common. These reactions may include acute localized urticaria and/or angioedema^{3,4} and tend to be mild and self-limiting. These reactions are not a contraindication to receiving the same vaccine in the future, as they do not pose a risk for future severe allergic reactions.

Non-allergic reactions to vaccines also include immunization stress-related responses that can mimic allergic reactions, and may include breath-holding, hyperventilation, and vasovagal syncope (fainting).¹³

To date, there have been more than 250 million reported cases of COVID-19 worldwide and over 5 million deaths¹⁴. By comparison, while approximately 7.5 billion COVID-19 vaccine doses have been administered¹⁴, there have been neither reported fatalities nor long-term morbidity associated with anaphylaxis following COVID-19 vaccine administration.