Use of Janssen Ad26.COV2.S COVID-19 Vaccine (JCOVDEN) and mRNA COVID-19 Vaccines in Four Large US National Insurers

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DISCLOSURES

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BACKGROUND AND RATIONALE

27 Feb 2021 — Emergency use authorization

Janssen Ad26.COV2.S COVID-19 Vaccine (JCOVDEN) is authorized for emergency use by the United States (US) Food and Drug Administration (FDA) in individuals aged 18 years and older.

Apr 2021 — Pause in administration of JCOVDEN

FDA and Centers for Disease Control and Prevention (CDC) recommended pause to evaluate benefit-risk related to thrombosis with thrombocytopenia syndrome, which was subsequently lifted.[1]

Dec 2021 — mRNA vaccines recommended over JCOVDEN due to safety concerns

FDA and CDC, on the basis of recommendations from the CDC's Advisory Committee on Immunization Practices (ACIP), recommended use of messenger RNA (mRNA) COVID-19 vaccines preferentially over JCOVDEN because of safety concerns identified from postmarketing safety surveillance.[2]

1 June 2023 — Emergency use authorization voluntarily rescinded

JCOVDEN is no longer authorized for use in the US.[3] *A postmarketing study is underway to assess its use and safety.*

Results are presented from a monitoring analysis to describe uptake of JCOVDEN and characteristics of users relative to other COVID-19 vaccines to inform the planned final safety analyses.

OBJECTIVE

- To assess utilization of the JCOVDEN and mRNA COVID-19 vaccines and to characterize recipients.

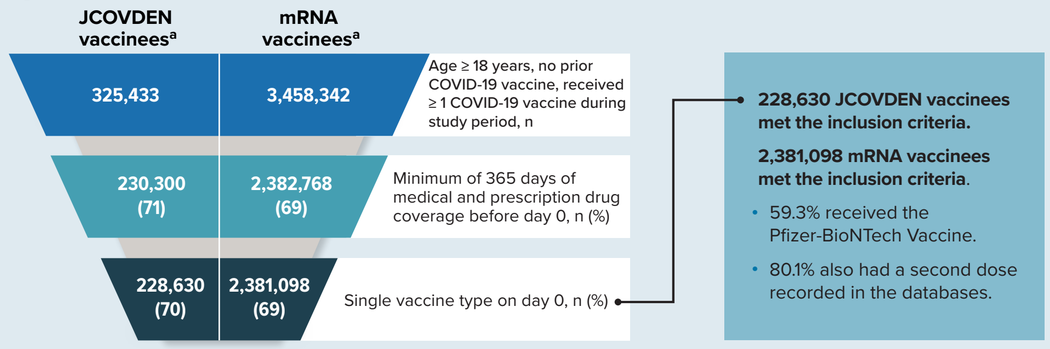
METHODS

- This monitoring analysis included claims data from 4 national commercial insurers (participating in the FDA's Sentinel System) for individuals vaccinated with a first dose of JCOVDEN or monovalent mRNA COVID-19 vaccine (index date/day 0) from 27 February 2021 through October 2021.
- Inclusion criteria:
  - Age of 18 years or older
  - Continuous medical and prescription drug insurance for ≥ 1 year before first JCOVDEN or mRNA COVID-19 vaccine receipt
  - No prior vaccination with any other COVID-19 vaccine before index date
  - No receipt of more than 1 COVID-19 vaccine type (JCOVDEN or mRNA) on index date
- Vaccinees were described by vaccine administration setting, baseline demographics, and clinical characteristics, stratified by initial COVID-19 vaccine type.
- The baseline period was the year before and including the index date, unless otherwise noted.

RESULTS

Vaccine Utilization

Figure 1. Cohort Attrition



COVID-19 = coronavirus disease 2019.
[a] Denominators for the percentages are individuals with at least 1 COVID-19 vaccine during the query period.

- **228,630 JCOVDEN vaccinees met the inclusion criteria.**
- **2,381,098 mRNA vaccinees met the inclusion criteria.**
- 59.3% received the Pfizer-BioNTech Vaccine.
- 80.1% also had a second dose recorded in the databases.

Table 1. Percentages of Total Vaccinees on Index Date, by Care Setting

	JCOVDEN vaccinees	mRNA vaccinees
Total vaccine counts, N	228,630	2,381,098
Vaccines by care setting, %[a]		
Outpatient dispensing (pharmacy)	64.0	55.7
Ambulatory visit	33.3	42.0
Other ambulatory visit	2.4	2.3

[a] The following accounted for ≤ 0.1% of all care settings for either vaccine type: emergency department, inpatient, non-acute institutional stay, or multiple settings.

Vaccinee Characteristics

Table 2. Comorbidity Prevalence and Healthcare Utilization During the Baseline Period by First-Dose COVID-19 Vaccine

Characteristic	JCOVDEN (N = 228,630)	mRNA (N = 2,381,098)
Demographics, %[a]		
Mean age (years)	49	48
Male, %	54.2	49.0
Comorbidity, %		
Obesity diagnosis	14.7	15.3
Heart conditions	10.8	11.1
Diabetes	10.4	10.7
History of COVID-19 before index date based on diagnosis code for COVID-19, coronavirus, or severe acute respiratory syndrome	8.2	7.8
Chronic kidney disease	7.4	7.7
Asthma	4.9	5.3
Immunocompromised states[b]	4.6	5.1
Cancer	3.5	3.8
Chronic obstructive pulmonary disease	3.5	3.4
Pregnancy status (on index date)[c]	2.5	3.8
Healthcare utilization		
Mean number of ambulatory care visits	5.7	6.4
Mean number of filled prescriptions	9.1	9.7
Use of other vaccines, %		
Influenza	40.5	46.4
Human papillomavirus vaccine	7.2	8.3
Shingles	4.3	4.9
Pneumococcus	3.3	3.7
Receipt of non-COVID-19 vaccine on index date, %	< 0.1	< 0.1

[a] In both vaccine groups, over 85% of vaccinees were missing race information, and over 98% were missing ethnicity information.
[b] Immunocompromised state includes HIV/AIDS, lymphoma, leukemia, primary immunodeficiency disease, antineoplastics, antiarthritics, and other immunosuppressant medications.
[c] The proportion of individuals pregnant on the index date is calculated among female vaccinees. Pregnancy status was evaluated using markers for pregnancy in the 200 days before the index date.

- **The baseline prevalence of comorbidities was similar between the 2 vaccine types.**
- **The most prevalent comorbidity among both JCOVDEN and mRNA vaccinees was obesity, followed by heart conditions and diabetes.**
- **JCOVDEN vaccinees were less likely than mRNA vaccinees to have had evidence of pregnancy at vaccine administration.**
- **JCOVDEN and mRNA vaccinees had similar measures of prior healthcare utilization.**
- **mRNA vaccinees were more likely than JCOVDEN vaccinees to receive influenza vaccine during the baseline period.**

Figure 2. JCOVDEN and mRNA Vaccinees by Age Group in US Commercially Insured Individuals

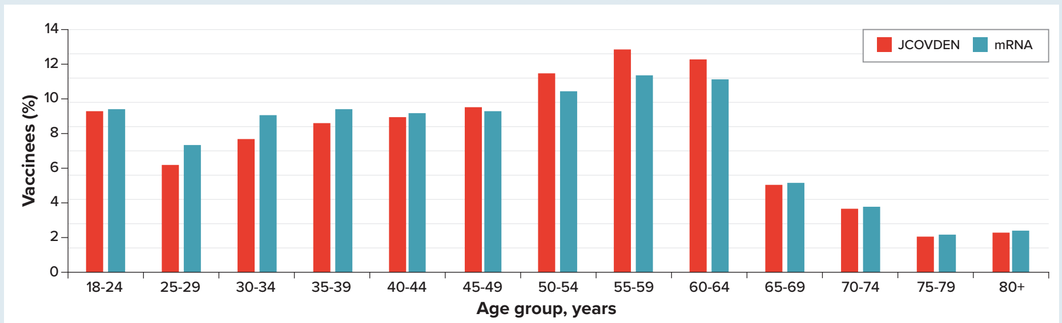
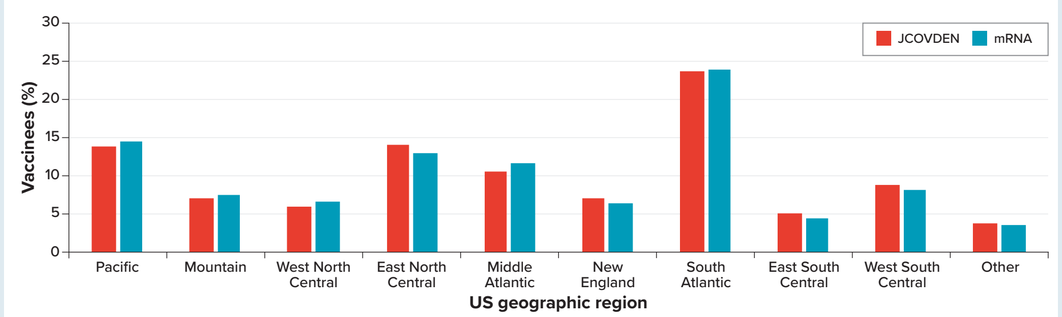


Figure 3. JCOVDEN and mRNA Vaccinees by US Census Geographic Region



CONCLUSIONS

- JCOVDEN represented less than 9% of first COVID-19 vaccine doses observed in these data, likely due to the FDA and CDC recommendations on the use of JCOVDEN.[2,4]
- The 2.6 million JCOVDEN and mRNA vaccinees meeting study inclusion criteria represent < 1.5% of all individuals receiving at least 1 dose of a COVID-19 vaccine in the US (as of 30 June 2021) and thus may not be broadly generalizable to the US population receiving COVID-19 vaccines.[5]
- The completeness of COVID-19 vaccine status is not currently known. However, research partners participating in this study are working to increase vaccine coverage by conducting linkages to state immunization registry data and Medicare for final safety analyses.
- Generally, the JCOVDEN and mRNA vaccinees were very similar regarding baseline demographics, geographic distribution, history of comorbidities (including history of COVID-19), healthcare utilization, and receipt of other vaccines.
- Small differences in the age and sex distribution between vaccine types may reflect channeling of men away from mRNA vaccines and targeted campaigns to use JCOVDEN, a single-dose vaccine. Controlling for any population differences will be critical for inferential analyses.

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