COVID – 19 VACCINE CONTRAINDICATIONS AND PRECAUTIONS BACKGROUND DOCUMENT 2021-04-29

NOTE: This table is to be used by Healthcare Professionals to assess clients with the following conditions who live or work in high-risk environments. This table does not address all Contraindications and Precautions.

For AstraZeneca/ COVISHIELD COVID-19 Vaccine Only:

- This vaccine is **not** recommended for use in clients under 40 years of age at this time.
- Clients with a history of the following conditions should **not** receive this vaccine due to very rare reports of a combination of blood clots and low levels of blood platelets following immunization:
  - Heparin Induced Thrombocytopenia (HIT)
  - Thrombosis associated with lupus anticoagulant (thrombotic anti-phospholipid syndrome)
  - Cerebral venous sinus thrombosis (CVST)
  - Venous or arterial thrombosis with thrombocytopenia after getting this vaccine

Condition	Recommendations	Script
Timing of COVID-19 immunization with other vaccines	Avoid administering COVID-19 vaccines and other vaccines at the same time when possible. The following intervals between vaccine doses are preferable: <u>Interval between a non-COVID-19 vaccine and COVID-19 vaccine</u> • **After administration of a non-COVID-19 vaccine**, it is preferred (if possible) to wait an interval 14 days before administering a COVID-19 vaccine. • **EXCEPTION**: If a client presents prior to 14 days, they may be immunized with their informed consent. Neither dose should be repeated. <u>Interval between a COVID-19 vaccine and a non-COVID-19 vaccine</u> • **After administration of a COVID-19 vaccine**, it is recommended to wait an interval of 28 days before administering a non-COVID-19 vaccine, however in consultation with their health care provider there may be exceptions. • **EXCEPTIONS**: ○ If a client presents prior to 28 days, the client may be immunized with their informed consent. Neither dose should be repeated. **NACI recommends that COVID-19 vaccines should not be given simultaneously with other vaccines (live or inactivated).** Currently, no data exist on the simultaneous administration of COVID-19 vaccine with other vaccines. In the absence of evidence, attempts should be made to avoid simultaneous administration to maximize benefits of COVID-19 vaccination while minimizing any risks of harm, including the potential for immune interference or the erroneous attribution of an adverse event following immunization (AEFI) to a particular vaccine. However, if a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated.	• Currently, there is no information on administering a COVID-19 vaccine and another vaccine at the same time. • Administration of the COVID-19 vaccine close together with another vaccine may result in lessened immune response to the vaccine. • **Based on your immunization history, it is preferable to wait at least 14 days to receive the COVID-19 vaccine.** • Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine? • Do you consent to being immunized with the (Brand) of COVID-19 vaccine?

Condition	Recommendations	Script
	In the absence of evidence, it would be prudent to wait for a period of at least 28 days after each vaccine dose of an mRNA or viral vector COVID-19 vaccine before the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis) due to the elicitation of an inflammatory cytokine response. It would be prudent to wait for a period of at least 14 days after the administration of another vaccine before administrating a COVID-19 vaccine to prevent erroneous attribution of an AEFI to a particular vaccine.	
SARS-CoV-2 (COVID-19) Infection Current or Previous	• **Residents of Long-Term Care Facilities and Personal Care Homes, and persons aged 80 years and older living in the community**, should be immunized, irrespective of whether and when they had SARS-CoV-2 infection, as long as they have recovered from their acute illness and there are no other contraindications, as they are extremely vulnerable and there is no clear evidence on the length of disease immunity among these populations. • **Recommendation for the general public younger than 80 years of age (including healthcare workers)** It is preferred immunization with COVID-19 vaccine is delayed for 90 days following a PCR-confirmed SARS-CoV-2 infection if the infection occurred before the first COVID-19 vaccine dose, as reinfections reported to date have been rare within the first three months following infection. ○ **EXCEPTION:** If it is not feasible to wait 90 days or if an individual presents for immunization less than 90 days after infection, immunization may be administered as long as the person has recovered from the acute illness and criteria have been met for them to discontinue isolation. ○ If a member of the general public (younger than 80 years old) develops SARS-CoV-2 infection between receiving doses 1 and 2 of their COVID-19 vaccine series, the 90 day deferral does not apply and their second dose should be provided as long as the individual has recovered from the acute illness and criteria have been met for them to discontinue isolation. **NACI recommends that a complete series with a COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine who have had previously PCR-confirmed SARS-CoV-2 infection. In the context of limited vaccine supply, initial doses may be prioritized for those who have not had a previously PCR-confirmed SARS-CoV-2 infection. (Discretionary NACI Recommendation)** **Summary of evidence and rationale:** • Testing for previous SARS-CoV-2 infection is not needed prior to COVID-19 vaccination. • Currently, there is a lack of evidence on potential differences in vaccine efficacy or safety between those with and without prior evidence of SARS-CoV-2 infection. In COVID-19 vaccine clinical trials to date, individuals with PCR-confirmed SARS-CoV-2 were excluded and there were only a small number of trial participants with serologic evidence of previous infection (IgG+) who had confirmed symptomatic COVID-19 during the trials, therefore efficacy in this population is uncertain.	**For Long-Term Care and Personal Care Home Residents and persons aged 80 years and older living in the community**: • Immunization does not need to be deferred for clients who have had a recent COVID-19 infection and are living in a long term care or personal care home, or are aged 80 years or older living in the community as long as the person is recovered from acute illness and criteria have been met to discontinue isolation. **For the general public younger than 80 years of age:** • Immunization is recommended to be deferred for 90 days for clients requiring their first dose and who have had a recent COVID-19 infection since reinfections have been rare within the first three months following infection. **For all clients:** • Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine? • **(If recommendation in second column supports immunization)** Do you consent to being

Condition	Recommendations	Script
	• The immune response to SARS-CoV-2, including duration of immunity, is not yet well-understood. Reinfections with SARS-CoV-2 have been reported and research to establish the severity, frequency, and risk factors of reinfection with SARS-CoV-2 is ongoing. • In the context of limited supply, to allow for the protection of a larger number of at-risk individuals, vaccination with a COVID-19 vaccine may be delayed for three months following a PCR-confirmed infection, as reinfections reported to date have been rare within the first three months following infection. • However, if challenging from a feasibility perspective, jurisdictions may elect to disregard prior PCR-confirmed SARS-CoV-2 infection status and vaccinate everyone in a given target group. • As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, and to minimize the risk of transmission of COVID-19 at an immunization venue, NACI recommends that it is prudent to wait until all symptoms of an acute illness are completely resolved before vaccinating with COVID-19 vaccine, as well as ensuring that the individual is no longer considered infectious based on current criteria. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#b9	immunized with the (Brand) of COVID-19 vaccine? • Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine?
Treatment with COVID19 Monoclonal Antibodies or Convalescent Plasma	• If client received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment of infection, delay vaccination with COVID-19 vaccine for at least 90 days. Delaying vaccination due to treatment is applicable to the first dose and second dose, depending on when treatment was received (e.g. if treatment is received after the first dose is administered, delay the second dose for at least 90 days). • For additional recommendations on timing of vaccination, see LETTER-COVID-19 Vaccine Immunization Recommendations for Persons with a Current or a Prior History of SARS-CoV2 Infection on the COVID-19 Immunization Manual website. • For persons receiving antibody therapies not specific to COVID-19 treatment (e.g., intravenous immunoglobulin, RhoGAM), they are recommended to receive and/or complete a full COVID-19 vaccine series either simultaneously with or at any interval before or after treatment. **NACI recommends that COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.** To date, there is insufficient evidence on the receipt of both a COVID-19 vaccine and anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention. Therefore, timing of administration and potential interference between these two products are currently unknown. Administration of these products close together may result in decreased effectiveness of a COVID-19 vaccine and/or anti-SARS-CoV-2 monoclonal antibodies because the monoclonal antibodies have high affinity for the spike protein expressed by the vaccines, which could prevent the production of antibodies stimulated by the vaccine.	• Currently, there is insufficient evidence on the receipt of both a COVID-19 vaccine and anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma. • Administering these products close together may result in less effectiveness of the COVID-19 vaccine and/ or the SARS-CoV-2 monoclonal antibodies. • **Based on your treatment the recommendation is to wait at least 90 days to receive the COVID-19 vaccine.** • **(If recommendation in second column supports immunization)** Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine?

Condition	Recommendations	Script
	In the post-exposure setting, expert clinical opinion should be sought on a case-by-case basis when deciding whether anti-SARS-CoV-2 monoclonal antibodies would be appropriate to administer after receipt of COVID-19 vaccine, taking into consideration the risk of exposure and the risk of severe COVID-19 disease in the individual. To date, there is also insufficient evidence on the receipt of both a COVID-19 vaccine and any monoclonal antibodies or convalescent plasma for treatment or prevention of non-COVID-19 disease. Therefore, timing of administration and potential interference between these two products are currently unknown and expert clinical opinion should be sought on a case-by-case basis. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#b11 **Centre for Disease Control (US)** **People who previously received passive antibody therapy** Currently, there are no data on the safety and efficacy of COVID-19 vaccines in people who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Based on the estimated half-life of such therapies and evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days. This is a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses. This recommendation applies to people who receive passive antibody therapy before receiving any vaccine dose and to those who receive passive antibody therapy after the first dose of an mRNA vaccine but before the second dose, in which case the second dose should be deferred for at least 90 days following receipt of the antibody therapy. Receipt of passive antibody therapy in the past 90 days is not a contraindication to receipt of COVID-19 vaccine. COVID-19 vaccine doses received within 90 days after receipt of passive antibody therapy do not need to be repeated. For people receiving antibody therapies not specific to COVID-19 treatment (e.g., intravenous immunoglobulin, RhoGAM), administration of COVID-19 vaccines either simultaneously with or at any interval before or after receipt of an antibody-containing product is unlikely to substantially impair development of a protective antibody response. Thus, there is no recommended minimum interval between antibody therapies not specific to COVID-19 treatment and COVID-19 vaccination. https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html	
Breastfeeding	• If the client is at high risk of exposure to COVID-19, they are recommended to receive and/or complete a full COVID-19 vaccine series. **The SOGC (Society of Obstetricians and Gynaecologists of Canada) Statement on COVID-19 Vaccination in Pregnancy Consensus Statement:**	**If client consents to immunization, ensure they sign the appropriate benefit/risk information form.** • Do you live or work in a high-risk environment for exposure to COVID-19?

Condition	Recommendations	Script
	• For individuals who are at high risk of infection and/or morbidity from COVID-19, it is the SOGC's position that the documented risk of not getting the COVID-19 vaccine outweighs the theorized and undescribed risk of being vaccinated during pregnancy or **while breastfeeding** and vaccination should be offered. • Informed consent must include discussion about the insufficient evidence on safety and efficacy in this population. **NACI recommends that a complete vaccine series with a COVID-19 vaccine may be offered to individuals in the authorized age group who are breastfeeding, if a risk assessment deems that the benefits outweigh the potential risks for the individual and the infant, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccines in this population. (Discretionary NACI Recommendation)** **Summary of evidence and rationale:** • Currently, there are no data on the safety and efficacy of COVID-19 vaccines in pregnancy or during breastfeeding. Pregnant or breastfeeding individuals were excluded from the mRNA and viral vector COVID-19 vaccine clinical trials. • It is unknown whether the vaccines are excreted in human milk, but there are no data on outcomes in breastfeeding individuals or their breastfed infants. There have been no theoretical concerns about these vaccines in breastfeeding individuals or their breastfed infants. • Individuals who are pregnant, breastfeeding, or of reproductive age may be at increased risk of exposure to SARS-CoV-2 (e.g., healthcare or essential workers) and/or at increased risk of severe COVID-19 disease (e.g., due to pre-existing medical condition, body mass index of 40 or more) and may wish to be vaccinated despite the lack of evidence of COVID-19 vaccination in pregnancy or during breastfeeding in order to protect themselves. Therefore, the balance of benefits and risks must be made on a case-by-case basis. • Vaccine recipients and health care providers are encouraged to report to COVID-19 vaccine during pregnancy or breastfeeding to the local public health authority as well as to the vaccine manufacturer for follow-up. Active surveillance in these vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves and update recommendations as needed. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#b11	• There are few studies about the efficacy or safety regarding COVID-19 vaccines given to breastfeeding women or their breastfeeding infants. It is unknown whether COVID-19 vaccine is passed on in breastmilk, thus risk to the newborn/infant cannot be excluded. • For individuals who are at high risk of infection and/or morbidity from COVID-19, it is the Society of Obstetricians and Gynecologists of Canada's position that the documented risk of not getting the COVID-19 vaccine outweighs the theorized and undescribed risk of being vaccinated while breastfeeding and vaccination should be offered. • Getting the COVID-19 vaccine is not a reason to stop breastfeeding. • Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine? • Do you consent to being immunized with the (Brand) of COVID-19 vaccine?
Pregnancy or Planning Pregnancy	• There are few studies about the efficacy or safety of the vaccine in pregnant women. • For clients planning pregnancy but indicate they will not or cannot wait 28 days after the COVID-19 vaccine series to conceive, the vaccine may be administered with the client's informed consent. • If a client becomes pregnant after receiving their first dose, the second dose should be administered as indicated, with the client's informed consent.	**If client consents to immunization, ensure they sign the appropriate benefit/risk information form.** • **(For clients who are currently pregnant)** There are few studies about the efficacy or safety about

Condition	Recommendations	Script
	• If a client has a scheduled immunization appointment (eligible based only on pregnancy) but is no longer pregnant at the time of the appointment, proceed with immunization. **NOTE:** Pregnancy is not a contraindication for any of the currently approved COVID-19 Vaccines, including AstraZeneca/COVISHIELD. **The SOGC (Society of Obstetricians and Gynaecologists of Canada) Statement on COVID-19 Vaccination in Pregnancy Consensus Statement:** • For individuals who are at high risk of infection and/or morbidity from COVID-19, it is the SOGC's position that the documented risk of not getting the COVID-19 vaccine outweighs the theorized and undescribed risk of being vaccinated **during pregnancy** or while breastfeeding and vaccination should be offered. • Informed consent must include discussion about the insufficient evidence on safety and efficacy in this population. • Reinforce side effects and treat even mild fever during pregnancy. • Being unknowingly pregnant and receiving the COVID-19 vaccine is not a reason to terminate the pregnancy. **NACI recommends that a complete vaccine series with a COVID-19 vaccine may be offered to pregnant individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccines in this population. (Discretionary NACI Recommendation)** • The evidence of pregnancy as an independent risk factor for severe COVID-19 is evolving. • Currently, there are no data on the safety and efficacy of COVID-19 vaccines in pregnancy or during breastfeeding. Pregnant or breastfeeding individuals were excluded from the mRNA and viral vector COVID-19 vaccine clinical trials. • Currently, there are no data to inform outcomes of inadvertent administration of COVID-19 vaccine to pregnant individuals or their developing fetus in clinical trials. Outcomes in participants who became pregnant during the clinical trials and fetal outcomes will be reported through registries and NACI will reconsider recommendations when these data become available. • Currently, there are limited data on the safety of COVID-19 vaccine from animal developmental and reproductive toxicity studies. In rats that received the Moderna COVID-19 vaccine prior to or during gestation, no safety concerns regarding female reproduction, fetal/embryonal development, or postnatal development were demonstrated. Developmental and Reproductive Toxicity (DART) animal studies for the Pfizer-BioNTech COVID-19 vaccine and AstraZeneca COVID-19 vaccine are ongoing. • Individuals who are pregnant, breastfeeding, or of reproductive age may be at increased risk of exposure to SARS-CoV-2 (e.g., healthcare or essential workers) and/or at increased risk of severe COVID-19 disease (e.g., due to pre-existing medical condition, body mass index of 40 or more) and	the COVID-19 vaccines given to pregnant women. • **(For clients who are planning pregnancy)** There is no information to guide the time between completion of a COVID-19 vaccine series and conception and due to this scientific uncertainty it is preferable (if possible) to delay pregnancy by 28 days or more after the administration of the complete vaccine series. • For individuals who are at high risk of infection and/or morbidity from COVID-19, it is the Society of Obstetricians and Gynecologists of Canada's position that the documented risk of not getting the COVID-19 vaccine outweighs the theorized and undescribed risk of being vaccinated during pregnancy and vaccination should be offered. • Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine? • Do you consent to being immunized with the (Brand) of COVID-19 vaccine?

Condition	Recommendations	Script
	may wish to be vaccinated despite the lack of evidence of COVID-19 vaccination in pregnancy or during breastfeeding in order to protect themselves. Therefore, the balance of benefits and risks must be made on a case-by-case basis. • There is currently no evidence to guide the time interval between the completion of the COVID-19 vaccine series and conception. In the face of scientific uncertainty, it may be prudent to delay pregnancy by 28 days or more after the administration of the complete two-dose vaccine series of a COVID-19 vaccine. A COVID-19 vaccine may be administered any time after pregnancy. • Individuals who become pregnant during their vaccine series or shortly thereafter should not be counselled to terminate pregnancy based on having received a COVID-19 vaccine. • Eligible individuals should be offered a complete vaccine series with an authorized COVID-19 vaccine post-partum and prior to attempting pregnancy so that the recommended interval between completion of the vaccine series and conception is maintained. • Vaccine recipients and health care providers are encouraged to report to COVID-19 vaccine during pregnancy or breastfeeding to the local public health authority as well as to the vaccine manufacturer for follow-up. Active surveillance in these vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves and update recommendations as needed. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#b11	
Immunocompromised **Also see sections below for Cancer/ Oncology patients** **And** **Patients with Auto-Immune Disease**	**It is preferred that clients on immunosuppressive therapy discuss the timing between their therapy and receiving the vaccine with their health care provider.** **(HSCT) Blood and Bone Marrow Stem Cell Transplant (autologous or allogeneic):** ○ Patients **MUST** talk with their oncology team prior to vaccine administration. ▪ If feasible vaccine should be administered 2 weeks prior to starting conditioning regimen for their transplant. ▪ Post-transplant - if transmission in the community is high, vaccination can be initiated 3 months after HSCT. If the transmission in the community is controlled, vaccination can wait until 6 months after HSCT. ▪ Postpone vaccination in severe, uncontrolled acute GVHD, Grade 3-4. **Medically stable SOLID ORGAN TRANSPLANT PATIENTS** followed up by the Saskatchewan Transplant Program **DO NOT NEED to consult their specialist prior to immunization with COVID-19 vaccines. However:** ○ **If the client had a recent transplant (less than month ago) or was recently (less than 1 month ago) treated for rejection or if the immunizer is unsure of the client's eligibility, please ask the client to contact the Saskatchewan Transplant Program to determine if and when they should receive the vaccine.** • It is preferred that all other clients with immune suppression discuss the vaccine with their healthcare provider prior to presenting. **However:** ○ If they have not discussed vaccination with their healthcare provider **AND** their **condition is UNSTABLE consult** with the area MHO.	**If client consents to immunization, ensure they sign the appropriate benefit/risk information form.** • Do you live or work in a high-risk environment for exposure to COVID-19? • Have you discussed the benefits and risks of the COVID-19 vaccine with your healthcare provider? (Review recommendations and proceed with script). • A client who is medically stable does not need to defer immunization with a COVID-19 vaccine, even if not discussed with their healthcare provider **(exception for HSCT blood and bone marrow stem cell transplant clients as outlined in the recommendations column)**.

Condition	Recommendations	Script
	○ If they have not discussed vaccination with their healthcare provider **AND** their **condition is stable** proceed as below. • NACI recommends that a complete COVID-19 vaccine series may be offered to individuals who are immunosuppressed due to disease or treatment in the authorized age group in this population, if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population. **NACI Summary of evidence and rationale**: **NACI recommends that a complete COVID-19 vaccine series may be offered to individuals who are immunosuppressed due to disease or treatment in the authorized age group in this population, if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccines in this population and the possibility that individuals who are immunosuppressed may have a diminished immune response to any of the authorized COVID-19 vaccines. (Discretionary NACI Recommendation)** • Currently, there is limited evidence that immunosuppression is an independent risk factor for severe COVID-19, though evidence is evolving. • Currently, there are no data on COVID-19 vaccination in individuals who are immunosuppressed. Participants in the COVID-19 vaccine clinical trials only included individuals who were not immunosuppressed, such as those with stable infection with human immunodeficiency virus (HIV), and those not receiving immunosuppressive therapy during the trial. • No safety signals of concern have been noted to date in non-immunosuppressed participants with an immunocompromising condition (e.g., stable HIV infection) included in the clinical trials. • The relative degree of immunodeficiency in individuals who are immunocompromised is variable depending on the underlying condition, the progression of disease and use of medications that suppress immune function. Therefore, the balance of benefits and risks must be made on a case-by-case basis. • Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. • In general, non-replicating vaccines may be administered to immunocompromised people because the antigens in the vaccine cannot replicate. However, the magnitude and duration of vaccine-induced immunity are often reduced. It is currently unknown whether immunocompromised individuals will be able to mount an immune response to the authorized COVID-19 vaccines. • People living with HIV who are considered immunocompetent may be vaccinated. • The amount of protection may not be as high. Advise to ensure they still need to take precautions against COVID – 19 disease. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html	• Currently, there are no data on COVID-19 vaccination in individuals who are immunosuppressed. • The vaccine antibody response in immune comprised individuals may not be a strong as the immune response in individuals who are not immune suppressed. Immunized individuals still need to take precautions against COVID–19 disease. • Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine? • **(If the treatment plan in second column supports immunization)** Do you consent to being immunized with the (Brand) of COVID-19 vaccine?

Condition	Recommendations	Script
Immuno-compromised **Oncology Patients**	**Cancer survivors** should be vaccinated against COVID-19 if there are no contraindications to receiving vaccine. Vaccinate as any other client who does not have a precaution or contraindication and a benefit/risk form does not need to be completed. **(HSCT) Blood and Bone Marrow Stem Cell Transplant (autologous or allogeneic):** ○ Patients **MUST** talk with their oncology team prior to vaccine administration. ▪ If feasible vaccine should be administered 2 weeks prior to starting conditioning regimen for their transplant. ▪ Post-transplant - if transmission in the community is high, vaccination can be initiated 3 months after HSCT. If the transmission in the community is controlled, vaccination can wait until 6 months after HSCT. ▪ Postpone vaccination in severe, uncontrolled acute GVHD, Grade 3-4. • It is preferred that **all other clients with cancer** discuss the vaccine with their healthcare provider prior to presenting. **However:** ○ If they have not discussed vaccination with their healthcare provider **AND** their **condition is UNSTABLE, consult** with the area MHO. ○ If they have not discussed vaccination with their healthcare provider **AND** their **condition is STABLE** proceed as below. The following guidelines on the **timing of COVID-19 vaccine in terms of cancer treatment** has been adapted from the information from inactivated influenza and other vaccines in immunocompromised patients. If client's therapy is: • **Targeted Hormonal and single agent immune therapy treatments:** Vaccine can be administered at any time during treatment. • **Radiation therapy:** Vaccine can be administered at any time during radiation therapy. • **Cytotoxic chemotherapy:** ○ **New treatment starts**: ▪ If possible, vaccination should be completed at least two weeks prior to starting systemic therapy or immunosuppressive therapy. If both of the doses cannot be given prior to starting treatment, at least the first dose of vaccine should be given two weeks before starting treatment. The second dose should be administered 4-5 days prior to the next cycle.	**If client consents to immunization, ensure they sign the appropriate benefit/risk information form.** • Do you live or work in a high-risk environment for exposure to COVID-19? • Have you discussed the benefits and risks of the COVID-19 vaccine with your healthcare provider? (Review recommendations and proceed with script). • A client who is medically stable does not need to defer immunization with a COVID-19 vaccine, even if not discussed with their healthcare provider **(exception for HSCT blood and bone marrow stem cell transplant clients)**. • Currently, there are no data on COVID-19 vaccination in individuals who are immunosuppressed. • The vaccine antibody response in immune comprised individuals may not be a strong as the immune response in individuals who are not immune suppressed. Immunized individuals still need to take precautions against COVID–19 disease. • **Based on your therapy the recommendation is as follows: refer to treatments in second column.** • Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine?

Condition	Recommendations	Script
	○ **Patients already on chemotherapy treatment**: ▪ Ideally a vaccine dose would be administered 4- 5 days prior to a dose of cytotoxic chemotherapy so that vaccine side effects and chemotherapy side effects don't overlap. • **B-Cell directed therapy** ((Anti CD 20 (rituximab, obinotuzimab), CD 19 – (blinatumomab), CD 22 antibodies (inotuzumab) and BTK inhibitors (ibrutinib)): ○ If therapy is of short duration (limited number of cycles), Vaccination should be postponed until 1-3 months after B- cell directed treatment due to decreased ability to develop immunity to COVID-19 by vaccination. ○ If therapy is part of a maintenance treatment, Vaccination should be given 4 weeks after the last dose of therapy. ○ Patients on BTK inhibitors (ibrutinib) can receive vaccination at any time. • **T-Cell directed therapy** (Calcineurin inhibitors (e.g. oral and injection: cyclosporine and tacrolimus) (e.g. topical: pimecrolimus, tacrolimus), ATG (e.g. antithymocyte globulin – rabbit and equine) or Alemtuzumab) ○ Vaccination should be postponed until 3 months after of T- cell directed treatment due to decreased ability to develop immunity to COVID-19 by vaccination. **NACI Summary of evidence and rationale**: **NACI recommends that a complete COVID-19 vaccine series may be offered to individuals who are immunosuppressed due to disease or treatment in the authorized age group in this population, if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccines in this population and the possibility that individuals who are immunosuppressed may have a diminished immune response to any of the authorized COVID-19 vaccines. (Discretionary NACI Recommendation)** • Currently, there is limited evidence that immunosuppression is an independent risk factor for severe COVID-19, though evidence is evolving. • Currently, there are no data on COVID-19 vaccination in individuals who are immunosuppressed. Participants in the COVID-19 vaccine clinical trials only included individuals who were not immunosuppressed, such as those with stable infection with human immunodeficiency virus (HIV), and those not receiving immunosuppressive therapy during the trial. • No safety signals of concern have been noted to date in non-immunosuppressed participants with an immunocompromising condition (e.g., stable HIV infection) included in the clinical trials. • The relative degree of immunodeficiency in individuals who are immunocompromised is variable depending on the underlying condition, the progression of disease and use of medications that suppress immune function. Therefore, the balance of benefits and risks must be made on a case-by-case basis.	• **(If the treatment plan in second column supports immunization)** Do you consent to being immunized with the (Brand) of COVID-19 vaccine?

Condition	Recommendations	Script
	• Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. • In general, non-replicating vaccines may be administered to immunocompromised people because the antigens in the vaccine cannot replicate. However, the magnitude and duration of vaccine-induced immunity are often reduced. It is currently unknown whether immunocompromised individuals will be able to mount an immune response to the authorized COVID-19 vaccines. • The amount of protection may not be as high. Advise to ensure they still need to take precautions against COVID – 19 disease. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html • **Patients with cancer may have diminished immune response to vaccine**. Efficacy will depend on the patient's ability to mount a response to the vaccine, which in turn will depend on multiple factors like age, comorbidities, type and stage of cancer, type and timing of immunosuppressive therapy.	

Autoimmune conditions
 	
See MS section below
	For AstraZeneca/COVISHIELD COVID-19 Vaccine only: clients with a previous history of thrombosis associated with lupus anticoagulant (thrombotic anti-phospholipid syndrome) should **not** receive this vaccine due to very rare reports of a combination of blood clots and low levels of blood platelets following immunization.
	
	For any autoimmune condition that involves the **neurological system, it is preferred** the client discuss vaccination with their primary physician / specialist before immunization is provided. If the client has not discussed vaccination with their primary physician or specialist, immunization can proceed with their informed consent.
	
	Clients receiving ongoing treatment with **Rituximab** should delay vaccination **until a minimum of 4 weeks** after last dose of Rituximab, unless directed differently by their health care provider/prescriber.
	• See table below for a list of common autoimmune conditions.
	• It is preferred that clients with immune suppression discuss the vaccine with their healthcare provider prior to presenting. **However:**
	  ○ If they have not discussed vaccination with their healthcare provider **AND** their **condition is UNSTABLE consult** with the area MHO.
	  ○ If they have not discussed vaccination with their healthcare provider **AND** their **condition is STABLE** proceed as below.
	NACI recommends that a complete vaccine series with a COVID-19 vaccine may be offered to individuals with an autoimmune condition in the authorized age group in these populations if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the insufficiency of evidence on the use of COVID-19 vaccines in these populations. (Discretionary NACI Recommendation)
		If client consents to immunization, ensure they sign the appropriate benefit/risk information form.
		• Do you live or work in a high-risk environment for exposure to COVID-19?
		• Have you discussed the benefits and risks of the COVID-19 vaccine with your healthcare provider? (Review recommendations and proceed with script).
		
		• A client who is medically stable does not need to defer immunization with a COVID-19 vaccine, even if not discussed with their healthcare provider. (Exception includes those **receiving treatment with Rituximab. See recommendations**).
		• Currently, there is limited data on COVID-19 vaccination in individuals who have autoimmune conditions. The numbers of individuals with autoimmune

<table>
<tr><th>Condition</th><th>Recommendations</th><th>Script</th></tr>
<tr><td></td><td>Summary of evidence and rationale:
Currently, there is limited evidence that having an autoimmune condition is an independent risk factor for severe COVID-19, though evidence is evolving.
Currently, there are very limited data on COVID-19 vaccination in individuals who have an autoimmune condition. Although participants with autoimmune conditions who were not immunosuppressed were not excluded from trials, they constitute a very small proportion of trial participants and represent a very narrow range of autoimmune conditions.
The spectrum of autoimmune conditions is diverse. The relative degree of autoimmunity in individuals with autoimmune conditions is variable depending on the underlying condition, the severity and progression of disease and use of medications that impact immune function. Therefore, the balance of benefits and risks must be made on a case-by-case basis.
Other applications of mRNA technologies have been for the treatment of cancer, which required an immune response directed against an individual's cancer cells. This raised the theoretical concern that mRNA vaccines for infectious diseases would behave similarly, eliciting inflammation and possibly exacerbating existing autoimmune diseases. Current applications of mRNA technology for COVID-19 vaccines have been optimized to reduce this risk.
Active surveillance in these vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves and update recommendations as needed.
Advise to ensure they still need to take precautions against COVID – 19 disease.
https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#b9</td><td>conditions in the vaccine studies were very small.
The vaccine antibody response in individuals with autoimmune conditions may not be as strong as the immune response in individuals who do not have an autoimmune condition. The immune response may vary according to condition severity and current medical treatment. Immunized individuals still need to take precautions against COVID–19 disease.
Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine?
(If the treatment plan in second column supports immunization) Do you consent to being immunized with the (Brand) of COVID-19 vaccine?</td></tr>
<tr><td>Autoimmune disorders

MULTIPLE SCLEROSIS</td><td>It is preferred that clients with Multiple Sclerosis (MS) discuss the vaccine with their healthcare provider prior to presenting. However:
If they have not discussed vaccination with their healthcare provider AND their condition is UNSTABLE consult with the area MHO.
If they have not discussed vaccination with their healthcare provider AND their condition is stable proceed as below, taking into consideration the timing of vaccines based on Disease Modifying Therapies (See Table below).
For <u>MULTIPLE SCLEROSIS (MS)</u> patients the following recommendations <u>should</u> be followed:<table><tr><th>Medication(s)</th><th>Effect on vaccination</th><th>Delay of vaccination after treatment*</th><th>Delay of treatment after vaccination**</th></tr><tr><td>Glatiramer acetate (any type)

Interferon-beta (any type)</td><td>Little to no effect</td><td>None required</td><td>None required</td></tr></table></td><td>If client consents to immunization, ensure they sign the appropriate benefit/risk information form.
Do you live or work in a high-risk environment for exposure to COVID-19?
Have you discussed the benefits and risks of the COVID-19 vaccine with your healthcare provider? (Review recommendations and proceed with script).
Currently, there are no specific data on COVID-19 vaccination in individuals who have MS.
The vaccine antibody response in MS patients may not be as strong as the immune response in</td></tr>
</table>

<table>
<tr><th>Condition</th><th>Recommendations</th><th>Script</th></tr>
<tr><td></td><td>
<table>
<tr><td>Teriflunomide

Dimethyl fumarate (or any type of fumaric acid ester)

Natalizumab</td><td></td><td></td><td></td></tr>
<tr><td>Fingolimod

Ozanimod

Siponimod</td><td>May have a modest decrease in vaccine effectiveness</td><td>None required</td><td>4 weeks for treatment initiation; no delay for treatment continuation</td></tr>
<tr><td>Ocrelizumab

Rituximab</td><td>May have a more pronounced decrease in vaccine effectiveness</td><td>4 weeks</td><td>4 weeks</td></tr>
<tr><td>Ofatumumab</td><td>May have a more pronounced decrease in vaccine effectiveness</td><td>4 weeks</td><td>4 weeks</td></tr>
<tr><td>Cladribine

Alemtuzumab</td><td>Unlikely to affect vaccine response after immune reconstitution has taken place</td><td></td><td>4 weeks</td></tr>
</table>
*: The time period after a treatment dose during which vaccine should not be administered.
**: The time period after a vaccination series (i.e. all doses) during which treatment should not be (re)started.

NACI recommends that a complete vaccine series with a COVID-19 vaccine may be offered to individuals with an autoimmune condition in the authorized age group in these populations if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the insufficiency of evidence on the use of COVID-19 vaccines in these populations. (Discretionary NACI Recommendation)

Summary of evidence and rationale:
• Currently, there is limited evidence that having an autoimmune condition is an independent risk factor for severe COVID-19, though evidence is evolving.</td><td>individuals who do not have MS. This will depend on the disease process and the client's MS treatment. Immunized individuals still need to take precautions against COVID–19 disease.
• Based on your therapy the recommendation is as follows: refer to treatments in Table.
• Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine?
• (If the treatment plan in Table supports immunization) Do you consent to being immunized with the (Brand) of COVID-19 vaccine?</td></tr>
</table>

Condition	Recommendations	Script
	• Currently, there are very limited data on COVID-19 vaccination in individuals who have an autoimmune condition. Although participants with autoimmune conditions who were not immunosuppressed were not excluded from trials, they constitute a very small proportion of trial participants and represent a very narrow range of autoimmune conditions. • The spectrum of autoimmune conditions is diverse. The relative degree of autoimmunity in individuals with autoimmune conditions is variable depending on the underlying condition, the severity and progression of disease and use of medications that impact immune function. Therefore, the balance of benefits and risks must be made on a case-by-case basis. • Other applications of mRNA technologies have been for the treatment of cancer, which required an immune response directed against an individual's cancer cells. This raised the theoretical concern that mRNA vaccines for infectious diseases would behave similarly, eliciting inflammation and possibly exacerbating existing autoimmune diseases. Current applications of mRNA technology for COVID-19 vaccines have been optimized to reduce this risk. • Active surveillance in these vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves and update recommendations as needed. • Advise to ensure they still need to take precautions against COVID – 19 disease. • https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#b9 • Some of the Disease Modifying Therapies (DMTs) may decrease vaccine effectiveness. Depending on the condition, the amount of protection may not be as high. Advise to ensure they still need to take precautions against COVID – 19 disease.	
Tuberculin (TB) Skin Test or TB Blood Work (IGRA)	• If TB skin testing or TB blood work is required, it should be administered and read before immunization or delayed for at least 4 weeks after vaccination with COVID-19 vaccine. • Vaccination with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing have been completed. Summary of Evidence • 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. • 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.	• Have you had a tuberculin (TB) skin test or need TB blood work (IGRA) done? If testing has been done but not read/completed: • Receiving the COVID-19 vaccine prior to having all steps of the TB test completed may cause the test to show a false-negative result which means the test negative result but it should be a positive result. • **The recommendation is to wait until your test result is read before receiving the COVID-19 vaccine.**

Condition	Recommendations	Script
		• **(If recommendation in second column supports immunization)** Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine?

Thrombosis and Thrombocytopenia	**AstraZeneca/COVISHIELD COVID-19 Vaccine Only:**
	• Clients with a previous history of the following conditions should not receive this vaccine.
	  ○ Heparin Induced Thrombocytopenia (HIT)
	  ○ Thrombosis associated with lupus anticoagulant (thrombotic anti-phospholipid syndrome)
	  ○ Cerebral venous sinus thrombosis (CVST)
	  ○ Venous or arterial thrombosis with thrombocytopenia after getting this vaccine
		• Due to very rare reports of a combination of blood clots and low levels of blood platelets following immunization with the AstraZeneca/COVISHIELD vaccine, it is not recommended people with a history of this condition to receive this vaccine.

References

1. Society of Obstetricians and Gynaecologists of Canada. SOGC Statement on COVID-19 Vaccination in Pregnancy. Version date: December 18, 2020
2. Cohn A, Mbaeyi S. What clinicians need to know about the pfizer-biontech COVID-19 vaccine. Centers for Disease Control and Prevention (CDC). 2020.
3. National Advisory Committee on Immunization. Recommendations on the use of COVID-19 vaccine(s). 2021-01-12 https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html
4. American Autoimmune Related Disease Ltd. https://www.aarda.org/diseaselist/
5. Centers for Disease Control: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Common Auto Immune Conditions*[1]

*This is not an exhaustive list

Addison's	Guillain-Barre syndrome	Optic Neuritis
Alopecia areata	Hashimoto's thyroiditis	Psoriasis
Amyloidosis	Hemolytic anemia	Psoriatic arthritis
Ankylosing spondylitis	Henoch-Schonlein purpura	Raynaud's syndrome
Celiac disease	Juvenile arthritis	Restless legs syndrome
Crohn's disease	Kawasaki disease	Rheumatoid arthritis
Diabetes (type 1)	Lupus	Sarcoidosis
Endometriosis	Meniere's disease	Scleroderma
Erythema nodosum	Multiple Sclerosis	Thrombocytopenic purpura
Fibromyalgia	Myasthenia gravis	Ulcerative Colitis
Graves' disease	Neutropenia	

[1]list obtained American Autoimmune Related Disease Ltd. https://www.aarda.org/diseaselist/