The Effect of a Post-Bronchodilator $FEV_1/FVC < 0.7$ on COPD Diagnosis and Treatment: A Regression Discontinuity Design

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Contributions: ATM participated in study design and analysis, drafted and revised the manuscript, and is the guarantor of the document. SDH and GEW participated in study design and analysis and revised the manuscript.

Funding: ATM reports funding from NHLBI F32 HL167456.

Conflicts of Interest: ATM, SDH, and GEW declare no relevant financial conflicts of interest.

Manuscript Word Count: 3196 / 3200

Abstract Word Count: 292 / 300

Tables and Figures: 4 / 5

References: 50 / 50

Abstract

Background

Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines recommend the diagnosis of chronic obstructive pulmonary disease (COPD) only in patients with a post-bronchodilator forced expiratory volume in 1 second to forced vital capacity ratio (FEV₁/FVC) less than 0.7. However the impact of this recommendation on clinical practice is unknown.

Research Question

What is the effect of a documented post-bronchodilator $FEV_1/FVC < 0.7$ on the diagnosis and treatment of COPD?

Study Design and Methods

We used a national electronic health record database to identify clinical encounters between 2007 to 2022 with patients 18 years of age and older in which a post-bronchodilator FEV_1/FVC value was documented. An encounter was associated with a COPD diagnosis if a diagnostic code for COPD was assigned, and was associated with COPD treatment if a prescription for a medication commonly used to treat COPD was filled within 90 days. We used a regression discontinuity design to measure the effect of a post-bronchodilator $FEV_1/FVC < 0.7$ on COPD diagnosis and treatment.

Results

Among 27 817 clinical encounters, involving 18 991 patients, a post-bronchodilator FEV_1/FVC < 0.7 was present in 14 876 (53.4%). The presence of a documented post-bronchodilator $FEV_1/FVC < 0.7$ had a small effect on the probability of a COPD diagnosis, increasing by

6.0% (95% confidence interval [CI] 1.1% to 10.9%) from 38.0% just above the 0.7 cutoff to 44.0% just below this cutoff. The presence of a documented post-bronchodilator FEV₁/FVC had no effect on the probability of COPD treatment (-2.1%, 95% CI -7.2% to 3.0%).

Interpretation

The presence of a documented post-bronchodilator $FEV_1/FVC < 0.7$ has only a small effect on the probability that a clinician will make a guideline-concordant diagnosis of COPD and has no effect on corresponding treatment decisions.

Introduction

Chronic obstructive pulmonary disease (COPD) is defined by the presence of obstruction on spirometry.^{1,2} According to Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, obstruction is present if the post-bronchodilator forced expiratory volume in 1 second to forced vital capacity ratio (FEV₁/FVC) is less than 0.7, with the diagnosis of COPD recommended only in patients with obstruction.³ Despite this, studies involving the performance of spirometry and its comparison with the prior clinical diagnosis of COPD have found that the presence of obstruction correlates only loosely with this diagnosis.^{4,5} Between 30 and 60 percent of patients who have been diagnosed with COPD do not have evidence of obstruction on spirometry,^{6–10} while between 60 and 80 percent of patients with obstruction have not been diagnosed with COPD.^{11–16}

This contrast between the presence of obstruction and the diagnosis of COPD has been attributed to the underuse of spirometry,^{17–21} with the assumption that physicians would diagnose COPD in accordance with GOLD guidelines if they had access to the results of spirometry. However, while access to the results of spirometry will better position physicians to arrive at an accurate diagnosis of COPD, diagnostic accuracy depends further on the proper use of these results. Studies comparing the prior performance of spirometry with the clinical diagnosis of COPD have found that even after spirometry has been performed, the diagnosis of COPD still often fails to correspond to the recommendations of GOLD guidelines.^{22–24}

To better understand the role of spirometry interpretation in medical decision making, we sought to estimate effect of the presence of a documented post-bronchodilator $FEV_1/FVC < 0.7$ on COPD diagnosis and treatment. We hypothesized that if physicians applied GOLD guidelines to spirometry to diagnose COPD, this would yield a substantial discontinuity in the probability of a COPD diagnosis at the 0.7 cutoff; COPD would generally not be diagnosed in patients with an $FEV_1/FVC \ge 0.7$ and would generally be diagnosed in patients with an $FEV_1/FVC < 0.7$. Because current GOLD guidelines do not recommend

that spirometry directly inform treatment decisions, though treatment decisions likely follow the establishment of a COPD diagnosis, we also hypothesized that a post-bronchodilator $FEV_1/FVC < 0.7$ would affect subsequent COPD treatment but to a lesser extent than it would affect diagnosis.

Methods

Data Source

We used data from the Optum Labs Data Warehouse (OLDW), a database composed of de-identified administrative claims and electronic health record (EHR) data from across the United States.²⁵ EHR data included in the OLDW were derived from provider notes using a proprietary natural language processing (NLP) system.²⁶ This use of NLP made it possible to link clinical data to specific clinical encounters in which physicians demonstrate access to these data by including them in their clinic notes. This linkage allowed us to study the effect of these data on diagnostic and therapeutic decision making.

Study Population

We included clinical encounters from 2007 to 2022 in the OLDW that involved patients 18 years of age and older and that documented a post-bronchodilator FEV_1/FVC measurement in the associated clinic note. We excluded encounters that involved only the performance of pulmonary function testing, as the diagnoses associated with these encounters are assigned prior to the encounter—and used to justify the performance of the test—rather than in response to the test results.

Exposure and Outcomes

The exposure was the documented presence of a post-bronchodilator $FEV_1/FVC < 0.7$. The primary outcome was whether an encounter was associated with the diagnosis of COPD. We defined an encounter as associated with a diagnosis of COPD if the encounter was assigned any ICD code for COPD, including chronic bronchitis and emphysema (e-Table 1). In addition to estimating the effect of the exposure on COPD diagnosis, we evaluated, as a secondary outcome, the effect of the same exposure on COPD treatment. We defined an encounter as associated with COPD treatment if an inhaler, oral corticosteroid, or other medication commonly used to treat COPD was filled within 90 days of the encounter (e-Table 2).

Study Design

We used a regression discontinuity design (RDD) to estimate the effect of the exposure on the primary and secondary outcomes. An RDD is method of causal inference that allows one to estimate the effect of an exposure on an outcome when the presence of the exposure is a function of whether the value of a continuous variable falls above or below a discrete cutoff.^{27,28} Given a sufficient amount of data, one can define a small enough bandwidth around the cutoff that observations within the bandwidth that fall on on one side or the other of the cutoff will, on average, differ only by the presence or absence of the exposure of interest.²⁹ The effect of the exposure can then be estimated as the discontinuity of a regression across this cutoff. In this way, an RDD can be used to provide an effect estimate from observational data that is free from unmeasured confounding.

The continuous variable in our RDD was the post-bronchodilator FEV_1/FVC while the cutoff was the 0.7 value used by GOLD guidelines to define the presence of obstruction. The bandwidth around the 0.7 cutoff was selected for minimal coverage error with robust bias-corrected inference.^{30,31} We used local linear regression to construct the point-estimator and local quadratic regression to construct the bias correction. We followed the convention of using a triangular kernel in our RDD, so as to increase the relative weight assigned to clinical encounters with post-bronchodilator FEV_1/FVC values within the bandwidth that were closer to the 0.7 cutoff.³⁰

In addition to estimating the effect of a documented post-bronchodilator FEV_1/FVC < 0.7 on the diagnosis and treatment of COPD, we also estimated its effect on specific types of COPD diagnosis—chronic bronchitis, emphysema, and other chronic obstructive lung disease—and specific classes of COPD treatment—inhaled corticosteroids, long-acting beta agonists, long-acting muscarinic antagonists, macrolide antibiotics, oral corticosteroids,

phosphodiesterase-4 inhibitors, short-acting beta agonists, and short-acting muscarinic antagonists.

In our primary analysis we used a sharp RDD, as the exposure of interest was present in all encounters in which the value of the continuous variable was less than the cutoff and was absent in all encounters in which the value of the continuous variable was equal to or greater than the cutoff. In a secondary analysis we used a fuzzy RDD to assess the effect of COPD diagnosis on COPD treatment, allowing for the facts that not all patients with an $FEV_1/FVC < 0.7$ were diagnosed with COPD and that this diagnosis could be present in patients with an $FEV_1/FVC \ge 0.7$. Much like an instrumental variable analysis, a fuzzy RDD involves two stages, the first of which associates an exogenous variable with the probability of exposure to an intervention, while the second of which associates the intervention with the outcome of interest.³²

Subgroups

In exploratory analyses we estimated the effect of a post-bronchodilator $FEV_1/FVC < 0.7$ on COPD diagnosis and treatment in pre-specified subgroups defined by age ≥ 65 , gender, race, history of tobacco use, history of COPD, encounter type, and physician specialty.

Validity Assessment and Sensitivity Analysis

We performed multiple tests to assess the validity of our RDD and further assessed the sensitivity of our results to different modeling assumptions. These analyses are described in our supplementary methods.

Statistical Analysis

All statistical tests were two sided and a P value < 0.05 was interpreted as statistically significant. R version 4.2.1 was used for data analysis.³³ The rdrobust package was used to

perform the RDD.³⁴ We followed the STROBE checklist for reporting observational studies in epidemiology (**e-Table 3**).³⁵ As the study involved the use of secondary, de-identified data it did not represent human subjects research and Institutional Review Board approval was not necessary.

Results

We identified 27817 clinical encounters in which a post-bronchodilator FEV_1/FVC measurement was documented, involving 18991 different patients and more than 2038 different physicians (**Table 1**). The encounters most often involved women (N = 14517, 52%), non-Hispanic White patients (N = 25083, 90%), patients at least 65 years old (N = 14586, 52%), and patients with a history of tobacco use (N = 14909, 54%). A total of 6674 (24.0%) encounters involved patients with a prior COPD diagnosis. The primary physician specialty was documented for 11755 encounters, with 1932 (6.9%) encounters with pulmonologists, 6705 (24.1%) with internists or non-pulmonologist internal medicine subspecialties, 643 (2.3%) with family medicine or general practitioners, 1527 (5.5%) with emergency medicine physicians, and 948 (3.4%) with surgeons.

COPD was diagnosed in 12697 (45.6%) encounters, including 3219 (25.3%) encounters in which a post-bronchodilator FEV_1/FVC was ≥ 0.7 . COPD was not diagnosed in 15120 (54.4%) encounters, including 5398 (35.7%) encounters in which a post-bronchodilator FEV_1/FVC was < 0.7. A total of 16515 (59.4%) encounters were associated with COPD treatment, including 6608 (40.0%) in which a post-bronchodilator FEV_1/FVC was ≥ 0.7 . A total of 11302 (40.6%) encounters were not associated with COPD treatment, including 4969 (44.0%) encounters in which a post-bronchodilator FEV_1/FVC was < 0.7.

The presence of a documented post-bronchodilator $FEV_1/FVC < 0.7$ had a small but statistically significant effect on the diagnosis of COPD (**Figure 1**). The probability of a COPD diagnosis increased from 38.0% just above the 0.7 post-bronchodilator FEV_1/FVC cutoff to 44.0% just below this cutoff, a discontinuity of 6.0% (95% CI 1.1% to 10.9%, *P* value = 0.016) at the cutoff (**Table 2**). This effect was not seen with pre-bronchodilator spirometry (**e-Table 4**) and was seen only in the diagnosis of chronic obstruction (5.4% 95%CI 0.9% to 9.8%) and not in the diagnosis of chronic bronchitis (1.3%, 95% CI -2.2% to 4.8%) or emphysema (-0.2%, 95% CI -2.0% to 1.7%) (**e-Table 5**).

The presence of a post-bronchodilator $FEV_1/FVC < 0.7$ did not affect COPD treatment

(Figure 1). The probability of treatment was 60.7% just above the 0.7 cutoff and 58.7% just below this cutoff, with a discontinuity of -2.1% (95% CI -7.2% to 3.0%) at the cutoff (Table 2). A significant effect was seen by treatment type only in the case of roflumilast (0.9%, 95% CI 0.1% to 1.7%) (e-Table 6). In our secondary analysis applying a fuzzy RDD to assess the effect of a COPD diagnosis on COPD treatment, the diagnosis of COPD diagnosis of the treatment (48.1%, 95% CI -55.7% to 152.0%).

Subgroup Analysis

Our exploratory subgroup analysis suggested that physician speciality and the history of a COPD diagnosis may both impact the role of spirometry in COPD diagnosis. While the presence of a post-bronchodilator FEV₁/FVC < 0.7 did not have a significant effect on the diagnosis of COPD among pulmonologists (9.8%, 95% CI -4.9% to 24.4%) or other internal medicine physicians (4.5%, 95% CI -3.8% to 12.7%), it did increase the probability of a COPD diagnosis in encounters with emergency medicine physicians (29.3%, 95% CI 7.3% to 51.3%). Notably, in patients with a prior diagnosis of COPD, the presence of a postbronchodilator FEV₁/FVC < 0.7 had no effect on the diagnosis of COPD (0.9%, 95% CI -6.1% to 7.9%), with a probability of diagnosis of 84.8% above the cutoff and a probability of 85.8% below the cutoff.

Validity Assessment and Sensitivity Analysis

As detailed in our supplementary results, the validity of our RDD was supported by the absence of evidence of manipulation of the continuous variable along with the negative results of all placebo tests,^{29,36} while our sensitivity analysis demonstrated that our results were generally robust to the adoption of different modeling assumptions.

Discussion

We applied an RDD to a national EHR database and found that the presence of a documented post-bronchodilator $FEV_1/FVC < 0.7$ only slightly increased the probability of a diagnosis of COPD. In the same RDD, the cutoff had no effect on COPD treatment even across a range of clinical contexts and encounter types. These findings suggest that GOLD guidelines have less of an effect on clinical decision making than has been assumed and that the performance of spirometry is insufficient to guarantee the diagnosis of COPD in accordance with these guidelines.

There are multiple potential etiologies for the observed discrepancy between the recommendations of GOLD guidelines and the diagnosis of COPD in this study. Though the OLDW database uses NLP to extract data from clinic notes, spirometry data may have been auto-populated and physicians who included these data in their documentation may nonetheless have been unaware of them. Other physicians may have been aware of the results of spirometry, but unaware of their implications. As European Respiratory Society and American Thoracic Society (ERS/ATS) guidelines for spirometry interpretation do not provide physicians with recommendations regarding the diagnostic implications of spirometry, physicians must independently decide if test results are consistent with a diagnosis of COPD.³⁷ Other physicians may have relied on different spirometric criteria to determine the presence of obstruction. There is a lack of consensus regarding the use of the fixed 0.7 cutoff recommended by GOLD to define the presence of obstruction on spirometry and some physicians may have instead used the FEV₁/FVC lower limit of normal to identify obstruction.³⁷ Finally, some physicians may have been aware of the diagnostic implications of spirometry and yet set aside the 0.7 cutoff as too simple a tool to apply to a clinically heterogenous disease such as COPD.^{38,39}

If physicians are largely unaware of the diagnostic implications of a post-bronchodilator $FEV_1/FVC < 0.7$, our study suggests a role for the use of clinical decision support to help physicians diagnose COPD in a manner concordant with GOLD guidelines.⁴⁰ Indeed, if

this is the case, our study suggests that in the absence of such decision support, COPD misdiagnosis may persist with some frequency even after spirometry has been performed. Attempts to improve COPD diagnosis, simply by increasing the performance of spirometry, as with recent proposals to screen for COPD with spirometry, will be less successful than imagined if spirometry interpretation—rather than just spirometry performance—represents an important limiting factor in COPD diagnosis.⁴¹

On the other hand, if the discrepancy between the recommendations of GOLD guidelines and the clinical diagnosis of COPD stems from the decision on the part of clinicians to depart from these guidelines, then simply alerting physicians to the fact that the post-bronchodilator FEV_1/FVC is less than 0.7 will have little effect on clinical practice. If this is the case, COPD diagnosis might be advanced by replacing the simple 0.7 cutoff with a more robust model of airway obstruction.^{42,43}

We found that the presence of a post-bronchodilator $FEV_1/FVC < 0.7$ had no effect on COPD treatment. While GOLD had previously recommended the use of spirometry to directly inform treatment decisions, more recent guidelines recommend instead that treatment decisions be informed by exacerbation history and respiratory symptoms. As such, the presence of a post-bronchodilator $FEV_1/FVC < 0.7$ was expected to have had less of an effect on COPD treatment than on diagnosis.³ Nonetheless, as GOLD guidelines have consistently recommended at minimum the prescription of a short-acting bronchodilator for patients with COPD, the presence of a post-bronchodilator $FEV_1/FVC < 0.7$ would be expected to have at least some effect on COPD treatment.⁴⁴

The results of our exploratory subgroup analysis suggest that physicians with different medical specialties may use spirometry in different ways to diagnose COPD. While the presence of a post-bronchodilator $FEV_1/FVC < 0.7$ had a significant effect on the diagnosis of COPD by emergency medicine physicians, a similar effect was not seen among other type of physicians. This finding suggests that physicians who have a longitudinal relationship with their patients may rely more on history and symptoms to diagnose COPD while physicians

without this type of clinical relationship may rely more on objective data in the form of spirometry. Likewise, while the presence of a post-bronchodilator $FEV_1/FVC < 0.7$ had a significant effect on the diagnosis of COPD in patients who had not been previously been diagnosed, it had no effect on the diagnosis of patients who already carried this diagnosis. Diagnostic momentum appears to play a significant role in COPD diagnosis and once a diagnosis of COPD has been made, spirometry seems to have little effect upon it.

Finally, this study provides the first estimate of the effect of spirometry interpretation on diagnostic and therapeutic decision making in clinical practice. While several recent studies have speculated as to the downstream clinical consequences that follow from the recommended adoption of race-neutral reference equations, these consequences have yet to be studied empirically.^{45–49} Our finding that the presence of a post-bronchodilator FEV_1/FVC < 0.7 has only a minimal effect on COPD diagnosis and no effect on COPD treatment challenges the assumption that whether a spirometric parameter falls above or below a lower limit of normal—the effect of adopting one set of reference equations or another—results in corresponding changes in clinical decision making. The relationship between spirometry interpretation and such clinical decisions is not as straightforward as has been assumed and empirical studies are needed to estimate the clinical consequences that follow from the adoption of novel reference equations.

This study has several strengths. First, we used a national EHR database and included encounters involving tens of thousands of patients and thousands of physicians. Second, the use of NLP to extract spirometry data from clinic notes allowed us to link these data to specific clinical encounters and conclude not only that spirometry had been performed but that the results of such performance were documented and thus accessible to physicians. Third, our use of an RDD mitigated the impact of unmeasured confounding on our effect estimates. Fourth, we performed an extensive sensitivity analysis and found that our results were generally insensitive to different modeling assumptions.

This study also has several limitations. First, we were unable to identify the FEV_1

percent predicted values or FEV₁/FVC lower limit of normal values to which the physicians in our cohort had access, and we were thus unable to assess the effect these components of spirometry may have had on diagnostic and therapeutic decision making. Second, though our data were drawn from a national EHR database, post-bronchodilator spirometry data were available for only a subset of the patients in this database. The selection effects mediating the inclusion of these data are unknown and may limit the external validity of our findings. Third, our use of ICD codes to associate COPD diagnoses with clinical encounters likely underestimates the prevalence of COPD diagnosis in our cohort as it is unlikely that an ICD code for COPD will be assigned to each clinical encounter with a patient diagnosed with COPD, given that some encounters will involve medical issues unrelated to this diagnosis. Fourth, our use of prescription data to associate COPD treatment with a clinical encounter likely overestimates the prevalence of COPD treatment as we were unable to identify the specific rationale for each prescription and many of these medications can be used to treat other diseases as well. Fifth, a fundamental limitation of the RDD is that it provides a local estimate of an effect at a cutoff. In our analysis we were thus unable to estimate the effect of a post-bronchodilator $FEV_1/FVC < 0.7$ for clinical encounters with FEV_1/FVC values that are far from the 0.7 cutoff.^{50}

Interpretation

In conclusion, we found that the presence of a documented post-bronchodilator FEV_1/FVC < 0.7 had only a small effect on the diagnosis of COPD and had no effect on COPD treatment. These findings suggest that the prevailing, guideline-recommended diagnostic cutoff for COPD may not meaningfully affect clinical decision making. Further work is needed to accurately and reliably incorporate spirometry data into the diagnostic process for COPD.

References

- Celli BR and Wedzicha JA. Update on clinical aspects of chronic obstructive pulmonary disease. N Engl J Med 2019;381:1257–66.
- 2. Christenson SA, Smith BM, Bafadhel M, and Putcha N. Chronic obstructive pulmonary disease. Lancet 2022;399:2227–42.
- Agustí A, Celli BR, Criner GJ, et al. Global Initiative for Chronic Obstructive Lung Disease 2023 report: GOLD executive summary. Am J Respir Crit Care Med 2023;207:819–37.
- Lamprecht B, Soriano JB, Studnicka M, et al. Determinants of underdiagnosis of COPD in national and international surveys. Chest 2015;148:971–85.
- Diab N, Gershon AS, Sin DD, et al. Underdiagnosis and overdiagnosis of chronic obstructive pulmonary disease. Am J Respir Crit Care Med 2018;198:1130–9.
- Abramson MJ, Schattner RL, Sulaiman ND, Del Colle EA, Aroni R, and Thien F. Accuracy of asthma and COPD diagnosis in Australian general practice: a mixed methods study. Prim Care Respir J 2012;21:167–73.
- Starren ES, Roberts NJ, Tahir M, et al. A centralised respiratory diagnostic service for primary care: a 4-year audit. Prim Care Respir J 2012;21:180–6.
- Ghattas C, Dai A, Gemmel DJ, and Awad MH. Over diagnosis of chronic obstructive pulmonary disease in an underserved patient population. Int J Chron Obstruct Pulmon Dis 2013;8:545–9.
- Gershon AS, Thiruchelvam D, Chapman KR, et al. Health services burden of undiagnosed and overdiagnosed COPD. Chest 2018;153:1336–46.
- 10. Sator L, Horner A, Studnicka M, et al. Overdiagnosis of COPD in subjects with unobstructed spirometry: a BOLD analysis. Chest 2019;156:277–88.

- Frank TL, Hazell ML, Linehan MF, and Frank PI. The diagnostic accuracies of chronic obstructive pulmonary disease (COPD) in general practice: the results of the MAGIC (Manchester Airways Group Identifying COPD) study. Prim Care Respir J 2006;15:286–93.
- 12. Tinkelman DG, Price DB, Nordyke RJ, and Halbert RJ. Misdiagnosis of COPD and asthma in primary care patients 40 years of age and over. J Asthma 2006;43:75–80.
- 13. Miravitlles M, Soriano JB, García-Río F, et al. Prevalence of COPD in Spain: impact of undiagnosed COPD on quality of life and daily life activities. Thorax 2009;64:863–8.
- Hill K, Goldstein RS, Guyatt GH, et al. Prevalence and underdiagnosis of chronic obstructive pulmonary disease among patients at risk in primary care. CMAJ 2010;182:673–8.
- Weiss G, Steinacher I, Lamprecht B, et al. Detection of chronic obstructive pulmonary disease in primary care in Salzburg, Austria: findings from the real world. Respiration 2014;87:136–43.
- 16. Casas Herrera A, Montes de Oca M, López Varela MV, et al. COPD underdiagnosis and misdiagnosis in a high-risk primary care population in four Latin American countries. a key to enhance disease diagnosis: the PUMA study. PLoS One 2016;11:e0152266.
- 17. Damarla M, Celli BR, Mullerova HX, and Pinto-Plata VM. Discrepancy in the use of confirmatory tests in patients hospitalized with the diagnosis of chronic obstructive pulmonary disease or congestive heart failure. Respir Care 2006;51:1120–4.
- Lee TA, Bartle B, and Weiss KB. Spirometry use in clinical practice following diagnosis of COPD. Chest 2006;129:1509–15.
- Joo MJ, Lee TA, and Weiss KB. Geographic variation of spirometry use in newly diagnosed COPD. Chest 2008;134:38–45.

- 20. Arne M, Lisspers K, Ställberg B, et al. How often is diagnosis of COPD confirmed with spirometry? Respiratory Medicine 2010;104:550–6.
- Nishi SPE, Wang Y, Kuo YF, Goodwin JS, and Sharma G. Spirometry use among older adults with chronic obstructive pulmonary disease: 1999-2008. Ann Am Thorac Soc 2013;10:565–73.
- Bolton CE, Ionescu AA, Edwards PH, Faulkner TA, Edwards SM, and Shale DJ. Attaining a correct diagnosis of COPD in general practice. Respir Med 2005;99:493–500.
- 23. White P, Thornton H, Pinnock H, Georgopoulou S, and Booth HP. Overtreatment of COPD with inhaled corticosteroids—implications for safety and costs: cross-sectional observational study. PLoS ONE 2013;8:e75221.
- 24. Collins BF, Ramenofsky D, Au DH, Ma J, Uman JE, and Feemster LC. The association of weight with the detection of airflow obstruction and inhaled treatment among patients with a clinical diagnosis of COPD. Chest 2014;146:1513–20.
- Optum Labs. Optum Labs and Optum Labs Data Warehouse (OLDW) descriptions and citation. Eden Prairie: Optum Labs, 2023.
- Wallace PJ, Shah ND, Dennen T, Bleicher PA, and Crown WH. Optum Labs: building a novel node in the learning health care system. Health Aff (Millwood) 2014;33:1187–94.
- Imbens GW and Lemieux T. Regression discontinuity designs: a guide to practice. J Econom 2008;142:615–35.
- Angrist JD and Pischke JS. Mastering 'metrics: the path from cause to effect.
 Princeton ; Oxford: Princeton University Press, 2015. 282 pp.
- Cattaneo MD and Titiunik R. Regression discontinuity designs. Annu Rev Econ 2022;14:821–51.

- Calonico S, Cattaneo MD, and Titiunik R. Robust nonparametric confidence intervals for regression-discontinuity designs. Econometrica 2014;82:2295–326.
- Calonico S, Cattaneo MD, and Farrell MH. On the effect of bias estimation on coverage accuracy in nonparametric inference. Journal of the American Statistical Association 2018;113:767–79.
- 32. Cattaneo MD, Idrobo N, and Titiunik R. A practical introduction to regression discontinuity designs: extensions. Elem. Quant. Comput. Methods Soc. Sci. 2024.
- Team RC. R: a language and environment for statistical computing. Vienna: R Foundation for Statistical Computing, 2021.
- 34. Calonico S, Cattaneo MD, and Titiunik R. rdrobust: an R package for robust nonparametric inference in regression-discontinuity designs. R J 2015;7:38–51.
- 35. Von Elm E, Altman DG, Egger M, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. PLoS Med 2007;4:e296.
- Cattaneo MD, Jansson M, and Ma X. Simple local polynomial density estimators. J Am Stat Assoc 2020;115:1449–55.
- Stanojevic S, Kaminsky DA, Miller MR, et al. ERS/ATS technical standard on interpretive strategies for routine lung function tests. Eur Respir J 2022;60:2101499.
- Lowe KE, Regan EA, Anzueto A, et al. COPDGene 2019: redefining the diagnosis of chronic obstructive pulmonary disease. Chronic Obstr Pulm Dis 2019;6:384–99.
- Celli B, Fabbri L, Criner G, et al. Definition and Nomenclature of Chronic Obstructive Pulmonary Disease: Time for Its Revision. Am J Respir Crit Care Med 2022;206:1317–25.

- 40. Sutton RT, Pincock D, Baumgart DC, Sadowski DC, Fedorak RN, and Kroeker KI. An overview of clinical decision support systems: benefits, risks, and strategies for success. NPJ Digit Med 2020;3:17.
- 41. Celli B. Screening for COPD: challenging the United Sates Preventive Services Task Force recommendation. Chest 2023;163:481–3.
- González G, Ash SY, Vegas-Sánchez-Ferrero G, et al. Disease staging and prognosis in smokers using deep learning in chest computed tomography. Am. J. Respir. Crit. Care Med. 2018;197:193–203.
- 43. Cosentino J, Behsaz B, Alipanahi B, et al. Inference of chronic obstructive pulmonary disease with deep learning on raw spirograms identifies new genetic loci and improves risk models. Nat Genet 2023;55:787–95.
- 44. Pauwels RA, Buist AS, Calverley PM, Jenkins CR, Hurd SS, and GOLD Scientific Committee. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: NHLBI/WHO Global Initiative for Chronic Obstructive Lung Disease (GOLD) workshop summary. Am J Respir Crit Care Med 2001;163:1256–76.
- 45. Bhakta NR, Bime C, Kaminsky DA, et al. Race and ethnicity in pulmonary function test interpretation: an official American Thoracic Society statement. Am J Respir Crit Care Med 2023:978–95.
- 46. Moffett AT, Bowerman C, Stanojevic S, Eneanya ND, Halpern SD, and Weissman GE. Global, race-neutral reference equations and pulmonary function test interpretation. JAMA Netw Open 2023;6:e2316174.
- 47. Diao JA, He Y, Khazanchi R, et al. Implications of race adjustment in lung-function equations. N Engl J Med 2024;390:2083–97.

- 48. Kanj AN, Scanlon PD, Yadav H, et al. Application of Global Lung Function Initiative Global spirometry reference equations across a large, multicenter pulmonary function lab population. Am J Respir Crit Care Med 2024;209:83–90.
- 49. Regan EA, Lowe ME, Make BJ, et al. Early evidence of chronic obstructive pulmonary disease obscured by race-specific prediction equations. Am J Respir Crit Care Med 2024;209:59–69.
- 50. Imbens GW and Angrist JD. Identification and estimation of local average treatment effects. Econometrica 1994;62:467–75.

Figure Legend

Figure 1. Association between Post-Bronchodilator FEV_1/FVC and the Diagnosis and Treatment of COPD.

Binscatter plots depict the association between post-bronchodilator FEV_1/FVC values and the probability that COPD is (A) diagnosed and (B) treated. Post-bronchodilator FEV_1/FVC values are binned at the 0.01 interval. The vertical dashed line represents the post-bronchodilator FEV_1/FVC cutoff of 0.7 recommended by GOLD guidelines. Abbreviations: COPD = chronic obstructive pulmonary disease; FEV_1 = forced expiratory volume in 1 second; FVC = forced vital capacity; GOLD = Global Initiative for Chronic Obstructive Lung Disease.

	All	$FEV_1/FVC < 0.7$	$\mathbf{FEV}_1/\mathbf{FVC} \ge 0.7$
	(N = 27817)	(N = 14876)	(N = 12941)
Patient Age			
18 - 40 years	2577~(9.3%)	754 (29.3%)	1823~(70.7%)
41 - 64 years	10654~(38.3%)	5278(49.5%)	5376(50.5%)
65 - 90 years	14586 (52.4%)	8844 (60.6%)	5742(39.4%)
Patient Gender	. ,		
Men	13295~(47.8%)	7812(58.8%)	5483~(41.2%)
Women	14517 (52.2%)	7060(48.6%)	7457(51.4%)
Patient Race and Ethnicity	. ,		
Asian	134(0.5%)	37(27.6%)	97 (72.4%)
Hispanic	531(1.9%)	165(31.1%)	366 (68.9%)
Non-Hispanic Black	1252(4.5%)	535(42.7%)	717 (57.3%)
Non-Hispanic White	25083(90.2%)	13736(54.8%)	11347 (45.2%)
Other	817 (2.9%)	403 (49.3%)	414 (50.7%)
Patient History of Tobacco Use		× /	
Yes	14909(53.6%)	9451~(63.4%)	5458(36.6%)
No	12908(46.4%)	5425(42.0%)	7483(58.0%)
Patient History of COPD Diagnosi	s		
Yes	6674~(24.0%)	5065(75.9%)	1609(24.1%)
No	21143(76.0%)	9811(46.4%)	11332(53.6%)
Encounter Type			
Inpatient	10680(38.4%)	5868(54.9%)	4812 (45.1%)
Outpatient	17137(61.6%)	9008(52.6%)	8129(47.4%)
Physician Specialty	· · · · ·		
Pulmonology	1932~(6.9%)	1120~(58.0%)	812 (42.0%)
Other Internal Medicine	6705(24.1%)	3644(54.3%)	3061(45.7%)
Family Medicine	643(2.3%)	319(49.6%)	324(50.4)%
Emergency Medicine	1527(5.5%)	910 (59.6%)	617(40.4%)
Surgery	948 (3.4%)	438 (46.2%)	510 (53.8%)
Unknown	16062(57.7%)	8 445 (52.6%)	7617(47.4%)

Table 1. Encounter Characteristics

 $COPD = chronic obstructive pulmonary disease; FEV_1 = forced expiratory volume in 1 second; FVC = forced vital capacity.$

Table 2. Effect of a Post-Bronchodilator $FEV_1/FVC < 0.7$ on COPD Diagnosis and Treatment

	Probability of Outcome		
Outcome	Above	Below	Change in Probability
	0.7 Cutoff	0.7 Cutoff	at 0.7 Cutoff $(95\% \text{ CI})^a$
COPD Diagnosis ^{b}	$38.0\% \\ 60.7\%$	44.0%	6.0% (1.1% to 10.9%)
COPD Treatment ^{c}		58.7%	-2.1% (-7.2% to 3.0%)

 $\rm CI=$ confidence interval; $\rm COPD=$ chronic obstructive pulmonary disease; $\rm FEV_1=$ forced expiratory volume in 1 second; FVC = forced vital capacity.

 a Bias-corrected discontinuity estimate with data-driven bandwidth selection and robust standard errors.

 b A clinical encounter is associated with a COPD diagnosis if the encounter is assigned an ICD code for COPD, including chronic bronchitis and emphysema.

 $^c\,$ A clinical encounter is associated with treatment for COPD if a medication used to treat COPD is prescribed within 90 days following the encounter.

	Probability of COPD $Diagnosis^a$			${\bf Probability \ of \ COPD \ Treatment}^b$		
	Above 0.7 Cutoff	Below 0.7 Cutoff	Change in Probability at 0.7 Cutoff $(95\% \text{ CI})^c$	Above 0.7 Cutoff	Below 0.7 Cutoff	Change in Probability at 0.7 Cutoff $(95\% \text{ CI})^c$
Age						
< 65 years	36.7%	41.6%	$4.9\% \ (-1.6\% \ \text{to} \ 11.3\%)$	63.8%	61.3%	-2.5% (-9.0% to 4.1%)
≥ 65 years	39.3%	46.9%	7.6% (0.6% to 14.6%)	58.4%	56.1%	-2.2% (-9.1% to 4.6%)
Gender						
Men	38.4%	45.7%	7.3% (0.3% to 14.2%)	59.9%	53.1%	-6.7% ($-14.5%$ to $1.0%$)
Women	37.8%	42.7%	4.8% (-1.6% to 11.3%)	61.6%	64.6%	3.0% (-2.4% to 8.5%)
Race						
White	38.4%	44.6%	6.2% (1.1% to 11.3%)	60.3%	58.2%	-2.1% (-7.4% to 3.2%)
Black	37.1%	32.0%	-5.2% ($-21.9%$ to $11.5%$)	68.1%	66.8%	-1.3% (-24.1% to 21.5%)
History of Tobacco Use						
Yes	54.6%	59.9%	$5.3\% \ (-1.6\% \ \text{to} \ 12.2\%)$	62.8%	58.7%	-4.1% (-10.4% to 2.3%)
No	23.0%	26.7%	$3.7\% \ (-2.5\% \ \text{to} \ 9.9\%)$	60.0%	56.7%	-3.3% (-11.1% to 4.5%)
History of COPD						
Yes	84.8%	85.8%	$0.9\% \ (-6.1\% \ \text{to} \ 7.9\%)$	60.7%	65.0%	4.3% (-5.6% to 14.2%)
No	26.1%	32.7%	6.6% (1.4% to 11.7%)	61.0%	57.1%	-3.8% (-9.8% to 2.2%)
Encounter Type						
Inpatient	47.4%	55.3%	$7.9\% \ (-0.4\% \ \text{to} \ 16.2\%)$	55.5%	55.2%	-0.4% (-8.7% to 8.0%)
Outpatient	32.3%	37.8%	$5.5\% \ (-0.1\% \ \text{to} \ 11.1\%)$	63.7%	61.1%	-2.6% (-8.6% to 3.3%)
Physician Specialty						
Pulmonology	29.9%	39.7%	9.8% (-4.9% to 24.4%)	66.5%	71.0%	4.5% (-16.1% to 25.0%)
Other Internal Medicine	51.5%	55.9%	4.5% (-3.8% to 12.7%)	58.2%	59.4%	1.2% (-8.2% to 10.6%)
Family Medicine	27.5%	49.4%	22.0% (-5.6% to 49.5%)	63.4%	65.8%	2.4% (-35.2% to 40.0%)
Emergency Medicine	43.7%	73.0%	29.3% (7.3% to $51.3%$)	64.0%	65.1%	1.1% (-17.4% to 19.5%)
Surgery	30.1%	15.4%	-14.8% ($-36.1%$ to $6.6%$)	25.8%	26.3%	0.5% (-22.9% to 23.8%)

Table 3. Effect of a Post-Bronchodilator $FEV_1/FVC < 0.7$ on COPD Diagnosis and Treatment by Subgroup

CI = confidence interval; COPD = chronic obstructive pulmonary disease.

 $\frac{25}{5}$

^a A clinical encounter is associated with a COPD diagnosis if the encounter is assigned an ICD code for COPD, including chronic bronchitis and emphysema.

^b A clinical encounter is associated with treatment for COPD if a medication used to treat COPD is prescribed within 90 days following the encounter.

 c Bias-corrected discontinuity estimate with data-driven bandwidth selection and robust standard errors.

Figure 1

