

Herpes Zoster Vaccines: Update

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Coverage and 2-dose completion

Monitoring System	Description	Coverage/ Uptake	2-dose Completion
TIPS Trends in Immunization Practice System	Immunization Information Systems	✓	✓
CMS Medicare Beneficiaries	Administrative Claims	✓	✓
VSD Vaccine Safety Datalink	Electronic Health Record	✓	✓
NHIS National Health Interview Survey	Survey	✓	✓
BRFSS Behavioral Risk Factor Surveillance System	Survey	✓	

Preliminary results for zoster vaccine uptake in Immunization Information Systems (IIS)

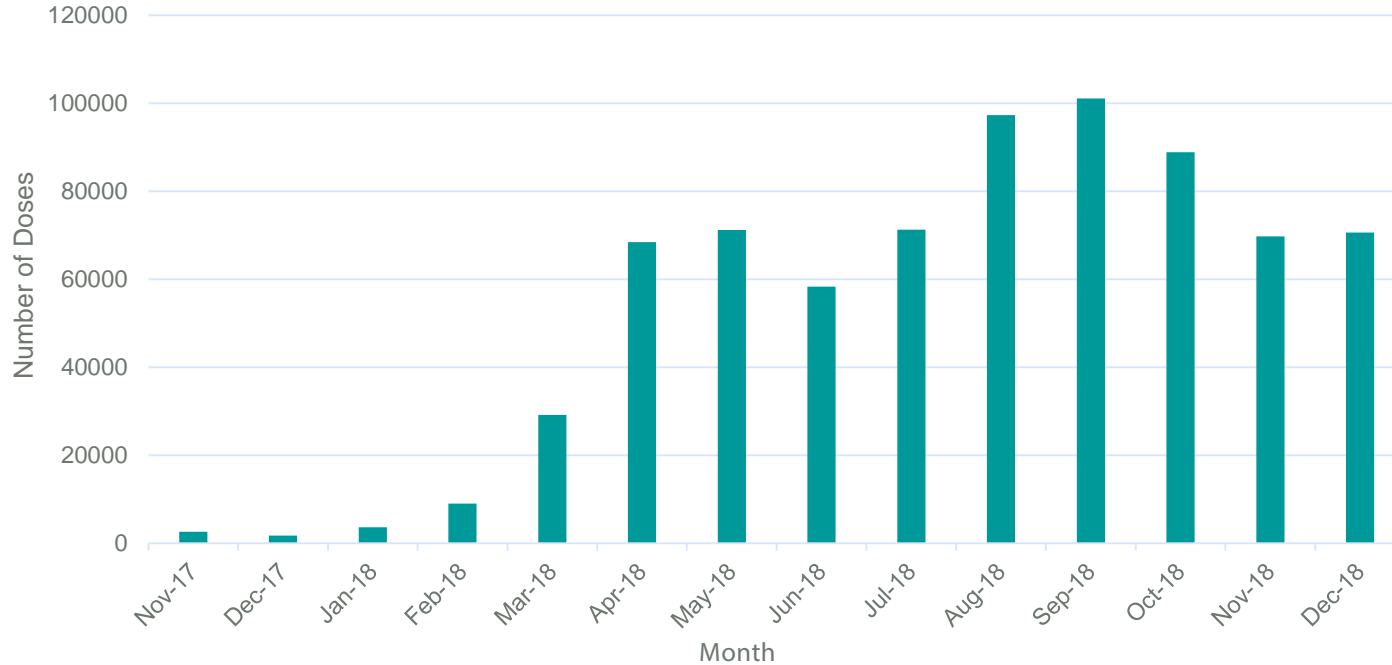
- Observation period: Oct 17, 2017 – Dec 31, 2018
- 6 jurisdictions: MN, MI, OR, ND, WI, NYC
- Inclusion criteria: age ≥ 50 yrs and RZV vaccination recorded in IIS
- Data pulled Feb 7-14- (data are dynamic)
- Analysis provided by IIS Sentinel Site Awardees

Age of persons who received doses of RZV in IIS*

	Number of Doses	
	#	%
Total	751,405	100%
Age		
<i>50-59</i>	155,594	21%
<i>60-69</i>	304,365	41%
<i>70-79</i>	210,487	28%
<i>80+</i>	80,959	11%

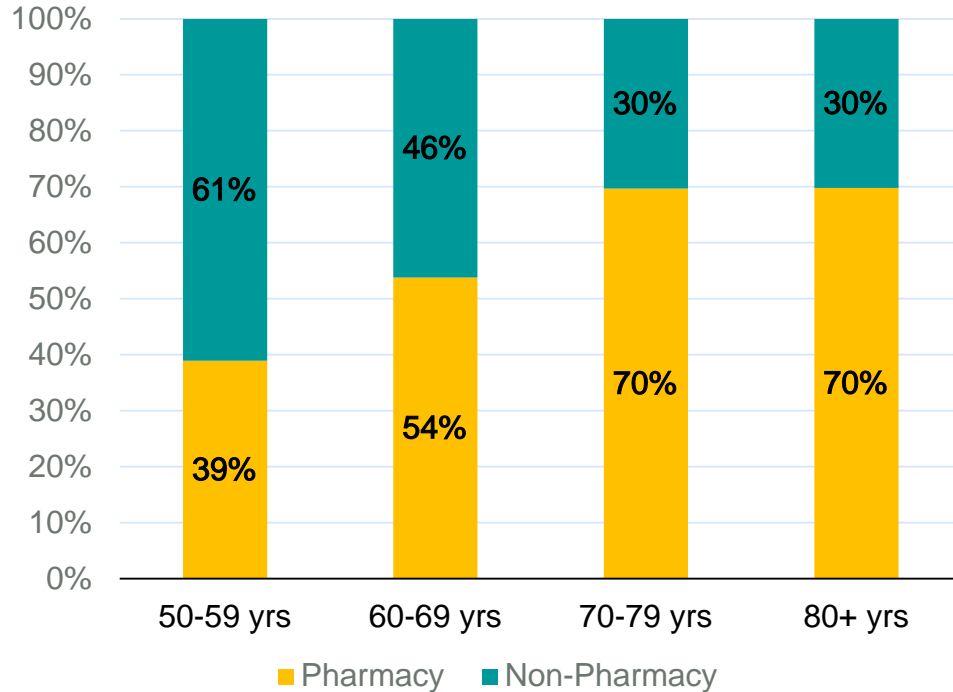
*6 jurisdictions

Number of RZV doses recorded in IIS*, by month, Oct 2017- Dec 2018



*6 jurisdictions

Location of RZV administration in IIS*: Pharmacy vs Non-Pharmacy



Administered in Pharmacy:

Range in jurisdictions: 28%-85%

All jurisdictions:

Older age ⇒ ↑ pharmacy RZV admin

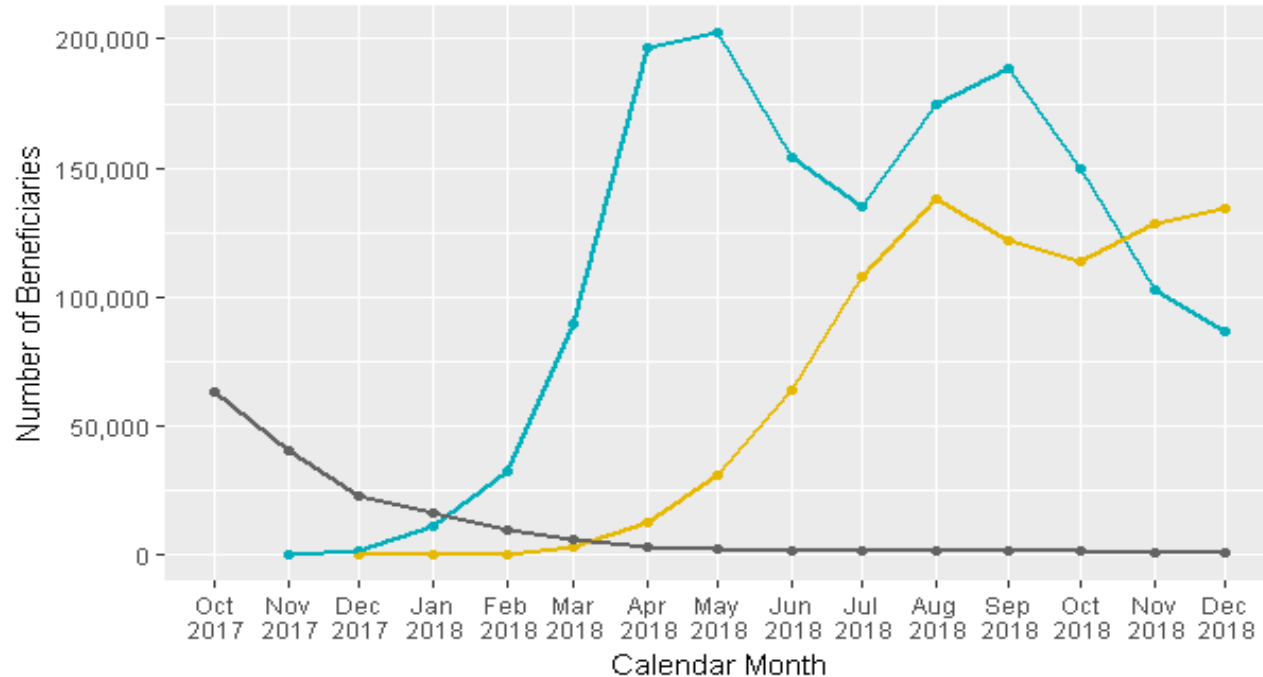
Preliminary results for zoster vaccine uptake among Medicare beneficiaries

- Observation period: Oct 1, 2017 – Dec 31, 2018
- Inclusion criteria for beneficiaries:
 - Aged into Medicare (≥ 65 yrs at Oct 2017)
 - Continuously enrolled in Medicare Part D from Oct 2017 to vaccination date
- Data pulled Feb 13-14 (data are dynamic)
- Analysis provided by Acumen, LLC through a collaboration with FDA, CMS and CDC

Characteristics of Medicare beneficiaries with at least one dose of RZV

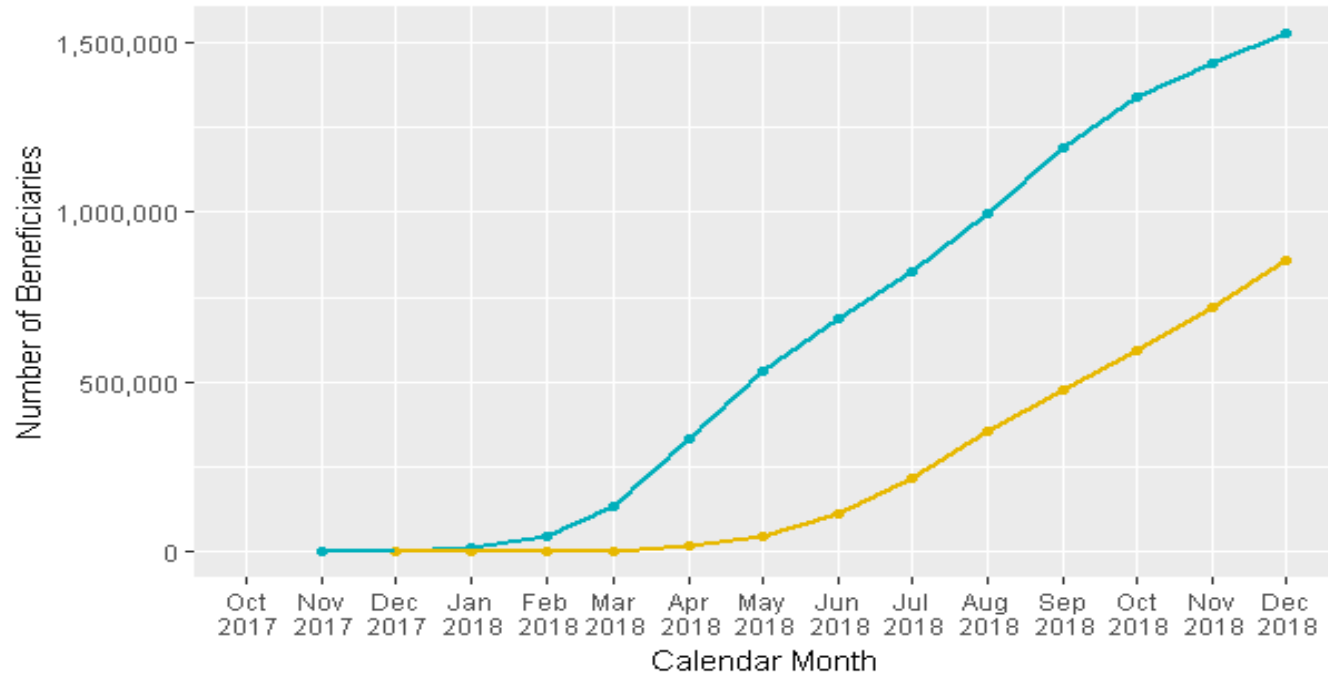
Demographic Variables	Vaccinated Beneficiaries	
	#	%
Total	1,526,326	100%
Age (Continuous)		
<i>Mean</i>	75	
<i>SD</i>	6.4	
Age (Categories)		
<i>65-69</i>	367,534	24%
<i>70-74</i>	470,683	31%
<i>75-79</i>	352,298	23%
<i>80-84</i>	200,438	13%
<i>85-89</i>	98,188	6%
<i>90+</i>	37,185	2%
Sex		
<i>Male</i>	632,279	41%
<i>Female</i>	894,047	59%

Number of ZVL and RZV vaccinated Medicare beneficiaries by month, Oct 2017- Dec 2018



Vaccine Type 1st RZV Administration 2nd RZV Administration ZVL

Cumulative number of RZV vaccinated Medicare beneficiaries, Oct 2017- Dec 2018



Time of Administered RZV — 1st Administration — 2nd Administration

RZV series completion and timing of the second dose

Month of First RZV Vaccination	Number of Beneficiaries With First Vaccination	Proportion of Vaccinated Beneficiaries Who Have Received Second Vaccination (Cumulative Time Since Vaccination)			
		2nd month (60 Days)	3rd month (90 Days)	6th month (180 Days)	9th month (270 Days)
Jan 2018	11,217	8%	47%	78%	86%
Feb 2018	32,412	7%	43%	77%	85%
Mar 2018	89,471	4%	37%	76%	
Apr 2018	196,464	3%	31%	77%	
May 2018	202,537	2%	33%	76%	
Jun 2018	153,839	3%	35%		
Jul 2018	135,398	3%	32%		
Aug 2018	175,008	2%	29%		
Sep 2018	188,710	3%			
Oct 2018	149,585				
Nov 2018	103,033				
Dec 2018	87,037				

RZV Supply Status

- GSK plans to manage RZV supply by continuing order limits during 2019
 - Providers will continue to experience shipping delays
- In response to demand for the vaccine during 2018, GSK has taken the following steps:
 - Increased the number of doses available for the US market in the second half of 2018
 - Planned for more frequent, higher volume shipments to increase supply and deliver doses more consistently for all customer types during 2019

Summary of HZ Work Group Discussions

- RZV demand continues to outpace supply
- ~8.59 M doses distributed through 2018, a greater number of doses expected in 2019
- 2-dose RZV series completion >75% among Medicare beneficiaries
- A preliminary statistical signal for GBS among RZV recipients has been observed based on 4 claims in administrative data
 - **HZ Work Group agrees that there is insufficient evidence at this time to support a change in policy or practice**
 - **More investigation is required to determine whether this is, or is *not*, is a safety problem**
 - ❑ **Clinical validation necessary (underway)**
 - ❑ **Evaluation of near real-time data in multiple systems (underway)**
 - **HZ Work Group will be updated on each step, as new information becomes available**

Questions