Update on COVID-19, vaccinations and Sjogren's

Cassandra Calabrese, DO

Assistant Professor of Medicine

Cleveland Clinic Lerner College of Medicine

Department of Rheumatologic and Immunologic Disease

Department of Infectious Disease







What have we learned about COVID risk in patients with rheumatic disease



The Global Rheumatology Community's Response to the Worldwide COVID-19 Pandemic

COVID-19 and RHEUMATIC DISEASE

https://rheum-covid.org/

Risk Factors for Hospitalization and Death COVID-19 Global Rheumatology Alliance

- Older age and more traditional co-morbidities continue to be the main risk factors for severe COVID-19
 - Heart disease, obesity, chronic lung disease, pregnancy
- In patients with Sjogren's, certain medications are risk factors too:
 - Being on prednisone 10 mg or more daily
 - Receiving treatment with rituximab

Risk for COVID-19 Infection, Hospitalization and Death by Age Group

Risk for COVID-19 Infection, Hospitalization, and Death By Age Group

Rate compared to 5–17-years old¹	0–4 years old	5–17 years old	18–29 years old	30–39 years old	40–49 years old	50–64 years old	65–74 years old	75–84 years old	85+ years old
Cases ²	<1x	Reference group	2x	2x	2x	2x	1x	1x	2x
Hospitalization ³	2x	Reference group	6x	10x	15x	25x	40x	65x	95x
Death⁴	1x	Reference group	10x	45x	130x	440x	1300x	3200x	8700x

All rates are relative to the 5–17-year-old age category. Sample interpretation: Compared with 5–17-year-olds, the rate of death is 45 times higher in 30–39-year-olds and 8,700 times higher in 85+-year-olds.



COVID-19 vaccine recommendations

- Pfizer 2 doses, 3 weeks apart
- Moderna 2 doses, 4 weeks apart
- J&J 2 doses, ≥ 8 weeks apart

Pfizer-BioNTech COVID-19 Vaccine FDA approved August 23, 2021 for ages 16 years and up

Clarifying Boosting Recommendations

Who gets what? When?

- Booster dose → non-immunocompromised
- Additional dose -> immunocompromised

EUA for "3rd dose" of mRNA COVID-19 vaccines for immunocompromised

- August 12, 2021 FDA modified EUA for Pfizer and Moderna vaccines to allow for administration of a 3rd "additional" dose for certain immunocompromised people
 - Preferably with the same mRNA vaccine as the initial 2-dose series
 - Given at least 28 days following 2nd dose
 - If Moderna → full dose

For our patients, the 3rd dose is not really a booster, but is now part of the recommended immunizations for those with compromised immune systems, who might not generate a robust response after just 2 shots

Additional COVID-19 vaccine dose recommendations for IMID patients

- Patients receiving immunosuppressing or immunomodulating drugs:
 - Any dose of chronic prednisone usage, methotrexate, sulfasalazine, mycophenolate, leflunomide, cyclophosphamide, azathioprine, cyclosporine, tacrolimus, IL-6 inhibitors, JAK inhibitors, TNF inhibitors, Rituximab, bemilimumab, IL-17 and IL-12/23 inhibitors, abatacept
 - Active treatment for cancer, including lymphoma. This does not include excisional treatment for non-melanoma skin cancers.
 - Receipt of a solid organ transplant that requires ongoing immunosuppressive therapy
 - Receipt of CAR-T cell or hematopoietic stem cell transplant within the past 2 years or ongoing immunosuppressive therapy
 - Moderate or severe primary immunodeficiency disorder, including combined variable immunodeficiency
 - Advanced or untreated HIV infection



FDA authorization for booster shots

- non-immunocompromised
 For select groups who received their 2nd Pfizer or Moderna vaccine ≥ 6 months ago:
- "Should"
 - ≥ 65 years
 - Residents ≥ 18 years living in long-term care facilities
 - 50-64 years with certain underlying medical conditions
- - 18-49 with *at-risk* conditions to make decisions based on their individual risk
 - Health care workers and others whose jobs put them at risk

FDA authorized "Mix and Max" strategy

EUA for Johnson & Johnson second dose

- 1 additional dose
- ≥ 2 months after primary dose
- To anyone ≥ 18 years old who receive the J&J primary dose

Now, a 4th dose!! Immunocompromised

"moderately to severely immunocompromised people ≥18 years who received a 2-dose mRNA primary series and an additional mRNA dose (3 total mRNA vaccine doses) are eligible for a single COVID-19 booster dose (Pfizer, Moderna or J&J), at least **6 months** after completing their 3rd mRNA vaccine dose"

COVID-19 and Flu Vaccine

- Flu vaccine for all not to be skipped this year!
- Ok to co-administer during same visit, if it will increase vaccine uptake
 - Different injection sites, preferably different arms

Fear of Sjogren's Flare after the COVID vaccine

- There are no data to suggest significantly increased risk of any rheumatic disease after the COVID vaccine
- In general, we like to consider the relative risk of dying from COVID vs. flare of Sjogren's
- People with multiple autoimmune diseases are not at greater risk of flare

Level of immunocompromised in Sjogren's patients varies

- Largely dependent on what drug you are receiving as treatment
- Drugs that compromise the immune system:
 - Prednisone and other steroids
 - Methotrexate
 - Rituximab
 - Cellcept (mycophenolate)
- Drugs that do NOT compromise the immune system:
 - Plaquenil (hydroxychloroquine),
 - NSAIDs (advil, etc)

Drugs that we know reduce the effectiveness of COVID vaccines

- Rituximab
- Methotrexate
- Cellcept (mycophenolate)
- Higher doses of prednisone
- If you are taking these medications, you should discuss with your rheumatologist about timing of the vaccine



AN OFFICIAL JOURNAL OF THE AMERICAN COLLEGE O RHEUMATOLOGY



Full Length | 🙃 Free Access

American College of Rheumatology Guidance for COVID-19 Vaccination in Patients With Rheumatic and Musculoskeletal Diseases: Version 2

Jeffrey R. Curtis 🔀 Sindhu R. Johnson, Donald D. Anthony, Reuben J. Arasaratnam, Lindsey R. Baden, Anne R. Bass, Cassandra Calabrese, Ellen M. Gravallese, Rafael Harpaz, Andrew Kroger ... See all authors 🗸

First published: 15 June 2021 | https://doi.org/10.1002/art.41877

Rituximab and COVID vaccine

- Rituximab significantly reduces the effectiveness of COVID vaccines
- In general, we recommend to wait as long after last rituximab infusion as possible, and 2-4 weeks before next infusion, if possible

COVID Vaccine Breakthrough

The current top five symptoms of COVID-19 among vaccinated people

All variants (including current dominant delta variant), UK self-reported symptoms from ZOE COVID study, up to June 23 2021.



1. headache



2. runny nose



3. sneezing



4. sore throat



5. loss of smell.



- Increased incidence of breakthrough infection in rheumatic disease patients
- Depends on several factors, including which immunosuppressive drug
- Biggest risk factors for breakthrough:
 - Older age
 - Being on rituximab
 - These factors are also associated with being sicker with breakthrough infection, in particular rituximab, and in in particular if you have more than one risk factor

he Conversation/ZOE COVID Symptom Study app, GC BY-ND

Other questions

- How long does it take for the 3rd shot to take full effect?
 - 14 days
- Any news on other formulas for vaccine like pill, nasal spray.
 - Not in the near future!
- Will COVID vaccines/boosters become annual like the flu shot?
 - TBD...

Thank You

calabrc@ccf.org

@CCalabreseDO

