

CONQUERING Sjögren's

January/February 2021

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Sjögren's Foundation Clinical Practice Guidelines:

Pulmonary Manifestations in Sjögren's

As part of the Sjögren's Foundation's ongoing initiative to develop the first-ever U.S. clinical practice guidelines for Sjögren's— we are proud to share with you the newest set of guidelines focusing on pulmonary manifestations in Sjögren's. Recently published in the prestigious medical journal, *CHEST*, these guidelines are a culmination of many years of work and are a major step forward for the Sjögren's community.

Sjögren's has been associated with a multitude of respiratory conditions and can affect every aspect of the respiratory system, highlighting the need for awareness of pulmonary manifestations and the importance of these new guidelines. Within the 12-page summary document, 52 recommendations are given to help standardize the quality and consistency of care for the assessment and management of pulmonary complications in patients.

This initiative began in 2009, with guidelines in rheumatology, oral medicine/dentistry and eye care being developed, which were then completed and published between 2015 and 2016. The Foundation is continuing to expand the work to include more topics, which will significantly increase the guidance offered on the management and treatment of Sjögren's patients.

The Foundation would like to thank our guidelines chairs and members of the Topic Review Groups and Consensus Expert Panels for volunteering their time and expertise on this important work. We would also like to thank all Foundation members and supporters for helping to make our decade-long dream of Sjögren's clinical practice guidelines a reality!

When reading these guidelines in this issue, please remember that they are intended for medical professionals. Should you be experiencing Sjögren's-related

pulmonary complications and/or have questions regarding these recommendations, please speak to your pulmonologist, rheumatologist or general practitioner. ■

Sjögren's Foundation Clinical Practice Guidelines

Published Sjögren's Clinical Practice Guidelines

- Systemic Manifestations in Sjögren's Patients*
- Oral Management: Caries Prevention in Sjögren's Patients*
- Ocular Management in Sjögren's Patients*
- Pulmonary Manifestations in Sjögren's*

Future Sjögren's Clinical Practice Guideline Topics

- Systemic Manifestations in Sjögren's
- Peripheral nervous system (PNS)
- Central nervous system (CNS)
- Lymphoma and other blood cancers
- Vasculitis
- Oral Manifestations in Sjögren's
- Mucosal management and symptom relief; Use of secretagogues; Caries management and restoration
- Parotid and lacrimal gland swelling
- Cross-Cutting Topics

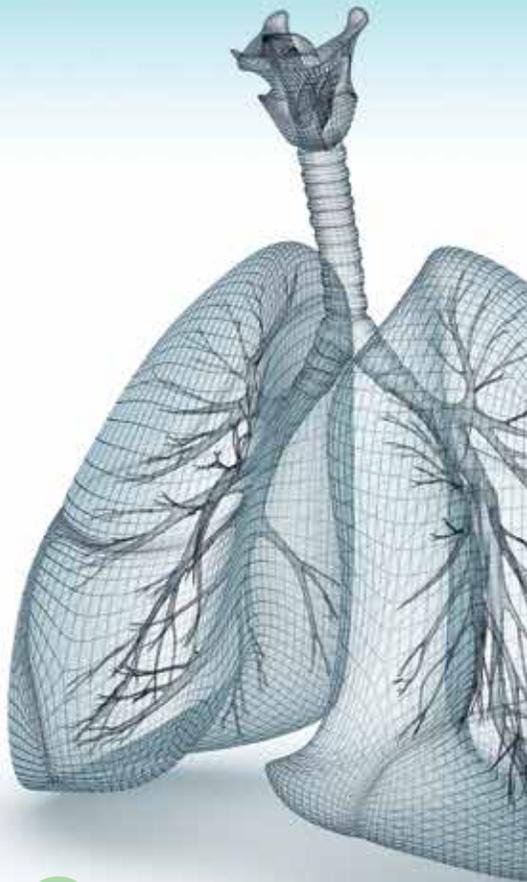
*These guidelines are published and available on the Foundation's website www.sjogrens.org.

Sjögren's Foundation Clinical Practice Guidelines

Pulmonary Manifestations in Sjögren's

Pulmonary complications occur much more frequently in Sjögren's than is often recognized by healthcare providers and are a potentially serious complication of Sjögren's. Clinical practice guidelines for pulmonary manifestations in Sjögren's were developed under the leadership of the Sjögren's Foundation to improve early identification, evaluation and consistency of care by primary care physicians, rheumatologists and pulmonologists. Of note:

- Approximately 16% of Sjögren's patients demonstrate pulmonary complications with increased mortality and lower quality of life. This figure may be low due to gaps in awareness and education.
- In all, 52 recommendations are provided for patient evaluation (by rheumatologists and primary care physicians for pulmonary symptoms and by pulmonologists for potential Sjögren's), airways disorders, interstitial lung disease (ILD) and lymphoproliferative disease.
- As many as 65% of asymptomatic Sjögren's patients will have abnormal pulmonary imaging, highlighting the need for awareness of pulmonary manifestations in Sjögren's.
- A baseline chest x-ray should be considered for all Sjögren's patients, and if concern is high for lung involvement, a high-resolution computerized tomography (HRCT) scan may be preferred.
- Airway disorders in Sjögren's are associated with a wide range of symptoms, including a dry nonproductive cough, dry trachea, reflux, vocal cord lesions, bronchiectasis (characterized by narrowed airways) and respiratory inflammation.
- Nearly 40% of Sjögren's patients will have a chronic cough, which should be investigated and the cause identified.
- ILD symptoms can include shortness of breath, cough, sputum production or chest pain. Onset of ILD in Sjögren's may increase with time following diagnosis of Sjögren's.
- Approximately 6% of Sjögren's-associated lymphomas may directly involve the lungs.
- A multidisciplinary approach for pulmonary complications is encouraged and should include a rheumatologist, primary care physician, pulmonologist, pathologist, radiologist, and, when appropriate, an oncologist.

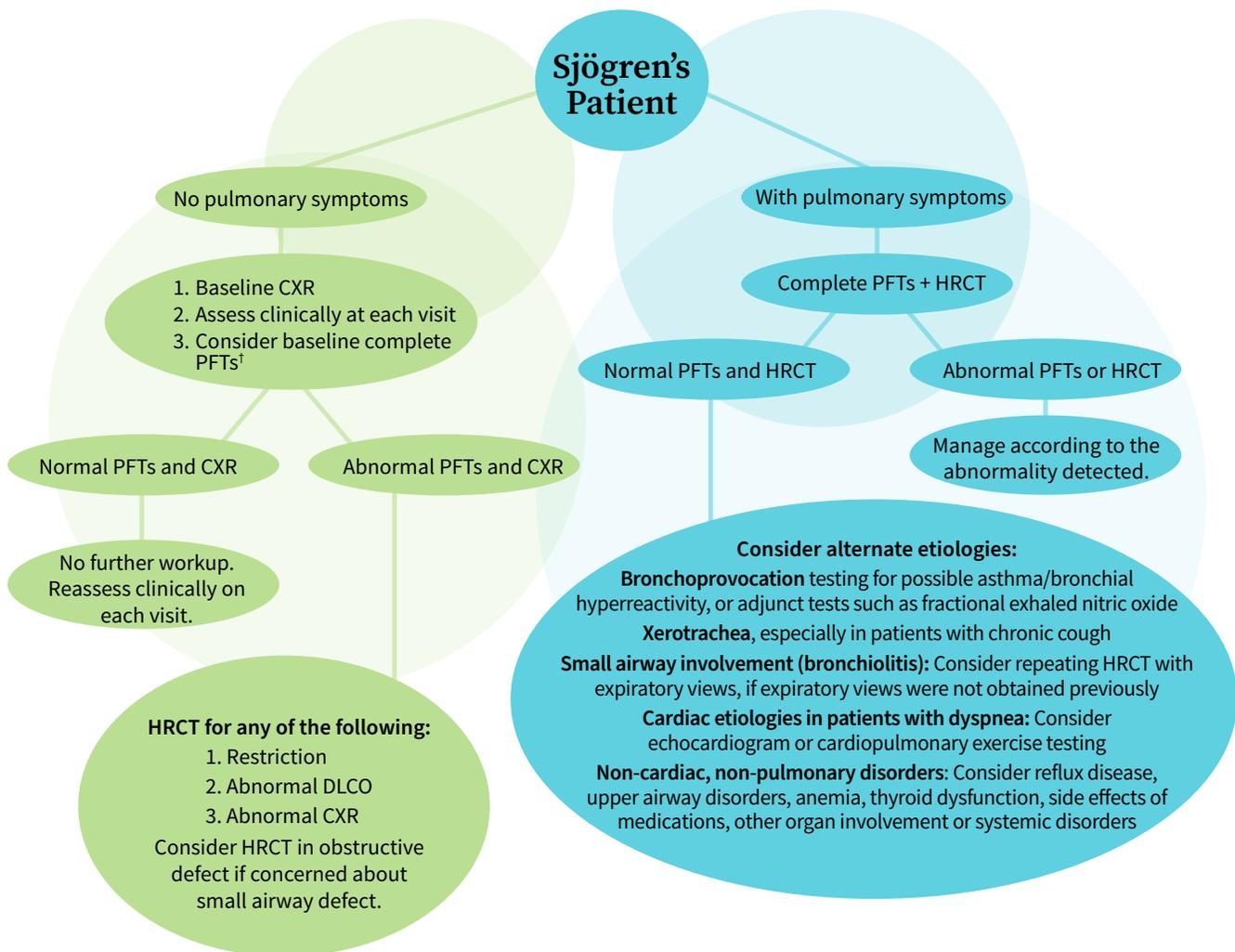


Recommendations for Patient Evaluation

Evaluating Asymptomatic Sjögren's Patients for Pulmonary Complications	Strength of Evidence	Strength of Recommendation
1. Serologic biomarkers must not be employed to evaluate for pulmonary involvement in patients with established Sjögren's disease.	INTERMEDIATE	STRONG
2. Due to the prevalence of respiratory involvement in Sjögren's, clinicians must obtain a detailed medical history inquiring about respiratory symptoms in all Sjögren's patients at the initial and every subsequent visit.	HIGH	STRONG
3. In Sjögren's patients without respiratory symptoms, a baseline two-view chest x-ray (CXR) may be performed. The baseline chest radiograph can 1) help identify pulmonary involvement despite the absence of symptoms, 2) identify alternate etiologies of sicca symptoms such as sarcoidosis, vasculitis and lymphoma, and 3) serve as a baseline for future comparisons.	INTERMEDIATE	WEAK
4. In Sjögren's patients who have no respiratory symptoms, baseline complete pulmonary function tests (PFTs) may be considered to evaluate for the presence of underlying pulmonary manifestations. PFTs should include pre- and post-bronchodilator spirometry, lung volumes, and diffusing capacity of the lung for carbon monoxide (DLCO). Abnormalities identified may require further corroboration with advanced testing.	INTERMEDIATE	WEAK
5. In asymptomatic Sjögren's patients, routine echocardiogram is not recommended.	INTERMEDIATE	STRONG
Evaluating Sjögren's Patients with Pulmonary Symptoms	Strength of Evidence	Strength of Recommendation
1A. In Sjögren's patients with chronic cough and/or dyspnea, complete PFTs and HRCT should be done to evaluate for pulmonary involvement.	INTERMEDIATE	MODERATE
1B. In a Sjögren's patient with respiratory symptoms, the interval for repeat HRCT and PFTs must be determined on a case-by-case basis and individualized according to the nature and severity of the underlying pulmonary abnormality and the degree of symptoms and functional impairment.	INSUFFICIENT	STRONG
2. In a Sjögren's patient with dyspnea, an echocardiogram is recommended in the following circumstances: <ul style="list-style-type: none"> • In patients with suspected pulmonary hypertension (PH) • In patients with unexplained dyspnea after pulmonary etiologies (asthma, small airways disease, bronchiectasis, ILD) have been excluded • In patients with suspected cardiac involvement 	HIGH	STRONG
3. In a Sjögren's patient with respiratory symptoms, a computed tomography pulmonary angiogram (CTPA) to look for pulmonary embolism must not be performed routinely in all patients but rather dictated by clinical suspicion for pulmonary embolism in individual circumstances. If clinically concerned about a pulmonary embolism, CTPA is the confirmatory test of choice. <p>Ventilation-perfusion (VQ) scan should only be considered in the following circumstances:</p> <ul style="list-style-type: none"> • To rule out chronic thromboembolic pulmonary hypertension (CTEPH) in patients with PH • When clinical concern for pulmonary embolism exists, and a physician is unable to do a CTPA because of patient allergy to contrast or renal insufficiency 	LOW	STRONG
Evaluating for Sjögren's in Patients with Lung Disease	Strength of Evidence	Strength of Recommendation
1. In patients who have an uncharacterized ILD, diffuse cystic lung disease (DCLD) or pulmonary lymphoma, clinical and serologic evaluation for Sjögren's is recommended.	HIGH	STRONG

Use of Bronchoscopy	Strength of Evidence	Strength of Recommendation
1. In a Sjögren's patient with respiratory symptoms, bronchoscopy with bronchoalveolar lavage (BAL) must not be performed routinely but determined on a case-by-case basis and limited to special circumstances, such as the need to: <ol style="list-style-type: none"> 1) Rule out infectious etiologies, especially in patients on immune suppression 2) Rule out endobronchial abnormalities such as amyloidosis in patients with chronic cough not otherwise responsive to treatment 3) Distinguish between other etiologies of sicca symptoms such as sarcoidosis 	LOW	STRONG
2. In a Sjögren's patient with respiratory symptoms, use of bronchoscopy with endobronchial biopsies and transbronchial lung biopsy are not recommended for routine use.	INSUFFICIENT	STRONG

Figure 1:
Respiratory Evaluation for Sjögren's Patients



† The benefit of obtaining baseline PFTs in asymptomatic Sjögren's patients with regards to long-term outcomes is not clear. This paucity of evidence and potential costs of the test should be taken into account and discussed with individual patients prior to proceeding with PFTs.

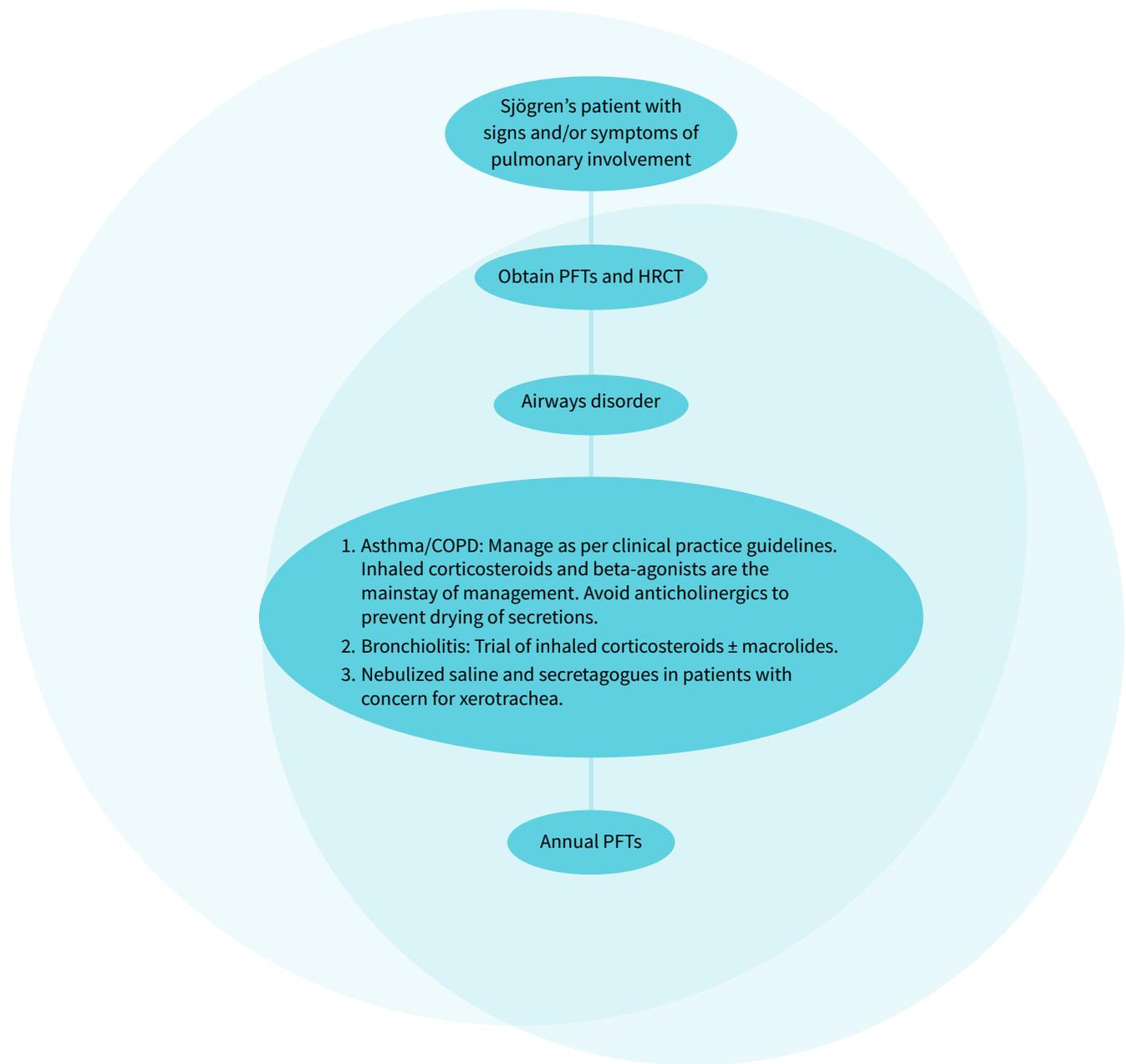
Complete PFTs includes spirometry, DLCO, lung volumes, ideally measured by body plethysmography

Abbreviations: CXR = chest x-ray; HRCT = high-resolution computed tomography; PFTs = pulmonary function tests; DLCO = diffusing capacity of lung for carbon monoxide

Recommendations for Assessment and Management of Upper and Lower Airway Disease in Sjögren's Patients

Assessment and Management of Upper and Lower Airway Disease in Sjögren's Patients	Strength of Evidence	Strength of Recommendation
1. In Sjögren's patients with symptomatic vocal cord cystic lesions ('bamboo nodules'), less aggressive interventions including voice therapy, inhaled corticosteroids or intralesional corticosteroid injection, should be tried first. Surgical resection should be considered if initial measures fail, with consultation by a laryngologist with experience in Sjögren's.	LOW	MODERATE
2. Sjögren's patients with dry bothersome cough and documented absence of lower airway or parenchymal lung disease must be assessed for treatable or preventable etiologies other than xerotrachea, including gastroesophageal reflux, post-nasal drip and asthma.	INTERMEDIATE	STRONG
3. In a Sjögren's patient with dry, nonproductive cough, humidification, secretagogues and guaifenesin may be empirically initiated after exclusion of other causes.	INSUFFICIENT	WEAK
4. The use of humidification for improving positive airway pressure (PAP) tolerance and compliance may be recommended in Sjögren's patients.	INSUFFICIENT	WEAK
5. Smoking cessation is recommended in all Sjögren's patients.	INTERMEDIATE	STRONG
6A. In Sjögren's patients with symptomatic small airway disease, bronchoscopic biopsy is not recommended as part of routine assessment or evaluation.	INSUFFICIENT	STRONG
6B. In Sjögren's patients with symptomatic small airway disease, complete pulmonary function testing must be performed to assess severity of small airways disease, and HRCT imaging with additional expiratory views can be helpful in suggesting its presence.	INSUFFICIENT	STRONG
7. In Sjögren's patients with small airways disease, time-limited empiric therapy in newly diagnosed and previously untreated disease may include: <ul style="list-style-type: none"> • A short course of systemic steroids for 2-4 weeks with a repeat spirometry to determine reversibility, especially if uncontrolled asthma is suspected • Nebulized or inhaled short or long-acting bronchodilators and/or inhaled corticosteroids if there is physiologic obstruction • Short course (i.e. 2-3 months) of empiric macrolide antibiotics (most commonly azithromycin 250mg three days a week) for persistent, non-reversible, symptomatic bronchiolitis 	LOW	WEAK
8. It is recommended that Sjögren's patients with clinically relevant bronchiectasis be treated similarly to those with primary or secondary bronchiectasis of other etiologies and may include any of the following: <ul style="list-style-type: none"> • Mucolytic agents/expectorants • Nebulized saline or hypertonic saline • Oscillatory positive expiratory pressure (PEP) • Postural drainage • Mechanical high frequency chest wall oscillation (HFCWO) therapies • Chronic macrolides in those without non-tuberculous mycobacterium (NTM) colonization or infection 	LOW	STRONG

Figure 2:
Evaluation and Management of Sjögren's Patients Who Exhibit Symptoms and/or Physical Examination Signs of Airway Disorders



Abbreviations: CXR = chest x-ray; HRCT = high resolution computed tomography; PFTs = pulmonary function tests; DLCO = diffusing capacity of lung for carbon monoxide; COPD = chronic obstructive pulmonary disease

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1. National Asthma Education and Prevention Program. Expert Panel Report 3 (EPR-3): Guidelines for the diagnosis and management of asthma summary report 2007. *J Allergy Clin Immunol.* 2007 Nov;120(5 Suppl):594-138.
2. Quaseem A et al. Diagnosis and management of stable chronic obstructive pulmonary disease: a clinical practice guideline update from the American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society, *Ann Intern Med.* 2011 Aug 2;155(3):179-91. doi: 10.7326/003-4819-155-3-201108020-00008.

Recommendations for Interstitial Lung Disease (ILD) in Sjögren's

ILD: Diagnosis, Evaluation and Management	Strength of Evidence	Strength of Recommendation
1. In a Sjögren's patient with suspected ILD, an HRCT with expiratory views is recommended.	HIGH	STRONG
2. In a Sjögren's patient with suspected ILD, oximetry testing is recommended as part of a patient's initial evaluation.	HIGH	STRONG
3. Baseline pulmonary function tests (PFTs) must be performed in all Sjögren's patients with suspected or established ILD and followed initially at 3-6 month intervals for at least 1 year. Subsequent testing requires consideration of the type of ILD, the clinical course and the pace of change noted on the serial PFTs. The baseline PFTs should include lung volumes by body plethysmography, spirometry, diffusing capacity and oxygen saturations at rest and exercise.	LOW	STRONG
4. In a Sjögren's patient with ILD, a surgical lung biopsy is not routinely recommended. A lung biopsy may be considered following a multidisciplinary review where a biopsy may have significant management implications, such as in: <ul style="list-style-type: none"> • Neoplastic and non-neoplastic lymphoproliferative disorder • Other cancers • Amyloid • Progressive deterioration and a suspected infection failing empiric therapies where less invasive testing proved nondiagnostic 	INTERMEDIATE	STRONG
5. If a Sjögren's-ILD patient is asymptomatic for lung disease or demonstrates minimal impairment on PFTs or HRCT, serial monitoring by PFTs is recommended every 3-6 months to establish disease trajectory and initiation of pharmacotherapy only if serial studies document a significant decline in lung function.	INTERMEDIATE	STRONG
Non-Pharmacological and Other Management	Strength of Evidence	Strength of Recommendation
1. Vaccination: All Sjögren's patients must be immunized against influenza and pneumococcal infection (Prevnar and Pneumovax) in accordance with U.S. Centers for Disease Control and Prevention (CDC) guidelines.	HIGH	STRONG
2. Pneumothorax and Cystic Lung Disease: Because a Sjögren's patient with cystic lung disease might have an increased risk of pneumothorax, patients and caregivers/family must be educated about signs and symptoms of pneumothorax and instructed to seek immediate medical attention if they experience signs or symptoms.	INTERMEDIATE	STRONG
3. Pulmonary Rehab and ILD: In a symptomatic Sjögren's patient with ILD and impaired pulmonary function, referral for pulmonary rehabilitation is recommended.	INTERMEDIATE	STRONG
4. Oxygen and ILD: In a Sjögren's patient with suspected ILD and clinically significant resting hypoxemia (defined by resting O ₂ sat <88%, PaO ₂ <55mm Hg or <60mm Hg with complication of chronic hypoxemia such as cor pulmonale), long-term oxygen therapy is recommended.	INTERMEDIATE	STRONG
5A. Air Travel and ILD: In a Sjögren's-ILD patient considering air travel, the need for supplemental oxygen should be evaluated by a physician.	INTERMEDIATE	MODERATE
5B. Air Travel and ILD: In a Sjögren's patient with ILD, discouraging air travel is not recommended unless the patient develops signs and symptoms of pneumothorax or new onset/unexplained chest pain or dyspnea prior to boarding.	INTERMEDIATE	STRONG
6. Lung Transplant and ILD: In a Sjögren's patient with ILD whose condition is advanced with resting hypoxia or whose lung function is rapidly deteriorating, lung transplant evaluation is recommended.	INTERMEDIATE	STRONG

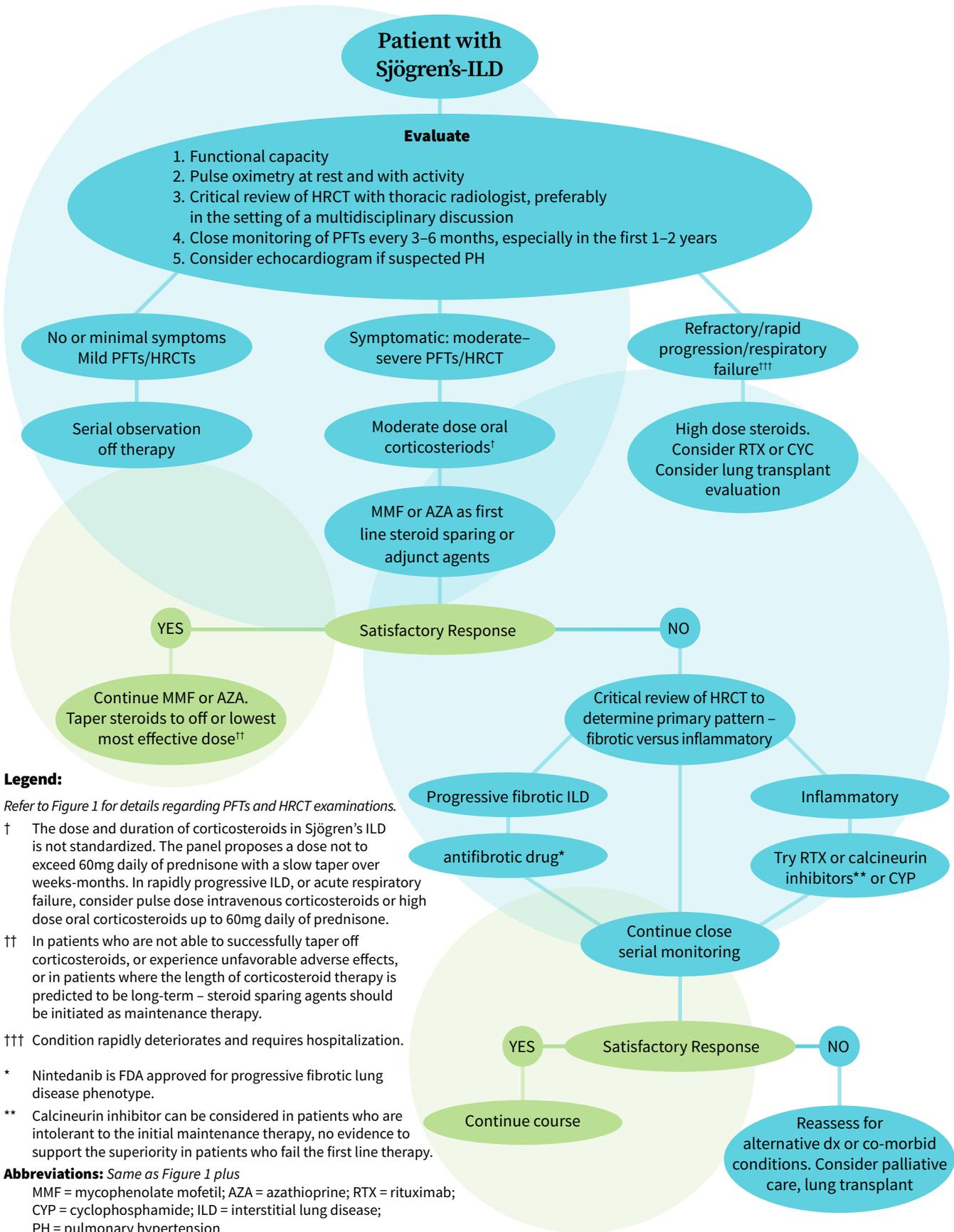
ILD: Pharmacological Interventions	Strength of Evidence	Strength of Recommendation
<p>1A. Symptomatic/Moderate-Severe ILD – Systemic Corticosteroids: In Sjögren’s patients with symptomatic ILD with moderate-to-severe impairment on lung function, imaging or in gas-exchange and especially in organizing pneumonia (OP), systemic steroids should be considered as a first-line treatment at a dosage based on the clinical context and disease severity, with standard dosage being 0.5-1.0 mg/kg.</p>	INTERMEDIATE	MODERATE
<p>1B. Cautions for Systemic Corticosteroids: In a Sjögren’s patient with ILD or related disorder and considering use of systemic steroids, patients and healthcare providers must be aware of the following risks/potential harms:</p> <p>Potential short-term side effects:[†]</p> <ul style="list-style-type: none"> ● Glucose intolerance ● Avascular necrosis ● Mineralocorticoid effect, leading to potential fluid retention and/or hypertension ● Myopathy ● Psychological, including hyperactivity, insomnia, psychosis ● Pancreatitis ● Hypertension ● Truncal obesity ● Acne ● Hematopoietic, including leukocytosis ● Ecchymosis ● Acanthosis nigricans <p>Potential long-term side effects:</p> <ul style="list-style-type: none"> ● Osteoporosis ● Diabetes ● Adrenal insufficiency ● Gastrointestinal symptoms, including peptic ulcer, hepatic steatosis ● Ophthalmological, including glaucoma, cataract ● Hyperlipidemia ● Congenital malformation in utero exposure (very rare) ● Growth suppression (only in pediatrics) 	HIGH	STRONG
<p>2A. Symptomatic/ Moderate-Severe ILD – Mycophenolate mofetil (MMF) or Azathioprine (AZA): In a Sjögren’s patient with symptomatic ILD with moderate to severe impairment as determined by lung function testing, imaging, or gas-exchange, mycophenolate mofetil (MMF) or azathioprine (AZA) should be considered when long-term steroid use is contemplated, and steroid-sparing immunosuppressive therapy is required.</p>	INTERMEDIATE	MODERATE
<p>2B. Cautions for Azathioprine: In a Sjögren’s patient with ILD or related disorder and considering use of azathioprine (AZA), patients and healthcare providers must be aware of potential risks for drug-induced pneumonitis, gastrointestinal upset, hepatotoxicity, bone marrow suppression, rash and hypersensitivity syndrome. Testing for Thiopurine methyltransferase (TPMT) activity or genotype before initiating AZA is recommended to reduce the risk of severe, life-threatening leucopenia due to complete lack of TPMT activity.[†]</p>	HIGH	STRONG
<p>2C. Cautions for Mycophenolate Mofetil (MMF): In a Sjögren’s patient with ILD or related disorder and considering use of mycophenolate mofetil (MMF), patients and healthcare providers must be aware of potential side effects, including nausea, diarrhea, hepatotoxicity and bone marrow suppression.[†]</p>	HIGH	STRONG
<p>3. Symptomatic/ Moderate-Severe ILD – Maintenance therapies: Following initial treatment for Sjögren’s patients with ILD who are symptomatic and in whom PFTs or HRCT demonstrated moderate-severe impairment, first-line maintenance drugs should be either mycophenolate mofetil (MMF) or azathioprine (AZA).</p>	LOW	MODERATE
<p>4A. Symptomatic/ Moderate-Severe ILD – Second-Line Therapies: If initial treatment with mycophenolate mofetil (MMF) or azathioprine (AZA) is insufficient or not tolerated in Sjögren’s patients with ILD who are symptomatic and in whom PFTs or HRCT demonstrated moderate-severe impairment, subsequent second line maintenance drugs may include rituximab (RTX) and calcineurin inhibitors, cyclosporine or tacrolimus.</p>	LOW	WEAK

ILD: Pharmacological Interventions <i>(continued)</i>	Strength of Evidence	Strength of Recommendation
<p>4B. Cautions for Rituximab (RTX): In a Sjögren's patient with ILD considering use of rituximab (RTX), patients and healthcare providers must be aware of the following potential risks/harms, although rare:[†]</p> <ul style="list-style-type: none"> ● Pneumonitis ● Worsening of ILD ● Infusion reactions ● Tumor lysis syndrome in those with NHL ● Bacterial, viral or fungal infections including: <ul style="list-style-type: none"> ● Hepatitis B reactivation with possible fulminant hepatitis ● Progressive multifocal leukoencephalopathy (PML) ● Hypogammaglobulinemia ● Cytopenias ● Severe mucocutaneous reactions ● Bowel obstruction and perforation ● Cardiac arrhythmias and angina ● In pregnancy and nursing, risk vs benefit must be carefully considered ● Avoid live vaccines with rituximab 	HIGH	STRONG
<p>5. Symptomatic/ Moderate-Severe Sjögren's-ILD – Antifibrotic drugs:^{††} The use of anti-fibrotic therapy such as nintedanib should be tried as a second-line maintenance therapy either alone or in combination with immunomodulatory agents in Sjögren's patients with progressive fibrotic ILD who are symptomatic and in whom PFTs or HRCT demonstrated moderate-severe impairment.</p>	LOW	MODERATE
<p>6. Rapidly progressive or exacerbating ILD – IV Steroids: In Sjögren's patients with ILD who are rapidly progressive or present with acute respiratory failure, a trial of high dose corticosteroids (such as intravenous methylprednisolone) is recommended. Alternative etiologies, such as infections or lymphoproliferative disorders, must be considered.</p>	INTERMEDIATE	STRONG
<p>7A. Symptomatic/Refractory, rapidly progressive or exacerbating ILD – Cyclophosphamide (CYP): In a Sjögren's patient with ILD who has acute or subacute hypoxic respiratory failure requiring hospitalization, despite initial therapies, rituximab (RTX) or cyclophosphamide (CYP) should be considered in addition to high dose corticosteroids.</p>	LOW	MODERATE
<p>7B. Cautions for Cyclophosphamide (CYP): In Sjögren's with ILD when cyclophosphamide is considered, the significant risks must be assessed[†], and Pneumocystis jiroveci prophylaxis provided. Risk of bladder cancer can be greatly reduced with intravenous versus oral route.</p>	INTERMEDIATE	STRONG
<p>8. Drug-induced lung disease: Clinicians and patients must be aware of pulmonary complications associated with medications used in Sjögren's and related CTDs, particularly when patients are progressive or refractory to therapies. Complications may include infections, malignancies, bronchospasm and drug-induced ILD, and may require bronchoscopy, biopsy and/or withdrawal of the medication. In addition to medication withdrawal, corticosteroids may be used if significant symptoms and respiratory impairment are present. While the risk is low for most agents (~1%), healthcare providers should keep in mind that medications used to treat Sjögren's have been associated with drug-induced ILD, including:</p> <ul style="list-style-type: none"> ● TNF-alpha inhibitors ● Sulfasalazine ● Cyclophosphamide ● Rituximab ● Leflunomide ● Methotrexate ● Sulfonamides 	INTERMEDIATE	STRONG

† Refer to the FDA label for additional information.

†† The antifibrotic, nintedanib, was FDA-approved for progressive fibrotic ILD just as these recommendations went to consensus. This factor, in addition to the authors' awareness of minimal experience with antifibrotics in autoimmune disease, precluded inclusion of a Recommendation listing cautions for antifibrotics. Please consult the Physician's Desk Reference (PDR) for potential risks and side effects.

Figure 3:
Evaluation and Management of Patients With Sjögren’s Who Exhibit Symptoms and/or Physical Examination Signs of Interstitial Lung Disease



Drug Maintenance Therapy for Sjögren's-ILD

Drug	Mechanism of action	Common side effects	Level of recommendation
Mycophenolate Mofetil	Antimetabolite, inhibition of DNA synthesis	Nausea, diarrhea, hepatotoxicity, bone marrow suppression. Pregnancy risk category D	First line therapy for symptomatic ILD with moderate to severe impairment. Moderate strength of recommendation
Azathioprine	Antimetabolite, inhibition of DNA synthesis	Nausea, diarrhea, hepatotoxicity, bone marrow suppression, rash, hypersensitivity syndrome. Pregnancy risk category D	First line therapy for symptomatic ILD with moderate to severe impairment. Moderate strength of recommendation
Cyclosporin	Calcineurin inhibitor T cell target agent	Nephrotoxicity, neurotoxicity, hypertension, hyperglycemia, hirsutism, gingival hyperplasia. Pregnancy risk category C	Second line therapy for symptomatic ILD with moderate to severe impairment. Weak strength of recommendation
Tacrolimus	Calcineurin inhibitor T cell target agent	Nephrotoxicity, neurotoxicity, hypertension, hyperglycemia, alopecia. Pregnancy risk category C	Second line therapy for symptomatic ILD with moderate to severe impairment. Weak strength of recommendation
Cyclophosphamide	Cytotoxic alkylating agent	Infection, bone marrow suppression, gonadal toxicity, bladder toxicity, malignancy risk. Pregnancy risk category D	First line therapy for symptomatic ILD with refractory, rapidly progressive or exacerbating condition requiring hospitalization. Moderate strength of recommendation
Rituximab	Anti CD20 monoclonal antibody B cell target agent	Infusion reaction, cytopenias, infection, hypogammaglobulinemia, hepatitis B reactivation, progressive multifocal leukoencephalopathy. Pregnancy risk category C	First line therapy for symptomatic ILD with refractory, rapidly progressive or exacerbating condition requiring hospitalization. Moderate strength of recommendation Second line therapy for symptomatic ILD with moderate to severe impairment. Weak strength of recommendation
Nintedanib	Tyrosine kinase inhibitor	Nausea, vomiting, diarrhea, weight loss, hepatotoxicity. Pregnancy risk category D	Second line therapy for symptomatic ILD with moderate to severe impairment with progressive fibrotic lung disease phenotype. Moderate strength of recommendation

Clinical Practice Guidelines Development

The Sjögren's Foundation brought rheumatologists, pulmonologists and a hematologist-oncologist together to develop clinical practice guidelines to guide healthcare professionals in the diagnosis, management and treatment of pulmonary manifestations in Sjögren's.

A rigorous and transparent methodology was followed according to guidelines from the American College of Rheumatology (ACR) and other professional organizations. A Consensus Expert Panel (CEP), comprised of 68 members including healthcare professionals in rheumatology and pulmonology as well as Sjögren's patients and family members in healthcare, reviewed and provided input on the guidelines.

Citation

Lee AS, Scofield RH, Hammitt KM, Gupta N, Thomas DE, Moua T, Ussavarungsi K, St Clair EW, Meehan R, Dunleavy K, Makara M, Carsons SE, Carteron NL. Consensus guidelines for evaluation and management of pulmonary disease in Sjögren's. *Chest*. 2020 Oct 16:S0012-3692(20)34902-3. doi: 10.1016/j.chest.2020.10.011. Epub ahead of print. PMID: 33075377.

Recommendations for Lymphoproliferative Disease in Sjögren's

Diagnosis, Evaluation and Management for Lymphoproliferative Disease in Sjögren's Patients	Strength of Evidence	Strength of Recommendation
1. The possibility of lymphoma must be further investigated in a Sjögren's patient with symptoms such as unexplained weight loss, fevers, night sweats, and/or the presence of head and neck lymphadenopathy and/or parotitis.	HIGH	STRONG
2. All Sjögren's patients must be clinically monitored for signs and symptoms of pulmonary lymphoproliferative disorders including lymphoma and amyloid.	HIGH	STRONG
3. In Sjögren's patients suspected of having lymphoproliferative complications, an HRCT chest scan should be considered more appropriate than a baseline CXR at the time of initial diagnosis.	INTERMEDIATE	MODERATE
4. In a Sjögren's patient with pulmonary lesions (nodules >8mm, consolidations, or lymphadenopathy) in whom a neoplasm is suspected, a positron emission tomography (PET) should be considered.	INTERMEDIATE	MODERATE
5. In Sjögren's patients with lymphadenopathy, growing lung nodules, and/or progressive cystic lung disease, a biopsy should be recommended. Clinical and radiographic observation may be appropriate in select patients with incidental subcentimeter nodules, stable cysts and isolated PET negative subcentimeter lymphadenopathy.	INTERMEDIATE	MODERATE
6. In a Sjögren's patient in whom a neoplasm has been confirmed or suspected, multidisciplinary review involving rheumatologist/primary care physician, pulmonologist, pathologist, radiologist and hematologist/oncologist is recommended.	LOW	STRONG

Checklist to Screen for Pulmonary Involvement in Sjögren's

1. Does the patient experience shortness of breath upon exertion?
2. Does the patient experience chronic cough?
3. Does the patient have a history of wheezing?
4. Does the patient have a recent diagnosis of asthma/COPD?
5. What is the patient history regarding cigarette smoking, or other inhalation exposures, including marijuana and vaping?

Checklist to Screen for Sjögren's in Pulmonary Patients

Questions to Ask Patient

Oral Symptoms:

- Does your mouth feel dry?
- Do you need liquids to swallow dry foods?
- Do you frequently sip/drink water?
- Do you have a burning sensation in the mouth?
- Do you have painful sores or red patches at the corners of the mouth (angular cheilitis)?
- Do you get frequent dental cavities, particularly gumline cavities?
- Do your teeth tend to chip, crack and/or erode on the surfaces?
- Do you suffer from gum inflammation or receding gums (gingivitis)?

Checklist to Screen for Sjögren's in Pulmonary Patients *(continued)*

Ocular Symptoms:

- Do your eyes frequently feel dry, irritated, itchy or painful?
- Do you have a sensation that there might be a foreign body in your eye?
- Are your eyes light sensitive?
- Do you frequently use eye drops for irritation or dryness?
- Is your vision frequently blurry, or do you have unexplained vision changes?

Other Symptoms:

- Have you noticed gland swelling in your face or along the jaw line (swollen parotid and/or submandibular glands)?
- Do you suffer dryness of the vagina (is intercourse painful?) or skin (is your skin itchy or flaking?)?
- Do your feet, legs or hands ever feel numb, have a change in sensation or have burning pain (peripheral neuropathy)?
- Do you suffer from extreme fatigue?
- Do your joints or muscles ache when you are not sick (arthralgias, myalgias)?
- Do you ever notice your fingers turning pale or blue in the cold (Raynaud's)?

Pulmonary Guidelines Fast Facts

- 52 Recommendations issued
- 9 Topic Review Group members (4 rheumatologists; 4 pulmonologists; 1 hematologist-oncologist)
- 68 Consensus Expert Panel members (40 rheumatologists; 21 pulmonologists; 7 patients/family of patients)
- 1,192 Abstracts reviewed
- 150 Full articles included in data extraction/guideline development
- To-date, 2 posters on pulmonary guidelines have been presented at professional conferences

Glossary of Pulmonary Terms

- **Amyloidosis:** Amyloid protein buildup in an organ(s)
- **Bronchiectasis:** Narrowing of airways due to inflammation/infection
- **Bronchiolitis:** Inflammation and congestion in small airways of the lung
- **COPD (chronic obstructive pulmonary disease):** A group of disorders that inhibit airflow and make breathing difficult
- **Dyspnea:** Shortness of breath/difficult breathing
- **Fibrotic/Fibrosis:** Formation of fibrous tissues
- **HRCT (high-resolution computed tomography):** Imaging with specific technique to enhance resolution. Commonly used when assessing lung disease.
- **Hypoxemia:** A low oxygen level in the blood
- **Hypoxia:** A low oxygen level at the tissue level
- **ILD (interstitial lung disease):** A group of disorders that may cause progressive scarring and inflammation of lung tissue
- **Lymphoproliferative disease:** A group of disorders that cause abnormal proliferation (rapid reproduction) of lymphocytes (white blood cells)
- **Pneumothorax:** A collapsed lung
- **Pulmonary Function Tests (PFTs):** Tests to show how the lungs are working, including:
 - **Bronchoscopy:** A technique to visualize the lungs and air passages
 - **DLCO (diffusing capacity of the lung for carbon monoxide):** Measurement of the lungs' ability to transfer gas from air (inhaled) to the bloodstream
 - **Lung Volumes:** A test to measure the volume of air in the lungs, including what remains after exhaling
 - **Spirometry:** A test to measure how much and the speed the lungs can inhale and exhale
- **Sarcoidosis:** Inflammatory disease that commonly affects the lungs

Walk for Sjögren's Celebrating our Strength



Walk for Sjögren's is a national awareness and fundraising program that takes place across the United States. To ensure everyone's health and safety with the COVID-19 outbreak, the Foundation has moved all spring Walks to virtual events. We are excited that now patients, their family and friends from around the country can attend any of our upcoming "local" Walks.

The Foundation was in awe of everyone who stepped up as we transitioned our spring and fall 2020 Walks to a virtual platform and showed us how strong our community is. These events were intimate and very rewarding - bringing the Sjögren's community together in the best way possible as we raised critical funding and awareness to help conquer Sjögren's! Here patients and their families joined us via Zoom for the Virtual Walk Opening Ceremony where they learned from Sjögren's experts, entered to win door prizes, and warmed up with our Team Trainer before taking a walk through their neighborhood.

We hope that you will join us virtually and experience a Walk for Sjögren's event that you otherwise might not have been able to attend. A listing of all upcoming walks can be viewed on page 17. Your support is needed now more than ever to help fuel Foundation advancements and our mission of providing vital Sjögren's research, education, awareness, and advocacy, as well as communicate and support all patients, especially in the times of COVID-19.

Why I Walk

"I walk for my mom, myself and for you! For over 15 years, I have been volunteering on the Denver Walk for Sjögren's Committee and personally fundraising to help conquer the complexities of Sjögren's. Two years ago, I joined the Sjögren's Foundation's staff to bring my passion for the Walk for Sjögren's across the country! As a patient myself, you are all a part of my circle of strength because together we are creating hope for a better future for all patients! I look forward to 'meeting' many of you in the upcoming months and hearing your stories about why you walk."



Jessica Levy (Colorado)

To learn more about Walk for Sjögren's events, please contact Jessica Levy at (301) 530-4420 ext. 218 or email jlevy@sjogrens.org.

We walk for a brighter future for all patients! ■



events.sjogrens.org



Sjögren's Foundation Virtual Event Calendar

Register and learn more about how to fundraise to receive your 2021 Walk for Sjögren's T-shirt and other prizes!



March

Southwest Virtual Walk for Sjögren's

(Arizona, New Mexico, and Utah)

Saturday, March 13, 2021

April

Florida and Georgia Virtual Walk for Sjögren's

Saturday, March 27, 2021

DC Metro Area Virtual Walk for Sjögren's

(DC, Maryland, and Virginia)

Saturday, April 17, 2021

May

Philadelphia Tri-State Virtual Walk for Sjögren's

Saturday, May 1, 2021

Colorado Virtual Walk for Sjögren's

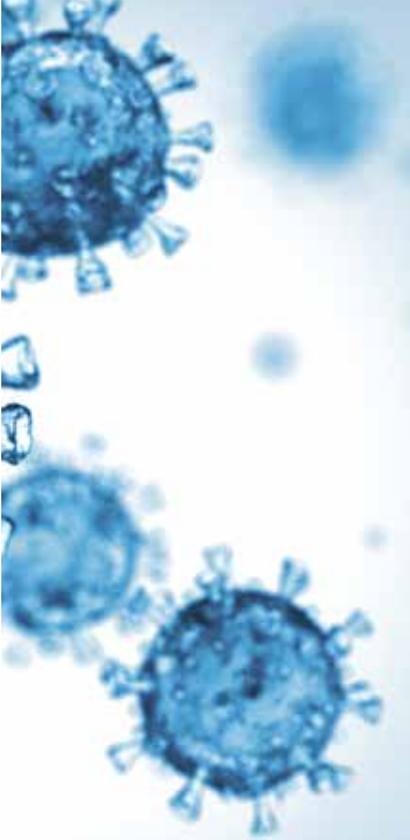
Saturday, May 22, 2021

June

Texas Virtual Walk for Sjögren's

Saturday, June 26, 2021

events.sjogrens.org



The Sjögren's Foundation Coronavirus/COVID-19 Resources and Vaccination Statement

The Sjögren's Foundation, in concert with our medical advisors, is continuously monitoring the COVID-19 outbreak and what the Foundation should be doing. The health and safety of our patients is our number one priority, and we aim to provide the support and guidance needed during this time.

The Foundation has established a COVID-19 Vaccination Committee made up of rheumatology and immunization experts. This committee is led by Dr. Alan Baer, a leading rheumatologist, chair of the Sjögren's Foundation's Medical and Scientific Advisory Council and Director of the Jerome L. Greene Sjögren's Syndrome Clinic at Johns Hopkins University.

We hope you will visit our website www.sjogrens.org to view all our COVID-19 resources, including patient support information, a document of frequently asked questions and our COVID-19 Vaccination Statement for Sjögren's patients.



Faces of Sjögren's Kristin's Story

When I first learned that Sjögren's Pulmonary Guidelines were being published, my first thought was, "Are these guidelines to help live with pulmonary complications or to recognize the symptoms of it? Either way, it will probably help a lot of people with Sjögren's."

I was diagnosed with Sjögren's when I was 24 and have been living with it for nearly ten years. I was under the impression that all of my symptoms were well managed until one day the persistent cough I'd had for almost a year turned bloody. It was weird; because academically, I knew Sjögren's could potentially impact my lungs but the focus had always been on managing my symptoms (dry eyes, dry mouth and arthritis) and I had never really discussed or thought about the progression to other parts of my body and how that could manifest. I wish I had been more aware of signs to look for.

I actually have two separate pulmonary complications linked to Sjögren's. The first is Lymphocytic Interstitial Pneumonitis (LIP) – basically it means I had some fibrosing tissue that formed cysts in my lungs, and it may have saved my life. The theory is that the coughing caused a cyst to break free which caused my bloody coughing fit. They showed up as small spots on my CT scan which prompted more scans and then a lung biopsy. During the biopsy the surgeon saw an area that looked "off" not related to the cysts and took a sample for good measure. It was Primary MALT Lymphoma and it had been caught

incredibly early. MALT lymphoma is a very rare variety of Non-Hodgkin's lymphoma, but the majority of people that get it also have Sjögren's. The lymphoma was actually the cause of the coughing, which had previously been dismissed by my primary physician as chronic allergies. If the cysts had not prompted my eventual biopsy, the lymphoma could have spread to multiple organs and become much more difficult to treat. I am, thankfully, in full remission.

The LIP actually has had a fairly significant impact on my life. I am an avid water sport enthusiast and lead a fairly active lifestyle. Due to the risk of a pulmonary embolism, I can no longer scuba dive and need to limit my depth to no more than about 9-10 feet. I also need to be very cognizant not to overexert myself when doing aerobic activities such as swimming, running, and hiking.

It is disappointing to no longer be able to do one of my favorite hobbies, but whenever I'm feeling particularly low, I remind myself that those same cysts served as an early warning system. Chest stretches and yoga breathing exercises before aerobic activity usually allow me to avoid serious impacts and complete most activities as I typically would. I've found that like most of my other Sjögren's symptoms, there is a learning curve to management and once you reach the top of that curve, management just becomes habit and the impact to your life decreases. I think the key is to listen to what my body is telling me; with some adjustments, I can still do everything I normally would. I just go about it slightly differently. ■



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Conquering Sjögren's

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If you would like to receive this newsletter but are not currently a Member, please contact us at (301) 530-4420

SAVE THE DATE

Virtual National Patient Conference

June 11-12, 2021

There is nothing more important to the Sjögren's Foundation than the health and safety of our patients, their families, volunteers and staff. Therefore, in light of the COVID-19 pandemic, the Foundation will, once again, deliver our annual National Patient Conference as a virtual/on-line event. You will experience the same valuable educational topics from leading Sjögren's experts but from the comfort of your own home and computer.

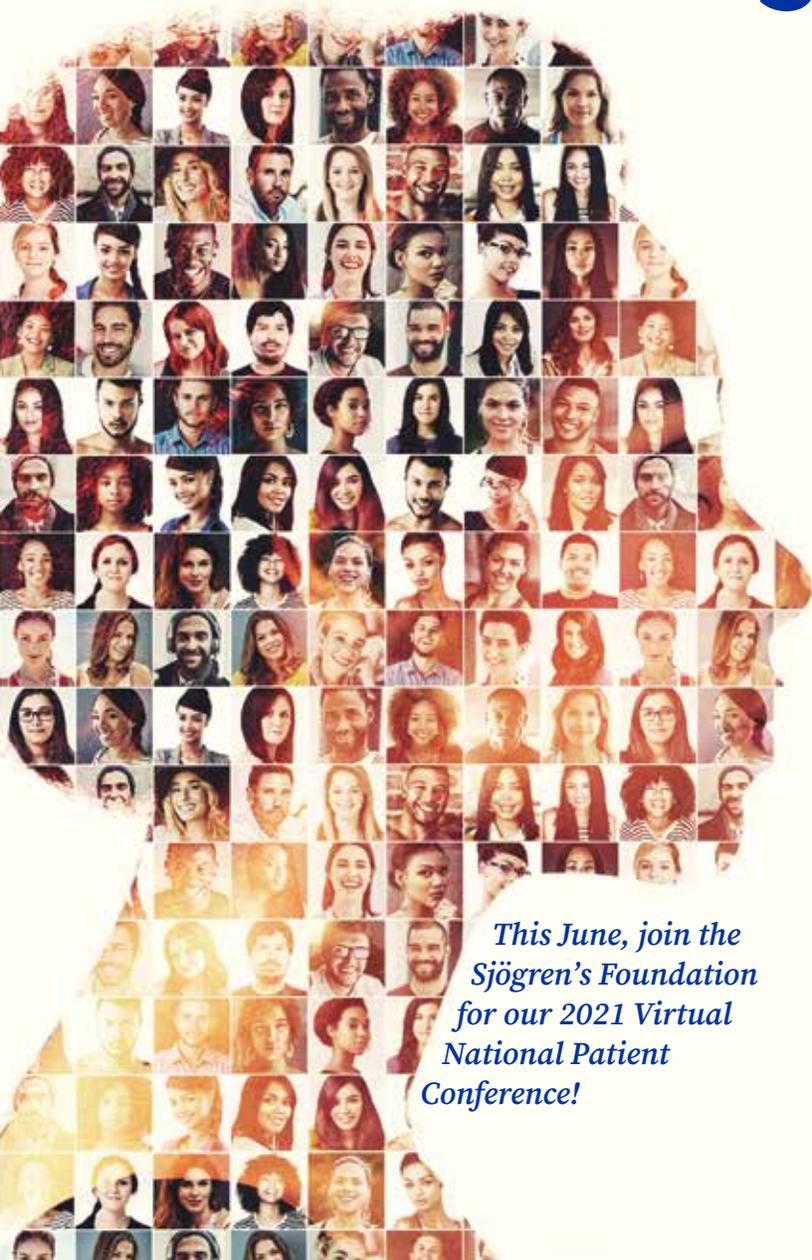
Sjögren's is not the same for every patient, which is why educating yourself is so important. This two-day educational experience will help you take control of your health while you learn how to manage and understand your Sjögren's symptoms and complications from leading Sjögren's experts.

We encourage you to take this opportunity to:

- Gain an understanding of all the key aspects of Sjögren's
- Learn from national Sjögren's experts and researchers

Watch for more exciting conference details...

in future issues of the *Conquering Sjögren's* newsletter and on the Foundation's website – www.sjogrens.org.



This June, join the Sjögren's Foundation for our 2021 Virtual National Patient Conference!