Sjögren's and COVID-19 Vaccination Statement

The advent of effective vaccines is a critical development in the global effort to contain the deadly COVID-19 pandemic. Two vaccines (Pfizer and Moderna) have received Emergency Use Authorization (EUA)* in the United States and additional ones will likely become available early in 2021. These vaccines are expected to be suitable for virtually everyone in the population based on their design and reported clinical trial experience in over 75,000 people. Based on what we know and the mechanism of action of these vaccines, we expect these vaccines to be safe in people affected by Sjögren's. We thus recommend COVID vaccination for individuals with Sjögren's, given their demonstrated efficacy against a deadly disease and favorable side effect profile.

This recommendation is based on information that has been made available to the public and on the expert opinion of our physician panel. It is also consistent with guidelines established by the Centers for Disease Control and other professional health care organizations, including the American College of Rheumatology, American Society of Hematology, Johns Hopkins University, and Cleveland Clinic. As new information becomes available, this document will be updated.

Overall vaccine safety has been proven in large clinical trials that have taken place to-date. In the Pfizer and Moderna mRNA vaccination** clinical trials alone, over 75,000 people have participated. In the Moderna trial, 41% of participants were at risk for progression to severe COVID-19 based on age (≥65 years of age) and/or comorbid illness (including diabetes, chronic lung disease, severe obesity, significant cardiovascular disease, liver disease, or infection with HIV). In the Pfizer trial, 46% of participants had comorbidities that would be expected to increase the risk of severe COVID-19. This included some people with autoimmune disease. We continue to learn more about the vaccinations from the millions of people who are currently receiving or will soon receive vaccinations against COVID-19: those on the front lines of healthcare and those in nursing homes as top priority followed by people >74 years of age and other front-line workers, such as those in grocery stores and teachers.

The CDC has stated that "people with autoimmune conditions may receive an mRNA COVID-19 vaccine" but also acknowledges that no data are currently available on the safety of these vaccines for these individuals. The risk of COVID vaccines in individuals with systemic autoimmune diseases is expected to be minimal, based on their mechanism of action. None of the COVID vaccines involve the use of live virus. The mRNA vaccines currently available do not include an adjuvant and do not become

incorporated in your own genetic material (i.e. DNA). Induction of flares in Sjögren's is a theoretic possibility but has not been reported and has never been reported with any other currently approved non-COVID vaccine. We expect that if they occur, these flares could be managed easily and should not deter someone from receiving the vaccine. We anticipate learning more as additional people are vaccinated and data gathered. Any adverse events will be reported to the FDA and announced.

Certain immunosuppressive medications used to treat Sjögren's may reduce efficacy of the COVID vaccine, especially if you are taking methotrexate or rituximab in close proximity to receipt of the vaccine. You should discuss with your rheumatologist about when to receive the COVID vaccine in relation to your dosing of these two medications. This decision must be individualized in order to balance the risk of a disease flare while stopping these medications temporarily versus ensuring an optimal response to the vaccine.

Frequently asked questions are found below.

*Emergency Use Authorization (EUA) is provided by U.S. law enabling the U.S. Food and Drug Administration (FDA) to allow use of medical products during a public health emergency to prevent or treat illness or disease.

**mRNA vaccination stands for Messenger Ribonucleic Acid vaccination. RNA is present in all living cells and is essential in biological coding and regulation and expression of genes. The mRNA vaccination prompts the production of the viral spike protein of SARS-CoV-2, stimulating the immune system to recognize this feature of SARS-CoV-2 and protect the vaccination recipient from infection.

Frequently Asked Questions about the COVID-19 Vaccination and Sjögren's

1) As a person with Sjögren's, should I receive a vaccination for COVID-19?
    - Yes. We recommend that all people with Sjögren's should be vaccinated, with the exception of children under the age of 16 (since children were not included in the trials that led to the EUA for the Pfizer and Moderna vaccines). However, this is a decision that people with Sjögren's may want to make in concert with their health care professional.

2) If I have already had COVID, should I receive the vaccine?
    - Yes. You might have gained some protection from your COVID infection, but we do not know how long that protection will last. In addition, the vaccine may provide more robust protection than was gained from your past COVID infection.

3) Has the U.S. federal government issued any guidance specifically for those with autoimmune diseases such as Sjögren's?
    - On December 27, 2020, the U.S. Centers for Disease Control and Prevention (CDC) issued guidance for those with underlying medical conditions, including those with autoimmune disease such as Sjögren's. The guidance states: "People with autoimmune conditions may receive an mRNA COVID-19 vaccine. However, they should be aware that no data are currently available on the safety of mRNA COVID-19 vaccines for them. Individuals from this group were eligible for enrollment in clinical trials." See Vaccination Considerations for Persons with Underlying Medical Conditions | CDC.

4) If I am planning to get pregnant this coming year or am already pregnant, should I get the COVID vaccine?
    - There are no data yet on the safety of the COVID mRNA vaccines during pregnancy. However, pregnant women are at increased risk of severe illness from COVID and COVID infection can increase the risk of adverse pregnancy outcomes. Thus, a pregnant woman may choose to be vaccinated and this decision may be facilitated through a conversation with her obstetrician. The American College of Obstetrics and Gynecology and the Society for Maternal-Fetal Medicine are recommending that COVID vaccines should not be withheld from pregnant or lactating individuals who meet criteria for vaccination. In addition, this organization recognizes that a conversation with a clinician about the advisability of a COVID vaccine may be helpful, but should not be required prior to vaccination
        - https://s3.amazonaws.com/cdn.smfm.org/media/2656/Provider_Considerations_for_Engaging_in_COVID_Vaccination_Considerations_12-21-20_(final).pdf
        - https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19

5) Are COVID-19 vaccinations less effective in people with Sjögren's than in the general population?
    - We expect the vaccinations will be as effective in people with Sjögren's as in the general population. Notably, this efficacy was observed across the entire range of participants in the Pfizer and Moderna trials, which included over 40% with co-morbid illnesses that would make them more vulnerable to adverse outcomes with COVID-19.
    - Some immunosuppressive medications may decrease vaccine effectiveness, in particular methotrexate and rituximab. Depending on the immunosuppressive drug and the dose, a person on these drugs might have an inadequate response to the vaccine. Accordingly, those on immunosuppressive drugs should talk with their healthcare provider about stopping these medications temporarily while receiving the vaccine doses. This decision should be individualized since the risk of a Sjögren's disease flare varies.
    - Higher doses of prednisone (>20mg daily) have been shown to alter the efficacy of other vaccines. We suggest that you discuss your steroid regimen with your healthcare provider.
    - Remember that being on an immunosuppressant does not mean the COVID-19 vaccination is contra-indicated but means that protection against COVID-19 might be reduced.
    - Anti-malarial drugs, such as hydroxychloroquine, can be continued during COVID vaccination since they would not be expected to blunt the resultant immune response.

6) Is one type of vaccination better (safer, more efficacious) than another for people with Sjögren's?
    - We do not have any data yet to inform us.

7) Can COVID-19 vaccinations cause a flare in people with Sjögren's?
    - There are no data to indicate that COVID-19 vaccines will result in a flare. However, a theoretic possibility for a flare exists, but if flares do occur, they are expected to be mild and easily managed.

8) What symptoms might occur after I have the COVID vaccine?
    - It is very common to have vaccine-related symptoms, especially after the second dose. These typically start 1-2 days after the vaccination, and last 1-2 days. The symptoms include a sore arm, fatigue, muscle aches, fever, and headache. These symptoms are an indication that the vaccine is working. You can take acetaminophen to help relieve the symptoms. If you have prednisone in your medicine cabinet or are taking it for your Sjögren's, do not start it or take a higher dose. However, if these symptoms persist beyond 1-2 days, or include cough, shortness of breath, then you should seek help from your health care provider.

9) Are people with Sjögren's more vulnerable to complications of developing new autoimmune or neurological symptoms/disorders from the COVID-19 vaccinations?
    - There are no data to suggest either at present.

10) Is there greater urgency for specific subgroups of people with Sjögren's to get vaccinated?
    - According to a study published in December 2020 based on the Big Data Sjögren Registry in Europe, people with Sjögren's and baseline comorbidities are at higher risk of complications from COVID-19. Those individuals with low lymphocyte counts, of older age, and/or on immunosuppressant drugs had an increased susceptibility for hospitalization. This was similar to those with other rheumatic diseases. The abstract is available online and may be shared with your doctor.
    - People with Sjögren's and related chronic lung or kidney disease might be at higher risk for complications with COVID. The CDC Emergency Use Authorization for use of monoclonal antibodies recognizes a risk of more severe disease in rheumatic disease patients with these manifestations. (For guidance on managing and treating pulmonary manifestations in Sjögren's, see the Sjögren's Foundation Consensus Guidelines published in October 2020: Consensus Guidelines for Evaluation and Management of Pulmonary Disease in Sjögren's - PubMed (nih.gov))

11) If someone has allergies, asthma, eczema, and/or medication allergies, do they have an increased likelihood of developing an "allergic" reaction to the vaccine?
    - This may be a possibility, but precautions and treatments are available. Discuss your history of allergies and allergic reactions with your healthcare provider and vaccination team.
    - The CDC Emergency Use Authorization fact sheet states that the only definite contraindication to the vaccine is prior severe allergic reaction to a vaccine component such as the preservative. If you have had a severe allergic reaction to a non-COVID vaccine in the past, you should discuss this with your health care professional prior to receiving a COVID vaccine.
    - The mRNA is packaged in nanoparticles that include polyethylene glycol (PEG) in both the Pfizer and Moderna vaccines. PEG has not previously appeared in vaccines and is under consideration as a potential factor in the rare cases of severe allergic reactions. However, at this time, no data exists linking allergic reactions to PEG.

12) Are vaccinations safe and effective in childhood Sjögren's?
    - While the Pfizer study included some 16-18 year-olds and the Moderna one included those 18 and older, we do not have sufficient data on immunizing children. At present, the two available vaccines are only authorized for use in children age 16 and older (Pfizer) or 18 and older (Moderna). The decision on vaccination in childhood Sjögren's should be made in consultation with the treating healthcare team.

For additional information and answers to general questions about the COVID-19 vaccinations, the CDC offers frequent updates:
Frequently Asked Questions about COVID-19 Vaccination | CDC

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