

Temporal changes in the baseline patient characteristics of COVID-19 patients

Margaret Okobi, MPH¹, Patricia Prince, MPH¹, Laura M. Roe, MMCI², Donna Rivera, PharmD, MSc³, Kenneth Quinto, MD, MPH⁴, Sandy Leonard, MPH⁵, Elizabeth M. Garry, PhD, MPH¹, Andrew Weckstein, BA¹, Melanie Wang, MPH, MBA¹, Nicolle M. Gatto, PhD, MPH¹

¹Aetion, New York, NY; ²Office of the Commissioner, U.S. Food and Drug Administration, Silver Spring, MD; ³Oncology Center of Excellence, U.S. Food and Drug Administration, Silver Spring, MD; ⁴Office of Medical Policy, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD; ⁵Partnerships and RWD, HealthVerity, Philadelphia, PA

Background

To facilitate patient-centered clinical and diagnostic guidelines, it is important to characterize the evolving presentation of coronavirus disease 2019 (COVID-19). This study summarizes temporal changes in patient characteristics prior to COVID-19 diagnosis.

Objectives

- Identify an extensive cohort of COVID-19 patients the United States
- Characterize prevalent medication use and comorbidity burden prior to COVID-19 diagnosis
- Describe changes in baseline patient characteristics over the course of the pandemic, including lockdown phases and early COVID-19 vaccine rollout

Methods

Data

- HealthVerity Chargemaster, medical and pharmacy claims data (April 2020–March 2021) that include patients in all 50 US states and all major payer types (commercial, Medicaid, and Medicare)

Study Population

- Patients indexed based on a COVID-19 ICD-10 diagnosis and/or positive SARS-CoV-2 lab result (183-day washout)
- Stratified by index month and diagnosis setting (inpatient, IP; outpatient, OP)

Patient Characteristics and Statistical Analyses

- Age at diagnosis reported as mean (standard deviation)
- Baseline medication use (by pharmacy claim or Chargemaster code) and comorbidities (by ICD-10 code) were assessed up to 183 days prior to index date (exclusive), and reported as percentages, for first and last month of the study period
- Heterogeneity in distributions of patient characteristics over time were evaluated using Cochran–Armitage trend tests
- All analyses were conducted using the Aetion Evidence Platform[®] (2021)

Results

Cohort Size and Demographics

- 4,318,439 COVID-19 patients
 - overall 87% OP; from 72% in April 2020 to 90% in March 2021

Baseline Comorbidities

All of the results below had $p < 0.01$ for Cochran–Armitage trend tests

- Charlson–Quan Comorbidity score ≥ 2 observed for 19% overall, 52% IP, and 15% OP, which decreased over time (overall: 32% to 15%, OP: 21% to 12%, IP: 61% to 45%) (**Figure 1**)
- Comorbidities decreased from April 2020 to March 2021, more notably in outpatient vs. inpatient settings: (**Figure 2**)
 - Cardiovascular disease: OP: 40% to 29% vs. IP: 77% to 63%
 - Hypertension: OP: 34% to 24% vs. IP: 68% to 53%
 - Overweight/obesity: OP: 27% to 21% vs. IP: 29% to 28%
 - Diabetes: OP: 20% to 12% vs. IP: 44% to 33%
- The same overall decreasing trends were observed in use of non-COVID related medications (e.g., anti-hypertensive, oral anti-diabetic, and statins); data not shown

Baseline COVID-19-related Medications

All of the results below had $p < 0.01$ for Cochran–Armitage trend tests

- Similar OP vs. IP trends were observed in COVID-19-related medications (**Figure 3**)
 - Antibiotics (excluding azithromycin): OP: 42% to 36% vs. IP: 42% to 42%
 - Steroid (systemic or non-systemic): OP: 37% to 32% vs. IP: 36% to 38%
 - Azithromycin: OP: 22% to 9% vs. IP: 17% to 12%
 - Systemic steroid: OP: 10% to 8% vs. IP: 10% to 11%

Conclusions

Metabolic syndrome and associated medications were the most prevalent baseline characteristics across the study period. Comorbidity burden and medication use at COVID-19 diagnosis decreased, in both inpatient and outpatient settings, especially during the first half of the study period. This pattern may reflect the increasing availability of testing in Q2 and Q3 of 2020, particularly in outpatient settings, resulting in capture of healthier COVID-19 patients. These findings may influence clinical guidelines, in terms of identifying high-priority groups for vaccination and exploring potential associations between baseline use of COVID-19 treatments and likelihood of COVID-19 diagnosis.

Disclosures

This work was conducted as a part of a Research Collaboration Agreement (RCA) with the U.S. Food and Drug Administration (FDA) to use Real-world Data to advance the understanding and the natural history of COVID-19 in specific patient populations, as well as treatment and diagnostic patterns during the COVID-19 pandemic. This work reflects the views of the authors and should not be construed to represent FDA's views or policies. PP, EMG, ARW, MW, and NMG are employees of Aetion, Inc., with stock options or existing equity. SL is an employee of HealthVerity.

Figure 1. Charlson-Quan Comorbidity Score

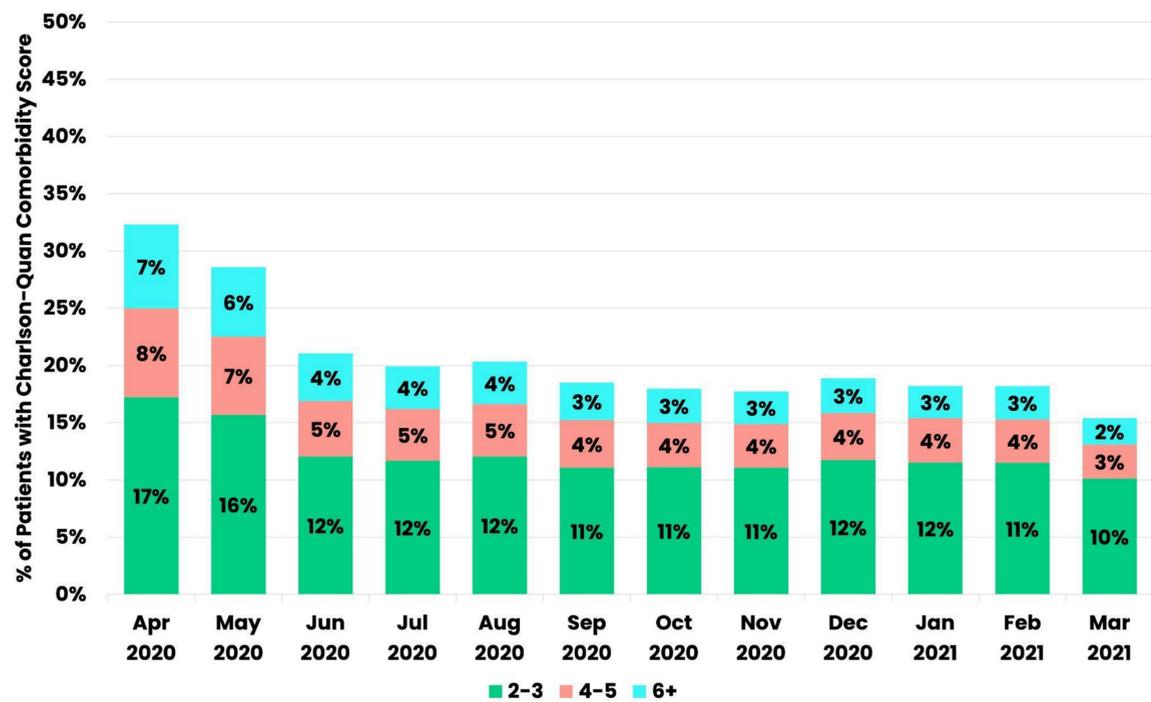


Figure 2. Top 10 Baseline Comorbidities

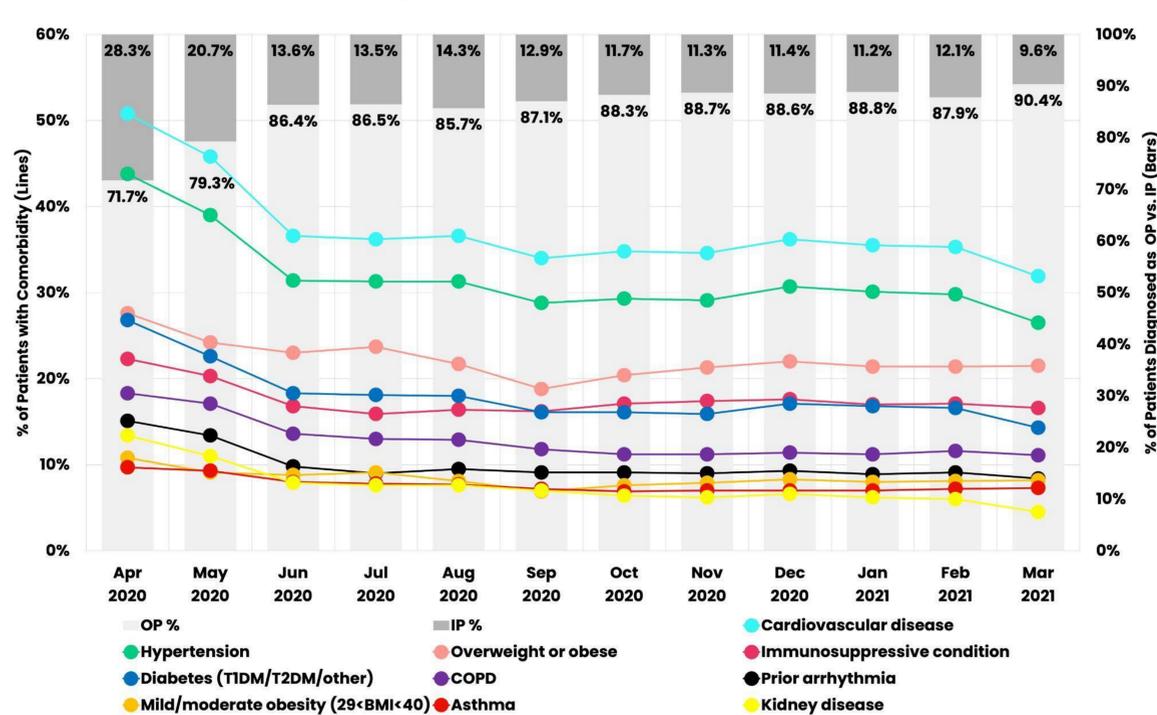


Figure 3. Top 10 Baseline Medications

