

# Characteristics and timing of treatment among patients with influenza-like illness

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## Background

- The FDA's Sentinel System is an active surveillance system that uses routine querying tools and pre-existing electronic healthcare data to monitor the safety of regulated medical products.
- Medical countermeasures (MCM) are FDA-regulated products (biologics, drugs, devices) that may be used in the event of a potential public health emergency. The US FDA and other agencies monitor the safety, effectiveness, and utilization of MCMs.
- Influenza is a use case for public health emergency events and influenza antivirals are examples of MCMs. Understanding the characteristics of those who do and do not receive treatment for influenza can aid in the design of future studies to evaluate MCMs in a real-world setting.

## Objective

To examine baseline characteristics of individuals with outpatient influenza-like illness (ILI) across two influenza seasons, by treatment status and timing

## Methods

### Population

Individuals ≥6 months of age with incident ILI (30-day washout) via influenza-specific diagnosis codes (without lab confirmation) in the outpatient and emergency department settings during two influenza seasons: July 2014 - June 2015 and July 2015 - June 2016

### Data

Truven Health MarketScan® Databases formatted to the Sentinel Common Data Model

### Analysis

- We identified incident treatment with influenza antivirals (oseltamivir, peramivir, zanamivir; 10-day washout) via dispensings and injections
- ILI episodes were stratified by treatment status and timing: treatment on ILI diagnosis date, treatment the day after diagnosis date, treatment 1-5 days after diagnosis date, and no treatment within 5 days of diagnosis
- We assessed presence of comorbidities in the 183 days preceding ILI diagnosis: asthma, diabetes, chronic obstructive pulmonary disease (COPD), and obesity
- We also examined influenza vaccination in the 183 days prior to ILI diagnosis and influenza testing ±7 days of diagnosis

## Results

More people with ILI were treated than not in each season (Figure 1). There were 51% fewer episodes of ILI in 2015-2016 compared to 2014-2015, consistent with the milder severity of that season.

**Figure 1. ILI episodes by season and treatment status**

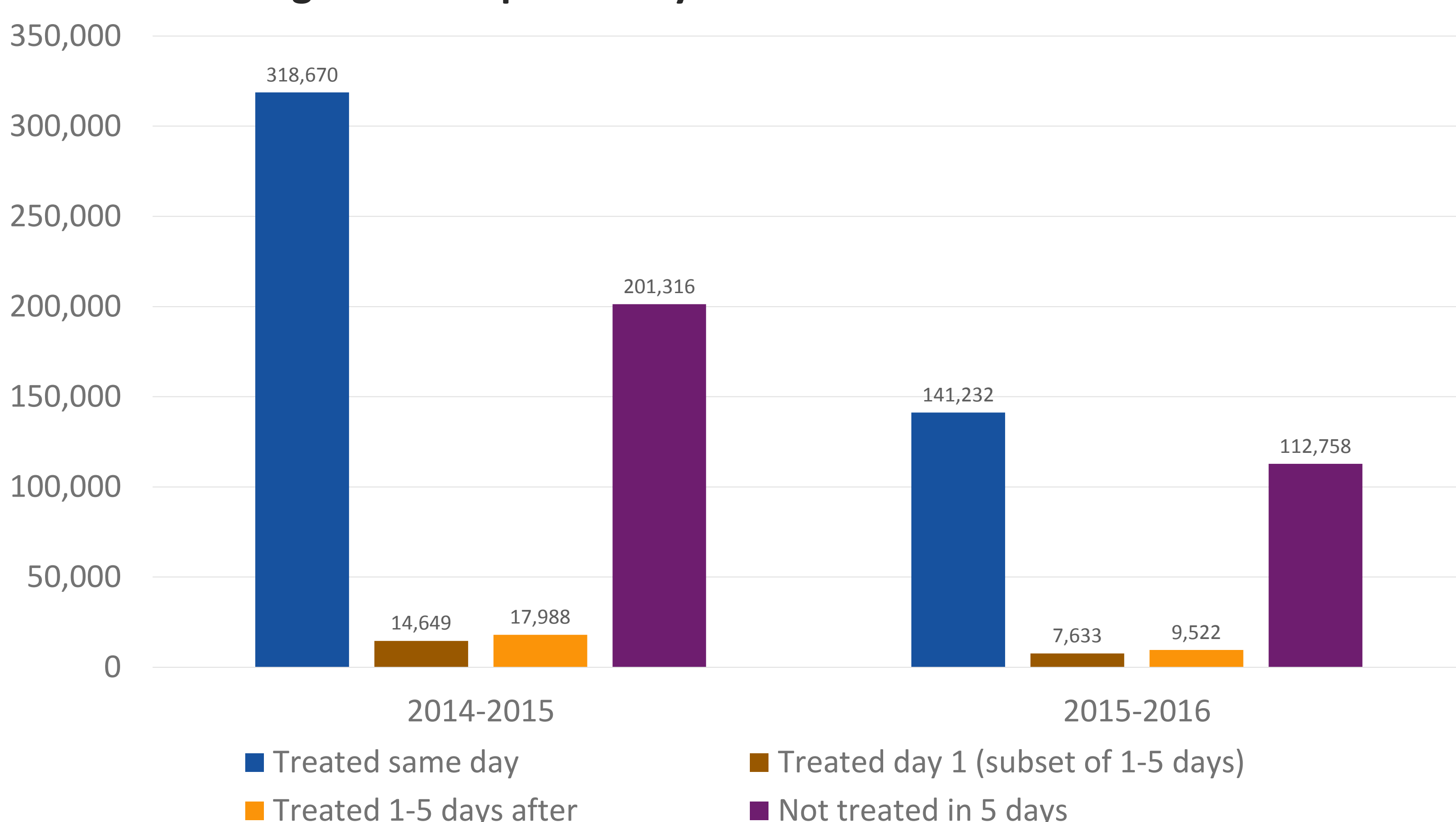


Table 1 and Figure 2 provide age information for ILI episodes by treatment status – those treated 1-5 days after diagnosis are older in both seasons.

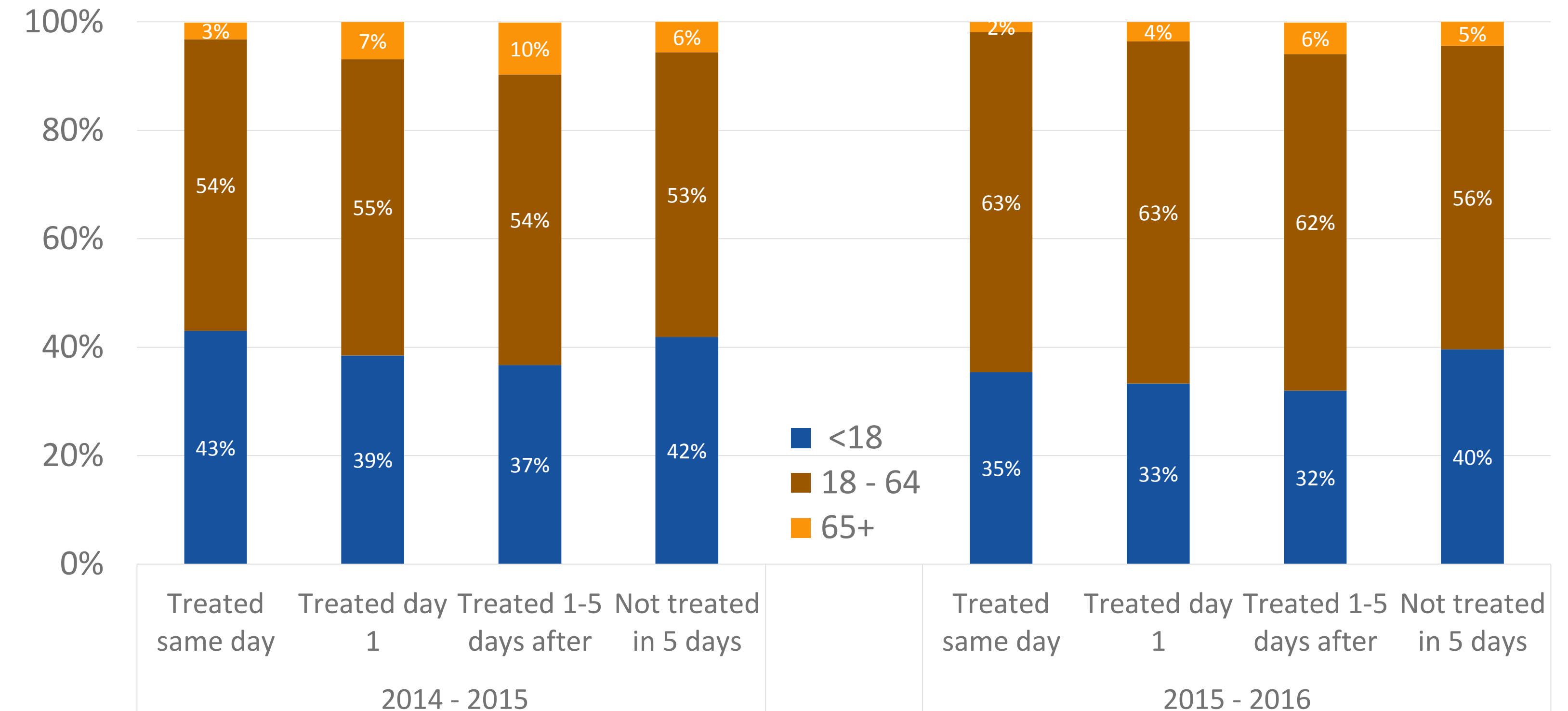
Table 1. Age (mean and SD) in years by treatment status		
	2014 - 2015	2015 - 2016
Treated same day	28.7 (20.5)	30.5 (19.5)
Treated day 1	31.0 (22.4)	31.1 (20.5)
Treated 1-5 days after	32.9 (23.7)	32.7 (21.6)
Not treated in 5 days	29.7 (22.1)	29.8 (21.3)

## Acknowledgements/Disclosures

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- This article reflects the views of the author and should not be construed to represent the U.S. FDA's views or policies.
- The authors have no conflicts of interest to disclose.

## Results (continued)

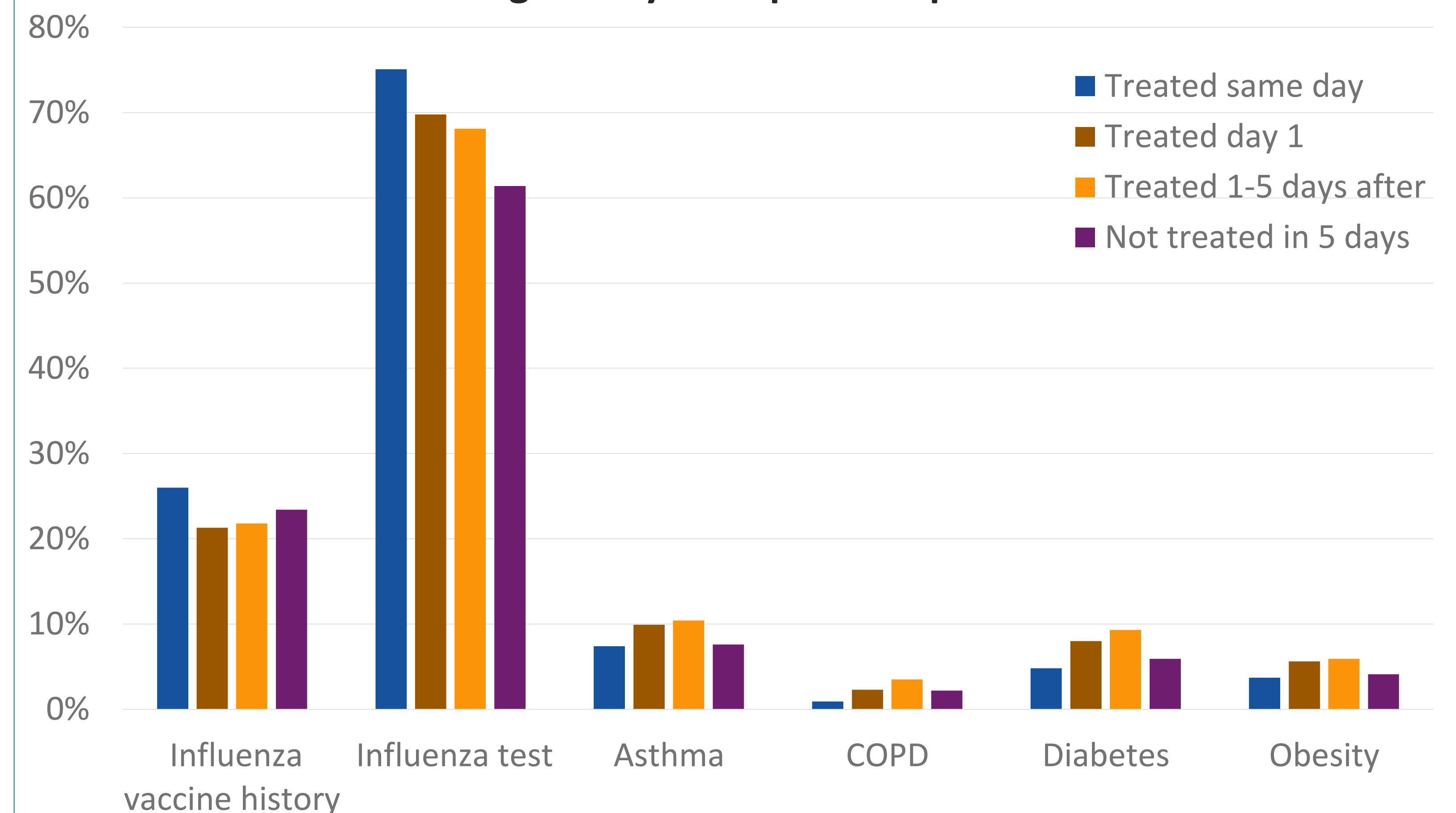
**Figure 2. Age distribution of ILI episodes by treatment status**



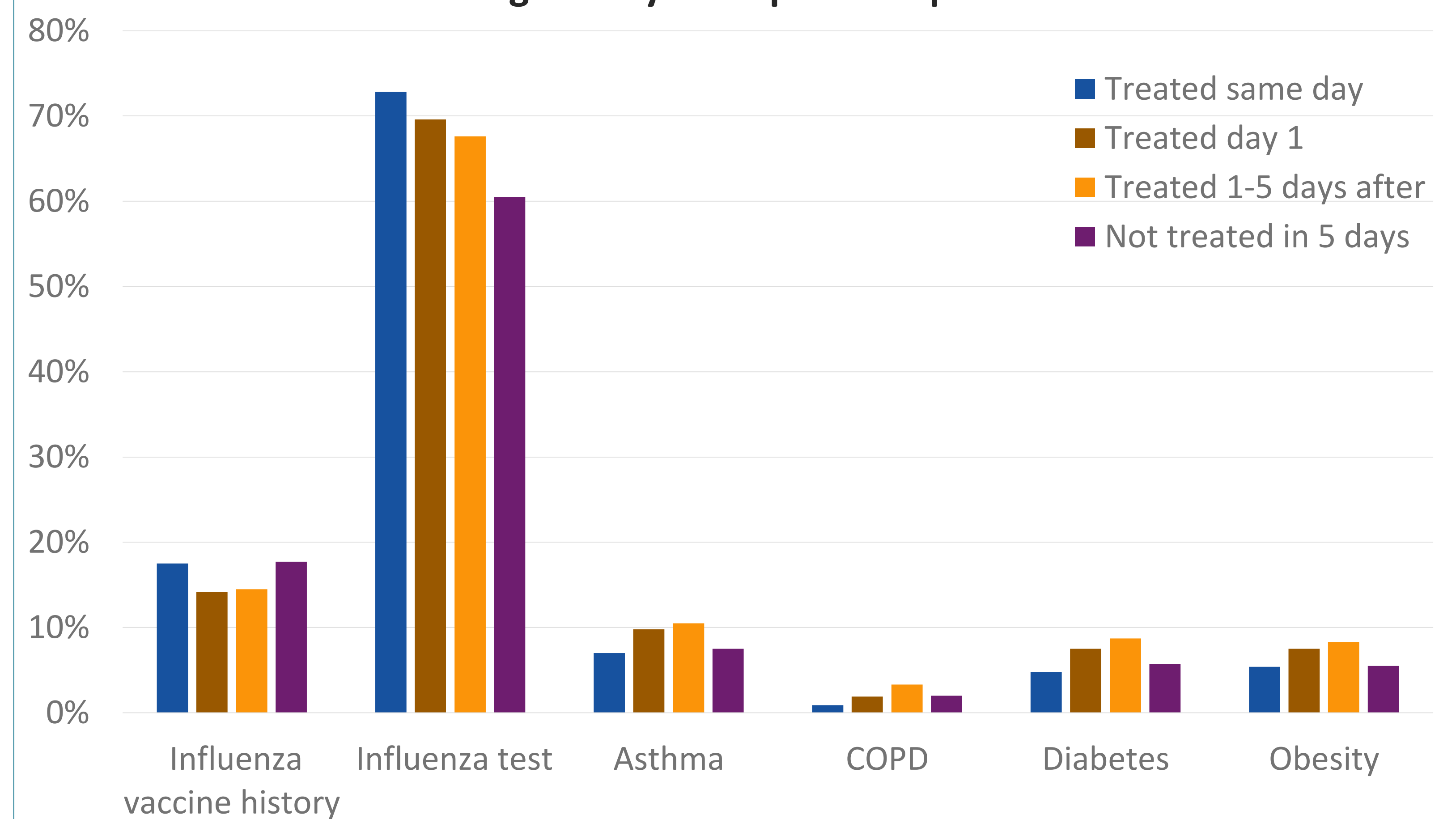
Baseline characteristics associated with the ILI patient episodes in each season are presented in Figures 3 and 4.

- History of asthma, COPD, diabetes, and obesity were higher among those treated on days 1-5 compared to the those treated the same day and untreated.
- Influenza vaccination was 21-26% across groups in 2014-2015, 13-18% in 2015-2016.
- Influenza testing within 7 days of diagnosis was high in all groups, but highest in those treated same day (73-75%).

**Figure 3. 2014-2015 season: comorbidity, influenza vaccine, and testing history of ILI patient episodes**



**Figure 4. 2015-2016 season: comorbidity, influenza vaccine, and testing history of ILI patient episodes**



## Conclusions

- For the 2014-2015 and 2015-2016 influenza seasons, more patients who met our ILI definition were treated with an influenza antiviral than were not.
- Individuals treated on days 1-5 were slightly older and had more comorbidities than those treated on the same day or not treated at all.
- Next, this analysis of baseline characteristics and treatment among those with outpatient ILI episodes will be conducted in the Sentinel distributed database.

## Limitations

- Influenza episodes were based on diagnosis codes and were not lab confirmed.
- Only outpatient and ED based diagnosis codes were used to define ILI, with treatment assessed in the outpatient setting, since there is limited inpatient treatment data.