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care centers, only a few patients from each center are included in this preliminary analysis. Future steps for the Tennessee and Mississippi consortium include analysis of the full patient population in the periods immediately before and after approval of ELX/TEZ/IVA to determine the effects of ELX/TEZ/IVA and the pandemic on observed CF outcomes. Culture positivity for acid-fast bacilli will be assessed. Data from children with CF will be compared with data from adults with CF.

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References

- [1] Heijerman HGM, McKone EF, Downey DG, Van Braeckel E, Rowe SM, Tullis E, *et al.* Efficacy and safety of the elexacaftor plus tezacaftor plus ivacaftor combination regimen in people with cystic fibrosis homozygous for the F508del mutation: a double-blind, randomised, phase 3 trial. *Lancet* 2019; 394(10212):1940–8.
- [2] Middleton PG, Mall MS, Dřevínek P, Lands LC, McKone EF, Polineni D, *et al.* Elexacaftor-tezacaftor-ivacaftor for cystic fibrosis with a single Phe508del allele. *N Engl J Med* 2019;381(19):1809–19.
- [3] U.S. Food and Drug Administration. Novel Drug Approvals for 2019. <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2019>.
- [4] Zemanick ET, Taylor-Cousar JL, Davies J, Gibson RL, Mall MA, McKone EF, *et al.* A phase 3 open-label study of elexacaftor/tezacaftor/ivacaftor in children 6 through 11 years of age with cystic fibrosis and at least one F508del allele. *Am J Respir Crit Care Med* 2021;203(12):1522–32.
- [5] Miller AC, Harris LM, Cavanaugh JE, Alaiwa MA, Stoltz DA, Hornick DB, *et al.* The rapid reduction of infection-related visits and antibiotic use among people with cystic fibrosis after starting elexacaftor-tezacaftor-ivacaftor. *Clin Infect Dis* 2022; [ciac117](https://doi.org/10.1093/cid/ciac117). <https://doi.org/10.1093/cid/ciac117>.

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Trends in Canadian cystic fibrosis health care use amidst the COVID-19 pandemic

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Background: The COVID-19 pandemic has resulted in widespread changes in health care use for Canadians with cystic fibrosis (CF). The objective of this analysis is to describe the impact of the COVID-19 pandemic on the delivery of usual CF health care.

Methods: The Canadian Cystic Fibrosis Registry is a national repository of longitudinal data from 42 CF clinics across Canada. This study included data on clinic visits (including virtual and telemedicine), hospitalizations, home intravenous (IV) medicine courses, and microbiology cultures recorded in the registry from 2016 to 2020. Clinical measurements typically collected during clinic visits include height, weight, and lung function—measured as percentage predicted forced expiratory volume in 1 minute (FEV₁pp). Lung function is not typically measured in young children, so analyses of FEV₁pp are restricted to individuals aged 6 and older. Health care use is described as the proportion of individuals who had at least one recorded measurement or encounter in the reporting year.

Results: The number of clinic visits, hospitalizations, and home IV medicine courses recorded monthly in the registry remained relatively stable from 2016 to 2019, averaging 1,528 clinic visits, 130 hospitalizations, and 81 home IV medicine courses per month from 2016 to 2019. With the declaration of the COVID-19 pandemic in early March 2020, the overall number of CF health care encounters decreased substantially. There were 29.7% fewer clinic visits in April 2020 than in April 2019, 67.6% fewer

pulmonary exacerbation (PEX) hospitalizations, and 39.6% fewer home IV courses. Looking at month-to-month changes in 2020, the trends in health care encounters appear to be inversely related to the number of COVID-19 cases recorded in Canada—although infection rates increased, CF health care use decreased. The proportion of individuals with at least one FEV₁pp measurement decreased from a mean of 97.0% during 2016 to 2019 to 89.0% in 2020, PEX hospitalizations decreased from a mean of 20.9% during 2016 to 2019 to 14.8% in 2020, and microbiology cultures (excluding COVID-19) decreased from a mean of 92.6% during 2016 to 2019 to 85.4% in 2020. It follows that the mean number of health care encounters (e.g., FEV₁pp and body mass index measurements, clinic visits, microbiology cultures) recorded per individual was also lower in 2020 than over the previous 4 years (Figure 1).

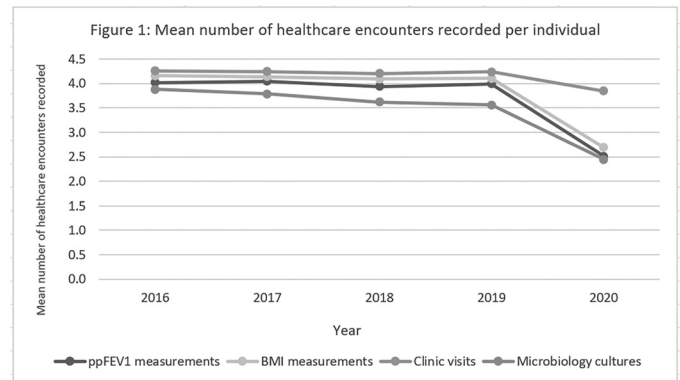


Figure 1. Mean number of health care encounters recorded per individual

Conclusions: The reduction in number of health care encounters for Canadians with CF provides insight into the impact of COVID-19 on delivery of CF care in 2020. The resulting lack of objective measurements typically assessed during clinic visits, such as lung function or new-onset infections, may not be appreciated or recognized until later than usual. Coinciding with the COVID-19 pandemic, some Canadians with CF also became eligible for the highly effective modulator therapy elexacaftor/tezacaftor/ivacaftor, which could be a confounding factor in the decrease in number of clinic visits or hospitalizations. Disentangling the combined effects of these events on the delivery of CF care will be an important subject for future analysis.

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Cutaneous rash with elexacaftor/tezacaftor/ivacaftor in children with cystic fibrosis

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Background: Elexacaftor/tezacaftor/ivacaftor (ELX/TEZ/IVA) is a triple-therapy modulator used to treat patients with cystic fibrosis (CF) since late 2019. It was approved in June 2021 for clinical use in children aged 6 to 11. Clinical trials of ELX/TEZ/IVA have reported skin rash as a commonly observed side effect. The rash is reported to be mild to moderate in severity and self-resolving in most cases. Clinical trials have also reported that the rash is more commonly seen in younger children (24% in aged 6–11) and children and adults with a single delta F508 mutation [1–3].

Methods: A retrospective chart review was conducted in all pediatric patients aged 6 and older with CF prescribed ELX/TEZ/IVA between October 2019 and April 2022. Patients were excluded if they were started on this