

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

Version 3.0 November 23, 2021

## Highlights of changes:

- Extended the recommendation to include the use of mRNA vaccines in persons Age  $\geq 12$  (adolescents)
- Considered the additional reports of pericarditis/myocarditis with mRNA vaccines (no change in recommendation)
- Added a point about mixing of vaccines (no change in recommendation; advice is to follow national/provincial guidance)

The Canadian Rheumatology Association guideline panel suggests using COVID-19 vaccination in persons aged 12 and older with autoimmune rheumatic disease.

**(Conditional recommendation, low certainty of the evidence about effects for age  $\geq 18$  BNT 162b2 (Pfizer-BioNTech), age  $\geq 18$  mRNA-1273 (Moderna) and age  $\geq 18$  Ad26.COV2.5 (Johnson & Johnson); very low certainty for age  $\geq 18$  ChAdOx1 (AstraZeneca), age 12-17 BNT 162b2 (Pfizer-BioNTech))**

## Remarks:

- This recommendation is based on evidence for currently approved COVID-19 vaccines: BNT 162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), Ad26.COV2.5 (Johnson & Johnson), and ChAdOx1 (AstraZeneca)
- For people aged 12-18, the recommendation applies to the approved mRNA vaccines: BNT 162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna)
- 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. This includes guidance on mixing of different vaccines

## Primary justification:

- The panel was unanimous that for the majority of patients the potential benefits outweigh the potential harms in people with autoimmune rheumatic diseases. 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.

[See Evidence-to-Decision Framework \(EtD\)](#)

## Justification

The CRA panel suggests using COVID-19 vaccination in adults age  $\geq 18$  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. The CRA panel suggests using mRNA COVID-19 vaccination in adolescents age 12-17 due to low certainty of large anticipated desirable effects, very low certainty of small anticipated undesirable effects, increased health equity, and probable acceptability and feasibility.

### Detailed justification

**Adults (age  $\geq 18$ ):** 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. The panel was clear that for the majority of patients the benefits will outweigh the uncertainty in potential harms in people with ARDs. 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.

**Adolescents (age 12-17):** The CRA panel decided on a conditional recommendation for COVID-19 vaccination. The panel balanced the low/very low certainty in the vaccine benefits (prevention of symptomatic and severe/critical COVID-19 infection) against the very low certainty of evidence for harms. The magnitude of the benefits was judged to be large, although lower than for adults. The best estimate of harms was judged to be small in magnitude, which was somewhat larger than the 'trivial' judgement for the adult population. Overall, the panel judged that for the majority of patients the benefits will outweigh the uncertainty in potential harms in people with ARDs. Voting was unanimous on the direction and strength of the 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 (Papp, Haraoui et al. 2019). Prior guidelines for other vaccines in patients with ARDs have recommended that immunization be deferred to  $\geq 4$ -5 months after the last dose and at least 4 weeks prior to the subsequent dose of rituximab (Papp, Haraoui et al. 2019).
- People taking other DMARDs: 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 patients with ARDs. 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 BSR (British Society for Rheumatology 2020). 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 (ACR COVID-19 Vaccine Clinical Guidance Task Force 2021). 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.
- Pregnant and breastfeeding women: Additional considerations apply for pregnant and breastfeeding women, and should be discussed between a patient and their perinatal care team. 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.
- 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 ([www.canimmunize.ca](http://www.canimmunize.ca)).

## Research priorities

The following research areas were considered a high priority:

Research priority	Rationale
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 to those without 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 on effectiveness	May help inform decisions regarding whether to hold medications around the time of vaccination and recommendations on optimal dosing intervals for 2-dose vaccines
Evidence on patient values preferences for the benefits and harms across different patient populations	Will help inform the relative importance of the outcomes
Understanding vaccine hesitancy and barriers to vaccine access faced by persons with ARDs	Will help inform strategies to address vaccine hesitancy
Understanding vaccine benefits and harms in populations at risk for inequities	Will help inform strategies to address inequity in vaccine access and uptake

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