

ADVISORY

SUBJECT: Medical Reasons to Not Receive an mRNA COVID-19 Vaccine

Date: August 30, 2021

Pages: 4

To: Primary Care Providers, Hospitals, Long-Term Care Homes,

Retirement Homes

From: Dr. Matthew Tenenbaum, Associate Medical Officer of Health

- Due to Directive #6, primary care providers may receive additional requests for notes documenting medical exemptions to COVID-19 vaccination.
- Medical exemptions are expected to be infrequent and should be supported by expert consultation.
- Individuals with a severe allergic reaction to the vaccine or one of its components should be referred to an allergist/immunologist for assessment. These instances should be reported to WDGPH.
- Individuals with other allergies can be immunized and do not require an exemption.
- Individuals with physician-diagnosed myocarditis or pericarditis following the first dose
 of a COVID-19 vaccine should defer their second dose at this time. These instances
 should be reported to WDGPH.
- All other physician-diagnosed cases of myocarditis or pericarditis can be vaccinated and do not require a medical exemption.
- Medical treatments that require vaccination timing to be altered should be identified and a time for immunizations determined with their specialist.
- Individuals with an adverse event following immunization (AEFI) do not automatically
 qualify for a medical exemption. These events should be reported to WDGPH, and
 WDGPH will follow up with the primary care providers if their patient should not receive
 further doses of vaccine.
- If you have patients that wish to decline vaccination for a non-medical reason, please be aware that there are no COVID-19 vaccine exemption affidavits for adults.

Background

On August 17, Ontario's Chief Medical Officer of Health issued <u>Directive #6</u>. This directive requires hospitals, home and community care providers, LHINs, and ambulance services to establish COVID-19 vaccination policies for their employees, staff, contractors, volunteers, and students, each of whom must provide:

- 1. Proof of full vaccination against COVID-19; or
- 2. Written proof of a medical reason for not being immunized, provided by a physician or nurse practitioner; or
- 3. Proof of completing an educational session about COVID-19 vaccination.¹

Wellington-Dufferin-Guelph Public Health (WDGPH) anticipates that the implementation of Directive #6 may result in a greater volume of requests for medical exemption notes from primary care providers.

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Medical Reasons to not be Vaccinated

Anyone who has not received a first or second dose of a COVID-19 vaccine should be offered an mRNA vaccine product (Pfizer-BioNTech or Moderna) as soon as possible.^{2,*} Given the safety and efficacy profile of these COVID-19 vaccines, there are very few valid medical reasons for an individual to not be immunized.

Medical reasons to not be vaccinated may be considered as two categories:

- 1. Indefinite medical reasons
- 2. Time-limited medical reasons

Indefinite Medical Reasons

Individuals with <u>severe</u> allergic reactions (e.g. anaphylaxis) to (1) a previous dose of an mRNA COVID-19 vaccine, or (2) a component of an mRNA COVID-19 vaccine (see attached resource) may not be able to be vaccinated. Before issuing a medical exemption note, WDGPH recommends that these clients be referred for assessment by an allergist/immunologist to determine possible methods for safely administering a COVID-19 vaccine. There are existing protocols to administer vaccine to individuals with other types of allergies.

Individuals with allergic reactions (including anaphylaxis) to other vaccines, medications, foods, or other allergens do not have a medical reason to not be vaccinated.

Time-Limited Medical Reasons

In some instances, an individual may have a medical reason to have their immunization deferred. In these scenarios, careful consideration should be given to the appropriate duration of this deferral. Individuals should not be left unimmunized (or incompletely immunized) for any longer than is necessary based on their medical reason.

At present, individuals who experienced physician-diagnosed myocarditis or pericarditis following the first dose of a COVID-19 vaccine, with no other cause identified, should defer their second dose. WDGPH is presently consulting Public Health Ontario regarding the conditions under which these individuals may be able to complete their vaccine series. Individuals with a prior history of myocarditis or pericarditis unrelated to a COVID-19 vaccine do not have a medical reason to not be vaccinated.

Some individuals may need to have the administration of their COVID-19 vaccine timed around a procedure or other medical treatment. For example, individuals on immunosuppressive therapies may need to have immunization timed to optimize their immune response. WDGPH recommends consulting with the relevant specialist to develop a patient-specific plan that minimizes delays in immunization.

^{*} According to the National Advisory Committee on Immunization (NACI), mRNA vaccines are now preferred over viral vector vaccines (AstraZeneca/COVISHIELD or Janssen/J&J) for both first and second doses. Please note that some individuals may have medical contraindications that are specific to viral vector vaccines (e.g. VITT) – individuals with these contraindications may still receive an mRNA vaccine.

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Vaccinating after an Adverse Event Following Immunization (AEFI)

Nearly all individuals who experience an adverse event following immunization (AEFI) can safely be re-immunized. All AEFI reports should be faxed to WDGPH at 1-855-934-5463. If a reported AEFI constitutes a valid medical reason that the individual should not receive further vaccine doses, this will be communicated to the individual's primary care provider.

Providing an Exemption Note

Individuals who require an exemption note due to Directive #6 should be provided a note that documents:

- A medical reason for not being fully vaccinated against COVID-19, and
- The effective time-period for the medical reason.¹

At present, there is no standardized form that needs to be used to document an individual's medical exemption. WDGPH will provide an update if a standardized form is made available. Additional guidance and resources related to COVID-19 immunization doctors' notes are available from the Ontario Medical Association and the College of Physicians and Surgeons of Ontario.

References:

- 1. Ontario Ministry of Health and Long-Term Care. Directive #6 for COVID-19 vaccination policy in health settings. August 17, 2021. Available from:

 https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/directives/vaccination-policy-in-health-settings.pdf
- 2. Government of Canada. Recommendations on the use of COVID-19 vaccines. July 22, 2021. Available from: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html

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Please consult the vaccine product monographs for the most up-to-date information.

Components of the Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)

Components of the Financial Conference (Divi 10252)	
Active Ingredient(s)	Non-Medicinal Ingredient(s)
Nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2	 ALC-0315 = (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide 1,2-distearoyl-sn-glycero-3-phosphocholine Cholesterol Dibasic sodium phosphate dihydrate Monobasic potassium phosphate Potassium chloride Sodium chloride Sucrose Water for injection
Potential Allergen found	Other products where the potential allergen may be found
in this Vaccine	
Polyethylene glycol (PEG)†	Over the counter (e.g., cough syrup, laxatives), and prescription medications, medical bowel preparation products for colonoscopy, skin care products, dermal fillers, cosmetics, contact lens care solutions, products such as ultrasound gel

Components of the Moderna COVID-19 Vaccine (mRNA-1273)

Active Ingredient(s)	Non-Medicinal Ingredient(s)
Messenger RNA (mRNA)) encoding the pre-fusion stabilized spike glycoprotein (S) of SARS-CoV-2	 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC) Acetic acid Cholesterol Lipid SM-102 PEG2000 DMG 1,2-dimyristoyl-rac- glycerol,methoxy-polyethyleneglycol Sodium acetate trihydrate Sucrose Tromethamine Tromethamine hydrochloride Water for injection
Potential Allergen found in this Vaccine	Other products where the potential allergen may be found
Polyethylene glycol (PEG)†	Over the counter (e.g., cough syrup, laxatives), and prescription medications, medical bowel preparation products for colonoscopy, skin care products, dermal fillers, cosmetics, contact lens care solutions, products such as ultrasound gel
Tromethamine (trometamol or Tris)	Component in contrast media, oral and parenteral medications.

[†] There is a potential of cross-reactive hypersensitivity between PEG and polysorbates, which can be round in medical preparations (e.g., vitamin oils, tablets, and anticancer agents) and cosmetics.