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12 April 2021

The Honourable Christine Elliott
Minister of Health
College Park 5th Flr, 777 Bay Street
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Re: Ontario's Ministry of Health's Vaccine Clinical Advisory Group (VCAG) Recommendations on Exceptions to Extended Dose Intervals for COVID-19 vaccines

On behalf of the Canadian Arthritis Patient Alliance (CAPA), we are writing about our concern regarding the Ministry of Health's announcement for the mandated delay of the second dose of the COVID-19 vaccine. Although the Vaccine Clinical Advisory Group (VCAG) identified select populations for exemption to the delayed dosing of the vaccine, there are populations that meet this criteria and that have not been included in the recommendation for exemption from Ontario's Ministry of Health. We ask that you please consider the experiences of those living with autoimmune conditions and who are on immunosuppressive therapies in your continued updates to the recommendations since additional data has become available. We sincerely appreciate this opportunity to provide our perspectives and thoughts on this important issue for people with rheumatic diseases. We argue that this approach is more equitable than the current approach and will explain why we feel this is the case.

To provide some background on CAPA, we are Canada's only volunteer-based arthritis patient organization run by patients for patients – we have no paid employees or physical office. True to our grassroots nature, CAPA is entirely patient-driven, independent, and supports a community of people living with arthritis across Canada. Our belief is that the first expert on arthritis is the person who lives with arthritis and provides a critical voice and perspective that needs to be heard in decision-making.

Like all Canadians, the COVID-19 pandemic has affected people who live with inflammatory arthritis – which account for roughly 2% of the Canadian population, or close to 0.75M individuals. In particular, our community has been deeply impacted by the anxiety and mental stress that was brought on by the COVID-19 pandemic, the hugely unforeseen shortage of hydroxychloroquine, and the various personal impacts COVID-19 has brought outside of those related to one's arthritis such as maintaining employment and benefits related to employment and children going to school.

The VCAG released recommendations for *"individuals with malignant hematologic disorders and non-hematologic malignant solid tumors receiving active treatment (chemotherapy,*

targeted therapies, immunotherapy)," as well as *"individuals who have received hematopoietic stem cell transplants are known to experience a prolonged period of immune suppression following transplantation"* to be exempt from the delayed administration of the second dose, following the product monographs. These two populations were selected based on: limited available data on vaccine efficacy and effectiveness, who are at increased risk of severe outcomes from COVID-19 and who may have a suboptimal immune response to vaccines on the basis of their underlying condition.

According to the justification provided by the VCAG to support exemption of these groups from delayed second dosing of the COVID-19 vaccine, the criteria would also apply to those who live with autoimmune disease and who are on immunosuppressant therapies. We outline the application of these criteria below.

1. There continues to be limited available data on vaccine efficacy and effectiveness in people with autoimmune disease who are on immunosuppressant therapies.

There is limited available data on vaccine efficacy and effectiveness in people with autoimmune disease who are on immunosuppressant therapies. One recent preprint was released by researchers from Washington University in St. Louis and the University of California, San Francisco that studies the immunological response of people with chronic inflammatory diseases to the COVID-19 vaccines. The study was conducted in 133 adults with chronic inflammatory diseases (CIDs) and 53 immunocompetent controls (people with healthy immune system function who do not take immunosuppressant medication) to study their immunological response to the Pfizer and Moderna COVID-19 vaccines.

The study found that **there was a three-fold reduction in antibodies and neutralizing antibodies compared to healthy controls. The response was not as high as those who do not take immunosuppressives and certain immunomodulating medications were associated with much lower responses to the vaccine. This is extremely concerning for our population of patients with autoimmune disease who are on immunosuppressant therapies.** Evidence demonstrates reduced efficacy and effectiveness in this group, and that was in accordance with the recommended 3-week dosing interval according to the product monograph. There is limited available data on vaccine efficacy and effectiveness in people with autoimmune disease who are on immunosuppressant therapies when the second dosing of the vaccine has been delayed beyond the 3-weeks outlined in the product monograph.

2. This group is also at increased risk of severe outcomes from COVID-19.

There are potentially grave consequences associated for people who live with autoimmune disease associated with not receiving the second dose of the COVID19 vaccine due to VCAG's

recommendation. Other studies have found increased risk of severe outcomes from COVID-19 in patients with autoimmune disease and who are on immunosuppressant therapies, beyond patients with malignant hematologic disorders, non-hematologic malignant solid tumors, or transplant recipients. For example, people with moderate or high disease activity were more likely to die from COVID-19 than those with low disease activity or people who were in remission.

From an equity perspective, to which Canada and the Ministry of Health subscribes, it is neither reasonable nor appropriate to request people who live with autoimmune disease to 'shield' at home and wait for the second dose while individuals with malignant hematologic disorders and non-hematologic malignant solid tumors (a specific group of patients with autoimmune disease or on immunosuppression) are able to receive the second dose as recommended. Health inequities are exacerbated when a group is excluded for lack of data while the baseline assumption should be no increased risk, unless there is the presence of data to suggest otherwise. Delaying access to COVID-19 vaccines will have lingering impacts on employment, access to benefits, participation in activities of daily living, and decisions relating to school for oneself or children. Today, people with rheumatic diseases are already disproportionately affected by the pandemic and have greater rates of work disability.

The British Society of Rheumatology deems people with autoimmune disease to be a clinically extremely vulnerable (CEV) population and recommends them receiving the vaccine:

> "CEV people are at high risk of severe illness from COVID-19; all are in a clinical risk group which should receive the vaccine. This includes: Individuals receiving immunosuppressive or immunomodulating biological therapy including, but not limited to, anti-TNF, alemtuzumab, ofatumumab, rituximab, patients receiving protein kinase inhibitors or PARP inhibitors, and individuals treated with steroid-sparing agents such as cyclophosphamide and mycophenolate mofetil. Individuals treated with (or likely to be treated with) systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (any age). … Some immunosuppressed patients may have a suboptimal immunological response to the vaccine. The prescriber should apply clinical judgment to take into account the risk of COVID-19 exacerbating any underlying disease that a patient may have, as well as the risk of serious illness from COVID-19 itself."

Furthermore, CEV people have been identified as a priority population and will receive COVID-19 vaccinations along with people aged 70 years and over.

3. This group has a suboptimal immune response to vaccines on the basis of their underlying condition.

As outlined previously, one study found that **there was a three-fold reduction in antibodies and neutralizing antibodies compared to healthy controls. The response was not as high as those who do not take immunosuppressives and certain immunomodulating medications were associated with much lower responses to the vaccine. This is extremely concerning for our population of patients with autoimmune disease who are on immunosuppressant therapies.** Evidence demonstrates a suboptimal immune response to vaccines in this group, and that was in accordance with the recommended 3-week dosing interval according to the product monograph.

4. There is a need for equitable access to people who live with autoimmune disease.

We are a uniquely immunosuppressed community and would argue that the additional stress people and their families feel about potentially being exposed to COVID-19 is significantly higher for many of us than that of the general population. Given that we are not aware of many of the long-term consequences of COVID-19 in 'healthy' individuals, those of us who already live with an autoimmune disease are even more concerned about not only having COVID-19, but what that might mean for us in the long-term. Delays in receiving a second dose of the COVID-19 vaccine may have long-term effects on our protection against this devastating virus.

Unfortunately, VCAG's recommendation for exemption to the delayed dosing of the second vaccine has created more anxiety and more burden for our community, burdens that will continue to grow in the context of peak community spread of COVID-19 as new, more transmissible variants emerge. And while the wording of the recommendation is meant to show there may be exceptions made for other people who live with autoimmune disease, we argue that again, this creates a significant burden for us as patients needing to self-advocate to gain access to a vaccine.

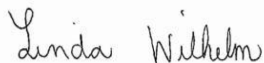
Lastly, the VCAG released the statement that they are *"committed to an ongoing review of evidence and immunological principles to inform recommendations for other sub-groups such as those on chronic dialysis"*. The VCAG has recognized the theoretical risks of poor immune response to COVID-19 immunization exist for other sub-populations, furthermore, the VCAG acknowledges that "alternate strategies of protection should be considered where the risk of severe disease and mortality is high and immune response to COVID-19 immunization is sub-optimal. The VCAG is also committed to examining these in the weeks ahead." We ask that you please consider our perspectives and preferences in your continued updates to the recommendations and as additional data become available. We sincerely appreciate this

opportunity to provide our perspectives and thoughts on this important issue for people with rheumatic diseases. We argue that this approach is more equitable than the current approach.

We are aware of the many groups and people who are struggling due to COVID-19. We understand the way VCAG works and their careful approaches to guidance, and we ask that vulnerable Canadians such as those outlined in this request be consulted for input, insight, and context to these recommendations that impact us as a population. We live with these diseases daily and our insights are often ones that even our health care providers are not privy to, given that they do not live with our diseases. While we understand the importance of evidence in decision making, we would also argue that during this unprecedented time, sometimes decisions need to be made and undertaken that are unlike those taken in ordinary circumstances. We urge you to consider the unintended inequity and discrimination that **all people** who live with autoimmune diseases and who are on immunosuppressant medications will face, due to the exclusionary VCAG recommendation and its wording.

We are open to discussing this with you, to learn how we may be of help, and to continue to share our perspectives as people who live with inflammatory arthritis and who are on immunosuppressants who allow us to make such contributions to society. We would like to highlight that patient preferences are a key part of GRADE and part of this includes respecting patient and physician shared decision-making. Rather than specifying certain patients with autoimmune disease and who are on immunosuppressant medications, it would be more appropriate for VCAG to remain mindful of the complex nature of inflammatory arthritis and its treatment (and other autoimmune disorders) due to limited evidence/ trial representation of certain groups. Final decisions about timing of vaccination and vaccination itself should be a shared decision between patients and our rheumatologists, taking into account individualized risk/ benefit and patient preferences. **All patients with autoimmune disease and who are on immunosuppressant medications should receive access to the second dose of the COVID-19 vaccination inline with the product monograph.** Canada is a nation that “leaves no one behind” and we certainly do not want to be left behind while every other Canadian can return to whatever life looks like after mass vaccinations. We look forward to interactions with you based on this request.

Sincerely,



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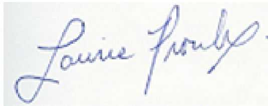

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