

COVID-19 Vaccine Considerations in Patients with Rheumatic Diseases

Arezou Khosroshahi, MD
Associate Professor of Medicine
Division of Rheumatology



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COVID-19 Vaccine Clinical Guidance Summary for Patients with Rheumatic and Musculoskeletal Diseases

Developed by the ACR COVID-19 Vaccine Clinical Guidance Task Force

*This draft summary was approved by the ACR Board of Directors on February 8, 2021, and updated on March 4, 2021.
A full manuscript is pending journal peer review.*



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COVID-19 Vaccine Clinical Guidance

- COVID-19 Vaccine Clinical Guidance Task Force was formed in Fall 2020
- Charge: Evaluate available data and provide guidance to address needs of patients with RMD
- Experts in Rheumatology, infectious disease and epidemiology
- ACR board of directors approved the document
- Full Manuscript under peer review in Arthritis & Rheumatology
- The guidance will be updated as additional data available



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General Considerations Related to COVID-19 Vaccination in Rheumatic and Musculoskeletal Disease Patients

Guidance Statement	Level of Task Force consensus
The rheumatology healthcare provider is responsible for engaging the RMD patient in a discussion to assess COVID-19 vaccination status and engage in a shared decision-making process to discuss receiving the COVID-19 vaccine.	Strong-Moderate
Acknowledging heterogeneity due to disease- and treatment-related factors, and after considering the influence of age and sex, AIIRD patients are at higher risk for hospitalized COVID-19 and worse outcomes compared to the general population.	Moderate
Based on their risk for COVID-19, AIIRD patients should be prioritized for vaccination before the non-prioritized general population of similar age and sex.	Moderate
Beyond known allergies to vaccine components, there are no known additional contraindications to COVID-19 vaccination for AIIRD patients.	Moderate
The expected response to COVID-19 vaccination for many AIIRD patients on systemic immunomodulatory therapies is likely to be blunted in its magnitude and duration compared to the general population.	Moderate
A theoretical risk exists for AIIRD flare or disease worsening following COVID-19 vaccination. However, the benefit of COVID-19 vaccination for RMD patients outweighs the potential risk for new onset autoimmunity.	Moderate
RMD = rheumatic and musculoskeletal disease; AIIRD=autoimmune and inflammatory rheumatic disease	



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Recommendations for Use of the COVID-19 Vaccine in RMD patients

Guidance Statement	Level of Task Force consensus
RMD and AIIRD patients should receive COVID-19 vaccination, consistent with the age restriction of the EUA and/or FDA approval.*	Moderate
RMD patients without an AIIRD who are on immunomodulatory therapy should be vaccinated in a similar fashion as described in this guidance for AIIRD patients receiving those same treatments.	Moderate
Based on the data for the mRNA COVID-19 vaccines available in the U.S., there is no preference for one COVID-19 vaccine over another. Therefore, AIIRD patients should receive either vaccine available to them.	Moderate
For a multi-dose vaccine, AIIRD patients should receive the second dose of the same vaccine, even if there are non-serious adverse events associated with receipt of the first dose, consistent with timing described in CDC guidelines.	Strong
Healthcare providers should not routinely order any lab testing (e.g., antibody tests for IgM and/or IgG to spike or nucleocapsid proteins) to assess immunity to COVID-19 post-vaccination, nor to assess the need for vaccination in a yet-unvaccinated person.	Strong
Following COVID-19 vaccination, RMD patients should continue to follow all public health guidelines regarding physical distancing and other preventive measures.	Strong
Household members and other frequent, close contacts of AIIRD patients should undergo COVID-19 vaccination when available to them to facilitate a 'cocooning effect' that may help protect the AIIRD patient. No priority for early vaccination is recommended for household members.	Moderate
While vaccination would ideally occur in the setting of well-controlled AIIRD, except for those patients with life-threatening illness (e.g., in the ICU for any reason), COVID vaccination should occur as soon as possible for those for whom it is being recommended, irrespective of disease activity and severity.	Strong-Moderate

*age ≥16 as of January 2021



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Guidance Related to the Use and Timing of Vaccination and Immunomodulatory Therapies in Relation to COVID-19 Vaccination Administration in RMD patients*

Medication	Timing Considerations for Vaccination & Immunomodulatory Therapy and Vaccination*	Level of Task Force Consensus
Hydroxychloroquine; IVIG; glucocorticoids, prednisone-equivalent dose <20mg/day	No modifications to either immunomodulatory therapy or vaccination timing	Strong-Moderate
Sulfasalazine; Leflunomide; Mycophenolate; Azathioprine; Cyclophosphamide (oral); TNFi; IL-6R; IL-1; IL-17; IL-12/23; IL-23; Belimumab; oral calcineurin inhibitors; Glucocorticoids, prednisone-equivalent dose ≥ 20mg/day**	No modifications to either immunomodulatory therapy or vaccination timing	Moderate
Methotrexate	Hold MTX 1 week after each vaccine dose, for those with well-controlled disease; no modifications to vaccination timing	Moderate
JAKi	Hold JAKi for 1 week after each vaccine dose; no modifications to vaccination timing	Moderate
Abatacept SQ	Hold SQ abatacept both one week prior to and one week after the <u>first</u> COVID-19 vaccine dose (only); no interruption around the second vaccine dose	Moderate

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continued

Guidance Related to the Use and Timing of Vaccination and Immunomodulatory Therapies in Relation to COVID-19 Vaccination Administration in RMD patients*

Abatacept IV	Time vaccine administration so that the first vaccination will occur four weeks after abatacept infusion (i.e., the entire dosing interval), and postpone the subsequent abatacept infusion by one week (i.e., a 5-week gap in total). No medication adjustments for the second vaccine dose.	Moderate
Cyclophosphamide IV	Time CYC administration so that it will occur approximately 1 week after each vaccine dose, when feasible	Moderate
Rituximab	Assuming that patient's COVID-19 risk is low or is able to be mitigated by preventive health measures (e.g., self-isolation), schedule vaccination so that the vaccine series is initiated approximately 4 weeks prior to next scheduled rituximab cycle; after vaccination, delay RTX 2-4 weeks after 2nd vaccine dose, if disease activity allows	Moderate



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Vaccinations against COVID-19 (VAXICOV)

THE LANCET
Rheumatology

COMMENT | VOLUME 3, ISSUE 4, E243-E245, APRIL 01, 2021

Vaccination against COVID-19: Expectations and concerns of patients with autoimmune and rheumatic diseases

Renaud Felten • Maxime Dubois • Manuel F Ugarte-Gil • Aurore Chaudier • Lou Kawka • Hugo Bergier • et al.

[Show all authors](#)

Published: February 22, 2021 • DOI: [https://doi.org/10.1016/S2665-9913\(21\)00039-4](https://doi.org/10.1016/S2665-9913(21)00039-4) • 

67% of patients with Rheumatic diseases were willing to get vaccinated

Patients' concern:

- The rapid rate of development and approval of the vaccines
- Low knowledge of vaccines and associated technologies
- Concern of disease flares and reactions or side effects.



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VAXICOV Study

The willingness of patients with to get the vaccines was highly depended on recommendations from their rheumatologist.

356 [69%] of 515 patients who were uncertain about vaccination and 36 (31%) of 118 patients who would be unwilling to get vaccinated would change their minds following physicians advice.



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Summary

- COVID-19 vaccination is highly recommended
- Vaccinations should preferably be given as soon as possible
- Decisions about individual patients should be made as part of shared decision-making based on their underlying health condition, disease activity level, treatments, risk of exposure
- Encourage continue following all public health guidelines
- Emphasize the crucial and timely role of rheumatologists in vaccination uptake.



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