CAPA
Canadian Arthritis Patient Alliance

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Dr. Caroline Quach-Thanh
Chair, National Advisory Committee on Immunization (NACI)
Professor, Departments of Microbiology, Infectious Diseases Immunology and Pediatrics, Université de Montréal
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Email: c.quach@umontreal.ca

Re: NACI's Recommendations on Approved COVID-19 Vaccines for People Who Live with Autoimmune Disease and are Taking Immunosuppressants

Dear Dr. Caroline Quach-Thanh:

On behalf of the Canadian Arthritis Patient Alliance (CAPA), we are writing about the National Advisory Committee on Immunization's (NACI's) recommendations on the currently approved COVID-19 vaccines. We ask that you please reconsider and revise the wording on your recommendations relating to those who live with autoimmune disease and who are on immunosuppressant therapies. While we are aware that this recommendation is based on the GRADE system which accounts for the current evidence available, and that people with autoimmune diseases were excluded from both the Pfizer-BioNTech and Moderna vaccine trials, we are also aware that patient preferences are a key aspect of GRADE. 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 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 comes along not only with the COVID-19 pandemic, but along with the various

personal impacts it has outside of those related to one's arthritis (e.g., maintaining employment and benefits related to employment, children going to school, etc.).

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.

Unfortunately, NACI's recommendation 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 some 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.

A few things that we respectfully ask NACI to consider:

- *People who live with autoimmune disease are encouraged to receive the flu vaccine each year to protect themselves.* Like the current COVID-19 vaccines, the flu vaccine is not a live virus and is deemed safe for us as a population. In fact, the risks associated with not receiving the vaccine are higher than receiving the flu vaccine. While the flu vaccine is not an mRNA-based vaccine, there is no evidence, to our knowledge, that supports mRNA-based vaccines being a greater risk for us than other traditional, non-live vaccines.
- *There are potentially grave consequences associated for people who live with autoimmune disease associated with not receiving the COVID19 vaccine due to NACI's recommendation.* From an equity perspective, to which Canada and then NACI subscribes, it is neither reasonable nor appropriate to request people who live with autoimmune disease to 'shield' at home while many of general population has access to these vaccines. 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.
- *Our personal preferences with respect to making our own informed decisions regarding receiving the vaccine.* Many of us already take a host of medications to deal with our inflammatory arthritis, and while these are tested in clinical trials (noting that many are

not tested in pregnant and breastfeeding women and children), each of us is a unique individual who must weigh risks and benefits associated with even taking these medications. Our community is very familiar already with patient-physician shared decision making, and are used to working for many years with our healthcare providers to make these types of decisions. We argue that we would apply the same thought and process to accessing COVID-19 vaccines, should we so wish. In fact many women with autoimmune disease are diagnosed during their child-bearing years, so are used to making decisions about medication based on an absence of clinical trial evidence.

- *NACI's recommendation has already led to inequitable policies being developed across the provinces related to people who live with autoimmune disease, which is disappointing given that Canadians should have the right to equitable access to important medications no matter where they live.* While a number of provinces appear to be following NACI's recommendations:
    - The Comité sur l'immunisation du Québec indicates "The CIQ considers that the benefits of vaccination outweigh the risks for people with an autoimmune or demyelinating disease and recommends that they be vaccinated. Data on the safety of the vaccine in people with this type of disease are limited at this time. There is a theoretical risk, not shown in studies, of side effects in these people. People to be vaccinated may choose to discuss this with their doctor as needed."
    - The Canadian Rheumatology Association has taken an approach to identify risk associated based on age, disease activity, etc., for which we commend them in terms of prioritizing which people with inflammatory arthritis should be vaccinated. However, as people living with these diseases, once priority populations within our disease category are vaccinated, vaccine must be offered to all people who live with inflammatory arthritis.
    - Provinces and health authorities are interpreting the NACI recommendation in different ways. For example, in Alberta, BC and federal jurisdictions (e.g. on-reserve) autoimmune disease patients have been screened out without the opportunity to have their own preferences taken in to consideration for receiving the vaccination. Meanwhile, in Ontario, the Ministry of Health recently updated its guidance relating to autoimmune disease patients who are healthcare workers to be provided with the vaccination if they so choose.
- *Recommendations of international organizations in rheumatology, that represent highly specialized professionals who care daily for people with autoimmune diseases, that are encouraging people with autoimmune disease to receive the COVID-19 vaccine:*
    - European League Against Rheumatism - "**These vaccines can be used safely in patients with RMDs [rheumatic musculoskeletal diseases] as well as in patients receiving drugs that influence the immune system. [bolding added by the League]** Other non-live vaccines have been proven to work for immune-suppressed patients. To say it more strongly, there is no reason to withhold

these vaccines from patients with RMDs and patients treated with drugs that influence the immune system."

- 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). Any patients who change CEV status during the roll out of the programme should be called in in their appropriate age cohort, or in priority group 6. 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.
- American College of Rheumatology is currently developing their guidance (available in early 2021), and indicates currently "We anticipate that any vaccine which is approved for use in the United States will have robust and extensive data showing that it is safe and effective against COVID-19. Once such a vaccine becomes available, the ACR will recommend that all eligible individuals, including our patients and co-workers, be vaccinated."

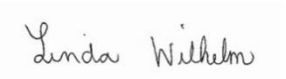
Further, while we appreciate NACI identifying that research for "What is the efficacy, effectiveness, immunogenicity, and safety of COVID-19 vaccines across diverse population groups (e.g., adults of advanced age, those with high-risk medical conditions including autoimmune conditions and transplant recipients, individuals with social or occupational vulnerabilities, individuals who are pregnant or breastfeeding, children, frailty)?," we hope that the Public Health Agency of Canada and other agencies (e.g. Canadian Institutes of Health Research, Drug Safety and Effectiveness Network, etc.) will have specific calls to respond to these priority research areas. There is a significant evidence gap in to which we as patients fall that we are all too eager to see closed by targeted research.

We are fully aware of the many groups and people who are struggling due to COVID-19. While we understand how NACI works and approaches its guidance, we ask that vulnerable Canadians such as those outlined in this request be consulted for input, insight, and context to

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 people who live with autoimmune diseases and who are on immunosuppressant medications will face due to the NACI 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 again reiterate that patient preferences are a key part of GRADE and part of this includes respecting patient and physician shared decision-making. Rather than making a general recommendation, it would be more appropriate for NACI to remain mindful of the complex nature of inflammatory arthritis and its treatment (and other autoimmune disorders) and that 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 in to account individualized risk/ benefit and patient preferences. 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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