

## Immunization Directive

<b>Number:</b>	Imm - 16
<b>Topic:</b>	<b>Administration of Janssen (Johnson &amp; Johnson) COVID-19 Vaccine</b>
<b>Approved:</b>	December 14, 2021
<b>Reviewed:</b>	
<b>Revised:</b>	January 17, 2022

### Procedure

Administer intramuscularly the Janssen (Johnson & Johnson) COVID-19 vaccine.

**Involvement of a Delegated Controlled Act:** Yes   X   No     

Controlled Act #5: Administering a substance by injection or inhalation. This is a controlled act, which is in the scope of nursing practice. A member of the College of Nurses may perform a procedure within the controlled acts authorized to nursing if a physician, dentist, chiroprapist, nurse practitioner or midwife orders it.

Controlled Act #8: Prescribing, dispensing, selling or compounding a drug as defined in the Drug and Pharmacies Regulation Act, or supervising the part of a pharmacy where such drugs are kept.

### Delegation of the Controlled Act

- This delegation applies to all student nurses, Registered Practical Nurses (RPN), Registered Nurses (RN) and Public Health Nurses (PHN) employed by the Simcoe Muskoka District Health Unit (SMDHU) who have the knowledge, skills and judgment to administer the vaccine safely.
- Delegation of Controlled Acts in the provision of a public health program under the authority of a Medical Officer of Health is acknowledged by the College of Physicians and Surgeons as falling under circumstances where the Controlled Act may be delegated in the absence of a physician order and in the absence of the doctor-patient relationship.
- Identification of Risks: The risk of treatment includes the potential for a serious reaction or allergy along with the possibility that the client will experience medication side effects. These risks are minimized by reviewing contraindications and medical history and by instructing clients where possible on how to reduce the occurrence or severity of side effects.
- See SMDHU Policy LG0104 – *Delegation of Controlled Acts* for responsibilities of the delegator, program manager and staff. See SMDHU Policy GEN0105 – *Directives & Standing Orders* for approval process and quality assurance. See SMDHU Policy LG0101 – *Consent for Treatment* for information pertaining to obtaining consent.

### Indications

Janssen COVID-19 Vaccine (Ad26.COVS.2.S, recombinant) is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

Every effort should be made to immunize with an mRNA vaccine. The Janssen vaccine should only be used when an mRNA vaccine is declined and after informed consent. Clients receiving the vaccine must read the [Janssen COVID-19 Vaccine Information Sheet](#) to ensure informed consent.

**Dosage and Administration:**

Age	Dosage (mL)	Immunization Schedule
18 + years	0.5ml	1 dose

Those who received one dose of either an mRNA vaccine or Az vaccine, who are contraindicated to receive further doses or choose not to receive further doses, can receive a dose of Janssen vaccine in order to complete their series.

Individuals eligible for a booster dose are recommended to receive an mRNA vaccine (Pfizer-BioNTech or Moderna) unless there are contraindications to receive an mRNA vaccine.

If an individual has a medical contraindication to receiving an mRNA vaccine or chooses to not receive mRNA vaccine, a booster dose of a viral vector vaccine and be provided with informed consent including a discussion about the lack of evidence on the use and effectiveness of an additional dose of viral vector COVID-19 vaccine and the increased risk of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), Capillary Leak Syndrome (CLS), and Guillain-Barre syndrome (GBS) following viral vector COVID-19 vaccines. Booster doses are recommended at 3 months (84 days) from last dose in primary series.

Janssen COVID-19 vaccine is to be administered intramuscularly in the deltoid muscle.

Nurses will store and handle the vaccine according to the instructions in the [manufacture's product monograph](#).

Janssen COVID-19 vaccine is a colorless to slightly yellow, clear to very opalescent suspension. The vaccine should be inspected visually for particulate matter and discoloration prior to administration. The vial should be inspected visually for cracks or any abnormalities, such as evidence of tampering prior to administration. If any of these should exist, do not administer the vaccine.

Before administering a dose of vaccine, carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. Do not shake.

Janssen COVID-19 vaccine must not be reconstituted, mixed with other Janssen medicinal products, or diluted.

**Unopened multidose vial (5 dose vial)**

Janssen COVID-19 vaccine should be stored in refrigerator (2° to 8° C). Do not freeze. Store in outer carton to protect from light. Use the product before the expiration date on the vial label.

**Opened multidose vial (5 dose vial)**

Once the vial has been punctured, the vaccine is stable for:

- 3 hours at room temperature, up to 25°C, or
- 6 hours in a refrigerator (2 to 8°C)

**Contraindications**

1. Janssen COVID-19 vaccine is contraindicated in those with an allergy to any component of the vaccine or an anaphylactic or other allergic reaction to a previous dose of this vaccine:

Vaccine	Vaccine Components	Contains Latex (Yes or No)
Janssen COVID-19 Vaccine	<ul style="list-style-type: none"> <li>• COVID-19 Vaccine (Ad26.COV2.S (recombinant))</li> <li>• 2- hydroxypropylβ-cyclodextrin (HBCD)</li> <li>• Citric acid monohydrate</li> <li>• Ethanol</li> <li>• Hydrochloric acid</li> <li>• Polysorbate-80</li> <li>• Trisodium citrate dihydrate</li> <li>• Sodium chloride</li> <li>• Sodium hydroxide</li> </ul>	No

2. Janssen COVID-19 vaccine is not to be administered to anyone under 18 years of age.
3. Individuals with the following conditions should not receive the Janssen COVID-19 vaccine:
  - History of blood clots with low platelets (i.e., major venous and/or arterial thrombosis with thrombocytopenia) following any vaccine
  - Thrombosis with thrombocytopenia syndrome (TTS) or vaccine induced immune thrombotic thrombocytopenia (VITT) following the AstraZeneca COVID-19 vaccine
  - History of capillary leak syndrome (CLS)
  - History of cerebral venous sinus thrombosis (CVST) with thrombocytopenia
  - History of heparin-induced thrombocytopenia (HIT)
  - Actively receiving monoclonal antibody therapy OR convalescent plasma therapy for the treatment or prevention of COVID-19
4. Janssen COVID-19 vaccine should only be administered in SMDHU clinics to the following groups if they have consulted with their treating physician and it has been determined that the potential benefits of vaccination outweigh the potential risks:
  - Those who are receiving the following immunosuppressive therapies: stem cell therapy, CAR-T therapy, chemotherapy, immune checkpoint inhibitors, monoclonal antibodies (e.g. rituximab) and other targeted agents (e.g., CD4/6 inhibitors, PARP inhibitors etc.)

**Pregnant & Breastfeeding Individuals**

Evidence is now available from real world use of mRNA COVID-19 vaccines, which has not indicated any safety concerns for pregnant and breastfeeding populations. There is less evidence regarding the safety of the Janssen vaccine including pregnant women and breastfeeding women. An mRNA COVID-19 vaccine is recommended by the National Advisory Committee on Immunization (NACI) since they have been shown to be more effective than viral vector vaccines and generally safer, with less side effects. Those who are pregnant or breastfeeding can receive Janssen vaccine under this directive with informed consent.

**Persons with Autoimmune Conditions & Immunocompromised persons (due to disease or treatment)**

While those receiving the severely immunosuppressive treatments outlined in contraindication #3 must speak with their treating HCP prior to vaccination, all other individuals with autoimmune conditions, immunodeficiency conditions or those immunosuppressed due to disease or treatment should be offered the vaccine. These individuals may choose to consult with their health care provider prior to vaccination (for example, to discuss immunosuppressive medication management/timing in relation to their vaccination).

**Rare cases of serious thrombosis (blood clots) and thrombocytopenia (low platelets): VITT (Vaccine-Induced Immune Thrombotic Thrombocytopenia)**

A combination of thrombosis and thrombocytopenia (TTS), in some cases accompanied by bleeding, that resembles HIT (heparin-induced thrombocytopenia) have been observed very rarely following vaccination with

Janssen COVID-19 Vaccine. This includes severe cases at unusual sites such as cerebral venous sinus thrombosis (CSVT) and splanchnic vein thrombosis, as well as arterial thrombosis, with thrombocytopenia.

Nurses administering the Janssen COVID-19 vaccine under this directive must inform clients to seek immediate medical attention for symptoms of thromboembolism and/or early signs of thrombocytopenia.

Symptoms to monitor for include: shortness of breath, chest pain, leg swelling or pain, persistent abdominal pain, skin bruising (other than at the site of vaccination) or petechiae (red or purple spots or blood blisters under skin); and neurological symptoms such as sudden onset of severe headaches, persistent or worsening headaches, blurred vision, double vision, confusion or seizures, difficulty speaking or moving a part of the body particularly those persisting or occurring approximately 4 days to 3-4 weeks after vaccination.

### **Guillain-Barré syndrome (GBS)**

There have been a small number of reports of people developing GBS after receiving a COVID-19 viral vector vaccine. GBS is a rare but potentially serious immune-mediated neurologic disorder that results in pain or numbness, muscle weakness, and paralysis in severe cases. Most people fully recover from GBS but some have residual deficits or symptoms and rarely, fatal cases can occur. As of September 15, 2021, there were 201 preliminary cases of GBS reported in the US Vaccine Adverse Events Reporting System (VAERS) among more than 14.7 million doses of the Janssen vaccine administered (estimated rate of 1.37 cases per 100,000 doses). In the US, reports of adverse events suggest an increased risk of GBS during the 42 days following vaccination with the Janssen COVID-19 vaccine.

Nurses administering the Janssen COVID-19 vaccine under this directive must inform clients to seek medical attention if they develop symptoms of GBS.

### **Precautions & Other Important Information**

- NACI has stated that COVID-19 vaccine can be given at the same time or at any time before or after receiving other vaccines including live, non-live, adjuvanted or unadjuvanted vaccines. As a precaution, NACI previously recommended that COVID-19 vaccines be given at least 28 days before and 14 days after other vaccines. After reviewing the evolving evidence on COVID-19 vaccines and considering the extensive data and experience of giving other routine vaccines at the same time or within days of each other, NACI has determined that a precautionary approach is no longer necessary.
- Tuberculin skin testing (TST) or interferon gamma release assay (IGRA) - There is a theoretical risk that mRNA or viral vector vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. If tuberculin skin testing or an IGRA test is required, it should be administered and read before immunization or delayed for at least 4 weeks after vaccination. Vaccination with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing have been completed. In cases where an opportunity to perform the TST or IGRA test might be missed, the testing should not be delayed since these are theoretical considerations. However, re-testing (at least 4 weeks post immunization) of individuals with negative results for whom there is high suspicion of TB infection may be prudent in order to avoid missing cases due to potentially false-negative results.
- COVID-19 vaccine should not be given simultaneously with monoclonal antibodies or convalescent plasma. There is insufficient evidence on the potential interference of COVID-19 vaccine and any monoclonal antibodies therefore expert opinion should be sought on a case-by-case basis.
- Currently there is limited evidence available to support the efficacy of this vaccine in preventing asymptomatic infection, reducing viral shedding or in prevention of transmission of the COVID-19 virus. Therefore, it is important that people continue to practice public health measures to decreased transmission even after they are vaccinated.
- Janssen COVID-19 vaccine may be offered to those who have had previously PCR-confirmed SARS-CoV-2 infection, but this will be in the context of vaccine availability and initial doses may be prioritized for those who have not had previous infection. People who are eligible for vaccination who have recently

tested positive for COVID-19 can be vaccinated once they have cleared isolation and their symptoms are resolving.

- Vaccination of those who may currently have SARS-CoV-2 infection is not known to have a detrimental effect on the illness. However, vaccination should be deferred in symptomatic individuals to avoid attributing any complications resulting from infection to being vaccine related.

### **Quality Assurance**

The program managers will ensure that:

- The directive is reviewed and updated as needed.
- Nurses are provided a comprehensive orientation program, including a review of all relevant resources as outlined below.
- A current list of nurses who have received directive training is maintained.
- All medication errors are reviewed as per agency policy.

### **References**

Product Monograph for [Janssen COVID-19 Vaccine](#), November 23, 2021

Canadian Immunization Guide: [COVID-19 vaccine Chapter](#)

Ontario Ministry of Health. [Janssen COVID-19 Vaccine Information Sheet](#). December 2, 2021

Ontario Ministry of Health. [COVID-19 Vaccine Administration](#). November 26, 2021.

Ontario Ministry of Health. [COVID-19 Vaccination Recommendations for Special Populations](#). December 31, 2021.

Ontario Ministry of Health. [COVID-19 Third Dose Recommendations](#). January 13, 2022.

Ontario Ministry of Health. [COVID-19 Vaccine Storage and Handling Guidance](#) – Revised January 5, 2022

SMDHU Policy [LG0101 - Consent for Treatment](#) – Revised September 2010

SMDHU Policy [LG0104 - Delegated Controlled Acts](#) – Revised August 25, 2010

SMDHU Policy [GEN0105 – Directives & Standing Orders](#) – Revised August 25, 2010

College of Nurses of Ontario (CNO), Practice Guideline, 41019, Directives Revised January 2018

[https://www.cno.org/globalassets/docs/prac/41019\\_medicaldirectives.pdf](https://www.cno.org/globalassets/docs/prac/41019_medicaldirectives.pdf)

CNO, Practice Standard, 41007, Medication Revised January 2019

[http://www.cno.org/docs/prac/41007\\_Medications.pdf](http://www.cno.org/docs/prac/41007_Medications.pdf)

CNO, Practice Standard, 41071, Decisions about Procedures and Authorities Revised March 2018

[https://www.cno.org/globalassets/docs/prac/41071\\_decisions.pdf](https://www.cno.org/globalassets/docs/prac/41071_decisions.pdf)

The College of Physicians and Surgeons Policy #5-12 - Delegation of Controlled Acts (revised Sept 2012)

<https://www.cpso.on.ca/admin/CPSO/media/Documents/physician/policies-and-guidance/policies/delegation-of-controlled-acts.pdf>

### **Educational Resources**

- Immunization Program Guidebook
- Canadian Immunization Guide, Evergreen Edition  
<http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php>

**Authorized to**

All student nurses, RPNs, RNs and PHNs employed by the Simcoe Muskoka District Health Unit, who have received the directive training and who have the following qualifications are authorized to administer these vaccines:

- Registered Nurses and Registered Nurses (temporary) listed as a member with the College of Nurses of Ontario with no restrictions or limitations on their registration.
- Registered Practical Nurses and Registered Practical Nurses (temporary) listed as a member with the College of Nurses of Ontario with no restrictions or limitations on their registration. Registered Practical Nurses that were registered with the College of Nurses prior to 2005 must also have an advanced medication course certificate.
- Current CPR certification Level C (updated annually).

**Authorization and Approval**

The steps outlined in this directive, and training and resources available provide staff with the necessary knowledge and skills to safely, effectively and ethically administer this vaccine in a clinic setting.

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Charles Gardner  
Medical Officer of Health

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Date

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Colin Lee  
Associate Medical Officer of Health

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Date

**Review/Revision History**

December 16, 2021 –updated precaution info for some of special populations to align with provincial guidance

January 17, 2022 – Booster doses