Asthma maintenance medication users in the Sentinel System

U.S. FOOD & DRUG ADMINISTRATION

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Background and Objective

- The 21st Century Cures Act mandates that the United States Food and Drug Administration (US FDA) evaluate the potential use of real-world evidence (RWE) to support regulatory decision making.

- Asthma and other respiratory diseases represent promising candidates for RWE comparative effectiveness research because effectiveness endpoints – such as asthma exacerbations in the inpatient and outpatient setting – also represent safety events requiring treatment that may be able to be captured in claims and electronic health records.

- The feasibility of using the Sentinel System to evaluate the comparative effectiveness of asthma maintenance medications in real-world settings is unclear.

- We examined demographic and clinical characteristics of asthma patients dispensed asthma maintenance medications in the Sentinel System.

Methods

- Study design: retrospective cohort study in Sentinel from 2008 to 2018 (Figure 1)

- Adult Asthma patients were identified from inpatient or outpatient claims using ICD-9 or ICD-10 asthma diagnosis code

- Evidence of the dispensing of asthma maintenance medications (Table 1) in the baseline period was required

- Subjects with evidence of other pulmonary comorbidities (Table 2) in the baseline period were excluded

- We calculated summary statistics for selected demographic and clinical characteristics (including: medication dispensings, proxies for disease exacerbations, and health services utilization) during the 1 year baseline and 1 year follow-up periods
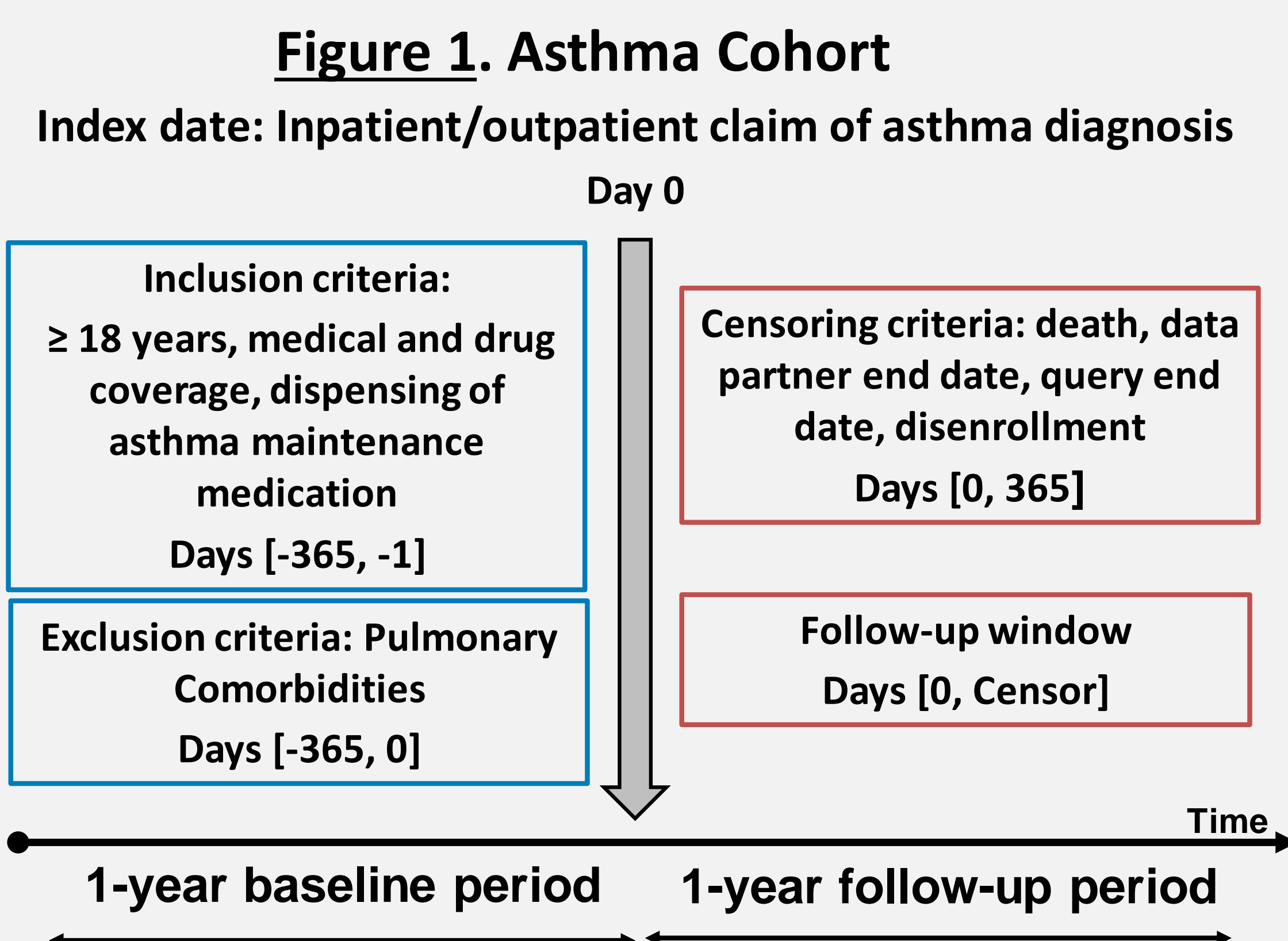
Figure 1. Asthma Cohort

Index date: Inpatient/outpatient claim of asthma diagnosis

Day 0

Inclusion criteria: ≥ 18 years, medical and drug coverage, dispensing of asthma maintenance medication Days [-365, -1]

Exclusion criteria: Pulmonary Comorbidities Days [-365, 0]

Censoring criteria: death, data partner end date, query end date, disenrollment Days [0, 365]

Follow-up window Days [0, Censor]

1-year baseline period | 1-year follow-up period

Time

Table 1. Asthma Maintenance Medications
- Inhaled Corticosteroids (ICS)
- Long-acting Beta-agonists (LABA)
- Long-acting Muscarinic antagonists (LAMA)
- Inhaled Combination Products (e.g., ICS/LABA)
- Leukotriene Receptor Antagonists (LTRA)
- Biological products for asthma(e.g anti-IL5-biologics)

Table 2. Excluded Pulmonary Comorbidities
- COPD
- Bronchiectasis
- Cystic Fibrosis
- Sarcoidosis
- Interstitial Lung Diseases
- Pneumoconioses
- Alpha-1 antitrypsin Deficiency

Results

■ **3,325,710 enrollees were identified as asthma maintenance medication users.**

41.6% Age 65+
57.0 Mean age

69.3% Female

80.5% White*
* Among patients with race information reported

1.8 (SD = 1.8) Mean Charlson/ Elixhauser combined comorbidity score[1]

27.2% Evidence of smoking history

28.7% Evidence of spirometry

42.3 Mean # of prescriptions

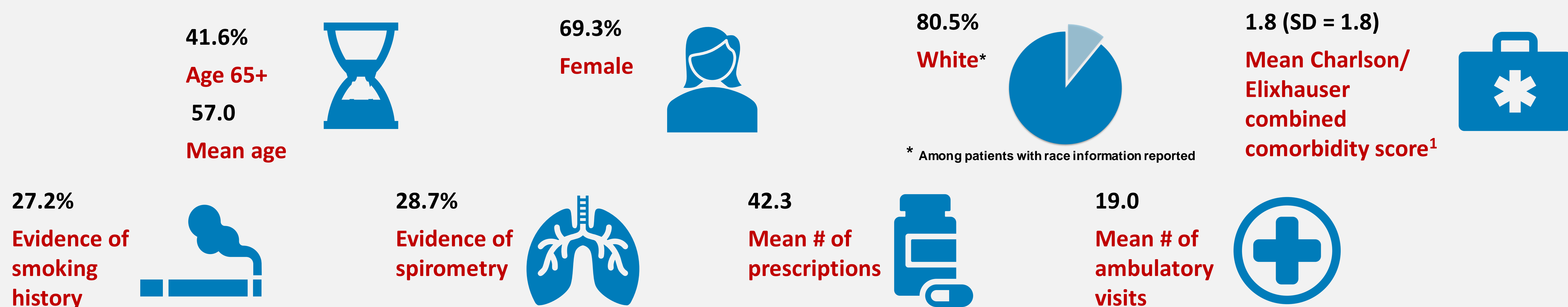**19.0** Mean # of ambulatory visits

Figure 2. Select baseline demographic and clinical characteristics of common asthma medication users

■ Use of ICS+LABA fixed dose combinations, LTRA, and ICS monoproducts were the most common maintenance medication observed (Figure 3).

ICS: inhaled corticosteroid
LABA: long-acting beta-agonists
LAMA: long-acting muscarinic antagonists
LTRA: leukotriene receptor antagonists

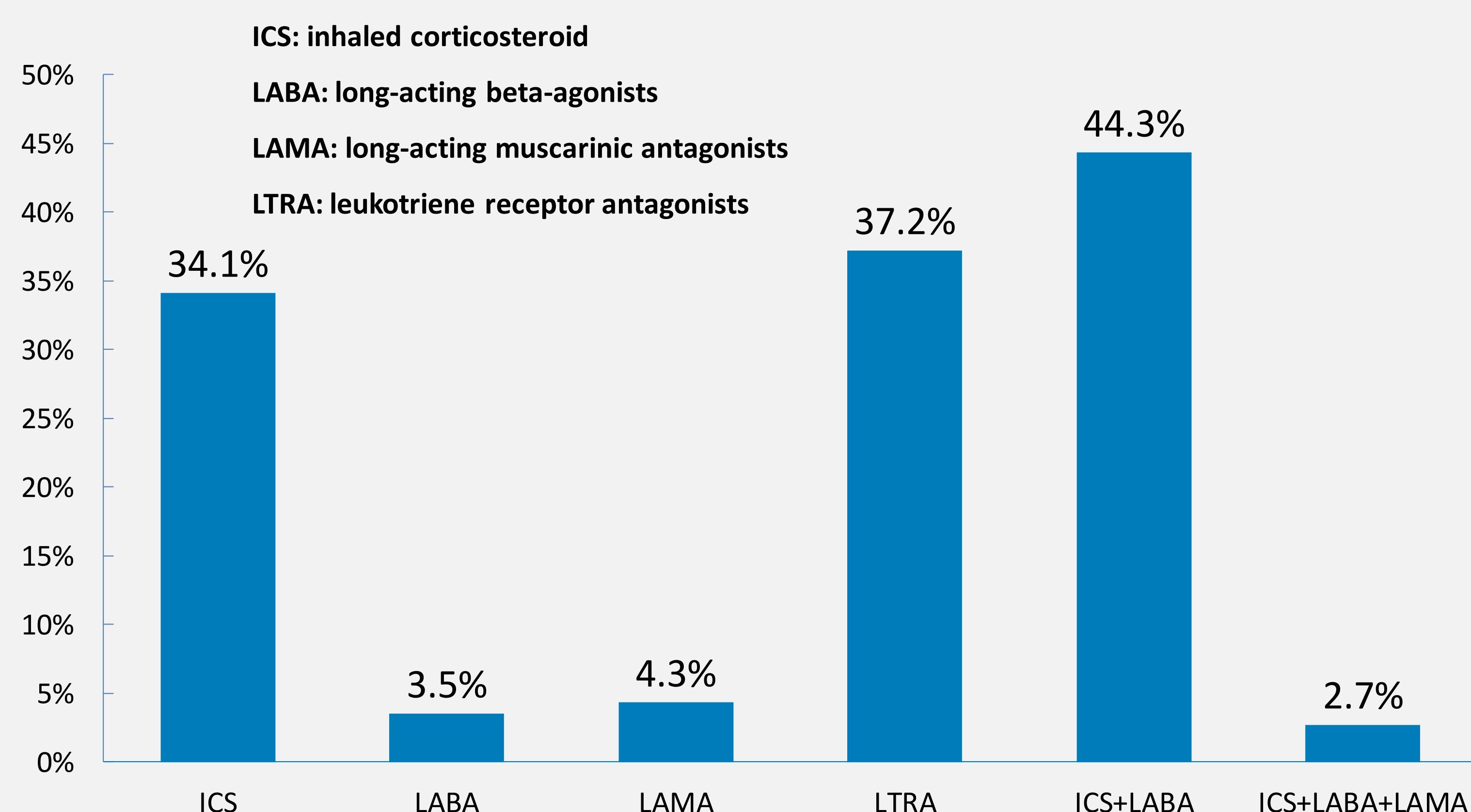ICS 34.1% | LABA 3.5% | LAMA 4.3% | LTRA 37.2% | ICS+LABA 44.3% | ICS+LABA+LAMA 2.7%

Figure 3. Proportion of patients with different asthma maintenance medication use (≥ 2 pharmacy dispensings) during the 2-year study period (N= 3,325,710)

■ Less than 20% of patients had ≥ 1 respiratory event coded as asthma exacerbation in any care setting in the baseline and follow up periods.

■ 37.9% of patients filled ≥1 oral corticosteroid (OCS) prescription in the follow-up period (Figure 4).

Baseline | Follow-up

* Encounters with ICD codes of asthma with acute exacerbation

"Asthma exacerbation", any care setting*: 19.9% / 14.4%
"Asthma exacerbation", inpatient setting*: 1.7% / 1.9%
OCS dispensing: 40.2% / 37.9%
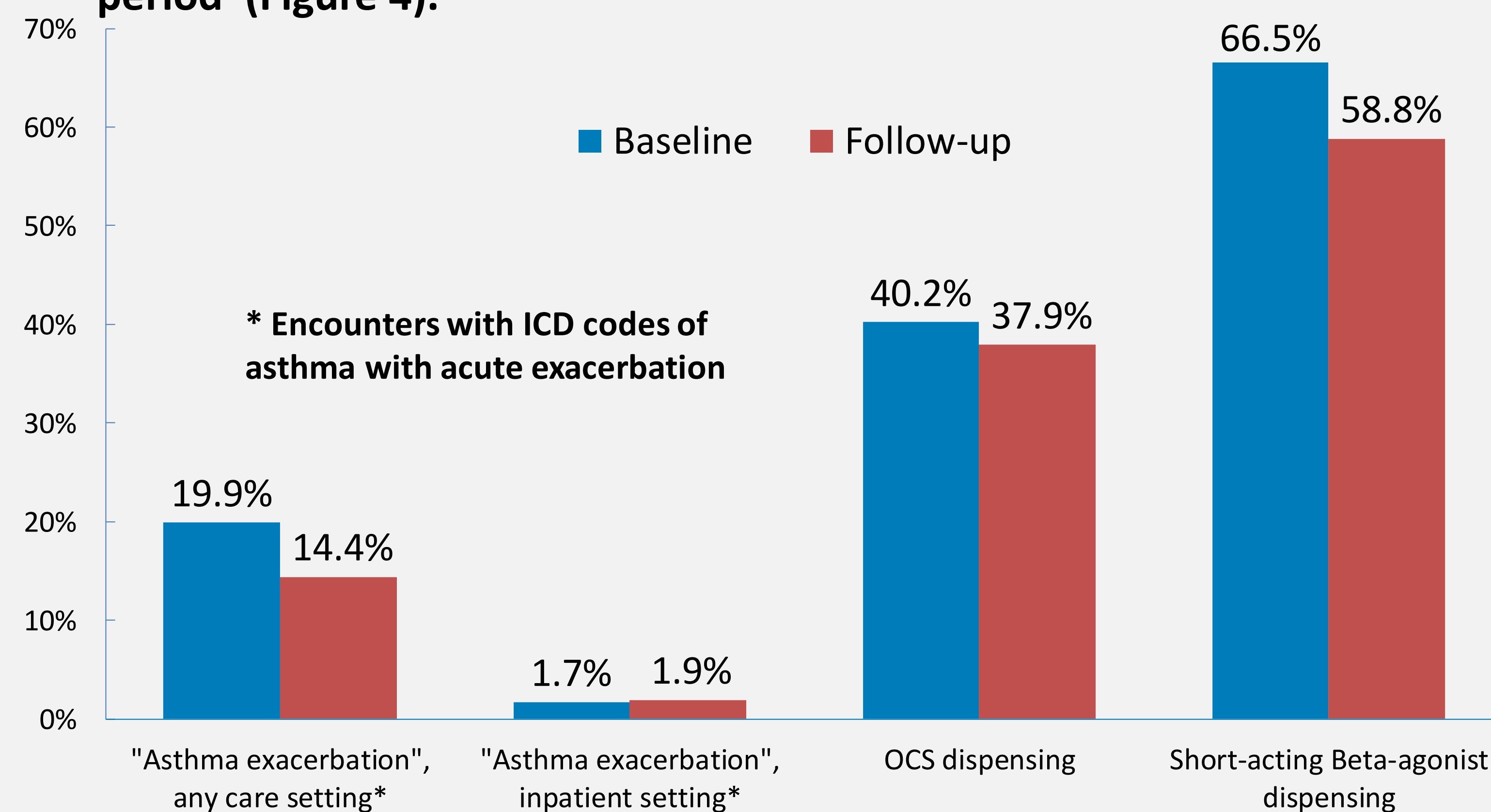Short-acting Beta-agonist dispensing: 66.5% / 58.8%

Figure 4. Proportion of patients with asthma exacerbation diagnosis* and treatment use during the 1-year baseline and follow-up period (N= 3,325,710)

Discussion and Conclusions

- These data on healthcare encounters, prescriptions, and comorbidities provide insight on the health status of asthma patients in the Sentinel System.

- The inconsistency between the proportion of patients with ICD codes for asthma exacerbation and the proportion filling OCS prescriptions warrants further examination.

- To our knowledge, these data represent the first comprehensive characterization of asthma patients in Sentinel, and they suggest that future analyses of asthma and exploration of asthma medication users in Sentinel are feasible.

- However, these exploratory data should be interpreted with caution. Our disease definitions of asthma are not validated. Our analyses did not assess asthma maintenance medication adherence over time. In addition, the interpretation of asthma exacerbation data are limited by inconsistent coding of these events, leading to the potential for misclassification without additional validation.

References: 1. Gagne, JJ. Glynn, RJ. Avorn. J. Levin, R. Schneeweiss, S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011 Jul;64(7):749-59.