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Cell Therapy Transplant Canada
Position Statement on COVID-19 Vaccination

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There are currently two Health Canada approved vaccines for COVID-19, both based on mRNA technology (tozinameran, developed by BioNTech and Pfizer, and mRNA-1273, developed by Moderna). Supplies are currently limited, and individual provinces are developing prioritization strategies based on recommendations from the National Advisory Committee on Immunization (NACI). NACI developed a suggested sequence of priorities, beginning with health care workers and the elderly, particularly those residing in long term care facilities, recognizing the need to protect those at highest risk of death.

The mortality rate of COVID infection in patients that occur in the months following allogeneic transplant is comparable to residents of long term care facilities. The largest study to date of patients with hematologic malignancies, including recipients of stem cell transplant, found an overall mortality rate of 36%.[1] Given that NACI recommended prioritizing vaccination to those at the highest risk of death from COVID, it would follow that a strategy to protect recipients of stem cell transplantation and cellular therapy would also be of the highest priority.

Stem cell transplantation is associated with significant immunocompromise, and these patients were not included in either of the pivotal phase III trials that provided the basis for the approval of the Pfizer or Moderna vaccines[2,3]. There are no studies currently ongoing specifically evaluating this patient population, and no studies are likely to be completed in the near future. Despite the lack of data, there is no data that these vaccines are more harmful than other inactivated (non-live) vaccines we currently administer to these patients. In addition, there is no risk of developing COVID from these vaccine products. In general, other vaccine products have not shown a risk of worsening acute or chronic graft versus host disease. Thus, despite the lack of data, it would be reasonable to conclude that these vaccines are likely safe in recipients of stem cell transplant and other cellular therapies such as CAR-T.

Patients that are immunocompromised may not develop the same immunologic response to the vaccine and might not benefit to the same degree as a member of the general public. That said, in most patients, given the very significant risk associated with COVID infection, the potential benefit associated with the vaccine is likely greater than any risks. Given that the immune response to the vaccine might be impaired in these patients, a strategy that

includes vaccinations of caregivers of stem cell transplant and cellular therapy patients is also critical, to mitigate any risk of transmission within the household.

Based on the above premises, we have the following recommendations. Our recommendations for vaccination are aligned with recommendations issued by the American and European cellular therapy socieities[4,5].

We recommend:

1. Given that patients following stem cell transplant and cellular therapies are at very high risk for mortality with COVID-19, a strategy to protect these patients should be at the highest priority for provinces to consider during vaccine delivery.

2. Physicians should discuss the risks and benefits of COVID vaccines with their patients and weigh the potential risks and benefits of vaccination. It is expected that in most circumstances, the recommendation will be to proceed with vaccination, given the probable safety of vaccination and the very significant risks of COVID-19 infection.

3. While data is limited, patients with chronic GVHD, particularly those with pulmonary involvement, are also likely to be at very high risk of poor outcome from a COVID9 infection, and they should be prioritized as well.

4. For patients in the first 3-6 months following allogeneic stem cell transplant, autologous cell transplant, CAR-T therapy, or on active immunosuppression, the timing of vaccination should be considered on a case-by-case basis. For patients in areas with high prevalence of COVID-19 (currently most of Canada), it may be reasonable to proceed immediately with vaccination. In areas with lower prevalence levels, it would be reasonable to wait for several months in the hopes of a more robust immune response.

5. For patients in the first 3-6 months following allogeneic stem cell transplant or CAR-T therapy, or on active immunosuppression, given uncertainty about the vaccine efficacy, a strategy to protect them must also include vaccination of primary caregivers residing with them, and the health care teams providing care for them. In general, the health care teams are already included in the prioritization plans for most provinces, but the vaccination of primary caregivers is not, but we view vaccinating caregivers and household contacts as critically important. Household transmission is the most common mechanism for acquisition of COVID-19, and a similar strategy is used in long-term care facilities (vaccination of all those residing with high risk patients) should be employed.

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6. In situations where vaccination of recipients of transplant or cellular therapies is not thought be useful, such as patients immediately post allogeneic transplant who might not mount an immune response to the vaccine, their caregivers and household contacts should be at the highest priority for vaccine availability to protect these vulnerable patients.

7. In general, most of the recommendations above could also apply to patients with other hematologic malignancies on active therapy, given their comparable risk.

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