CRA Recommendation on Covid-19 Vaccination in Persons with Autoimmune Rheumatic Disease

The Canadian Rheumatology Association guideline panel suggests using COVID-19 vaccination in persons with autoimmune rheumatic disease (conditional recommendation, low certainty of the evidence about effects).

- This recommendation is based on evidence for currently approved COVID-19 vaccines: BNT 162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna)
- The panel agreed that for the majority of patients the potential benefits will probably outweigh the potential harms in people with ARDs. Some patients at low risk for symptomatic COVID-19 infection and severe COVID-19 (e.g. young otherwise healthy patients who are able to follow public health measures), or patients who find the uncertainty of potential harms important, might choose to wait until more direct information is available.
- Persons with autoimmune rheumatic diseases should be informed that direct evidence of benefits and safety of the COVID-19 vaccine in people with autoimmune rheumatic disease is not yet available.
- Persons with autoimmune rheumatic diseases who meet local eligibility criteria for COVID-19 vaccination should not be denied access to vaccination and should not be required to take additional steps compared to people without autoimmune rheumatic diseases to obtain their vaccination.

View the Evidence Profiles and Evidence-to-Decision Framework.

Justification

The CRA panel suggests using COVID-19 vaccination due to moderate certainty of large anticipated desirable effects, low certainty of trivial anticipated undesirable effects, increased health equity, and probable acceptability and feasibility. This recommendation places a relatively high value on the large desirable anticipated effects based on moderate certainty evidence, and a relatively lower value on the trivial undesirable anticipated effects based on low certainty evidence.

Detailed justification

The CRA panel decided on a conditional recommendation for COVID-19 vaccination. The panel balanced the moderate certainty in the vaccine benefits (prevention of symptomatic and severe/critical COVID-19 infection) against the low certainty of evidence for harms. Although the magnitude of the best estimate of harms was judged to be trivial, the uncertainty in the evidence led to a conditional recommendation. The panel was clear that for the majority of patients the benefits will outweigh the uncertainty in potential harms in people with ARDs. Some patients at low risk for COVID-19 infection and severe COVID-19 (e.g. young otherwise healthy
patients who are able to follow public health measures), or patients who find the uncertainty of potential harms important, might choose to wait until more direct information is available. Voting was unanimous on the direction of the recommendation (favouring the vaccine), but was not unanimous on the strength of the recommendation. Two panelists felt a strong recommendation for the vaccine should be made. The remaining panelists felt that if direct evidence of vaccine safety and efficacy in people with autoimmune rheumatic diseases was available, a strong recommendation could be supported. This is a living recommendation and will be reassessed when important new evidence becomes available.

Subgroup considerations

- People taking rituximab: Based on serological studies from other vaccines, rituximab is expected to decrease immunogenicity. Prior guidelines for other vaccines in patients with ARDs have recommended that immunization be deferred to ≥5 months after the last dose and at least 4 weeks prior to the subsequent dose of rituximab [2].
- People taking other DMARDs: Some other DMARDs may reduce protection from the vaccine. Given the large magnitude of benefit of the COVID-19 vaccines, it is likely that the benefits of the vaccine will still be large for most ARD patients. Continuing medications will often be the safest option to prevent disease flares until more evidence is available. This is in line with guidance from the British Society of Rheumatology [5]. Recent guidance from the American College of Rheumatology recommended holding some medications (methotrexate, JAK inhibitors, abatacept) around the time of COVID-19 vaccination [45]. The CRA COVID-19 guideline panel did not feel that this guidance could be endorsed at this point but will review the full guidance document and evidence review once published. Any decision to hold medications should be discussed between a patient and their rheumatologist or healthcare team.
- Additional considerations apply for pregnant and breastfeeding women. These were not covered in the scope of this guideline.

Implementation considerations

- As vaccine access is determined by provincial health authorities, it will be essential to ensure people with ARDs do not face unnecessary additional barriers to vaccine access. For instance, people with ARDs should not be required to obtain a physician letter as proof of an informed decision discussion. A decision tool, co-developed by the Canadian Rheumatology Association and the Canadian Arthritis Patient Alliance to support decision-making for the COVID-19 vaccine in people with ARDs is available at: https://rheum.ca/decision-aid/.
- People with ARDs may have mobility limitations and appropriate access to vaccine clinics should be ensured.

Monitoring and evaluation
Monitoring of vaccine uptake should occur in people with ARDs, including populations at risk of inequity. Low uptake may point to barriers to access or hesitancy.

The frequency of serious adverse events, disease flares, and COVID-19 infection/serious outcomes should be followed in patients with ARDs who do and do not receive the vaccine.

### Research priorities

The following research areas were considered a high priority:

- Observational evidence on the frequency of harms (in particular serious adverse events/serious disease flares) in people with ARDs: If very infrequent, may lower the importance of these outcomes
- Evidence comparing the frequency of serious adverse events and autoimmune adverse events in people with ARDs: if not different with sufficient certainty, the panel may decide not to rate the quality of evidence for harms down for indirectness
- Evidence on the benefits (both clinical outcomes and serological studies) in people with ARDs on different medications: May help identify subpopulations of patients with lower benefits and inform decisions regarding whether to hold medications around the time of vaccination.
- Evidence on patient values preferences for the benefits and harms across different patient populations
- Understanding vaccine hesitancy and barriers to vaccine access faced by persons with ARDs
- Understanding vaccine benefits and harms in populations at risk for inequities. We additionally encourage the collection of data that documents vaccine access difficulties for patients facing barriers to accessing vaccination, to support advocacy for improved prioritization protocols and vaccine delivery.

### REFERENCES

6. COVID-19 vaccine tracker.


31 ANZMUSC. An Australian Living Guideline for the Pharmacological Management of Inflammatory Arthritis. 2020;Version 0.4.


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