Vaccinations in patients with interstitial lung diseases: a narrative review

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Vaccination is a key preventive strategy in interstitial lung diseases, reducing infection-related morbidity, mortality and acute exacerbations. Improving coverage and tailored immunisation strategies are essential to protect this vulnerable population. https://bit.ly/4u6aFLh

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Abstract

Interstitial lung diseases (ILDs) comprise a heterogeneous group of lung disorders marked by progressive fibrosis and increased vulnerability to respiratory infections, which can trigger sudden outbreaks and worsen outcomes. Vaccination is a key preventive strategy in ILD patients to reduce infection-related morbidity and mortality. This review examines the importance of immunisation in individuals with ILDs, with particular emphasis on influenza, pneumococcal and severe acute respiratory syndrome coronavirus 2 vaccines endorsed by major health organisations. Despite evidence of their effectiveness, vaccination rates among patients with ILD remain low. Tailored vaccine strategies may enhance protection in this group. Additionally, although data are limited, immunisations against respiratory syncytial virus, *Haemophilus influenzae*, varicella-zoster virus, and pertussis may provide additional protection, particularly in older adults and those receiving immunosuppressive therapy. Hepatitis B vaccination should also be considered for patients on immunosuppressive therapies to prevent infection. Healthcare providers should actively encourage vaccination and address obstacles to immunisation in ILD patients. More research is necessary to assess the safety, effectiveness and optimal vaccination approaches for this vulnerable group. Ultimately, implementing systematic vaccination programmes and clear clinical guidelines is essential to improve preventive care and health outcomes for those with ILDs.

Introduction

Interstitial lung disease (ILD) includes a group of pulmonary parenchymal disorders that are classified together due to their shared clinical presentation, chest radiographic features, and physiological traits. The main categories of ILD include those associated with environmental exposures (*e.g.* hypersensitivity pneumonitis, pneumoconiosis), ILD secondary to connective tissue diseases (*e.g.* scleroderma, rheumatoid arthritis), sarcoidosis, and idiopathic interstitial pneumonias. Fibrotic interstitial lung diseases represent a subgroup of ILDs characterised by progressive scarring of the lung tissue, leading to a decline in lung function and frequently resulting in a poor prognosis [1–3].

Respiratory infections represent a major clinical concern for patients with ILD. In the general population, respiratory infections such as influenza, pneumococcal disease, and other viral lower respiratory tract infections are significant causes of morbidity and mortality, especially among older adults and those with chronic lung diseases [4, 5]. In ILD patients, particularly those with idiopathic pulmonary fibrosis (IPF), this risk is significantly increased. These individuals are more vulnerable to community-acquired pneumonia and opportunistic infections because of immunosuppressive treatments such as corticosteroids, mycophenolate mofetil, azathioprine or rituximab, which further suppress their immune response.

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Importantly, infections are not only a cause of severe pneumonia, but also a recognised trigger for acute exacerbations of ILD. These events are characterised by sudden, clinically significant respiratory deterioration accompanied by new bilateral ground-glass opacities or consolidations seen on chest imaging, which cannot be fully explained by cardiac failure or fluid overload. Such events are associated with a poor prognosis and limited treatment options [6].

Respiratory infections are well-recognised drivers of disease worsening and are associated with increased rates of hospitalisation and mortality in ILD [7]. In this context, vaccination may play a key role not only in preventing infections, but also in influencing disease trajectories by reducing infection-related exacerbations and their downstream clinical consequences.

In light of these considerations, prevention of respiratory infections through vaccination is essential in ILD management [8, 9]. Vaccination serves as a key preventive strategy for ILD patients, aimed at lowering the risk of severe infections that could accelerate disease progression or lead to life-threatening complications.

This review aims to examine the role of vaccination in patients with fibrotic ILD and to underscore the importance of immunisation in the prevention of infectious complications.

Material and methods

A search of relevant medical literature in the English language was conducted for this narrative review in MEDLINE/PubMed, Embase and Scopus, covering articles published up to December 2025, including observational, interventional studies, reviews and guidelines. Keywords used to perform the research are reported in table 1. Editorials, conference abstracts, case reports, smaller case series, and preprint publications were excluded. Relevant abstracts and articles were searched and screened independently by seven authors (G. Franco, U. Zanini, G. Peri, S. Promi, S.M. Mazzotta, I. Galbardi, P. Faverio).

In cases of disagreement, the articles were collectively reviewed, with consideration of their relevance, strengths and limitations. Articles in other languages with abstracts in English were also reviewed if sufficient detail was present in the abstract. A summary of the studies is presented in table 2.

Immunological considerations in ILD

Among the various factors contributing to ILD pathogenesis and progression, immune system dysfunction plays a critical role. ILD may arise from both autoimmune and non-autoimmune mechanisms, with immune dysregulation representing a central feature in many forms of the disease.

Importantly, ILD represents a heterogeneous group of conditions, and vaccine response may vary across different subtypes. Patients with idiopathic pulmonary fibrosis (IPF) may retain a relatively preserved vaccine response compared with patients with systemic autoimmune rheumatic disease-associated ILD or progressive pulmonary fibrosis receiving immunosuppressive therapies. In these latter groups, both the degree and type of immunosuppression may significantly influence vaccine immunogenicity and should be considered when planning vaccination strategies, including timing in relation to treatment initiation.

IPF is a chronic, progressive fibrosing interstitial lung disease in which both innate and adaptive immune processes are involved. Although IPF is primarily considered a fibroproliferative rather than an inflammatory disease, immune responses contribute significantly to its progression. Pro-inflammatory alveolar macrophages, neutrophils and T-lymphocytes promote the release of pro-fibrotic cytokines such as transforming growth factor-β, interleukin-6, platelet-derived growth factor and tumour necrosis factor (TNF)-α, thereby driving myofibroblast differentiation and promoting fibrotic lung remodelling [18–20].

TABLE 1 Keywords used to perform the research

interstitial lung diseases (OR ILD OR diffuse parenchymal lung diseases OR IPF) AND vaccination, interstitial lung diseases (OR ILD OR diffuse parenchymal lung diseases OR IPF) AND influenza vaccine, interstitial lung diseases (OR ILD OR diffuse parenchymal lung diseases OR IPF) AND pneumococcal vaccination, interstitial lung diseases (OR ILD OR diffuse parenchymal lung diseases OR IPF) AND SARS-CoV-2 vaccination, interstitial lung diseases (OR ILD OR diffuse parenchymal lung diseases OR IPF) AND RSV vaccination

ILD: interstitial lung disease; IPF: idiopathic pulmonary fibrosis; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2; RSV: respiratory syncytial virus.

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TABLE 2 Summary of key clinical studies evaluating the effectiveness, safety, and immunogenicity of influenza, pneumococcal, and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines in patients with interstitial lung diseases (ILDs)

Vaccine, first author, year [ref.]	Aim	Design	Study groups	Results
Influenza				
Li, 2021 [10]	To evaluate risk factors for mortality in hospitalised ILD patients with viral infections	Retrospective cohort study conducted across two tertiary academic hospitals, China	282 patients with ILD (42.9% IPF)	The 30-day mortality rate was 20.6%. Patients with non-influenza virus infections had higher mortality than those with influenza, probably due to the efficacy of available anti-influenza drugs like oseltamivir.
Marijic, 2022 [11]	To compare all-cause mortality and hospitalisation between vaccinated and unvaccinated ILD patients	Multicentric epidemiological analysis of German statutory health insurance (Allgemeine Ortskrankenkasse) data across four influenza seasons (2014–2018)	87 477 patients with ILD	Vaccination showed a protective effect on mortality in two out of the four seasons (2014–2015 and 2015–2016). No significant differences were found regarding hospitalisation rates.
Tavana, 2012 [12]	To evaluate the safety and immunogenicity of the influenza vaccine specifically in patients with pulmonary sarcoidosis	Case–control clinical trial at a single medical centre, Iran	23 patients with sarcoidosis *versus* 26 healthy controls	Serological response was comparable between patients and healthy controls. No major adverse events or disease flare-ups were observed during the 6-month follow-up.
Mohr, 2020 [13]	To analyse the use of and adherence to influenza and pneumococcal vaccines in high-risk patients with chronic pulmonary diseases (COPD, asthma and ILD)	Prospective, single-centre study, Germany	637 total patients, 104 with ILD	Vaccination rates were low, remaining below 30%. Vaccinations were performed almost exclusively by general practitioners (>90%), while specialists rarely evaluated vaccination status (<15%).
Pneumococcal				
Oda, 2018 [14]	To examine the impact of respiratory comorbidities (such as bacterial pneumonia) on mortality in hospitalised IPF patients.	Multicentric retrospective study using a Japanese nationwide database	5665 hospitalised patients diagnosed with IPF	Bacterial pneumonia occurred in 9.5% of patients, with *S. pneumoniae* identified as the most common pathogen (31.6%). Pneumonia significantly increased 30-day mortality (HR 1.30), highlighting vaccination as a vital preventive strategy.
Kuronuma, 2018 [15]	To examine the immunogenicity of pneumococcal vaccines in ILD patients undergoing immunosuppressive treatment	Open-label, single-centre study, Japan	126 ILD patients (including IPF, CVD-IP, and IIPs) and 93 healthy controls	IgG concentrations increased in all groups. However, IPF patients on immunosuppressive therapy showed a significantly lower response compared to those not on such therapy. The vaccines were confirmed to be safe, with no acute exacerbations of ILD reported.
SARS-CoV-2				
Inanc, 2022 [16]	To investigate the safety and efficacy of SARS-CoV-2 vaccination specifically in patients with primary Sjögren syndrome	International, multicentre study (Sjögren Big Data Consortium) using electronic questionnaires	1237 patients with Sjögren ILD	Adequate humoral response was detected in 95% of patients. Adverse events were mostly mild to moderate (67%), and breakthrough infections were rare (0.24%). Systemic disease flares were very rare (1.2%).
Gallay, 2021 [17]	Compare COVID-19 mortality across different ILD types	Multicentric observational survey (OrphaLung network)	123 patients with ILD	Fibrotic ILD mortality (35%) confirms these patients are a priority group for targeted preventive vaccination

The table details study aims, designs, populations, and primary outcomes, emphasising the impact of vaccination on mortality, hospitalisation, immunogenicity, and safety across different ILD subtypes. IPF: idiopathic pulmonary fibrosis; *S. pneumoniae*: *Streptococcus pneumoniae*; HR: hazard ratio; CVD-IP: connective tissue and vascular disease-related interstitial pneumonia; IIP: idiopathic interstitial pneumonia.

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Autoimmune-related ILDs, such as those associated with systemic sclerosis, Sjögren disease or rheumatoid arthritis, are characterised by abnormal activation of the adaptive immune system, including autoreactive T-cells and B-cell hyperactivity, leading to chronic inflammation and tissue remodelling [21, 22].

Many patients with ILD, particularly those with sarcoidosis (10–30%) [23], autoimmune-related ILD (50–70%) [24, 25], and hypersensitivity pneumonitis (~70%) [26, 27], are treated with immunosuppressive therapies aimed at controlling inflammation and limiting disease progression. These treatments include corticosteroids, mycophenolate mofetil, azathioprine, anti-TNF antibodies, rituximab, and other disease-modifying antirheumatic drugs. However, these treatments may impair the immune system's ability to mount an effective response to vaccination [15]. Studies have shown that patients with ILD undergoing immunosuppressive treatment may exhibit reduced seroconversion rates and lower antibody titres [15, 28]. Vaccine efficacy is significantly influenced by both the degree of immunosuppression and the specific agent used. High-dose glucocorticoids (prednisone >20 $mg \cdot day^{-1}$) are associated with reduced antibody titres and seropositivity, while lower doses (<7 $mg \cdot day^{-1}$) generally preserve vaccine responsiveness [29]. B-cell-depleting therapies (anti-CD20, anti-CD19, anti-CD38) are associated with the most profound and prolonged impairment of vaccine responses, particularly for inactivated and mRNA vaccines. Other agents, such as antimetabolites (*e.g.* mycophenolate), CTLA4 agonists, and JAK inhibitors, also reduce immunogenicity, although typically to a lesser extent [30–32]. These findings underscore the need for tailored immunisation strategies, including booster doses, adjuvanted or high-dose vaccines, and alternative vaccination schedules, to enhance immune responses in this high-risk population. High-dose influenza vaccines and adjuvanted formulations have demonstrated improved immunogenicity in immunocompromised hosts, including transplant recipients and those with autoimmune diseases [33]. For COVID-19, the World Health Organization (WHO) and other expert groups recommend an extended primary series (comprising an additional dose beyond the standard two-dose regimen) and at least two booster doses for all immunocompromised patients, regardless of age, to achieve adequate protection [34]. Further large-scale randomised controlled trials are needed to define the optimal use of high-dose and adjuvanted vaccines, as well as alternative schedules, in diverse immunocompromised populations. In addition, antifibrotic therapies such as nintedanib and pirfenidone have not been specifically evaluated in relation to vaccine immunogenicity, and currently no data are available; this evidence gap should be acknowledged and warrants further investigation.

Vaccination strategies should integrate both individual risk factors and the seasonal epidemiology of respiratory viruses. Immunisation is ideally administered prior to periods of peak viral circulation, typically in autumn and early winter in temperate regions in the northern hemisphere, in accordance with national vaccination programmes, to maximise protective efficacy.

In clinical practice, tailored strategies should be implemented based on the degree of immunosuppression and local healthcare resources. For patients with severe immunosuppression, especially those receiving B-cell-depleting agents, combination immunosuppressive regimens, or with suspected impaired vaccine responsiveness, vaccination planning could benefit from a multidisciplinary approach involving pulmonologists, treating specialists, and dedicated vaccination, infectious diseases, or clinical immunology services, when available.

Influenza vaccine

Influenza remains a major public health concern and is associated with an increased risk of hospitalisation and death, especially among high-risk groups based on their underlying health conditions [35–37]. Globally, seasonal influenza is estimated to cause 3–5 million cases of severe illness and between 290 000 and 650 000 respiratory deaths each year, according to WHO estimates [38]. In the United States of America alone, data from the US Centers for Disease Control and Prevention (CDC) indicate that influenza has accounted for 9–41 million illnesses, between 140 000 and 710 000 hospitalisations, and 12 000 to 52 000 deaths per year over the past decade, with the greatest burden observed among older adults and individuals with underlying cardiopulmonary conditions [39].

Patients affected by ILD, especially those with IPF, are at increased risk of severe influenza-related complications, including acute exacerbations, respiratory failure, and increased mortality. In a retrospective study, Li *et al.* [10] analysed 282 patients with ILD (42.9% with IPF and 36.9% with connective tissue diseases-ILD) who were hospitalised for acute exacerbation and viral respiratory infections at two tertiary academic hospitals in China between 1 January 2013 and 31 December 2019, reporting a 30-day mortality rate of 20.6% among this population. During the influenza season (November, December, January, February), immunocompromised patients predominantly exhibited influenza virus (25.7%), respiratory

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syncytial virus (RSV) (14.9%) and cytomegalovirus, whereas among immunocompetent patients, influenza virus was markedly more prevalent (44.8%), followed by RSV (11.5%) and human rhinovirus (9.2%).

Beyond preventing infection, influenza vaccination may have a clinically relevant impact on ILD-specific outcomes by reducing the risk of infection-triggered acute exacerbations and related hospitalisation, which are key drivers of disease progression and mortality.

The continuous antigenic evolution of influenza viruses requires ongoing global surveillance and periodic reformulation of seasonal vaccines. The WHO convenes technical consultations in February and September each year to recommend the viral strains to be included in seasonal influenza vaccines for the northern and southern hemispheres, respectively. The annual influenza vaccine is typically quadrivalent, containing antigens from two influenza A subtypes (H1N1 and H3N2) and two influenza B lineages (Victoria and Yamagata). Several types of influenza vaccines are currently available and approved for use in adults [40]. Inactivated influenza vaccines are the most widely used in clinical practice, particularly among high-risk populations. Based on the manufacturing process, they are further classified as split-virus or subunit formulations. Another option is represented by recombinant influenza vaccines, which are produced using recombinant DNA technology in a baculovirus expression system [41]. Lastly, live-attenuated influenza vaccines, which contain weakened live virus, are administered intranasally and are primarily used in paediatric populations. However, they are contraindicated in immunocompromised individuals due to the theoretical risk of vaccine-related infection [42].

Vaccination rates remain suboptimal among patients with ILD. Mohr *et al*. [13] reported that, in a single-centre study conducted in southeast Germany, vaccination rates were <30% during the 2016–2017 to 2019–2020 seasons. In a retrospective study, Marijic *et al.* [11] compared influenza-vaccinated and unvaccinated patients with ILD across four influenza seasons from 2014–2015 to 2017–2018. The impact of vaccination varied, with significant reductions in all-cause mortality observed in 2014–2015 (risk ratio 0.79, 95% CI 0.65–0.97; p=0.02) and 2015–2016 (risk ratio 0.66, 95% CI 0.54–0.80; p=0.001) and a trend toward a lower risk of hospitalisation in those seasons, underlining the clinical relevance of vaccination.

In a prospective case–control study, Tavana *et al*. [12] evaluated the immunogenicity and safety of seasonal influenza vaccination in 23 patients with pulmonary sarcoidosis. In this study, serological responses to influenza A (H1N1, H3N2) and influenza B antigens were comparable between sarcoidosis patients and healthy controls, with no major adverse events or disease flare-ups observed during the 6-month follow-up period.

According to the WHO, all individuals with chronic pulmonary diseases should receive annual influenza vaccination [43], including those with ILD. Due to chronic damage to lung tissue in ILD, even a mild viral infection such as influenza may precipitate a significant respiratory decline or trigger an acute exacerbation [44, 45]. The European Alliance of Associations for Rheumatology (EULAR) strongly recommends that influenza vaccination should be considered for patients with autoimmune inflammatory rheumatic diseases [46]. Although the 2022 guideline from the American Thoracic Society, European Respiratory Society (ERS), Japanese Respiratory Society, and Latin American Thoracic Association does not include a formal graded recommendation regarding vaccination [47], the medical literature consistently supports these vaccines as part of supportive care for IPF [48, 49]. Therefore, yearly vaccination is strongly recommended for patients with ILD.

Pneumococcal vaccine

Streptococcus pneumoniae (pneumococcus) is a pathogen responsible for a broad spectrum of diseases, ranging from noninvasive infections such as otitis media and sinusitis to severe invasive diseases including pneumonia, meningitis and bacteraemia. Pneumococcal pneumonia remains one of the leading causes of community-acquired pneumonia worldwide. In adults, pneumococcal infections represent a major cause of hospitalisation and mortality, particularly among individuals aged ⩾65 years and those with underlying comorbidities. Specifically, adults with chronic lung diseases, including COPD, have been shown to have a higher risk of developing pneumococcal pneumonia compared with age-matched healthy individuals [50–52]. In a study by Oda *et al*. [14], involving 5665 hospitalised patients with IPF from April 2010 to March 2013, bacterial pneumonia was identified in ∼9.5% of cases. *S. pneumoniae* was the most frequently isolated pathogen, accounting for 31.6% of bacterial infections. Importantly, bacterial pneumonia was associated with a significantly increased risk of 30-day in-hospital mortality (hazard ratio 1.30, 95% CI 1.04–1.63; p=0.023), and this association remained unchanged after adjustment for age and sex [14].

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Given the association between bacterial pneumonia and adverse outcomes in ILD, pneumococcal vaccination may contribute to improved clinical outcomes by reducing infection-related exacerbations, hospitalisation and mortality. According to the Advisory Committee on Immunization Practices (ACIP) of the US CDC, vaccination is recommended for all adults aged ⩾50 years and for individuals with predisposing chronic medical conditions, such as chronic lung disease, immunocompromising conditions, functional or anatomic asplenia and conditions associated with an increased risk of meningitis [53]. Pneumococcal vaccines are divided into 23-valent pneumococcal polysaccharide vaccine (PPSV23) and pneumococcal conjugate vaccines (PCV) [53, 54]. PPSV23 contains 23 purified capsular polysaccharides from serotypes that are historically common in adults, although many of these have been progressively replaced by higher-valent conjugate vaccines [54]. Conjugate vaccines (PCV13, PCV15, PCV20, PCV21) chemically link these polysaccharides to a protein, thereby stimulating stronger immunological memory and mucosal immunity. This mechanism reduces nasopharyngeal colonisation, provides herd protection, and ultimately influences the distribution of circulating serotypes [53].

Pneumococcal vaccination strategies have evolved considerably in recent years, with a shift toward simplified approaches based on higher-valent conjugate vaccines. The ACIP recommends a single dose of PCV20 (or PCV21, where available) or a sequential strategy with PCV15 followed by PPSV23, which have largely replaced earlier PCV13-based schedules in many settings. For most adults, administration of PCV21, when available, is preferred as it provides broader coverage of serotypes that predominantly affect adults and offers the simplicity and lower cost of a single-dose regimen. If PCV21 is unavailable, the patient should receive PCV20 (or PCV15 followed by PPSV23) [53]. Additionally, in patients at high risk (*e.g.* immunocompromised individuals, presence of a cochlear implant or cerebrospinal fluid leak), PPSV23 should be administered ⩾8 weeks after PCV20 to extend protection against serotypes included in but not covered by PCV20 (serotypes 9N, 20, 17F) [53]. While higher-valent conjugate vaccines are under development, these remain investigational and are not yet part of routine clinical practice.

Pneumococcal vaccination is recommended by ERS/EULAR guidelines for patients with connective tissue disease-associated ILD, especially those receiving immunosuppressive treatments, who are at increased risk of pneumococcal disease. Immunosuppressive therapy may attenuate vaccine-induced immune responses, as demonstrated in studies in which ILD patients receiving such treatments had lower serotype-specific IgG responses to pneumococcal vaccine [55]. A study by Kuronuma *et al*. [15] found that PCV13 and PPSV23 significantly increased serotype-specific immunoglobulin (Ig)G concentrations in patients with ILD, including those undergoing corticosteroid therapy. Furthermore, a study by Mohr *et al*. [13] revealed that adherence to pneumococcal vaccination among ILD patients remains suboptimal, with <10% receiving PCV13 and only 33% receiving PPSV23. Additionally, sequential vaccination was performed in only 13.5% of ILD patients.

Overall, pneumococcal vaccination plays a critical role in the management of patients with fibrotic ILD, as it reduces the incidence and severity of pneumococcal infections, which can cause significant morbidity and may exacerbate the underlying lung condition. Despite its benefits, vaccine immunogenicity may be attenuated in individuals receiving immunosuppressive therapies commonly used to treat specific ILD subtypes. This reduced immune response highlights the importance of the need for timely vaccination, ideally before the initiation of immunosuppressive treatment. Furthermore, improving vaccination coverage and adherence within this vulnerable population is essential. It should be a pivotal goal of clinical care strategies that involve patient education and the systematic implementation of preventive measures.

SARS-CoV-2 vaccination

COVID-19 is an infectious illness caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Vaccination against SARS-CoV-2 has played a crucial role in mitigating the global impact of the pandemic, substantially reducing the incidence of severe disease, hospitalisations and deaths. Although the World Health Organization officially declared the end of the pandemic phase on 5 May 2023, COVID-19 continues to pose a significant burden of morbidity and mortality, particularly among vulnerable populations. Patients with ILD are particularly at risk, as they often have compromised respiratory function and a increased susceptibility to severe complications following SARS-CoV-2 infection. During the COVID-19 pandemic, mortality among patients with ILD increased significantly [56–60]. An international multicentre study involving 185 patients with ILD who were diagnosed with COVID-19 demonstrated a significantly increased risk of death when hospitalised, particularly those with impaired baseline lung function or obesity [61]. Similarly, a study of 123 French ILD patients identified several factors significantly associated with increased mortality, including male sex, advanced age, a diagnosis of fibrotic idiopathic ILD compared to other ILD subtypes, and the presence of comorbidities such as hypertension, cardiovascular disease, cancer or haematological malignancy, and pulmonary

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hypertension. In addition, lower forced vital capacity, reduced diffusing capacity for carbon monoxide, chronic use of supplemental oxygen (at rest or during exertion), and treatment with antifibrotic agents were also associated with poorer outcome [17].

These findings underscore the need for targeted preventive strategies in this high-risk population, with vaccination representing a central intervention. The updated COVID-19 vaccines for the 2024–2025 season, including Comirnaty (Pfizer-BioNTech) mRNA, Spikevax (Moderna) mRNA and Nuvaxovid (Novavax) recombinant protein formulations, have been specifically designed to target a SARS-CoV-2 subvariant [62, 63].

SARS-CoV-2 vaccination is recommended for all individuals, with priority given to older adults, immunocompromised patients, pregnant women, healthcare workers and individuals with chronic diseases. Among these groups, patients with chronic respiratory diseases (such as ILD) require particular attention due to their increased susceptibility to severe COVID-19-related complications [64].

Multiple studies have demonstrated that, despite the rapid development and global approval of various vaccine candidates, SARS-CoV-2 vaccination has consistently and effectively reduced infection rates, disease severity, hospitalisations and mortality (including among individuals with underlying respiratory conditions) since the beginning of the vaccination campaigns [65].

However, despite broad vaccination coverage, immunocompromised patients, including many individuals with ILD, especially those receiving immunosuppressive treatment, may mount a suboptimal immune response to the vaccine. In cases of marked immunosuppression, administration of more than one vaccine dose per year (ideally at intervals of ∼6 months) may be considered, rather than relying on a single annual dose [66].

Despite the undeniable efficacy of COVID-19 vaccination, some studies have reported cases of acute exacerbation temporally associated with recent vaccination. This finding raises the possibility that, in susceptible individuals, vaccine-induced immune activation may trigger pathobiological cascades culminating in disease exacerbation [67–69], although the small number of reported cases in this study may reflect a random association.

In conclusion, SARS-CoV-2 vaccination has been highly effective in reducing infection rates, disease severity, hospitalisations, and mortality. Nevertheless, updated vaccination strategies, such as the use of variant-adapted vaccines and more frequent dosing in immunocompromised individuals, are essential to optimise protection in this high-risk population. Although rare, reports of acute exacerbations temporally associated with vaccination highlight the need for continued vigilance, further research, and a personalised approach in the management of vulnerable populations.

Other vaccines

Patients with ILD represent an ageing and highly vulnerable population, often affected by multiple comorbidities and progressive respiratory impairment. Advanced age and the common use of immunosuppressive or antifibrotic therapies further increase their susceptibility to severe complications from respiratory infections.

The level of evidence supporting vaccination in patients with ILD varies considerably by pathogen. While robust clinical data and international guidelines support recommendations for influenza, pneumococcal and SARS-CoV-2 vaccines, direct evidence for several other vaccines remains limited. Although no specific studies have evaluated the effectiveness of vaccination against RSV, varicella-zoster virus (VZV) or pertussis in this patient population, immunisation may represent a key preventive strategy to protect these patients from such infections and, consequently, reduce the risk of severe disease, hospitalisation and mortality. Accordingly, the following considerations are based on extrapolation from studies conducted in other high-risk populations and should be interpreted as expert opinion rather than formal evidence-based recommendations.

RSV is a single-stranded RNA virus belonging to the Paramyxoviridae family, primarily known for causing bronchiolitis and pneumonia in infants and children aged <5 years. However, in recent years, RSV has increasingly been acknowledged as an important pathogen in adults, particularly in elderly individuals and those with underlying comorbidities [70]. The burden of RSV in older adults is significant. In 2015, an estimated 336 000 hospitalisations for RSV-associated acute respiratory infections occurred worldwide among individuals aged ⩾65 years [71]. A recent modelling study in high-income countries estimated a

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hospitalisation rate of 347 per 100 000 in this age group with an in-hospital mortality rate of 6.1% [72]. As observed in paediatric populations, adults with underlying health conditions are at increased risk of severe RSV disease. A population-based prospective study conducted in the United States of America showed that individuals with COPD, asthma, diabetes, coronary artery disease, or congestive heart failure had significantly higher rates of RSV-related hospitalisation compared to those without these comorbidities [73]. In recent years, several vaccines have been developed and approved to prevent RSV infection [74]. Currently, three vaccines are approved in multiple countries. The first RSV vaccine was RSVPreF3 (Arexvy; GlaxoSmithKline), an adjuvanted recombinant prefusion F-protein vaccine, approved by the US Food and Drug Administration (FDA) for the prevention of acute respiratory infections in subjects aged >60 years on 23 May 2023 and by the European Medicines Agency (EMA) in June 2023 [75]. The second RSV vaccine, RSVpreF (Abrysvo; Pfizer), a bivalent prefusion F-protein vaccine was approved by the FDA on 31 May 2023 for the prevention of RSV-lower respiratory tract disease (LRTD) in adults aged ⩾60 years, and on 21 August 2023 for pregnant subjects to confer passive protection of infants from birth to 6 months of age against RSV-LRTD and severe RSV-LRTD [76]. Most recently, mRNA-1345 (mRESVIA; Moderna), an mRNA-based vaccine encoding the membrane-anchored RSV-A prefusion F protein encapsulated in a lipid nanoparticle, was approved by the FDA in May 2024 and by the EMA in August 2024 for the prevention of RSV-related disease in adults aged ⩾60 years [77]. The US CDC recommends RSV vaccination for all adults aged ⩾75 years, and for those aged 60–74 years with conditions such as chronic heart or lung disease, immunosuppression, other serious medical conditions, or residence in long-term care facilities, all of which increase the risk of severe RSV disease [78].

Haemophilus influenzae is a Gram-negative coccobacillus that can cause a wide spectrum of diseases, particularly in children, ranging from mild respiratory tract infections, such as otitis media and sinusitis, to severe invasive conditions, including meningitis, sepsis, pneumonia and epiglottitis [79]. The species *H. influenzae* comprises encapsulated strains (a–f) and noncapsulated strains commonly referred to as non-typeable (NTHi) [80]. Among the six known serotypes, serotype b (Hib) is responsible for 95% of all invasive diseases caused by *H. influenzae* [81]. To prevent *H. influenzae* infections, an effective conjugate vaccine has been developed, consisting of the capsular polysaccharide conjugated to a protein carrier to enhance immunogenicity in young children. According to the CDC-recommended schedule, the primary series is administered at 2, 4 and 6 months of age, followed by a booster dose at 12–15 months [82]. Routine Hib vaccination is not recommended for individuals aged ⩾5 years, unless they are unvaccinated and have specific medical conditions such as anatomic or functional asplenia, immunodeficiency or have a history of a haematopoietic stem cell transplantation, in which case vaccination is advised regardless of prior immunisation status [82]. In countries with high vaccine coverage, routine immunisation of infants with Hib conjugated vaccines has dramatically decreased the incidence of invasive Hib disease [83]. However, despite the efficacy of Hib conjugate vaccines, invasive disease caused by non-vaccine-preventable *H. influenzae* strains continues to occur [84]. The introduction of pneumococcal conjugate vaccines has altered the ecology of nasopharyngeal colonising pathogens, leading to an increased prevalence of NTHi. Localised infections in which *H. influenzae* plays a significant role, such as acute exacerbations of COPD in adults, are almost exclusively associated with NTHi isolates [85]. Currently, no vaccine is available against NTHi, primarily due to the genetic heterogeneity of circulating strains and the difficulty in identifying immunogenic antigens using conventional approaches, although several vaccine candidates are under active investigation [85].

VZV, a human herpesvirus, is responsible for varicella (primary infection) and for herpes zoster upon reactivation from latency in sensory ganglia. Herpes zoster leads to painful dermatomal rash and may cause post-herpetic neuralgia, especially in older adults and immunocompromised individuals [86]. >95% of immunocompetent individuals aged ⩾50 years are seropositive for VZV and are therefore at risk of developing herpes zoster [87]. VZV-specific cell-mediated immunity declines with advancing age, coinciding with the sharp increase in herpes zoster incidence and related complications observed from around the age of 50 years. The lifetime risk of developing herpes zoster is estimated at 25–30%, rising to ∼50% in individuals aged ⩾80 years [88]. The overall incidence of herpes zoster is estimated at 3.4–4.82 cases per 1000 person-years in the general population, increasing to >11 cases per 1000 person-years in adults aged ⩾80 years [89]. Herpes zoster incidence is markedly higher in immunocompromised populations. The highest rates are observed in patients undergoing bone marrow or stem cell transplantation, followed by those with solid organ transplants, HIV infection, and systemic lupus erythematosus. Additionally, individuals receiving immunosuppressive therapies or chemotherapy exhibit significantly higher rates of herpes zoster compared to those not on such treatments [89]. Currently, two vaccines are approved for herpes zoster prevention [90]. The live-attenuated VZV-vaccine (Zostavax; Merck) [91] is indicated for adults aged ⩾50 years, but is contraindicated in immunocompromised individuals due to the risk of viral reactivation. Zostavax has been removed from the adult immunisation

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schedule in the United States of America since 2021, and is no longer available in the United States due to its lower and waning efficacy over time compared to the newer recombinant zoster vaccine, as well as safety concerns associated with its use in immunocompromised individuals; however, it remains available in many other countries. The adjuvanted VZV glycoprotein E (gE) subunit vaccine (recombinant zoster vaccine, Shingrix; GlaxoSmithKline) [92] has demonstrated >90% efficacy in preventing herpes zoster and post-herpetic neuralgia, with proven safety in immunocompromised patients. The CDC recommend Shingrix for all adults aged ⩾50 years, administered as a two-dose series spaced 2–6 months apart. Additionally, Shingrix is recommended for adults aged ⩾19 years who are immunocompromised due to disease or therapy, with the second dose administered 1–2 months after the first if necessary [93].

Pertussis, commonly known as whooping cough, is a highly contagious respiratory disease caused by *Bordetella pertussis*, a Gram-negative bacterium that adheres to the respiratory epithelium and produces toxins leading to airway inflammation and mucosal damage [94]. Although traditionally considered a childhood illness, pertussis affects individuals of all ages, particularly adolescents and adults with waning immunity [95]. Globally, pertussis continues to cause significant morbidity. The WHO estimates that there were ∼151 000 cases of pertussis worldwide in 2018, although the true incidence is probably underestimated due to underreporting and diagnostic challenges in adults [96]. In this population, pertussis typically presents as a prolonged cough lasting several weeks, but it can cause severe complications, particularly in individuals with pre-existing lung disease. Patients with chronic respiratory diseases, including those with ILD, are particularly vulnerable to pertussis-related complications. Although specific epidemiological data in ILD patients are limited, pertussis infection in individuals with chronic lung diseases such as asthma and COPD has been associated with disease exacerbations, increased hospitalisation rates, and impaired lung function recovery [97, 98]. At present, there are no data demonstrating that pertussis directly exacerbates ILD, particularly IPF, although this hypothesis warrants further investigation. Currently, acellular pertussis vaccines combined with tetanus and diphtheria toxoids are widely used. The CDC recommends pertussis vaccination for infants, children, adolescents, pregnant women, and adults. Infants require a primary series of three doses of DTaP (diphtheria, tetanus and acellular pertussis) to develop strong protection against whooping cough. These doses are recommended at 2, 4 and 6 months of age. To maintain this protection during early childhood, two additional DTaP booster doses are advised at 15–18 months and again at 4–6 years of age. Adolescents should receive a single booster dose of Tdap (tetanus, diphtheria, and acellular pertussis) at 11 or 12 years of age to reinforce their immunity. For adults, a booster dose of either Td (tetanus and diphtheria) or Tdap is recommended every 10 years to maintain protection against tetanus and diphtheria; Tdap is preferred for individuals who have not previously received it. Additionally, Tdap vaccination is specifically recommended during each pregnancy, preferably between 27 and 36 weeks of gestation, to protect both the mother and the newborn through passive antibody transfer [99].

Given the high prevalence of immunosuppressive therapy among patients with ILD, ensuring protection against the hepatitis B virus (HBV) is also crucial. HBV reactivation is a well-recognised risk in individuals receiving immunosuppressive treatments, including corticosteroids and certain biological agents, potentially leading to severe hepatitis and liver failure [100, 101]. For this reason, the European Association for the Study of the Liver recommends HBV screening for all individuals being considered for or undergoing immunosuppressive or immunomodulatory therapy. In patients without evidence of prior immunity, vaccination against HBV should be strongly considered to prevent infection and reduce the risk of HBV reactivation during treatment [102]. A three-dose series of recombinant HBV vaccine (at 0, 1 and 6 months) is generally recommended, with post-vaccination serological testing to confirm protective antibody levels [102].

Conclusions and future perspectives

Vaccination represents a cornerstone in the prevention of respiratory infections and disease exacerbations in patients with ILDs.

Immunisation against influenza, pneumococcus and SARS-CoV-2 has demonstrated significant benefits in reducing morbidity and mortality, although immunosuppressive therapies may attenuate vaccine-induced immune responses (figure 1 and table 3). Despite strong recommendations, vaccination coverage among patients with ILD remains suboptimal, underscoring the need for targeted educational initiatives and structured strategies.

Despite the absence of specific data for patients with ILD, vaccination against respiratory syncytial virus, *H. influenzae*, VZV and pertussis should also be considered in this population, as prevention of these

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infections may reduce the risk of severe respiratory complications. Future studies are needed to assess the efficacy and safety of these vaccines in ILD populations.

Several barriers contribute to the low vaccination uptake in patients with ILD, including limited awareness among healthcare providers, fragmented care pathways, and uncertainty about vaccination responsibility among specialists. Patient-related factors, such as vaccine hesitancy and underestimation of infection risk, also play a role. To address these issues, targeted strategies are needed, such as enhancing physician education, promoting multidisciplinary collaboration, and establishing clear vaccination pathways. Implementing structured vaccination programmes and reminder systems within routine ILD care can improve vaccine uptake and clinical outcomes in this high-risk population.

Clinicians should adopt a more proactive role in promoting vaccination, ensuring that ILD patients are prioritised for access to vaccines, including through dedicated vaccination programmes. Furthermore, clinical guidelines should explicitly recommend vaccination in this vulnerable population in order to standardise preventive care and improve overall outcomes.

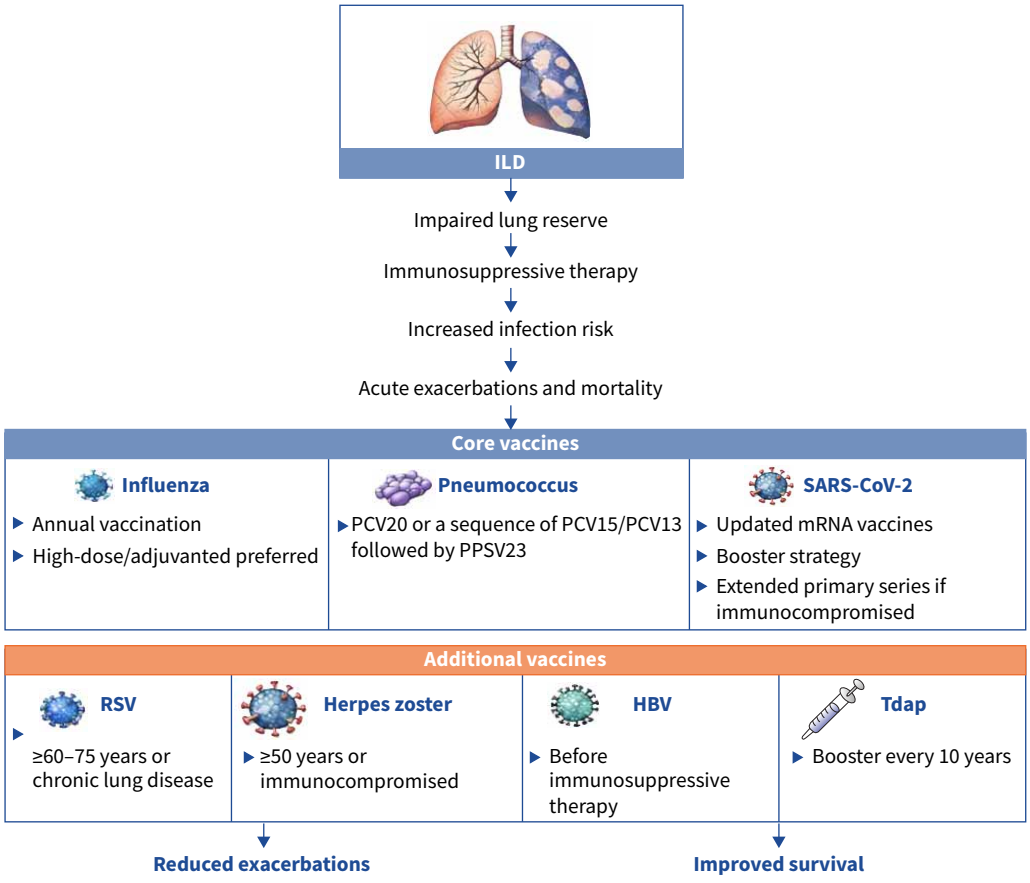


FIGURE 1 Vaccination strategy for patients with interstitial lung disease (ILD). Patients with ILD often have reduced lung capacity and are frequently on immunosuppressive treatments, which increase their risk of infections, sudden worsening of their condition, and death. Essential vaccines include the influenza vaccine (annual, preferably high-dose or adjuvanted to lower mortality), pneumococcal vaccines (such as pneumococcal conjugate vaccines (PCV)20 or a sequence of PCV15/PCV13 followed by 23-valent pneumococcal polysaccharide vaccine (PPSV23) to prevent bacterial pneumonia) [52], and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines (updated mRNA versions with booster schedules and extended primary courses for immunocompromised patients). Additional vaccines recommended are respiratory syncytial virus (RSV) for older adults or those with chronic lung issues, herpes zoster for those aged ⩾50 years or immunocompromised, hepatitis B virus (HBV) before starting immunosuppressive therapy, and a tetanus, diphtheria, and acellular pertussis (Tdap) booster every decade. This thorough immunisation plan is designed to lower exacerbations and enhance survival outcomes in ILD patients.

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TABLE 3 Recommended vaccinations in patients with interstitial lung diseases (ILD)

	Target ILD population (who?)	Recommended schedule (which?)	Timing (when?)	Special considerations	Recommendation	Reimbursement
Influenza	All ILD patients, especially aged ⩾60 years or receiving immunosuppressive therapy	1 dose annually (seasonal, quadrivalent)	Annually before influenza season	Prefer high-dose or adjuvanted formulations when available; avoid live-attenuated vaccines in immunocompromised patients	Standard recommendation	Generally reimbursed in chronic lung disease and elderly populations
Pneumococcal	All ILD patients aged ⩾50 years and younger adults with chronic lung disease or immunocompromising conditions	Single dose of PCV20 or PCV21 or PCV15 followed by PPSV23 (⩾8 weeks in high-risk; ⩾1 year in standard-risk adults) when PCV20/21 unavailable	No strict timing	In patients at high risk, PPSV23 should be administered ⩾8 weeks after PCV20 to extend protection	Standard recommendation	Commonly reimbursed in adults with chronic lung disease
SARS-CoV-2	All ILD patients	Updated seasonal dose (annual); extended primary series in immunocompromised	Periodic vaccination aligned with seasonal campaigns	Reduced immune response in patients on B-cell-depleting therapies; severely immunocompromised patients may require additional booster every ~6 months	Standard recommendation	Widely reimbursed in most countries
RSV	Aged ⩾75 years or 60–74 years with chronic lung disease or immunosuppression	Single dose	Prior to RSV season (according to regional epidemiology)	Particularly relevant in elderly ILD patients with functional limitation	Conditional recommendation	Reimbursement varies by country
Herpes zoster	Aged ⩾50 years; aged ⩾19 years if immunocompromised	2 doses (0 and 2–6 months)	Preferably before immunosuppressive therapy	Safe in immunocompromised; avoid live-attenuated vaccine	Conditional recommendation	Often reimbursed in older adults or high-risk groups
Pertussis (Tdap booster)	All adults, including ILD patients	Booster every 10 years	Administer before immunosuppressive therapy when possible	Particularly relevant in patients with incomplete vaccination history	Conditional recommendation	Included in routine adult immunisation schedules
Hepatitis B	ILD patients prior to or during immunosuppressive therapy	3 doses (0, 1, 6 months) + post-vaccination serology	Ideally before immunosuppressive therapy	Strongly recommended in HBV-naïve patients; check HBsAg, anti-HBs, anti-HBc before therapy	Conditional recommendation	Reimbursed in high-risk groups
***Haemophilus influenzae* type b (Hib)**	Only in specific risk conditions (*e.g.* asplenia, stem cell transplant)	Single dose if indicated	No strict timing	Not routinely recommended in adults with ILD without additional risk factors	Conditional recommendation	Limited to specific indications

SARS-CoV-2: severe acute respiratory syndrome coronavirus 2; RSV: respiratory syncytial virus; Tdap: tetanus, diphtheria, and acellular pertussis; PCV: pneumococcal conjugate vaccine; PPSV23: 23-valent pneumococcal polysaccharide vaccine; HBV: hepatitis B virus; HBsAg: hepatitis B surface antigen; HBc: HBV core antigen.

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Points for clinical practice

- Individuals diagnosed with ILD present an elevated risk of severe respiratory infections and associated complications.
- Routine vaccination against influenza, pneumococcus, and SARS-CoV-2 is recommended for individuals with ILD.
- Vaccination should ideally be administered prior to the initiation of immunosuppressive therapy.
- Although immunosuppressive treatments can diminish vaccine immunogenicity, vaccination continues to provide clinical benefit.
- Improving vaccination coverage is essential to reduce infection-related morbidity, mortality and acute exacerbations in ILD.

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