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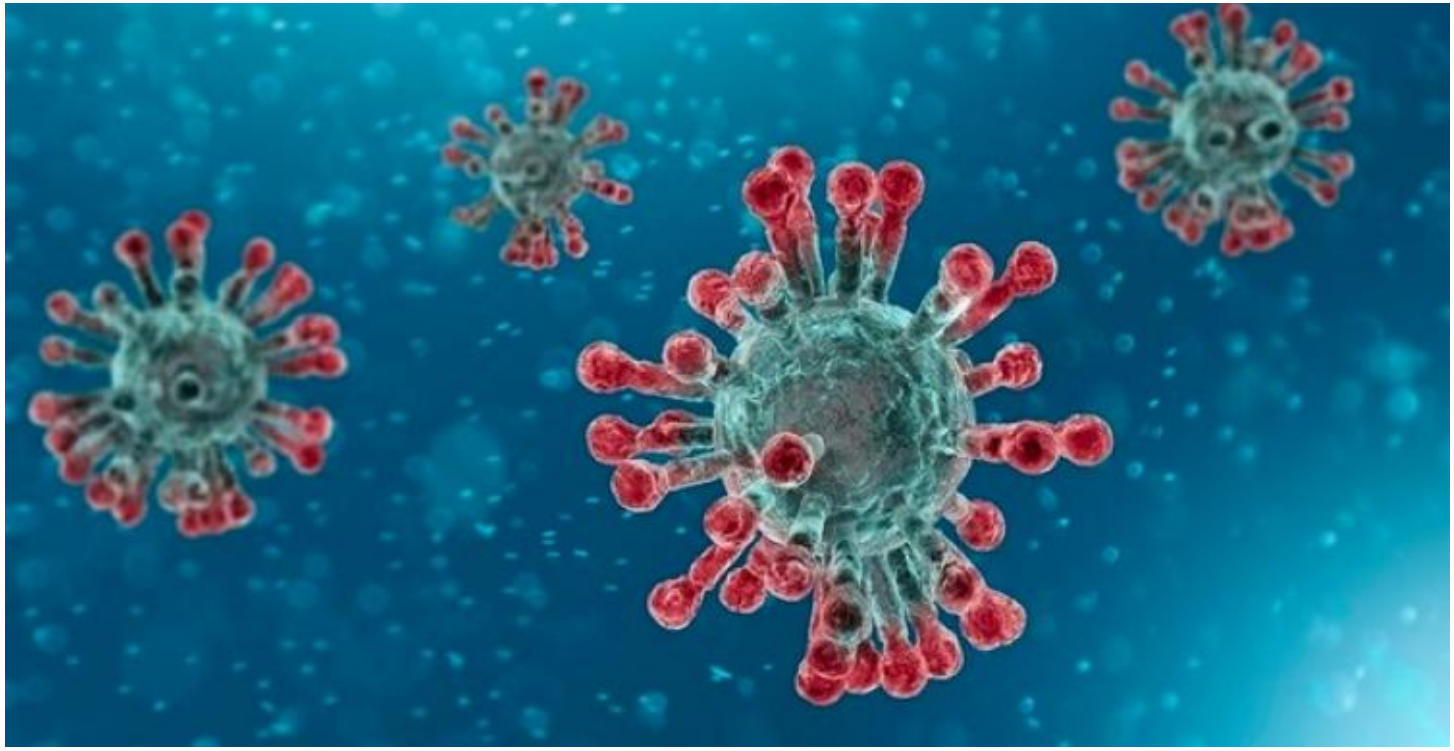
Janssen COVID-19 Vaccine Orientation



Presented by
Provincial Population & Public Health
Provincial CDC Immunization Team
January 10, 2022

Objective

- To provide clinical information related to Janssen COVID-19 vaccine
  - **NOTE**: always use the online resources for up-to-date information
- Operational questions will NOT be addressed during this presentation (i.e., scheduling, vaccine distribution specifics)

Introduction

For more detailed information it is important to refer to additional program resources such as:

- AHS COVID-19 Health Professional Immunization Information
  - Insite for AHS employees or External site for non-AHS employees
- AHS Immunization Program Standards Manual (IPSM) Vaccine Biological pages are located at
  - Insite for AHS employees or External site for non-AHS employees
- COVID-19 Vaccine Product Monographs
- AHS Vaccine Storage and Handling Standard and e-learning modules*
- Alberta Health Adverse Events Following Immunization (AEFI) Policy
- Site specific reporting requirements and data collection guidelines

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Refer to COVID-19 Vaccine Orientation to review:

- What is COVID-19
- Third dose indications
- Fit to Immunize Assessment
- Infection Prevention and Control
- Commitment to Comfort Principles
- Anaphylaxis
- Vaccine Recording
- Adverse Events Following Immunization Reporting
- Vaccine Administration
- Immunocompromised and Auto-Immune Disorders
- Administration with Other Products
- Tuberculin Skin Testing and COVID-19 vaccines
- Vaccine Storage and Handling Principles
- General Pregnancy Information
- General Breastfeeding Information

COVID-19 Vaccines Available in Alberta

- **Viral Vector-based**
  - AstraZeneca/COVISHIELD
  - Janssen (Johnson & Johnson)

- **mRNA**
  - Pfizer Ultra Frozen Vaccine
  - Moderna Frozen Vaccine

What are Viral Vector COVID-19 Vaccines?

- **AstraZeneca/COVISHIELD** and **Janssen** COVID-19 vaccines are based on viral vector platforms using a modified adenovirus virus to carry genes that encode SARS-CoV-2 spike proteins into the host cells.
- The vector virus is a type of adenovirus that has been modified to carry COVID-19 genes and to prevent replication.
    - These modifications are intended to prevent the viral vector from causing disease. (i.e., they are non-replicating).
- Once inside the cell, the SARS-CoV-2 (or COVID-19) spike protein genes are transcribed into mRNA in the nucleus and translated into proteins in the cytosol of the cell.

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Janssen Vaccine Summary

	Janssen COVID-19 Vaccine
Dosage/Route	0.5 mL / IM
Packaging	Multi-dose vial – 5 doses per vial
Diluent	No
Eligibility	As per indication

Indication	• Janssen vaccine may be considered for individuals 18 years of age and older
	  ○ A complete series with an mRNA COVID-19 vaccine is preferentially recommended for individuals in the authorized age group without contraindications to the vaccine.
	  ○ Should not be used as the booster/additional dose for individuals who are eligible.
	  ○ Should not be used to complete an mRNA or AstraZeneca COVID-19 vaccine series.
	  ▪ Individuals with an incomplete primary series and a contraindication to currently available COVID-19 vaccines can receive Janssen COVID-19 vaccine with a minimum of 28 days from any previously received COVID-19 vaccine.

Composition	• Recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the SARS-CoV-2 Spike (S) protein. • No adjuvants or preservatives
Schedule	• 1 dose currently, however there is a possibility that in the future, individuals who received one dose of the Janssen vaccine may need an additional dose to be considered fully immunized. • Recommended that individuals who received only the single dose Janssen COVID-19 vaccine be offered an additional dose of mRNA vaccine as a booster dose at least 5 calendar months after the single dose.

Janssen Vaccine Storage

Janssen Vaccine	Storage temperatures and time limits
Pre-puncture storage:	Store at -25° to -15°C until expiry date Store at +2° to +8°C for 6 months, not exceeding the original expiry date May be stored up to +25°C for up to 12 hours (At room temperature it will take approx. 4 hours to thaw a 10 vial carton, an individual vial will take approx. 1 hour to thaw. At +2° to +8°C it will take approx.13 hours to thaw a 10 vial carton, an individual vial will take approx. 2 hours to thaw)
Post-puncture storage:	+2°C to +8°C for 6 hours **OR** +8°C to +25°C for 3 hours
Post-puncture usage limit:	Punctured vials (first dose is withdrawn) can be stored at +2°C to +8°C for up to 6 hours or at room temperature (up to +25°C) for 3 hours. Discard if not used within this time.
Check puncture date/time and storage time limits prior to administration **DO NOT REFREEZE ONCE IN THAWING STATE** **PROTECT FROM LIGHT**	

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Janssen Vaccine Reactions

Common	Uncommon	Rare
• Pain, redness, warmth, and swelling at injection site • Fever, chills • Fatigue • Headache, myalgia, arthralgia • Nausea	• Rash • Muscle weakness • Feeling weak • Arm/leg pain • Malaise	• Anaphylaxis • Urticaria • Seizures • Vertigo • Tinnitus • Vomiting/diarrhea • Paresthesia and hypoesthesia • Lymphadenopathy • Thrombosis with thrombocytopenia syndrome (TTS) • Venous Thromboembolism (VTE) • Immune Thrombocytopenia (ITP) • Capillary Leak syndrome • Guillain-Barre syndrome

As with any immunization, unexpected or unusual side effects can occur.
Refer to product monograph for more detailed information.

Janssen Vaccine Efficacy

- It is recommended that individuals who received only the single dose Janssen COVID-19 vaccine be offered an additional dose of mRNA vaccine as a booster dose at least 5 calendar months after the single dose.
- With a vaccine effectiveness between 67 and 72%, an additional dose of mRNA vaccine is recommended to provide better protection. This does not apply to individuals who received any dose of mRNA vaccine previously. Other booster dose indications may still apply.

Note: The Janssen vaccine is currently licensed as a one dose vaccine series and individuals are considered fully-immunized 14 days following the immunization at this time. However, there is a possibility that in the future individuals who received one dose of the Janssen vaccine may need an additional dose to be considered fully-immunized.

Viral Vector COVID-19 Vaccine Rare Events

- A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely in the U.S. following immunization with Janssen COVID-19 Vaccine.
  - This includes severe cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, mesenteric vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia.
- As of September 29, 2021, approximately 15 million doses of Janssen vaccine were administered in the U.S and the Vaccine Adverse Event Reporting System (VAERS), the national vaccine safety monitoring system, had received 47 reports of thrombosis with thrombocytopenia syndrome (TTS) after Janssen COVID-19 immunization. The rate has been highest in females aged 18 to 49 years and some cases have been fatal. The majority of cases occurred within three weeks following immunization.

Viral Vector COVID-19 Vaccine Rare Events

- A causal relationship with the vaccine is considered plausible, but the exact mechanism by which the Janssen vaccine triggers these very rare but serious events is still under investigation. No specific risk factors have been identified at this time.
- The Advisory Committee on Immunization Practices concluded that the benefits of Janssen COVID-19 immunization among persons aged ≥18 years outweighed the risks and reaffirmed its interim recommendation under FDA's Emergency Use Authorization, which includes a new warning for rare clotting events, primarily among women aged 18 to 49 years.
- The European Medicine Agency safety committee reviewed all the currently available evidence including US reports and concluded that the overall benefits of Janssen COVID-19 vaccine in preventing COVID-19 outweigh the risks of side effects and a warning about unusual blood clots with low blood platelets should be added to the product information as a very rare side effect of the Janssen COVID-19 vaccine.

Viral Vector COVID-19 Vaccine Rare Events

- Health Canada has assessed the available data on the reported events and has determined that the benefit of Janssen COVID-19 vaccine outweigh the risk of thrombosis and thrombocytopenia. Health Canada has worked with Janssen Inc. to update the Product Monograph for Janssen COVID-19 vaccine to include this new safety information to inform Canadians of the possible side effects and to provide information about the signs and symptoms and when to seek prompt medical attention following immunization.
- Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia and be aware of TTS including how to diagnose and treat the condition.

Viral Vector COVID-19 Vaccine Rare Events

- Those immunized should be instructed to seek immediate medical attention if they develop symptoms of thromboembolism and/or thrombocytopenia between days 4 and 28 following receipt of the Janssen vaccine such as:

• Severe headache that does not go away • Seizure • Difficulty moving part(s) of the body • New blurry vision that does not go away • Difficulty speaking	• Shortness of breath • Chest pain • Severe abdominal pain • New severe swelling, pain or colour change of an arm or leg

Viral Vector COVID-19 Vaccine Rare Events

- Cases of Immune Thrombocytopenia (ITP) have been reported very rarely within the first four weeks after receiving Janssen COVID-19 vaccine and that include serious cases with very low platelet counts.
- If an individual has a history of ITP, healthcare professionals should consider the risk of developing low platelet levels prior to administering the vaccine. In individuals with a history of ITP, it is recommended to monitor platelet levels following immunization with the Janssen COVID-19 vaccine.
- Cases of Venous thromboembolism (VTE) have also been observed rarely following immunization with Janssen COVID-19 vaccine. The risk of VTE should be considered for individuals with increased risk factors for thromboembolism (blood clots).

Janssen COVID-19 Vaccine – Contraindications

- Less than 18 years of age
- Have a known **severe hypersensitivity** to any component of the vaccine:
  - One non-medicinal ingredient in the vaccine that has the potential to cause type 1 hypersensitivity reactions is polysorbate 80. Polysorbate 80 may be found in medical preparations (e.g., vitamin oils, tablets, anticancer agents) and cosmetics.
- Known severe hypersensitivity to any other adenovirus-based vaccine
- Previous history of capillary leak syndrome (CLS). CLS is a rare disease characterized by acute episodes of limb edema, hypotension, hemoconcentration and hypoalbuminemia.
- Experienced previously major venous and/or arterial thrombosis with thrombocytopenia following immunization with AstraZeneca/COVISHIELD/Janssen COVID-19 vaccine.

Janssen COVID-19 Vaccine – Precautions

- Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.
- Administration should be postponed in individuals suffering from acute severe febrile illness.
- Prior to receiving the Janssen vaccine, individuals should be informed of what is currently known about the risk of the rare but serious events of thrombosis with thrombocytopenia (TTS), venous thromboembolism (VTE), immune thrombocytopenia (ITP), capillary leak syndrome or Guillain-Barre syndrome (GBS) that were reported following immunization of the vaccine. This should be part of the benefit-risk discussion to help them make an informed decision.

COVID-19 Vaccine – Other Considerations

- Individuals with a history of lab confirmed COVID-19 infection who have no contraindications can be immunized with COVID-19 vaccine as soon as their isolation period is over.
- Individuals presenting for immunization do not need to be tested for previous COVID-19 infection.
- Immunization of individuals who may be currently infected with COVID-19 is not known to have a detrimental effect on the illness.
    - However, individuals with COVID-19-like symptoms should not go to an immunization venue in order to minimize the risk of COVID-19 transmission. They should isolate, seek testing and get immunized as soon as their isolation period is over.
    - For individuals who are isolated due to COVID-19-like symptoms can be provided COVID-19 vaccine as long as they are well enough to be immunized.

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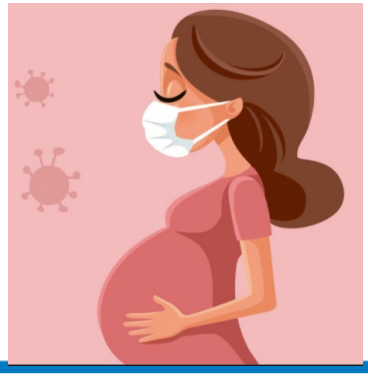
Pregnancy



- mRNA COVID-19 vaccine is preferentially recommended for pregnant individuals in the authorized age group without contraindications to the vaccine.
- Janssen vaccine may be offered to individuals in the eligible group who are pregnant if a risk assessment with their primary health care provider or obstetrician determines that the benefits outweigh the potential risks for the woman and fetus.
- However, the individual may also be immunized without consulting their primary health care provider or obstetrician following their acknowledgment of the absence of evidence on the use of a viral vector COVID-19 vaccine in this population and the preference for an mRNA vaccine due to published safety data and concerns about the complexities of the treatment of Vaccine-Induced Immune Thrombotic Thrombocytopenia in pregnancy should it occur after immunization.
  - See ‘Safety Information: Risk of Thrombosis with Thrombocytopenia’ section below.
  - Additional resource: Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy

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Breastfeeding

- It is unknown whether Janssen COVID-19 vaccine is excreted in human milk as breastfeeding individuals were excluded from the initial trials. A risk to the newborns/infants cannot be excluded.
- Janssen COVID-19 vaccine can be offered to individuals in the eligible group who are breastfeeding.
- It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions or concerns.
- However, consultation with a primary health care provider or medical specialist is not required to receive Janssen COVID-19 vaccine. Breastfeeding individuals can be immunized following routine informed consent discussion.

Immunocompromised & Auto-Immune Disorders

- Janssen vaccine may be considered for individuals 18 years of age and older with immunocompromising and auto-immune disorders, however, a complete series with an mRNA COVID-19 vaccine is preferentially recommended for individuals in the authorized age group without contraindications to the vaccine.
- Not recommended as the booster/additional dose for individuals recommended to have a third dose. An mRNA vaccine should be administered as the third dose except in the event of contraindication or refusal.
- Refer to COVID-19 Vaccine Orientation to review additional information re: immunocompromising and auto-immune disorders.

Interchangeability

- Currently, no data exists on the interchangeability of COVID-19 vaccines.
- There are no data available on the use of the Janssen COVID-19 vaccine to complete a series initiated with another COVID-19 vaccine.

Administration with Other Products

In the absence of evidence, COVID-19 vaccines may be co-administered with, or at any time before or after other vaccines (including, live, inactivated, adjuvanted, or unadjuvanted vaccines).

- COVID-19 vaccines were previously recommended to be administered alone, with a minimum interval of 14 days before or after administration of any other vaccines. This was out of an abundance of caution during a period when these vaccines were new and not due to any known safety or immunogenicity concerns. However, substantial data have now been collected regarding the safety of COVID-19 vaccines.
- In addition, it was determined that the potential harms of not co-administering during the influenza season (e.g., missed immunization opportunities; insufficient healthcare resources to run the programs in parallel) and missed doses for other vaccines outweighed the theoretical harms of co-administration.

Administration with Other Products – cont'd

- It is currently not known if the reactogenicity of COVID-19 vaccines is increased when co-administered with other vaccines. While no specific safety concerns have been identified for various other vaccines when co-administered, there is potential for increased reactogenicity with co-administration of COVID-19 vaccines and other vaccines, particularly those known to be more reactogenic, such as newer adjuvanted vaccines.
- The safety profile for non-COVID inactivated vaccines is well known, therefore any new safety signals that arise can likely be attributed to the COVID-19 vaccine administered.

Administration with Other Products

- COVID-19 vaccines should be delayed for at least 90 days after the receipt of SARS-CoV-2 monoclonal antibodies or convalescent plasma provided for treatment of COVID-19 infection. This applies to people who received these therapies before receiving any COVID-19 vaccine dose and between doses.
- Timing of administration and potential interference between COVID-19 vaccine and monoclonal products or convalescent plasma as part of COVID-19 treatment are currently unknown and administering these products close together may result in less effectiveness of the COVID-19 vaccine.
- A deferral for at least 90 days is based on the estimated half-life of such therapies and evidence suggesting that reinfection is uncommon within the 90 days after initial infection.
    - This is a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses.
    - COVID-19 vaccine doses inadvertently received within 90 days after receipt of passive antibody therapy do not need to be repeated.

Administration with Other Products – cont'd

- Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for the treatment of COVID-19 infection are currently unknown. Medical consultation with primary care physician is advised.
- COVID-19 vaccines may be given at any time before or after an immunoglobulin preparation (including RhIg) or blood product has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.

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Tuberculin Skin Testing & COVID-19 Vaccines

- Currently there is no data on the impact of the COVID-19 vaccines on tuberculin skin testing or IGRA (QFT) test results. There is a theoretical risk that COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative tuberculin skin testing or IGRA (QFT) test results.
- If tuberculin skin testing or an IGRA test is required for baseline screening, it should be administered and read before administration of any COVID-19 vaccine or delayed for at least 28 days after a dose of COVID-19 vaccine.
- Immunization with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing (including read) have been completed.
- If tuberculin skin testing is required for other reasons (e.g., contact tracing, immigrants, query LTBI), testing should not be delayed, as these are theoretical considerations. However, re-testing (at least 28 days after a dose of COVID-19 vaccine) 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.

Informed Consent

- Clients must give informed consent before immunization
- Prior to immunizing the immunizer must:
  - Determine that the client is eligible (based on current phase and/or eligibility requirements)
  - Review the disease being prevented
  - Review vaccine
  - Discuss:
    - risks and benefits of getting the vaccine and not getting the vaccine
    - side effects and after care
    - how the vaccine is given
  - Provide the opportunity to ask questions
  - Affirm verbal consent

Janssen Informed Consent

Immunizers must ensure that the informed consent counselling includes:

- Data about the efficacy of Janssen vaccine
  - Effectiveness of one dose is about 67% to 72% (as compared to the two dose mRNA vaccines that have effectiveness of 88% to 93%)
  - Possibility of Janssen becoming a two dose vaccine series for being considered fully immunized in the future
- Potential adverse events
  - As noted in previous slides, specifically related to the risk of the rare but serious events of thrombosis with thrombocytopenia (TTS), venous thromboembolism (VTE), immune thrombocytopenia (ITP), capillary leak syndrome or Guillain-Barre syndrome (GBS)

Questions?

- Clinical immunization questions should first be directed to your site lead. You may be asked to contact CDCIMM@ahs.ca

- Process and operational questions should be directed to your Site Lead

References

1. Alberta Health, Health System Accountability and Performance Division, Alberta Immunization Policy (2022 January 10. COVID-19 Vaccine Janssen Ad26.COV2.S [recombinant].
2. Centers for Disease Control and Prevention. (2021 April 27). Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021. https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7017e4-H.pdf
3. Centers for Disease Control and Prevention. (2021, September). Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination
4. Centers for Disease Control and Prevention. (2021 October 18). Selected Adverse Events Reported after COVID-19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html
5. European Medicine Agency (Pharmacovigilance Risk Assessment Committee. (2021 April 20). COVID-19 Vaccine Janssen: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets. https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7017e4-H.pdf

References

6. European Medicine Agency (Pharmacovigilance Risk Assessment Committee. (2021 September). Meeting highlights from the Pharmacovigilance Risk Assessment Committee. https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-27-30-september-2021
7. European Medicine Agency (Pharmacovigilance Risk Assessment Committee. (2021 October). COVID-19 Vaccine Janssen. https://www.ema.europa.eu/en/documents/overview/covid-19-vaccine-janssen-epar-medicine-overview_en.pdf
8. Health Canada. (2021 April 26). Janssen COVID-19 Vaccine and the Risk of Thrombosis with Thrombocytopenia. https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75479a-eng.php
9. Janssen (2021 October 20). Fact Sheet for Healthcare Providers Administering Vaccine. https://www.fda.gov/media/146304/download