Immunization Directive

Number:	**Imm - 16**
Topic:	**Administration of Janssen (JCOVDEN™) COVID-19 Vaccine**
Approved:	December 14, 2021
Reviewed:	
Revised:	January 11, 2023

Procedure

Administer intramuscularly the Janssen (JCOVDEN™) 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, chiropodist, 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.COV2.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.

Dosage and Administration:

NACI continues to preferentially recommend the use of mRNA COVID-19 vaccines due to the excellent protection they provide against severe illness and hospitalization, and their well-known safety profiles. **The Janssen COVID-19 vaccine may be offered to individuals who have contraindications to all other authorized COVID-19 vaccines, as identified by an appropriate physician or nurse practitioner.**

A Primary series of Janssen COVID-19 vaccine consists of just one dose. Individuals that received Janssen COVID-19 vaccine for their primary series are recommended to receive an mRNA bivalent COVID-19 vaccine for their booster dose(s). A booster dose of Janssen COVID-19 vaccine should only be offered when all other Health Canada authorized COVID-19 vaccines are contraindicated.

Informed consent for Janssen COVID-19 vaccine should include discussion about 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 and the very limited evidence on the use and effectiveness of an additional dose of viral vector COVID-19 vaccine.

Age	Dosage (mL)	Recommended Interval	Minimum Interval
18+ years	0.5ml	Primary Series • 1 dose Booster Doses • 6 months (168 days) after last dose	Primary Series • 1 dose Booster Doses • 3 months (84 days) after last dose

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

Vaccine Storage and Handling

Nurses will store and handle the vaccine according to the Ministry of Health COVID-19 Vaccine Storage and Handling Guidance, and the manufacturer's instructions in the product monograph.

Janssen vaccine is **not** to be reconstituted or diluted. Janssen vaccine comes in a 5 dose multidose vial.

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.

Unopened multidose vials are to 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.

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

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

Interval Between Previous SARS-CoV-2 Infection and COVID-19 Vaccination

NACI and the Ministry of Health recommend that COVID-19 vaccines should be offered to individuals with previous SARS-CoV-2 infection without contraindications to the vaccine at the intervals outlined below:

Infection timing relative to COVID-19 vaccination	Population	Suggested interval between infection* and vaccination
Infection prior to completion or initiation of primary vaccination series	Individuals 6 months of age and older who are not considered moderately to severely immunocompromised and with no previous history of multisystem inflammatory syndrome in children (MIS-C)	Receive the vaccine 2 months (56 days) after symptom onset or positive test (if asymptomatic)
	Individuals 6 months of age and older who are moderately to severely immunocompromised and with no previous history of MIS-C	Receive the vaccine dose 1 to 2 months (28 to 56 days) after symptom onset or positive test (if asymptomatic)
	Individuals 6 months of age and older with a previous history of MIS-C (regardless of immunocompromised status)	Receive the vaccine dose when clinical recovery has been achieved or ≥90 days since the onset of MIS-C, whichever is longer
Infection after primary series	Individuals currently eligible for booster dose(s)	A minimum of 3 months (84 days) after symptom onset or positive test (if asymptomatic); however, a 6 month (168 day) interval may provide better immune response regardless of the product given.

*A previous infection with SARS-CoV-2 is defined as:

- Confirmed by a molecular (e.g., PCR) or rapid antigen test; or
- Symptomatic **AND** a household contact of a confirmed COVID-19 case.

NACI recommends that COVID-19 booster doses may be offered at an interval of 6 months since previous COVID-19 vaccine dose or SARS-CoV-2 infection. However, a shorter interval of at least 3 months may be warranted in the context of heightened epidemiological risk, as well as operational considerations for the efficient deployment of the program.

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	• COVID-19 Vaccine (Ad26.COV2.S (recombinant)) • 2- hydroxypropylβ-cyclodextrin (HBCD) • Citric acid monohydrate • Ethanol • Hydrochloric acid • Polysorbate-80 • Trisodium citrate dihydrate • Sodium chloride • Sodium hydroxide	No

2. 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

3. 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 and Breastfeeding Individuals

COVID-19 vaccination during pregnancy is effective at protecting against severe or critical COVID-19 disease, hospitalization, and ICU admission from COVID-19 infection, as well as intubation and maternal mortality in those with severe disease. As such, pregnancy or breastfeeding individuals should receive all recommended COVID-19 vaccine doses (including booster doses) as soon as they are able. NACI has identified pregnant individuals to be at increased risk of severe illness from COVID-19 as such, it is strongly recommended that these individuals be offered a booster dose regardless of the number of booster doses previously received.

It is recommended that a complete vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are pregnant or breastfeeding. An mRNA vaccine is preferred due to reassuring published data on the safety of these vaccines in pregnancy.
Janssen COVID-19 vaccine may only be offered to pregnant or breastfeeding individuals when all other authorized COVID-19 vaccines are contraindicated.

Persons with Autoimmune Conditions and 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

- For individuals 6 months of age and older, COVID-19 vaccines may be given concurrently (i.e., same day), or at any time before or after, non-COVID-19 vaccines (including live and non-live vaccines). Informed consent should include a discussion of the benefits and risks given the limited data available on administration of COVID-19 vaccines at the same time as, or shortly before or after, other vaccines.

- 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 vaccines should not be given concurrently with anti-SARS-CoV-2 monoclonal antibodies. Administration of these products concurrently may result in decreased effectiveness of the COVID-19 vaccine and/or anti-SARS-CoV-2 monoclonal antibodies. Anti-SARS-CoV-2 monoclonal antibodies have high affinity for the spike protein expressed by COVID-19 vaccines, which could prevent the production of antibodies stimulated by the vaccine, or binding of vaccine antigen to the monoclonal antibody may neutralize the antibody. Timing of administration of COVID-19 vaccines following administration of therapeutic or post-exposure anti-SARS-CoV-2 monoclonal antibodies should be assessed in consultation with clinical experts 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.

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, Revised October 27,2022

Canadian Immunization Guide: COVID-19 vaccine Chapter

Ontario Ministry of Health. COVID-19 Vaccine Guidance – Revised November 7, 2022

Ontario Ministry of Health. COVID-19 Vaccine Storage and Handling Guidance – Revised October 13, 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. Updated June 2020.
https://www.cno.org/globalassets/docs/prac/41019_medicaldirectives.pdf

CNO, Practice Standard, 41007, Medication. Updated June 2022.
http://www.cno.org/docs/prac/41007_Medication.pdf

CNO, Practice Standard, 41071, Decisions about Procedures and Authorities, Revised January 2020.
https://www.cno.org/globalassets/docs/prac/41071_decisions.pdf

The College of Physicians and Surgeons Policy #5-12 – Delegation of Controlled Acts. Revised March 2021
https://www.cpso.on.ca/Physicians/Policies-Guidance/Policies/Delegation-of-Controlled-Acts

Educational Resources

- Ministry of Health COVID-19 Vaccine Administration
- Ministry of Health COVID-19 Vaccine Storage and Handling Guidance
- 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.

Charles Gardner
Medical Officer of Health

Date

Colin Lee
Associate Medical Officer of Health

Date

Lisa Simon
Associate Medical Officer of Health

Date

Mary Ann Holmes
Program Manager - Immunization

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

November 10, 2022 - Updated to reflect current COVID Vaccine Administration guidance document with respect to schedule and booster doses

January 11, 2023 – updated coadministration statement to 6 months and older, and updated M. Holmes title