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***THE COVID-19 VACCINE AND CANCER: FREQUENTLY ASKED QUESTIONS***

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The following are frequently asked questions around the COVID-19 vaccine and adult cancer patients. The information is:

- related to the Pfizer and the Moderna COVID-19 vaccines that use mRNA technology
- current as of January 6<sup>th</sup>, 2021.

The information below may not be appropriate for all patients. Prescribers must determine whether adopting suggested COVID-19 vaccine information is clinically appropriate for individual patients through a risk-benefit assessment. Consult appropriate clinical prescribing guidelines and local institutional guidance for patient prioritization to inform treatment and vaccination decisions.

Everyone should receive a COVID-19 vaccination, when available, unless contraindicated. There are limitations to the current knowledge around the use of COVID-19 vaccines in the cancer population. The advice below is based on the best available evidence at this time. Guidance will be updated as more real-world evidence becomes available.

Patients should continue to practice recommended public health measures for prevention of COVID-19 infection regardless of vaccination status.

**1. Are all COVID-19 vaccines safe for cancer patients?**

COVID-19 vaccine candidates use either conventional or novel mechanisms of action to safely elicit immune responses. Conventional platforms include recombinant viral proteins, live attenuated vaccines and inactivated vaccines, while novel methods include viral vector-based vaccines and mRNA-based vaccines.<sup>8</sup>

Although the safety of COVID-19 vaccines in cancer patients has yet to be studied, prior experience with other protein-based or inactivated vaccines have not reported unique or major side effects in immunocompromised patients.<sup>7</sup> The most frequently reported side effects of COVID-19 vaccine candidates were usually mild or moderate and include pain at the site of injection, fatigue, headache, myalgias and fever.

Live attenuated vaccines carry the risk of disease caused by vaccine strains and are not recommended during and after immunosuppressive therapy (such as chemotherapy).<sup>3</sup>

Currently there are 2 vaccines approved for active immunization to prevent COVID-19. On December 9, 2020 Health Canada authorized the Pfizer COVID-19 mRNA vaccine (Tozinameran or BNT162b2) with conditions. On December 23, 2020 Health Canada authorized the Moderna COVID-19 Vaccine (mRNA-1273 SARS-CoV-2 vaccine). Both vaccines are administered intramuscularly as a series of two doses with the Pfizer vaccine at an interval of 21 days apart (in the clinical trial doses were given 19 – 23 days apart; however, several guidelines suggest a minimum of 19 days between doses, with a recommended interval of 21-28 days)<sup>1,2</sup> and the Moderna vaccine at an interval of 28 days apart (minimum 21 days between doses).<sup>2,4</sup>

Both the Moderna and Pfizer vaccines use COVID-19's genetic code in the vaccine, exploiting the host cell to translate the code and make the target spike protein, eliciting both neutralizing antibody and cellular immune responses.<sup>4</sup> As there is no whole or live virus involved, the vaccines cannot cause disease and, therefore, may be administered to cancer patients after a risk-benefit assessment by the cancer health care team. It is important to note that immunocompromised persons, including individuals receiving immunosuppressant therapy, may not make a full antibody response and should therefore continue to follow Public Health guidance to avoid exposure unless otherwise advised by their health care team.

Patients with a history of severe allergy (e.g. anaphylaxis) to the COVID-19 vaccine or any of its components, including PEG, or polysorbate should not receive it. Refer to section 7: "Can a cancer patient receive the COVID-19 vaccine if they have allergies?" for more information.

#### References:

1. An Advisory Committee Statement - National Advisory Committee on Immunization (NACI): Recommendations on the use of COVID-19 Vaccine(s), December 2020.
2. COVID-19 About Vaccines. Ministry of Health. Version 1, December 12, 2020
3. Lopez A, Mariette X, Bachelez H, et al. Vaccination recommendations for the adult immunosuppressed patient: a systematic review and comprehensive field synopsis. *J Autoimmun* 2017;80:10–27.
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5. Pfizer-Biontech COVID-19 Vaccine Product Monograph. December 9, 2020.
6. Product Monograph: Pfizer-Biontech COVID-19 Vaccine [COVID-19 mRNA Vaccine]. Pfizer Canada, December 9, 2020.
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## 2. Which cancer patients are at a higher risk of becoming infected with COVID-19 and/or having severe complications with COVID-19?

Cancer patients have a higher risk of contracting COVID-19 and some cancer patients are at higher risk for poorer outcomes with the infection. The following patients are at a higher risk:

- Patients with **hematological cancers**
- Patients with **lung cancer**
- Patients who were **diagnosed with cancer within the last year**
- Patients who are on (or recently completed (within **the last 6 months**)) **immune checkpoint inhibitors**
- **Patients who have had a stem cell transplant within the last 6 months**, and
- Patients on or for whom the plan is to begin **active systemic treatment that has any risk of neutropenia** (i.e. chemotherapy, monoclonal antibodies, targeted therapies)

Also consider the following patient factors when determining risk:

### 1. Time since diagnosis:

Patients with a recent diagnosis (within the last year) especially those with a hematologic malignancy have an increased risk of mortality with COVID-19 compared to those with a less recent diagnosis. Patients with a diagnosis 1 to 5 years prior have a higher risk of mortality than patients with a diagnosis beyond 5 years. Patients with hematologic malignancy or following allogeneic stem cell transplant may remain at high risk of infection and mortality even beyond 5 years, as they are often on a prolonged course of treatment or have ongoing significant immunosuppression.

### 2. Cancer type:

In general, patients with hematologic cancers who are at any stage of treatment (especially those  $\geq 60$  years of age) and patients with lung cancer have a higher risk of mortality compared to patients with other cancer diagnoses.

### 3. Treatment type:

Patients currently or recently (within the last 6 months) treated with immune checkpoint inhibitors are at a higher risk of mortality. In general, other systemic treatment types (such as chemotherapy and targeted therapy) do not appear to increase the risk of mortality from COVID-19; however, these patients are at an increased risk of neutropenia and development of infections. Patients who have had a stem cell transplant within the last 6 months are also considered to be higher risk.

### 4. Other factors:

- (a) Older patients ( $\geq 65$ ) are at higher risk of mortality compared with younger patients.
- (b) Patients who have recently had neutropenia (within 90 days) and patients with lymphopenia at time of COVID-19 diagnosis are at a higher risk of mortality.
- (c) Patients with other comorbidities, including obesity, may be at risk for increased hospitalizations and mortality. Follow local public health advice to determine risk based on non-cancer related factors.
- (d) Consideration of COVID-19 vaccination should be given to household or close contacts of cancer patients at higher risk of infection/mortality to reduce the risk of exposure to the virus.

## Rationale:

Current available data suggest that COVID-19 mortality is higher in patients with cancer than in the general population.<sup>1,2,3,4,5</sup> A pooled analysis of 18,650 found the probability of death to be 25.6% in patients with both a COVID-19 and cancer diagnosis.<sup>3</sup> A multivariate analysis of over 10,000 COVID-19 deaths from the UK found that, relative to patients without cancer, patients with nonhematologic malignancy diagnosed within one year prior to a COVID-19 diagnosis had a 1.8-fold higher risk of death, and a hematologic malignancy carried a fourfold higher risk.<sup>5</sup> The risks were lower for patients diagnosed with cancer 1 to 4.9 years prior to COVID-19 when compared those diagnosed within the preceding year; however, risk was still elevated compared with people without cancer. Beyond five years, risks for death remained elevated for those with hematologic but not for those with nonhematologic malignancies.<sup>5</sup>

Most studies show a higher risk of mortality among patients with hematologic and lung cancers.<sup>1,6,7</sup> A small Chinese study suggested that lung cancer, metastatic disease, and hematologic malignancy may be associated with higher rates of COVID-19–related death and intensive care unit (ICU) admission.<sup>6</sup> A larger study of 309 cancer patients with a diagnosis of COVID-19 found that hematologic malignancies were associated with increased COVID-19 severity and patients with lung cancer demonstrated higher rates of severe or critical COVID-19 events.<sup>1</sup>

An analysis of 536 Italian patients with hematologic malignancy and COVID-19 found that mortality was significantly higher than in the general Italian population with COVID-19, regardless of age.<sup>7</sup> A large meta-analysis found the risk of death among adults with hematologic malignancies (n = 3240) was 34 percent, and patients ≥60 years of age had a significantly greater risk of dying than did younger patients (relative risk [RR] 1.82, 95% CI 1.45-2.27).<sup>8</sup>

A multi-institutional international registry study including 400 patients with thoracic cancer also diagnosed with COVID-19 showed that many patients were hospitalized (78%), and 36 percent of patients died.<sup>9,10</sup> Patients who had received chemotherapy within three months had a higher risk of dying from COVID versus patients who did not (hazard ratio 1.7, 95% CI 1.1-2.6); however, in univariate analysis, there were no factors that were identified, including active cancer treatment, as being associated with mortality.<sup>10</sup>

Recent active oncologic therapy does not appear to increase the risk of mortality from COVID-19. Jee et al reported that cytotoxic chemotherapy was not significantly associated with a severe or critical COVID-19 event and a systemic review indicated that there was no association between receipt of a particular type of oncologic therapy and mortality.<sup>4</sup> Patients on active immunosuppressive therapy (such as chemotherapy) are, however, more likely to be neutropenic and are at a high risk of developing infection.<sup>12</sup> An analysis of 423 patients with cancer and COVID-19 indicated that age older than 65 years and treatment with immune checkpoint inhibitors (ICIs) were predictors for hospitalization and severe disease, whereas receipt of chemotherapy and major surgery were not. In this study, treatment with ICI predicted both hospitalization and severe disease, although there was considerable heterogeneity in ICI-treated tumor types, and disease-specific factors could not be individually addressed.<sup>11</sup>

Lymphopenia at COVID-19 diagnosis was associated with higher rates of severe critical illness.<sup>1</sup> Patients with baseline neutropenia 14-90 days before a COVID-19 diagnosis had worse outcomes.<sup>1</sup> In addition, current literature suggests that the likelihood of a severe illness and death from COVID-19 is higher among adult patients with cancer who have other comorbidities, including obesity.<sup>2</sup>

## References:

1. Jee J, Foote MB, Lumish M, et al. Chemotherapy and COVID-19 outcomes in patients with cancer. *J Clin Oncol* 2020;38. DOI <https://doi.org/10.1200/JCO.20.01307>
2. Giannakoulis V, Papoutsis E and Siempos II. Effect of cancer on clinical outcomes of patients with COVID-19- a meta-analysis of patient data. *JCO Global Oncol* 2020;6:799-808.
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12. Covid-19 mRNA vaccine BNT 162b2 vaccine REG 174 INFORMATION FOR UK HEALTHCARE PROFESSIONALS. Accessed on December 9, 2020.

### 3. When will cancer patients receive immunity (mount an immune response) after the COVID-19 vaccine?

In the general population, individuals may not receive optimal protection until 7-14 days after their 2<sup>nd</sup> dose of both authorized mRNA COVID-19 vaccines.<sup>1,2,7</sup> Immunocompromised individuals were excluded in the Phase 2/3 clinical studies.<sup>1,2</sup> More research is required to determine the safety and efficacy of the COVID-19 vaccine for cancer patients. Immunocompromised patients, including **cancer patients**, may have a diminished antibody response and should continue to follow Public Health guidance to avoid exposure to COVID-19, unless otherwise advised by their health care team.<sup>1,2</sup> No data are available regarding concomitant use of immunosuppressants.<sup>1</sup>

**Patients with hematologic malignancy** may be at a significant risk to COVID-19 as a result of both their underlying condition and their treatment that may affect antibody producing B-cells.<sup>3</sup> Although immune response may be sub-optimal, inactivated vaccines should be administered to patients with hematologic malignancy according to a risk-benefit assessment by the cancer health care team.<sup>4,5</sup> COVID-19 vaccination may still offer some protection, and some protection is better than none.<sup>6</sup>

Immunization should be given prior to the start of immunosuppressive therapy or when effects of immunosuppressive therapy are at the lowest level, unless the risk of exposure is high.<sup>4</sup> As with any vaccine, vaccination may not protect all recipients.<sup>1,2</sup> Consideration should be given to household or close contacts of cancer patients.<sup>4</sup>

#### References:

1. [Covid-19 mRNA vaccine BNT 162b2 vaccine REG 174 INFORMATION FOR UK HEALTHCARE PROFESSIONALS](#). Accessed on December 9, 2020.
2. Pfizer-Biontech COVID-19 Vaccine Product Monograph. December 9, 2020.
3. [Adults with Malignant Neoplasm \(Including Leukemia and Lymphoma\)](#). BC Centre for Disease Control. October 2019.
4. Canadian Immunization Guide. [Immunization of Immunocompromised Persons](#). Accessed on December 9, 2020.
5. [Joint Committee on Vaccination and Immunisation: advice on priority groups for COVID-19 vaccination](#). December 2, 2020.
6. [The coronavirus vaccine: what you need to know](#). Blood Cancer UK. November 25, 2020.
7. [Recommendations on the use of COVID-19 vaccines](#). National Advisory Committee on Immunization (NACI). Accessed on December 23, 2020.

#### 4. When is the optimal time for cancer patients to receive the COVID-19 vaccine?

Clinical trials for COVID-19 vaccines to date have not included immunocompromised patients, and thus **the optimal timing for COVID-19 vaccination of patients receiving cytotoxic chemotherapy, immunotherapy, targeted therapy and radiation therapy has not yet been established**. Based on experience with other protein-based and inactivated vaccines, inactivated vaccines have been shown to be safe in most immunocompromised patients,<sup>1,17</sup> although the exact effects of the COVID-19 vaccine in cancer patients is unknown. The efficacy, however, will depend on the patient's ability to mount a response to the vaccine. Based on experience with the flu vaccine, response rates can be highly variable, and the **effectiveness of the vaccine will depend on underlying disease, the type, and timing of treatment that could hinder a patient's ability to mount an immune response**.<sup>17,18</sup>

The following guidance on the timing of the COVID-19 vaccine administration, in relation to treatment for cancer patients has been adapted from information pertaining to the inactivated influenza vaccine.

### General guidelines:

- When feasible, vaccines should be administered at least 2 weeks before initiation of chemotherapy or immunotherapy to optimize immunogenicity.<sup>1,2,4,20</sup>
- Clinical judgement should be exercised around administration of *both* doses of the vaccine prior to initiation of chemotherapy or immunotherapy. Prioritization of systemic treatment over vaccination, or vice versa, should be determined via risk assessment, considering factors such as patient's age, comorbidities, treatment intent, type of treatment, etc.
- If both doses cannot be administered 2 weeks before the start of treatment, when feasible, the first dose of the vaccine should be administered at least 2 weeks before initiation of chemotherapy or immunotherapy, and the second dose within a few days prior to the next cycle. Although evidence around timing with systemic treatment varies, this can minimize uncertainty around the cause of mild flu-like symptoms or infusion-related reactions if vaccine is administered around the day of chemotherapy.<sup>5,6,20,21</sup>
- If the second dose cannot be administered within a few days of the next cycle, a risk assessment should be conducted around prioritization of either the treatment schedule or vaccination schedule, with consideration for factors such as patient's age, comorbidities, treatment intent, type of treatment, etc.
- If administration of the second dose of the vaccine is delayed, it should be administered as soon as possible.<sup>19</sup>
- Patients receiving vaccine during treatment may have an attenuated or absent response to the vaccine and should continue to exercise precautions when possible (wearing a mask when unable to maintain social distance etc.).<sup>1,2,4,20</sup>
- Patients who are not on active treatment may receive the vaccine after an appropriate time has passed since their last treatment was completed, depending on the agents used.

### Cytotoxic Chemotherapy

- During active chemotherapy treatment, both doses of the vaccine should be administered within a few days prior to next chemotherapy cycle, if possible.<sup>5,6,20</sup>
- Immunization in patients receiving chemotherapy when blood counts are low, is discouraged.<sup>13,14</sup>
- Induction Chemotherapy for Leukemia:
  - Vaccine should be given at least 2 weeks prior to the start of immunosuppressive therapy or when effects of immunosuppressive therapy are at the lowest level<sup>2</sup>
  - Where the vaccine cannot be given prior to start of induction treatment in acute leukemia, it may be given upon blood count recovery, prior to the start of consolidation treatment.

### Targeted therapy

- Vaccine may be administered at any time during treatment for most targeted therapies. Consideration for timing should be taken for targeted treatments that may cause neutropenia or lymphopenias.<sup>3,20</sup>

## Immunotherapy

- Monoclonal antibodies:
  - Patients receiving maintenance rituximab may receive vaccine at any time during treatment; although there may be a reduced response, extrapolated evidence suggests it is unlikely to cause harm.<sup>7,20</sup>
- Immune checkpoint inhibitors (ICI):
  - Many trials using ICI do not allow vaccinations due to a concern of increased autoimmune events. However, recent evidence suggests that patients receiving ICI therapy may not experience an increase in immune-related adverse events when they receive inactivated influenza vaccine within 2 months of treatment.<sup>9,10</sup>
  - For patients receiving a combination of ICI, the risk of increased autoimmune events is uncertain and should be weighed against the definite risk of a patient potentially contracting COVID. Experience with vaccinations in this population is mostly with the influenza vaccine and more data will need to be collected before any further recommendations can be made.

## Radiation Therapy

- Patients who are receiving radiation therapy alone (not in combination with chemotherapy) may receive vaccine at any time during treatment.<sup>20</sup>

## Stem cell transplant:

- If feasible, both doses of the vaccine should be administered at least 2 weeks before initiation of transplant conditioning regimen, and at least 2 weeks prior to stem cell collection for donors.<sup>2</sup>
- Post-transplant, the vaccine may be administered as early as 3-6 months after transplant.<sup>12,18</sup>

## CAR T-Cell Therapy

- If feasible, both doses of the vaccine should be administered at least 2 weeks before CAR T-cell therapy.<sup>18</sup>
- Vaccines should not be administered until at least 6 months after completion of therapy.<sup>18</sup>

## References:

1. Rubin LG, Levin MJ, Ljungman P, et al. 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host. *Clinical Infectious Diseases* 2014;58(3):309–18
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21. Waqar SN, Boehmer L, Morgensztern D, et al. Immunogenicity of influenza vaccination in patients with cancer. *Am J Clin Oncol*. 2018 March; 41(3): 248–253

## 5. When should the COVID-19 vaccine be given in relation to other vaccinations?

mRNA vaccines (e.g. Pfizer, Moderna) are not live vaccines and can neither cause infection nor change the host's DNA. There is no data on the co-administration of COVID-19 vaccines with other vaccines. In order to maximize the benefits of COVID-19 vaccines and minimize risks (e.g. immune interference, uncertainty around the cause of side effects), COVID-19 vaccines should not be given simultaneously with other vaccines.<sup>1,2</sup>

Do not administer any other vaccine until at least 28 days after the second dose of the COVID-19 vaccine, except in the case where another vaccine is required for post-exposure prophylaxis. If the COVID-19 vaccine is given after another vaccine, there should be a wait period of at least 14 days.<sup>1,2</sup>

**References:**

1. An Advisory Committee Statement - National Advisory Committee on Immunization (NACI): [Recommendations on the use of COVID-19 Vaccine\(s\)](#), December 2020.
2. [COVID-19 Vaccine Information Sheet Pfizer-BioNTech COVID-19 Vaccine](#). Ministry of Health. Version 1 – December 12, 2020 (amended December 13, 2020).

## 6. What are possible side effects of the vaccination?

Side effects of the Pfizer and the Moderna COVID-19 vaccines were usually mild or moderate and generally resolved in a few days.<sup>1,4,6,7</sup> Local reactions for both vaccines included pain, redness or swelling at the injection site.<sup>2,7</sup> Systemic side effects were similar for both vaccines and included fatigue, headache, muscle/joint pain, diarrhea, chills, fever, nausea/vomiting, and lymphadenopathy.<sup>2,7</sup> Frequencies of systemic effects were generally higher after the second dose, and in patients < 56 years of age for the Pfizer vaccine and between 18 to < 65 years for the Moderna COVID-19 vaccine.<sup>2,3,7,8</sup>

Patients should be educated to seek medical attention if the symptoms last longer than 48-72 hours, since these are similar to symptoms of COVID-19 or other infections.

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1. COVID-19 vaccination programme information for healthcare practitioners. V.2. Public Health England, December 2020.
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6. [COVID-19 About Vaccines](#). Ministry of Health. Version 1, December 12, 2020.
7. Product Monograph: Moderna COVID-19 Vaccine. Moderna Therapeutics Inc. December 23, 2020.
8. [Regulatory Decision Summary - Moderna COVID-19 Vaccine - Health Canada](#). Accessed December 24, 2020

## 7. Can a cancer patient receive the COVID-19 vaccine if they have allergies?

Severe allergic reactions to the vaccine have been reported.<sup>1,2,3,4</sup>

Patients with a history of severe allergy (e.g. anaphylaxis) to the COVID-19 vaccine or any of its components should not receive it.

Polyethylene glycol (PEG), a water-soluble polymer used as a drug delivery vehicle, is a component of both Pfizer and Moderna vaccines and is known to cause mild to severe hypersensitivity reactions.<sup>6,7</sup> Patients who have had anaphylactic reactions to PEG should not receive the vaccine. Cancer medications containing PEG include (but are not limited to) the following:

- PEGaspargase (Oncaspar®)
- Pegfilgrastim (e.g. Neulasta® and others)
- PEG-liposomal irinotecan (Onivyde®)
- PEG-liposomal doxorubicin (Caelyx®)

Polysorbate, a surfactant and emulsifier used as an excipient in some drug formulations,<sup>7</sup> is not a component of either vaccine, but is structurally related and has the potential for cross-reactivity to PEG. Patients who have had an anaphylactic reaction to polysorbate should not receive the vaccine. Cancer medications containing polysorbate include (but are not limited to) the following:

- Cabazitaxel
- Docetaxel
- Etoposide
- Fosaprepitant (IV)
- Rituximab (reactions with rituximab are typically a result of cytokine release syndrome and may not be related to polysorbate)
- Paclitaxel (contains the excipient, Cremophor EL (polyethoxylated castor oil) which has the potential for cross-reactivity with polysorbate)<sup>9</sup>

Not all medications that contain PEG or polysorbate will cause allergic reactions and many drugs, including oral medications, may contain PEG or polysorbate in various concentrations, depending on the manufacturer. Clinicians should consult individual product monographs for a full list of non-medicinal ingredients if their patients have had a history of anaphylactic reactions to their cancer medications. Patients should be counseled about the risks of developing a severe allergic reaction against the benefits of vaccination.

Refer to Ministry of Health guidance on COVID-19 vaccines and allergies for more information.

### References:

1. Product Monograph: Pfizer-BioNTech COVID-19 Vaccine [COVID-19 mRNA Vaccine]. Pfizer Canada, December 9, 2020.
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### 8. Are any trials of COVID-19 being done in immunocompromised populations?

Several vaccine candidates are currently in clinical trials authorized by Health Canada;<sup>1</sup> however, none of these studies have included immunocompromised patients or patients receiving immunosuppressive therapy. Thus, the efficacy and safety of a COVID-19 vaccine has not been established in the different immunocompromised patient populations. Given the diversity of cancer patient populations, it is possible that COVID-19 vaccine candidates may differ in their efficacy and safety for these patients.

#### References:

1. Clinical trials: [Drugs and vaccines for COVID-19: Authorized clinical trials - Canada.ca](#)

**Prepared Date:** December 15<sup>th</sup>, 2020

**Last Updated:** January 6<sup>th</sup>, 2021

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