

**Vaccines and Related Biological Products
Advisory Committee October 14-15, 2021 Meeting
Presentation Meeting**

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Vaccines and Related Biological Products Advisory Committee Meeting

Review of RWE to Assess the Effectiveness of a single dose of Janssen COVID-19 Vaccine (Ad26.COV2.S)

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Outline

1. Data Sources and Study Design
2. Cohort Description
3. Effectiveness Data
4. Study Limitations
5. Conclusions and Summary



Data Sources for the RWE Study

HealthVerity COVID-19 dataset

- ~47.5 million individuals nationally
- Medical and pharmacy claims, laboratory, hospital transactional records
- Data lag between 2-6 weeks, depending on source

Comparability Between HealthVerity and US Census Populations

Data	HealthVerity Population	US Census Population
East North Central	16.5%	15.0%
East South Central	5.5%	6.0%
Middle Atlantic	13.2%	13.2%
Mountain	7.2%	7.2%
New England	4.4%	4.7%
Pacific	15.5%	16.2%
South Atlantic	18.3%	19.4%
West North Central	5.6%	6.6%
West South Central	13.8%	11.8%
Gender		
Female	53.9%	50.9%
Male	46.1%	49.1%
Ages		
0-17 years	25.3%	23.1%
18-44 years	34.3%	36.2%
45-64 years	25.3%	26.2%
≥65 years	15.2%	14.5%

Design and Data Collection Period

Inclusion Criteria

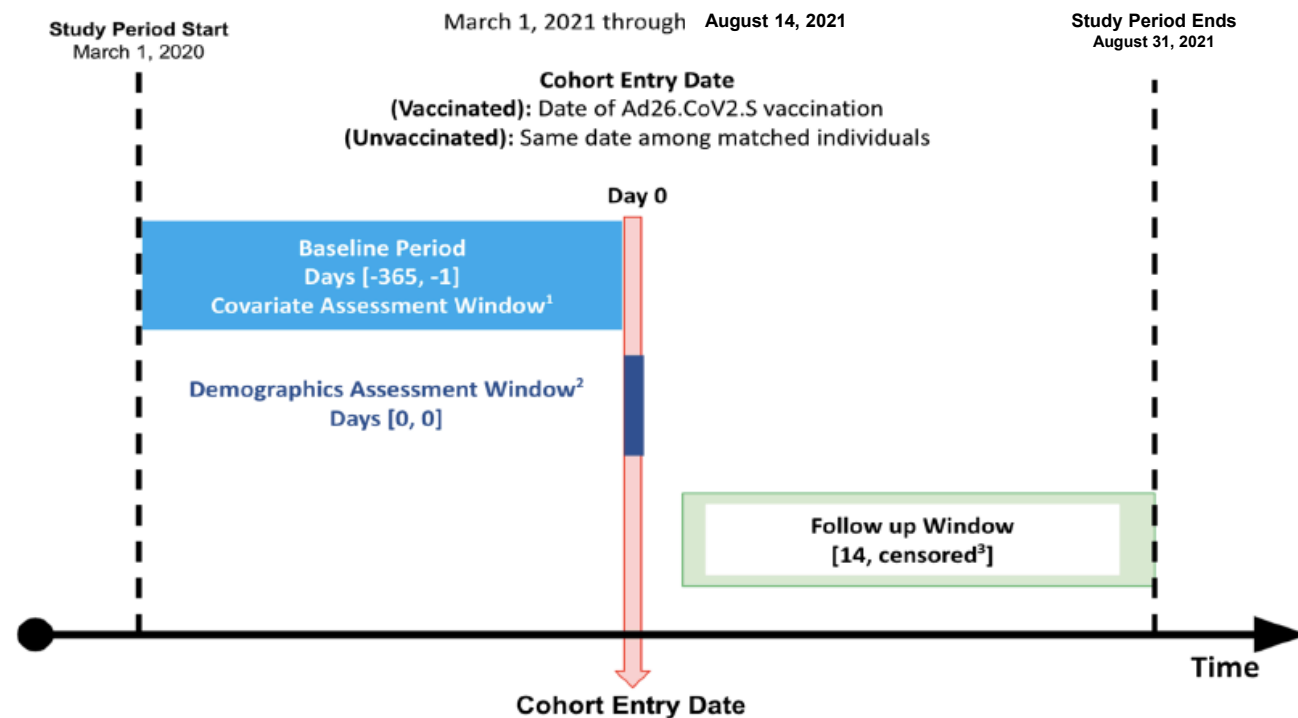
1. No prior COVID-19 vaccination before start date
2. 1 claim in the prior 12-months from index date
3. Continued enrollment in medical/pharmacy insurance 12-months prior to index date

Matching

1. Exact matching on age (4-year bins), sex, 3-digit zip codes
2. Matches were further refined via propensity scores based on patient characteristics and relevant comorbidities

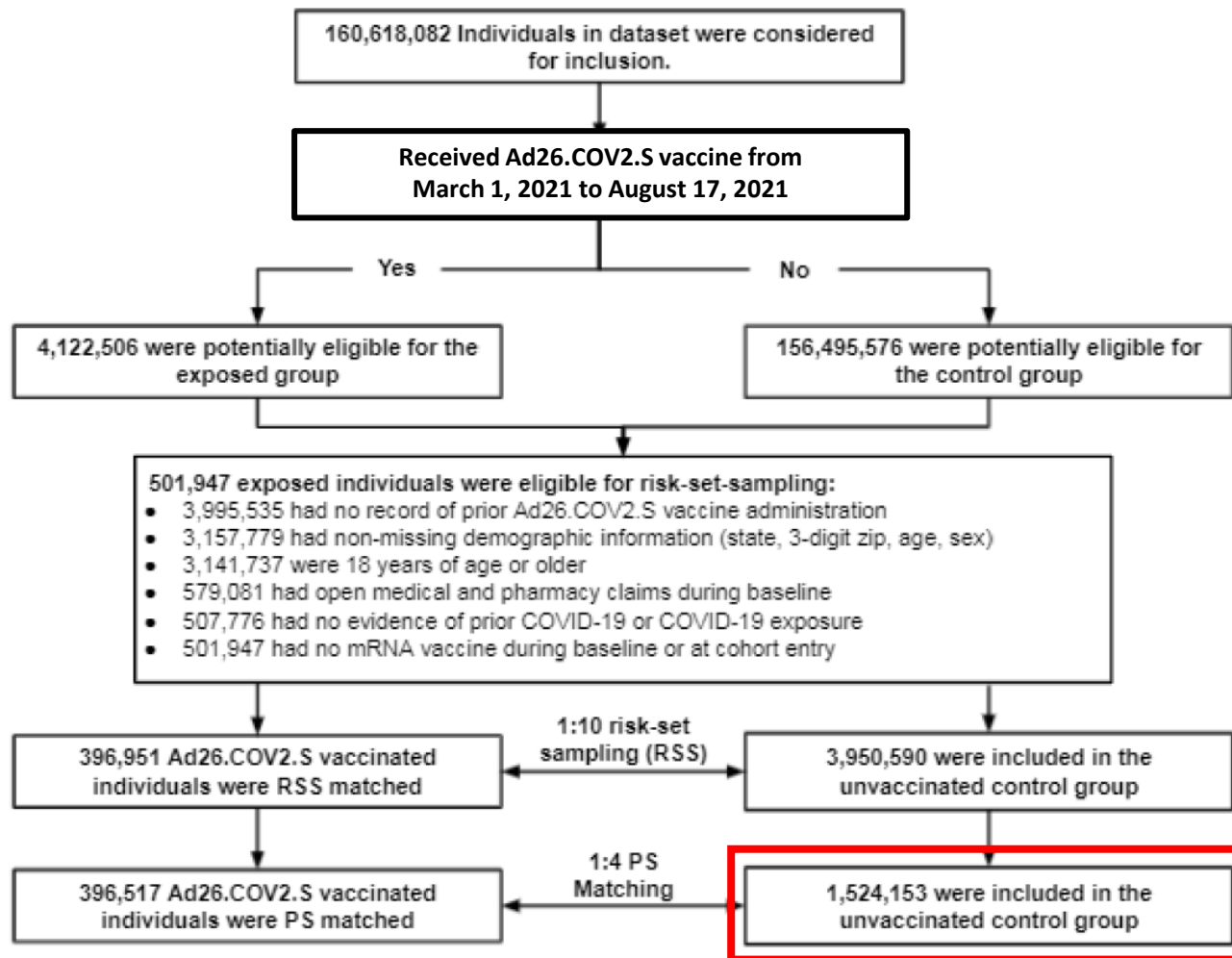
Endpoints

1. Any observed COVID-19 claim
2. COVID-19-related hospitalization



- 1 - Number of pharmacy/medical claims and comorbidities
- 2 - Age, sex and state
- 3 - Day 14 through observed endpoint or censoring

Study Design – Cohort Selection





Vaccination Under-Ascertainment in RWE

- CDC reported 57% of individuals 12 years and older were vaccinated on July 22, 2021
- HealthVerity data contained documented vaccination for only 34% of individuals (~60% of CDC amount)
- To explore the effects of vaccination under-ascertainment, a sensitivity analysis was performed to assess the impact on VE estimates under various percentages of vaccination under-ascertainment in the referent cohort
- The “corrected” numbers presented assume a 40% under-ascertainment of vaccination in the referent cohort



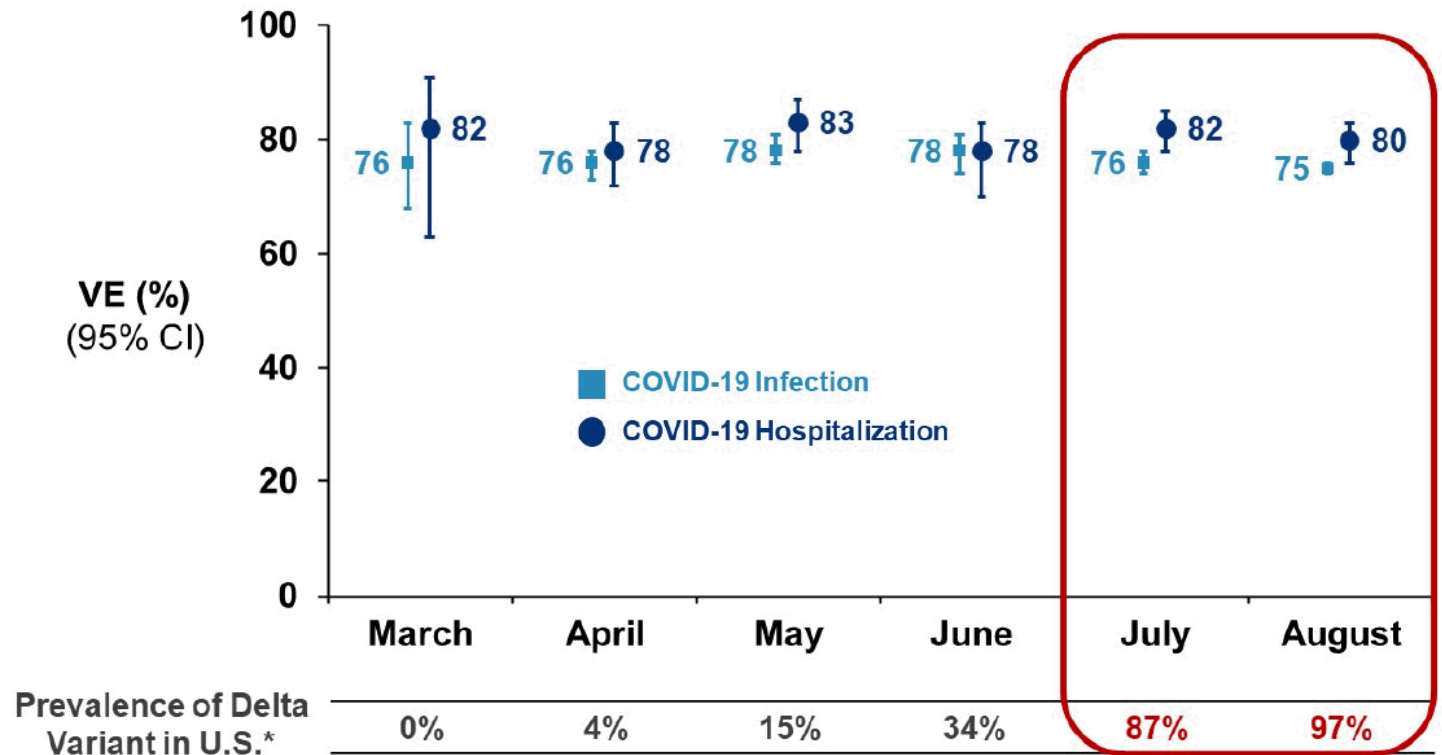
Vaccine Effectiveness – Overall and Cohort Subsets

- Uncorrected VE estimates were 10-13% lower than the corrected estimates for the any observed COVID-19 endpoint, and 7-13% lower than the corrected estimates for COVID-19-related hospitalization
- Those aged less than 65 showed 7% and 14% improved VE for both endpoints, compared to those aged 65 or greater
- Immunocompromised individuals were estimated to have 16% and 19% less VE for documented COVID-19 and COVID-19-related hospitalization, respectively

	Vaccinated Cases (N) Person-yrs	Uncorrected VE% (95% CI)	Corrected ^c VE% (95% CI)
National Cohort			
Any observed COVID-19	2,632 141,717	66% (64%, 67%)	76% (75%, 77%)
COVID-19 hospitalization	440 142,047	72% (69%, 74%)	81% (78%, 82%)
Age <65			
Any observed COVID-19	1,880 97,790	68% (66%, 69%)	78% (77%, 79%)
COVID-19 hospitalization	188 98,044	78% (75%, 81%)	85% (83%, 87%)
Age ≥65			
Any observed COVID-19	752 43,927	61% (58%, 63%)	72% (70%, 74%)
COVID-19 hospitalization	252 44,004	62% (57%, 67%)	74% (70%, 77%)
Immunocompromised			
Any observed COVID-19	246 9,915	51% (44%, 57%)	64% (59%, 68%)
COVID-19 hospitalization	68 9,946	54% (40%, 64%)	67% (57%, 74%)
Non-Immunocompromised			
Any observed COVID-19	2,386 131,802	67% (65%, 68%)	77% (76%, 78%)
COVID-19 hospitalization	372 132,101	73% (70%, 75%)	83% (80%, 83%)

Vaccine Effectiveness*: March – August 2021

- VE against any observed COVID-19 and COVID-19-related hospitalization was stable over the 6-months of the interim analysis
- VE was also comparable in the summer months, when there were higher amounts of circulating Delta variant



*Numbers displayed are corrected assuming 40% under-ascertainment of vaccination in the referent cohort

Limitations

1. Under-ascertainment of vaccination among referent cohort
2. 3-digit zip codes used for matching
 - a) Insufficient to capture socio-economic factors, race, and other risk factors that vary over more granular regions
3. Representativeness of HealthVerity COVID-19 dataset
 - a) Contains only 396,000 of ~15,000,000 total vaccinations (2.6%)

Summary

- Study 4002 showed similar VE to what was reported in 3002 using real-world data
- Vaccine effectiveness remained stable between March and August 2021, showing supportive evidence for effectiveness during months when Delta variant was dominant strain in the United States
- The real-world effectiveness data provides supportive information, but has important limitations