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Impact of KP.2 BNT162b2 COVID-19 Vaccine on Health-Related Quality of Life Among Symptomatic U.S. Adults with SARS-CoV-2 During the 2024-2025 Respiratory Season

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INTRODUCTION

- The impact of COVID-19 extends beyond acute symptoms and includes clinically meaningful declines in health-related quality of life (HRQoL) [1-4].
- Vaccination may mitigate these declines; a prior study of earlier BNT162b2 formulations among US outpatient adults found that vaccinated individuals experienced smaller declines in HRQoL following infection compared with those who were unvaccinated [5].
- Evidence on the impact of the updated 2024-2025 BNT162b2 KP.2 vaccine [6] on HRQoL outcomes among outpatient adults remains limited.

OBJECTIVE

- This research evaluated the effect of the Pfizer-BioNTech BNT162b2 KP.2 COVID-19 vaccine on HRQoL during the first week of infection among test-confirmed symptomatic adults in the 2024-2025 respiratory season.

METHODS

- Symptomatic adults ≥ 18 years testing positive for SARS-CoV-2 at ambulatory care clinics within a national pharmacy chain between October 24, 2024, and August 29, 2025, were enrolled (CT.gov:NCT05160636).
- Participants provided consent and completed a self-reported online survey capturing demographics, clinical history, and vaccination status on enrollment day (Survey 1). Surveys 2 and 3 were completed 1 and 2 days after enrollment.
- Vaccinated status was defined as: Vaccinated = received the Pfizer-BioNTech BNT162b2 KP.2 vaccine; Unvaccinated = did not receive any updated COVID-19 vaccine.
- HRQoL was measured using EuroQol 5-Dimension 5-Level (EQ-5D-5L) utility index (UI) [7]; range -0.573 to 1, higher scores indicate better health)
- UI was collected daily post-enrollment and retrospectively recalled for the pre-infection period at enrollment.
- Regression-based least-squares mean estimates (LSE) for changes from pre-infection UI were calculated and compared between KP.2 vaccinated patients and unvaccinated patients.
- A running average of means was computed for each survey time point to estimate the average daily UI from symptom onset through Survey 3 (a median of 7 days from symptom onset).

RESULTS

- Among 608 participants, the mean age was 45.9 years; 76.5% were female; 53.9% used antiviral treatment; and 57.9% had ≥1 comorbidity.
- The median time from symptom onset to enrollment was 4 days.
- A total of 106 participants (17.4%) received the 2024-2025 KP.2 vaccine, and 502 (82.6%) were unvaccinated (Table 1).
- Vaccinated participants had a median (Interquartile range [IQR]) time since vaccination of 161 (89-240) days.
- Pre-infection EQ-UI scores were similar between groups (vaccinated: mean 0.934, SD 0.091; unvaccinated: mean 0.941, SD 0.085; P=0.447).
- The vaccinated group had less impairment in EQ-UI overall (Figure 1).
- At the third survey (median of 7 days from symptom onset), the running average change in EQ-UI from pre-infection was 0.023 points higher in the vaccinated group compared with the unvaccinated group (SE: 0.010; P=0.036), indicating a smaller decline in HRQoL among vaccinated adults (Table 2). This difference corresponds to an approximately 20.1% smaller relative change in HRQoL following infection in the vaccinated group.

Table 1. Patient Characteristics

	Vaccinated with BNT162b2 KP.2	Unvaccinated
Total, n	106	502
Age, years, mean (SD)	51.3 (14.6)	44.7 (13.8)
Gender, n (%)		
Female	75 (70.8)	390 (77.7)
Male	31 (29.2)	111 (22.1)
Unknown	0 (0.0)	1 (0.2)
Race/Ethnicity, n (%)		
White or Caucasian	79 (74.5)	357 (71.1)
Black or African American	8 (7.5)	40 (8.0)
Hispanic	12 (11.3)	67 (13.3)
Asian	5 (4.7)	20 (4.0)
Other	2 (1.9)	18 (3.6)
US Geographic Region, n (%)		
Northeast	15 (14.2)	58 (11.6)
South	59 (55.7)	309 (61.6)
Midwest	27 (25.5)	106 (21.1)
West	5 (4.7)	28 (5.6)
Other/Unknown	0 (0.0)	1 (0.2)
Social Vulnerability Index[a], mean (SD)	0.32 (0.18)	0.38 (0.21)
Antiviral use, n (%)	55 (51.9)	273 (54.4)
≥1 comorbid condition[b], n (%)	67 (63.2)	285 (56.8)
Time since 2024-2025 KP.2 BNT162b2 COVID-19 vaccine, days, median (IQR)	161 (89-240)	-
Pre-infection EQ-UI, mean (SD)	0.934 (0.091)	0.941 (0.085)

[a] Social Vulnerability Index is a score that ranges from 0 to 1. Higher values correspond to higher vulnerability [8].

[b] Comorbid conditions include cancers or malignancies (other than skin cancer), cerebrovascular disease, chronic kidney disease, chronic lung conditions, chronic liver disease, diabetes mellitus, heart conditions, mental health conditions, obesity (BMI >30), weakened immune system/ immunocompromised, smoker, or active tuberculosis [9].

Figure 1. LSE of change in EQ-UI scores from pre-infection by vaccination status

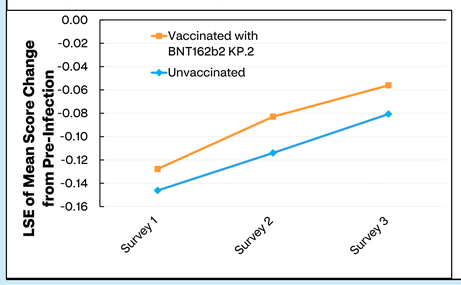

Table 2. Running average in the LSE of mean change in EQ-UI scores from pre-infection by vaccination status

	Vaccinated with BNT162b2 KP.2 LSE (SE) [a]	Unvaccinated LSE (SE) [a]	Difference in LSE of score change between groups	
			LSE (SE) [a]	P value
Survey 1	-0.133 (0.012)	-0.150 (0.005)	0.016 (0.011)	0.207
Survey 2	-0.114 (0.010)	-0.137 (0.005)	0.023 (0.011)	**0.045**
Survey 3	-0.091 (0.010)	-0.114 (0.005)	0.023 (0.010)	**0.036**

[a] Mixed-models for repeated measures include covariates of time, high-risk status, sex, age group, race/ethnicity, US region, social vulnerability index category, antiviral use, receipt of Pfizer COVID-19 vaccine, baseline composite symptom score, insurance type, number of comorbidities by categories, and interaction terms between time and high-risk status, as well as time and receipt of the COVID-19 vaccine, with unstructured correlation matrix for repeated measures. Bolded values are significant at P<0.05.

LIMITATIONS

- Key limitations include reliance on self-reported data, which may introduce missingness, reporting errors, recall bias, and selection bias, potentially limiting generalizability.

CONCLUSIONS

- **Receipt of the BNT162b2 KP.2 vaccine was associated with more favorable HRQoL during the first week following SARS-CoV-2 infection in the 2024–2025 respiratory season. This observed difference may reflect fewer or less severe symptoms among individuals who received the KP.2-updated vaccine formulation.**
- **Consistent with prior research [5], these findings suggest that updated BNT162b2 vaccination may attenuate short-term declines in quality of life following COVID-19 infection among outpatients.**
- **Overall, these results highlight potential humanistic and societal benefits of COVID-19 vaccination in outpatient populations and underscore the importance of remaining up to date with current vaccine recommendations.**

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Disclosures

A.Y., J.C.C., T.H., M.D.F., and M.B.G., and are employees of Pfizer and may hold stock or stock options of Pfizer. R.B. and X.S. are employees of CVS Health® and may hold stock or stock options of CVS Health. This study was funded by Pfizer Inc.

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