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INTRODUCTION

Background

- In randomized clinical trials, inhaled corticosteroid (ICS)-based medications (also known as glucocorticosteroids, glucocorticoids, steroids) have demonstrated effectiveness on asthma endpoints¹
- Despite their potential benefit, real-world data describing medication adherence across large asthma populations are limited

Setting

- The U.S. Food and Drug Administration's Sentinel System is a large real-world data source consisting mainly of administrative and claims data from health insurers (Data Partners)
- We used data from 14 Data Partners participating in the Sentinel System

Objectives

- To estimate proxies of medication adherence among ICS-based asthma medication users in the Sentinel System over a fixed one-year follow-up period

METHODS

Study Cohort

- We conducted a retrospective cohort study and identified two ICS-based asthma medication user cohorts from January 1, 2008 to July 31, 2019: 1) ICS/long-acting beta-agonist fixed dose combination therapy (ICS/LABA); 2) ICS monotherapy
- Cohort entry date or index date was based on the first qualifying ICS-based medication dispensing
- We selected users aged ≥ 18 years with continuous enrollment in health plans and an asthma ICD-9/10-CM diagnosis in the 183 days prior to the index date
- Users with other respiratory comorbidities², including chronic obstructive pulmonary disease, in the 183 days prior to and including the index date were excluded
- We further excluded users with ≥ 2 dispensings of other long-acting asthma maintenance medications³ during the 365 days after and including the index date
- We required all users to be continuously enrolled in health plans in the 365 days after the index date to facilitate calculation of dispensings and PDC

Outcome Measurement

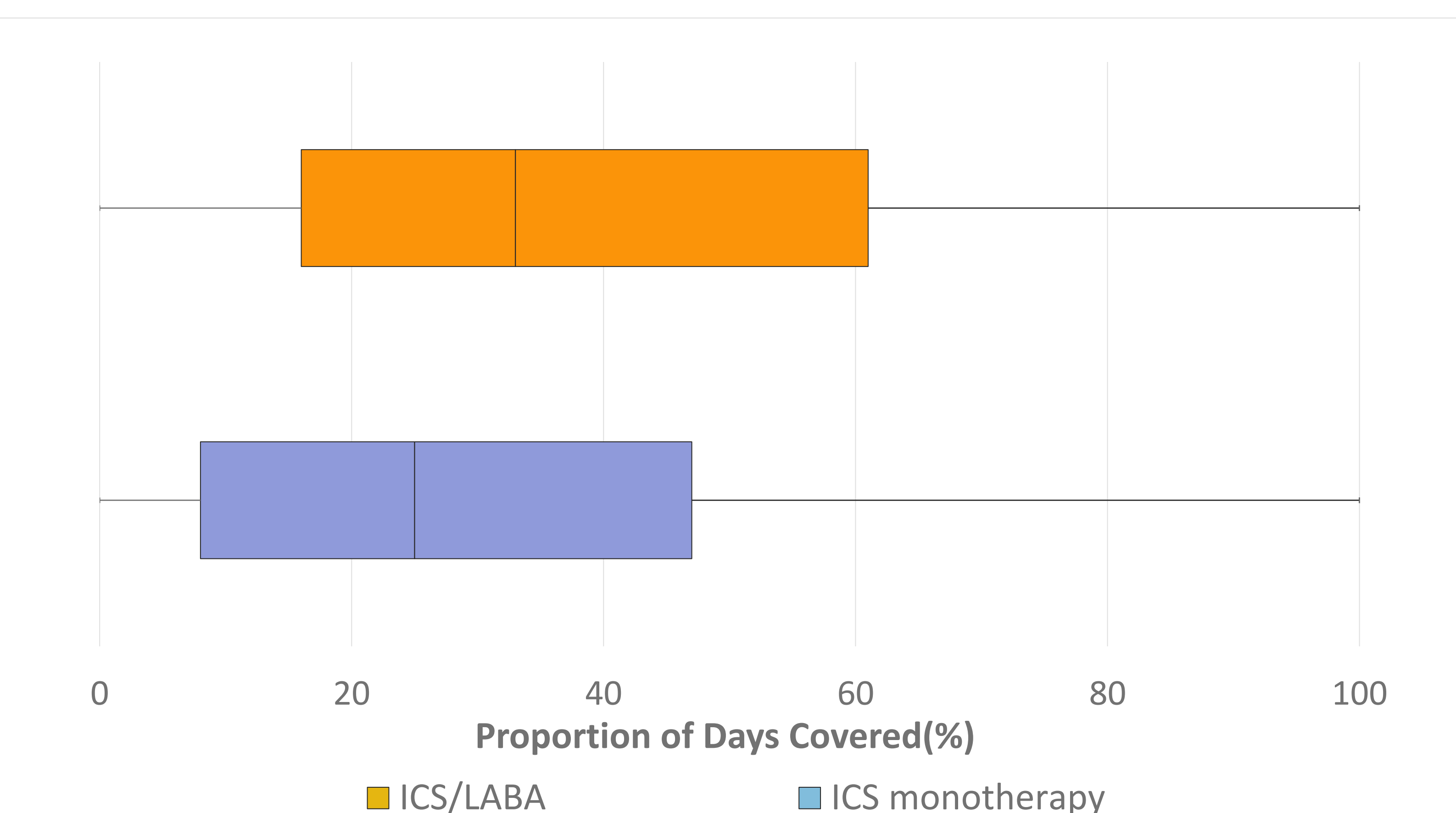
- ICS-based asthma medication adherence proxies included 1) medication use at the dispensing level, and 2) Proportion of Days Covered (PDC) for the treatments of interest, calculated by dividing a patient's cumulative prescription days supply by 366 days

RESULTS AND DISCUSSION

Table 1. Baseline Table for ICS-Based Medication Users

	ICS/LABA		ICS monotherapy	
Number of Medication Users	1,188,694		802,637	
Demographics	Mean	STD	Mean	STD
Mean Age (Years)	58.3	14.9	54.4	16.1
	N	%	N	%
Age (18-64 years)	660,582	55.6%	519,087	64.7%
Age (65+ years)	528,112	44.4%	283,550	35.3%
Sex (Female)	789,544	66.4%	549,811	68.5%

Figure 1. Descriptive Statistics for PDC* over One Year of Follow-up



- The median PDC over one year was 33% (interquartile range (IQR): 16%-61%) for ICS/LABA users, and 25% (IQR: 8%-47%) for ICS monotherapy users

CONCLUSION

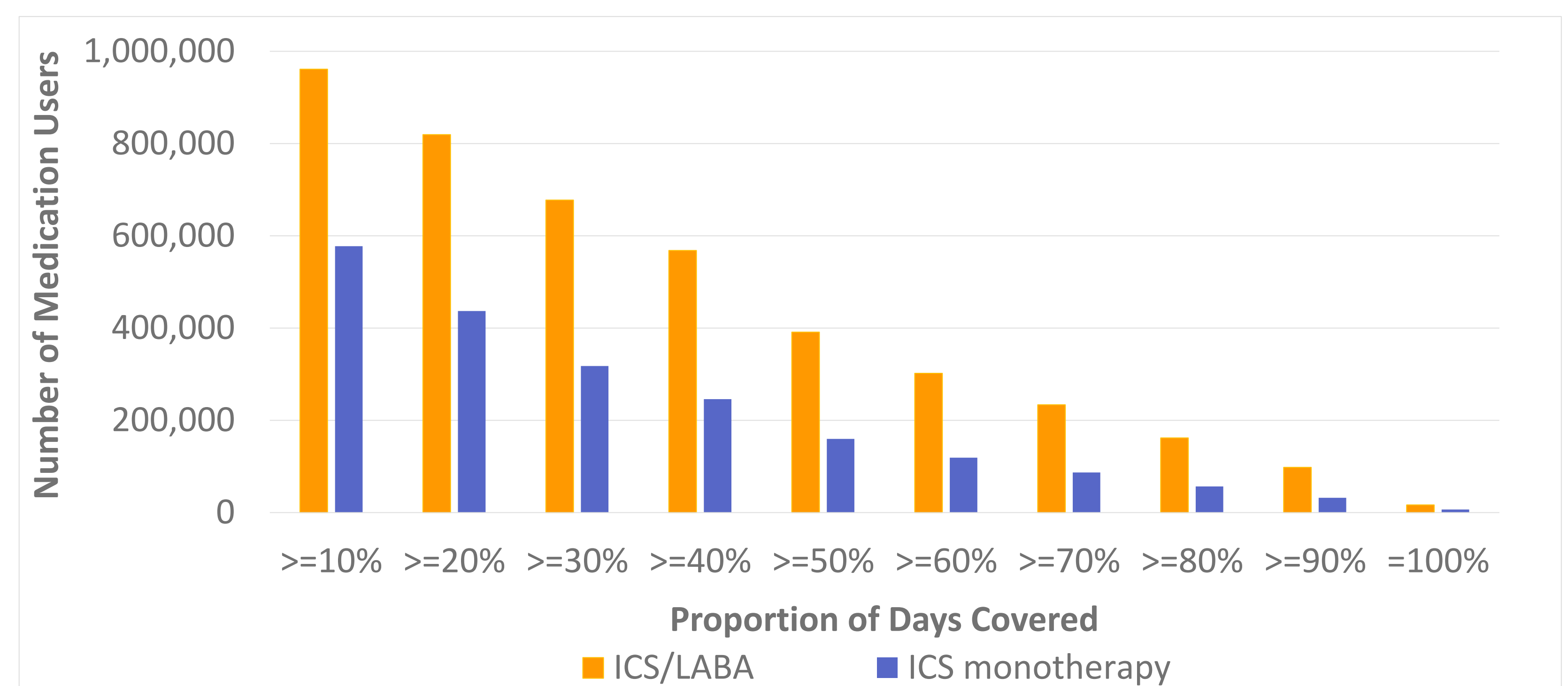
- In our data, ICS/LABA users had a higher median number of dispensings and had a numerically higher PDC compared to ICS users
- Over a one-year follow-up, we observed a median PDC ranging from roughly 25% to 33% for asthma medications intended for chronic daily use
- Real-world data on utilization metrics such as the PDC may reveal inconsistencies between clinical recommendations and proxies of adherence, informing the design of future comparative effectiveness analyses
- Limitation: the study assumed that the dispensings of interest were used as indicated; potential off-label use could influence the interpretation of the observed results

¹Peter J. Barnes. Inhaled Corticosteroids. *Pharmaceuticals (Basel)*. 2010 Mar; 3(3): 514–540.

²List of respiratory comorbidity excluded: COPD, Alpha-1-antitrypsin deficiency, Sarcoidosis, Cystic Fibrosis, Bronchiectasis, interstitial lung diseases, pneumoconioses, and other lung disease

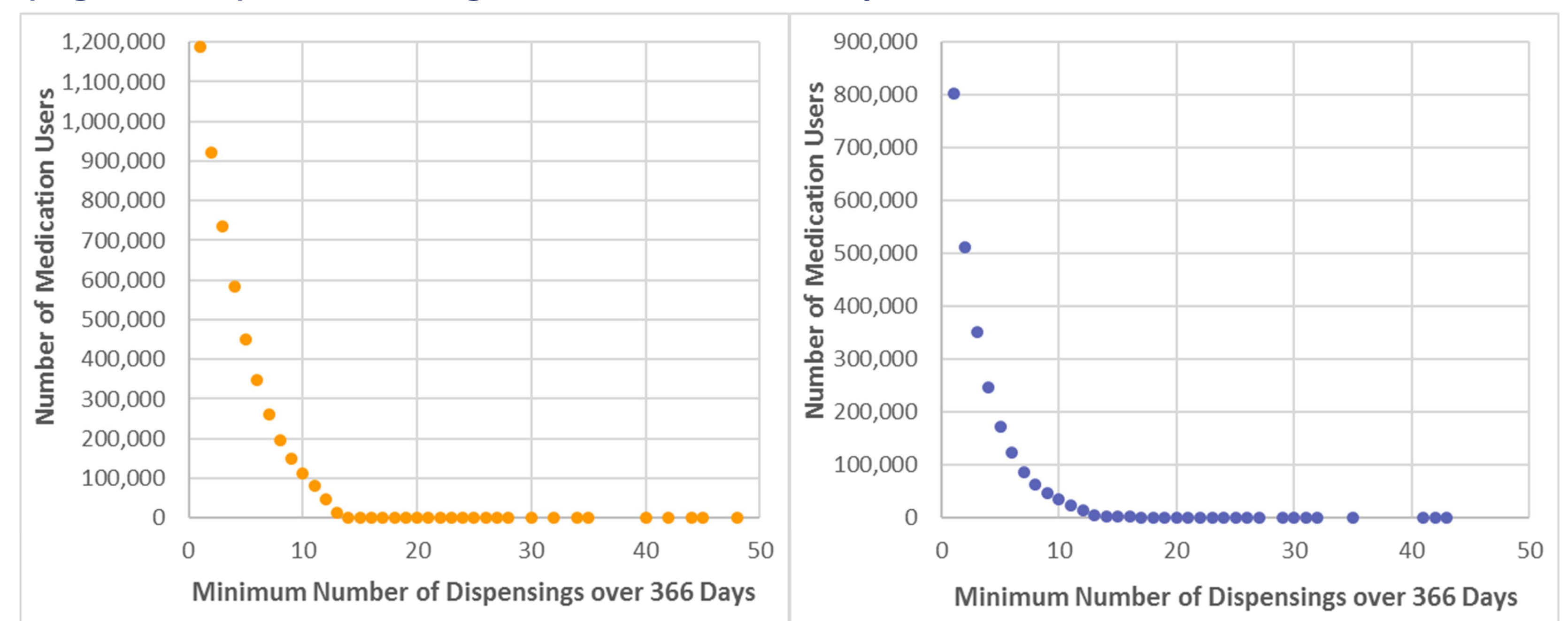
³List of asthma maintenance medication excluded: long-acting beta agonist (LABA), long-acting muscarinic antagonist mono-product (LAMA), LABA and LAMA combination product (LABA/LAMA), ICS, LABA and LAMA combination product (ICS/LABA/LAMA), leukotriene receptor antagonist (LTRA), cromolyn, theophylline, interleukin 4 receptor (IL4R), and interleukin 5 (IL5)

Figure 2. Number of Medication Users Meeting and Exceeding the Specified PDC



- Over a fixed one-year follow-up, 161,844 (14%) of ICS/LABA users and 56,690 (7%) of ICS monotherapy users had greater than 80% of their days covered by medication based on days supply

Figure 3. Minimum Number of Dispensings for ICS/LABA (Left Panel) and ICS Monotherapy (Right Panel) Users During One Year of Follow-up



- Over a fixed one-year follow-up, ICS/LABA and ICS monotherapy users filled their ICS-based medication prescriptions a median of 3 (IQR: 2-6) times and 2 (IQR: 1-4) times, respectively

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DISCLOSURES

The authors have no conflicts of interest to disclose. This poster includes the personal views and opinions of the co-authors. It is not intended to convey official FDA policy, and no official support or endorsement by the FDA is provided or should be inferred.