

NOTE: This table is intended to be used by Healthcare Professionals to assess clients with the following conditions who live or work in high-risk environments.

Condition	Recommendations	Script	
Breastfeeding	 If the client at high risk of exposure to COVID-19, they are recommended to receive and/or complete a full COVID-19 vaccine series. 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 vaccine in this population. NACI 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 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 breastfeed infants. There have been no theoretical concerns about these vaccines in breastfeeding individuals or their breastfeed infants. 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 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 may wish to be vaccinated despite the lack of evidence of COVID-19 vaccination in pregnancy or during breastfeeding in order to	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 during breastfeeding with your healthcare provider? (Review recommendations and proceed with script). 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	NACI recommends that a complete vaccine series with a COVID-19 vaccine may be offered to	If client consents to immunization, ensure they sign	
	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	the appropriate benefit/risk information form.Do you live or work in a high-risk environment	



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	discussion about the absence of evidence on the use of COVID-19 vaccine in this population.	for exposure to COVID-19?
	NACI Summary of evidence and rationale:	
	· ·	 Pregnant women at risk should be offered the COVID-19 vaccine. Have you discussed the benefits and risks of the COVID-19 vaccine during pregnancy with your healthcare provider? (Review recommendations and proceed with script). There are few studies about the efficacy or safety about the COVID-19 vaccines given to pregnant women. 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?



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	 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.	
Immunocomp romised See section below for cancer / Oncology patients	 ALL TRANSPLANT PATIENTS must consult their specialists prior to immunizing. It is preferred that all other clients with immune suppression discuss the vaccine with their healthcare provider prior to presenting. However:	 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. 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? Do you consent to being immunized with the (Brand) of COVID-19 vaccine?



Condition	Recommendations	Script
	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 mRNA vaccines. • People living with HIV that 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.	·
Immune suppressed 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. 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. mRNA and vector based vaccine technology is deemed safe in cancer and immunosuppressed patients. 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 RATIONALE 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 vaccinacion in individuals who are immunosuppressed. Participants in the mRNA 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. 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 fu	 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. 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 1 – 7 in second column. 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
	Beneral, representing vaccines may be damminated to immunication profits	immunized with the (Brand) of COVID-19





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	because the antigens in the vaccine cannot replicate. However, the magnitude and duration of	vaccine?
	vaccine-induced immunity are often reduced. It is currently unknown whether	
	immunocompromised individuals will be able to mount an immune response to mRNA vaccines.	
	According to the SK Cancer Agency (Jan. 2021), both of the two currently available vaccines in Canada have been shown to be safe and effective in the general population. There is limited evidence in cancer and immunocompromised patients; therefore, the advice below is based on the best available evidence at this time. The recommendations will be revised as new evidence becomes available.	
	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	
	What is the optimal timing for COVID-19 vaccine in cancer patients on treatment?	
	The following guidelines on the timing of COVID-19 vaccine has been adapted from the information	
	from inactivated influenza and other vaccines in immunocompromised patients.	
	If client's therapy is:	
	1. Targeted and Hormonal treatments:	
	Vaccine can be administered at any time during treatment.	
	2. Radiation therapy:	
	Vaccine can be administered at any time during radiation therapy.	
	3. <u>Cytotoxic chemotherapy</u>	
	a) 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.	
	b) 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.	
	4. B-Cell directed therapy ((Anti CD 20 (rituximab, obinotuzimab), CD 19 – (blinatumomab), CD 22	
	antibodies (inotuzumab) and BTK inhibitors (ibrutinib)):	
	Vaccination should be postponed until 6 months after B- cell directed treatment due to	
	decreased ability to develop immunity to COVID-19 by vaccination. Consult area MHO.	
	5. 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	



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	decreased ability to develop immunity to COVID-19 by vaccination. Consult area MHO.	
	6. Patients on Immune checkpoint inhibitors: (pembrolizumab, nivolumab, atezolizumab) Patients	
	must talk with their oncology team prior to vaccine administration to determine if the potential	
	risk of vaccination is outweighed by the benefits.	
	7. (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.	
Autoimmune	• ANY autoimmune condition that involves the NEUROLOGICAL SYSTEM the client must discuss this	If client consents to immunization, ensure they sign
conditions	with the client's primary physician / specialist before immunization is provided.	the appropriate benefit/risk information form.
	See table below for a list of common autoimmune conditions.	Do you live or work in a high-risk environment
See MS	• It is preferred that clients with immune suppression discuss the vaccine with their healthcare provider	for exposure to COVID-19?
section below	prior to presenting. However:	Have you discussed the benefits and risks of the
	 If they have not discussed vaccination with their healthcare provider AND their condition is 	COVID-19 vaccine with your healthcare provider?
	UNSTABLE consult with the area MHO.	(Review recommendations and proceed with
	 If they have not discussed vaccination with their healthcare provider AND their condition is 	script).
	STABLE proceed as below.	A client who is medically stable does not need to
	 NACI recommends that a complete vaccine series with a COVID-19 vaccine may be offered to 	defer immunization with a COVID-19 vaccine,
	individuals with an autoimmune condition in the authorized age group in these populations if a risk	even if not discussed with their healthcare
	assessment deems that the benefits outweigh the potential risks for the individual, and if informed	provider.
	consent includes discussion about the insufficiency of evidence on the use of COVID-19 vaccine in these	Currently, there is limited data on COVID-19
	populations.	vaccination in individuals who have autoimmune
	NACI Summary of evidence and rationale:	conditions. The numbers of individuals with
	Currently, there is limited evidence that having an autoimmune condition is an independent risk	autoimmune conditions in the vaccine studies
	factor for severe COVID-19, though evidence is evolving.	were very small.
	 Currently, there are very limited data on COVID-19 vaccination in individuals who have an 	The vaccine antibody response in individuals
	autoimmune condition. Although participants with autoimmune conditions who were not	with autoimmune conditions may not be a
	immunosuppressed were not excluded from trials, they constitute a very small proportion of trial	strong as the immune response in individuals
	participants and represent a very narrow range of autoimmune conditions.	who do not have an autoimmune condition. The
	The spectrum of autoimmune conditions is diverse. The relative degree of autoimmunity in	immune response may vary according to
	individuals with autoimmune conditions is variable depending on the underlying condition, the	condition severity and current medical
	severity and progression of disease and use of medications that impact immune function.	treatment. Immunized individuals still need to
	Therefore, the balance of benefits and risks must be made on a case-by-case basis.	take precautions against COVID–19 disease.
	Other applications of mRNA technologies have been for the treatment of cancer, which required	Do you have any additional questions or
	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. • Advise to ensure they still need to take precautions against COVID – 19 disease.	concerns about getting immunized with the COVID-19 vaccine? Do you consent to being immunized with the
- Marise to chisare they still need to take precaditions against covident as disease.	(Brand) of COVID-19 vaccine?
oimmune • It is preferred that clients with Multiple Sclerosis (MS) discuss the vaccine with their healthcare	f client consents to immunization, ensure they sign he 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 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 1 – 4 in second column. Do you have any additional questions or concerns about getting immunized with the COVID-19 vaccine?





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	any type of fumaric acid ester), and natalizumab.	
	Patients who previously received cladribine, alemtuzumab, mitoxantrone, cyclophosphamide or	
	a hematopoietic stem cell transplant, and have reconstituted their lymphocytes (generally >=	
	0.5-0.8 109 cells/L).	
	2. Patients on the following treatments may have a modest decrease in vaccine effectiveness , but they	
	need no alteration in vaccine timing.	
	Fingolimod, ozanimod, and siponimod.	
	3. Patients on the following treatments may have a more pronounced decrease in vaccine effectiveness,	
	and it may be prudent to delay the first dose until 4 weeks after vaccine completion. If treatment	
	has already started, the vaccine should be given at least 4 weeks before and 4 weeks after a	
	treatment dose.	
	Ocrelizumab, rituximab, and ofatumumab.	
	4. Patient on the following treatments should delay vaccination until appropriate immune	
	reconstitution has taken place (which they need o discuss with their physician/specialist):	
	Cladribine, alemtuzumab, mitoxantrone, cyclophosphamide, and hematopoietic stem cell	
	transplant.	
	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.	



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/

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	

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

