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

Version 2.0 May 20, 2021

Highlights of Changes:

- Updated to include ChAdOx1 (AstraZeneca Oxford; Serum Institute of India) and Ad26.COV2.S (Johnson & Johnson) vaccines, in addition to BNT 162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna).

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 for BNT 162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna) and Ad26.COV2.S (Johnson & Johnson); very low certainty for ChAdOx1 (AstraZeneca))

Remarks:

This recommendation is based on evidence for currently approved COVID-19 vaccines: BNT 162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), Ad26.COV2.S (Johnson & Johnson), and ChAdOx1 (AstraZeneca).

The recommendation needs to be viewed in the context of any restrictions to vaccine use for the general public set by national or provincial bodies, that may change over time.

Primary justification:

The panel was unanimous that for the majority of patients the potential benefits outweigh the potential harms in people with ARDs. The recommendation was graded as conditional because of uncertainty about the effects in the population of interest.

Primary implementation consideration for policy makers and providers:

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 Profile and Evidence-to-Decision Framework for the question: should mRNA COVID vaccine vs. placebo be used for preventing COVID?

View the Evidence Profile and Evidence-to-Decision Framework for the question: should ChAdOx1 SD/SD vs. MenACWY/saline be used for preventing COVID?

View the Evidence Profile and Evidence-to-Decision Framework for the question: should Ad26.COV2.S COVID vaccine (J&J) vs. placebo be used for preventing COVID?

Justification

The CRA panel suggests using COVID-19 vaccination due to moderate certainty of large anticipated desirable effects, low/very low certainty of trivial anticipated undesirable effects, increased health equity, and probable acceptability and feasibility.

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/very 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. 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 [2]. Prior guidelines for other vaccines in patients with ARDs have recommended that immunization be deferred to ⩾4-5 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 [14]. Recent guidance from the American College of Rheumatology recommended holding some medications (methotrexate, JAK inhibitors, abatacept) around the time of COVID-19 vaccination, but the full guideline had not been published and the evidence supporting this was unclear [12]. The CRA COVID-19 guideline panel did not feel that this guidance could be endorsed at this point but will review new evidence as it emerges. 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's 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/ [13].
- People with ARDs may have mobility limitations and appropriate access to vaccine clinics should be ensured.
- The available data is for on-label dosing (doses separated by 1-month for mRNA and AZ vaccines). Given that people with ARDs may have reduced vaccine-induced immunity, the benefits of off-label dosing may be lower compared to people without AIRDs. As such, the CRA has recently advocated for on-label dosing for immunosuppressed patients [13].

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.
- People with ARDs should be encouraged to track their immunization history using an online Canadian vaccination tracker, developed with funding support from the Public Health Agency of Canada (https://www.canimmunize.ca/en/home).

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 AIRDs: 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, including the impact of off-label dosing in effectiveness: 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.

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