Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

(48.6%) were fully vaccinated, twelve (16.6%) were recovered from COVID-19, all of them unvaccinated prior to infection. Disease course was mild in all affected patients.
Conclusion: Despite intensive COVID-19 vaccination campaigns at CF centres and among the general population, only a limited proportion of people with CF chose to be vaccinated. A coverage similar to the flu vaccination (52% in the year 2018) has been achieved[1]. Further work on vaccination promotion is warranted.

Reference

Praprotnik M *et al. J Cyst Fibros*. 2019;18 Suppl 1: P077.

P077
Vaccination of patients with cystic fibrosis during the COVID-19 pandemic in Croatia

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Objectives: Vaccination against COVID-19 is a major public health challenge in the general population. Patients with CF are considered highly vulnerable individuals due to their increased risk of developing severe forms of respiratory infections. In this study, we aimed to evaluate the prevalence of vaccination status against COVID-19 and influenza among patients with CF in a Croatian adult centre.
Methods: A single-centre study was conducted at the Adult CF Centre that provides care to all adult CF patients in Croatia. It is based at the Clinic for Lung Diseases at the University Hospital Centre Zagreb. The outcomes of this study were prevalences of COVID-19 and influenza vaccination.
Results: The total number of CF patients enrolled in the study was 41 (44% male, 56% female). Median age was 26 (18–37) years and median BMI was 20 (18–27) kg/m^2.
Among the participants, 23 (55%) were vaccinated. Eight (20%) of them received ChAdOx1 (AstraZeneca) vaccine, 12 (29%) BNT162b2 (Pfizer) vaccine and 3 (7%) of them received mRNA-1273 (Moderna) vaccine. Only 12 (29%) patients had a booster dose. Seven (17%) patients had 3 doses of an mRNA vaccine and 5 (12%) of them were vaccinated with a combination of viral vector vaccine with a mRNA vaccine in third dose. In addition, among the participants, only 18 (44%) of them were vaccinated against influenza.
Conclusion: The overall prevalence of COVID-19 and influenza vaccination among CF patients was lower than World Health Organization recommendation. A majority of the unvaccinated adult CF patients are from southern Croatia, which has the lowest vaccination status in Croatia. Unfavorable attitudes toward vaccination could be related to cultural, social and political influences. Therefore, it is imperative that pulmonology providers offer vaccinations to CF patients as well as direct vaccination guidance to help educate them about safety and efficacy of the vaccine, as regards COVID-19 and influenza.

Pulmonology/Inflammation/Immunology

P078
Adverse effects of Kaftrio® in an adult cystic fibrosis clinic

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Objectives: To measure the rate of adverse drug events in adult patients with CF within the first 12 months of commencing treatment with Kaftrio® (elexecaftor/tezacaftor/ivacaftor). To describe the range of events and the degree of severity including whether treatment was stopped, dose reduced and/or successfully restarted.
Methods: A dedicated CFTR modulator clinic was set up and patients were followed up at Month 1, 3, 6, 9 and 12. Prospective data was collected during routine clinic appointments and follow-up reviews. Patients were asked about adverse effects and medical records checked for clinicians' documentation of events for all new patients commencing treatment over the 12-month period. Treatment decisions were recorded, including continuing treatment, altered monitoring (for example, more regular liver function tests), suspending treatment, stopping treatment, dose reduction, reintroduction or slow dose escalation. The severity of reactions were graded considering whether treatment had to be interrupted, and patient/clinician opinion.
Results: [in progress]
112 patients reviewed after 12 months of Kaftrio® treatment
64 had at least 1 ADE (57.1%) [45 mild, 19 moderate]
Total number of ADEs 90 [19 patients with >1 ADE]
Treatment stopped 17 [15.2%]
Successfully restarted 12; 5 stopped long-term
Types of reaction [% of total reactions]
Liver function tests increased 25 [28%]
Skin reaction 16 [18%]
GI upset 14 [16%]
Respiratory symptoms 6 [7%]
Sinus/nasal symptoms 5 [6%]
Eye disorder 4 [4%]
Hypoglycaemia 3 [3%]
Gynaecological disorder 3 [3%]
Muscoskeletal 2 [2%]
Weight increased [TBC]
CNS [TBC]
Other 5 [6%]
Conclusion: Adverse events caused by Kaftrio® are more common in the real-world CF population than in clinical trials. However, these are generally mild and treatment can be continued. In some patients, a more severe reaction necessitates treatment interruption but most of these can be restarted successfully with close monitoring and follow-up.

P079
Real-life data on the efficacy and safety of tezacaftor/ivacaftor in people living with cystic fibrosis homozygous for F508del and heterozygous for F508del and a residual function mutation

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Objectives. In this post-approval study, we wanted to examine safety and efficacy of tezacaftor/ivacaftor (TEZ-IVA) in a real-life setting.
Methods. A multi-centric retrospective observational study, including adult patients eligible for TEZ-IVA, with assessments at baseline and 3 months and 6 months after start of treatment. Outcomes studied included change in ppFEV$_1$, Lung Clearance Index (LCI), estimated number of annualised acute exacerbations (AE) and body mass index (BMI). We also assessed safety.
Results: Forty-two adult patients (28 (57%) men, median age 29.3 ± 11.5 (SD) years) were included. Two patients dropped out of the study due to pregnancy wish and incompliance. None of the patients developed clinically important side-effects. Only 1 patient (2.5%) had clinically relevant elevation of liver function tests at 6 months, yet not leading to treatment interruption. At baseline, median FEV$_1$ was 67(IQR:45;81)%P, and median improvement after 3 months of treatment was +4(IQR:0;9)%P, which was maintained after 6 months of treatment. By defining subgroups of responders and non-responders, based on whether their individual FEV$_1$ increase exceeded 4%P, this led to 20 responders and 20 non-responders. In the responders (FEV$_1$ 57(IQR:44;71)%P at baseline), median FEV$_1$ improvement was +7(IQR:2; 12)%P after 6 months of treatment. Corresponding mean LCI improvement was −26(IQR: −36; −16)%P, down from 175 (IQR:150; 210)%P at baseline. In the entire study group the estimated annual AE rate decreased after 6 months of treatment. The only discriminating factor between responders versus non-responders was median baseline FEV$_1$ (57%P versus 78%P, respectively).
Conclusion: This real-life study shows that TEZ-IVA is safe and efficacious in terms of improvement of lung function and reduction of estimated annual AE rate, in adult F/F and F/RF patients, after 6 months of treatment. Patients with a lower FEV$_1$ seem to benefit more from this treatment as compared to patients with higher FEV$_1$.