

# Cystic Fibrosis Research News

## Title:

**Use of FEV<sub>1</sub> in Cystic Fibrosis Epidemiologic Studies and Clinical Trials:  
A Statistical Perspective for the Clinical Researcher**

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## What was your research question?

The goal of this work was to summarize past analyses of pulmonary function data, specifically FEV<sub>1</sub> (forced expiratory volume in 1 second) in cystic fibrosis (CF) studies and to identify analytic methods that answer clinical questions in CF observational studies and trials.

## Why is this important?

Measuring FEV<sub>1</sub> is a common and clinically important way to monitor the clinical course of CF, especially changes over time or in response to treatments. It is however important that researchers use consistent and optimal approaches to analyse FEV<sub>1</sub> so that studies are interpretable and generalizable.

## What did you do?

In this paper, we discussed how the statistical methods that are used to analyse FEV<sub>1</sub> could improve our understanding of new therapies and developments in clinical care. We



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compared the statistical methods that are widely applied to analyse FEV<sub>1</sub> with new techniques and summarized the strengths and weaknesses of each approach.

## **What did you find?**

FEV<sub>1</sub> has a long history as an important clinical measure because of rigorous statistical work to show its association with morbidity and mortality in CF. However, researchers must be cautious when analysing FEV<sub>1</sub> over time and be able to identify possible sources of bias. FEV<sub>1</sub> is summarized differently across CF therapeutic trials depending on study population, duration, and desired interpretation -making it difficult to compare different treatments.

## **What does this mean and reasons for caution?**

The clinical research community could adopt advanced statistical methods, provided that such methods can be replicated across studies, offer significant improvements over traditional methods, and yield study results that can be interpreted by CF clinicians.

## **What's next?**

Further work is needed to establish best practices for the analysis of FEV<sub>1</sub> in a wide range of CF research settings.

## **Original manuscript citation in PubMed**

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