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Impact Of COVID-19 Vaccination With BNT162b2 On The Frequency Of Acute Symptoms Among Symptomatic US Adults Testing Positive For SARS-CoV-2 At A National Retail Pharmacy

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INTRODUCTION

- Evidence on the efficacy, safety and effectiveness of the different formulations of the Pfizer/ BioNTech BNT162b2 COVID-19 vaccine is extensive [1].
- Longitudinal estimates of vaccine impact on disease symptoms remain limited, especially for the acute phase and in outpatient settings [1-3].

OBJECTIVE

- This study characterized the frequency of acute COVID-19 symptoms by original monovalent BNT162b2 COVID-19 vaccine status through one month following laboratory-confirmed SARS-CoV-2 from a national retail pharmacy.

METHODS

- Symptomatic US adults with positive RT-PCR for SARS-CoV-2 at CVS Health were recruited between 01/31-04/30/2022 (CT.gov: NCT05160636) [4].
- Self-reported demographics, clinical characteristics and vaccination status were collected, along with self-reported systemic, respiratory, and gastrointestinal symptoms, which were assessed at enrollment/testing day, Week 1 and 4 after testing.
- Frequency of individual and total number of symptoms (0, 1–2, 3–5, 6+) were compared across BNT162b2 vaccination status (Boosted: >2 doses, Primed: 2 doses, and Unvaccinated: 0 doses) using chi-square test (or Fisher's exact test, if cell count <5) for categorical variables, and t-test or Wilcoxon rank-sum test for quantitative outcomes.

RESULTS

- 370 study participants included 87 (24%) Boosted, 86 (23%) Primed, and 197 (53%) Unvaccinated. Mean age was 41.9 years, 74.6% were female, 25.7% had ≥1 comorbidity, 44.4% had prior infection. In the vaccinated groups, the mean (SD) time since vaccination was 153 (102) days overall; 84 (55) days among Boosted and 222 (90) days among Primed (**Table 1**).

RESULTS (continued)

Table 1. Patient Characteristics

	All	Boosted	Primed	Unvaccinated
Total n	370	87	86	197
Age, years, mean (SD)	41.9 (14.3)	44.3 (17.0)	41.7 (14.2)	40.9 (12.9)
Female, % (n)	276 (74.6%)	58 (66.7%)	68 (79.1%)	150 (76.1%)
Race / Ethnicity				
White or Caucasian	257 (69.5%)	63 (72.4%)	65 (75.6%)	129 (65.5%)
Black or African American	17 (4.6%)	2 (2.3%)	2 (2.3%)	13 (6.6%)
Hispanic	51 (13.8%)	9 (10.3%)	16 (18.6%)	26 (13.2%)
Other	45 (12.1%)	13 (15.0%)	3 (3.5%)	29 (14.8%)
Prior positive test	138 (44.4%)	32 (41.0%)	28 (40.6%)	78 (47.6%)
Time since last vaccine dose, days, mean (SD)	153 (102)	84 (55)	222 (90)	-
≥1 comorbid condition*	95 (25.7%)	28 (32.2%)	24 (27.9%)	43 (21.8%)

* Comorbid conditions include asthma or chronic lung disease, cirrhosis of the liver, immunocompromised conditions or weakened immune system, diabetes, heart conditions or hypertension, overweight or obesity, smoking

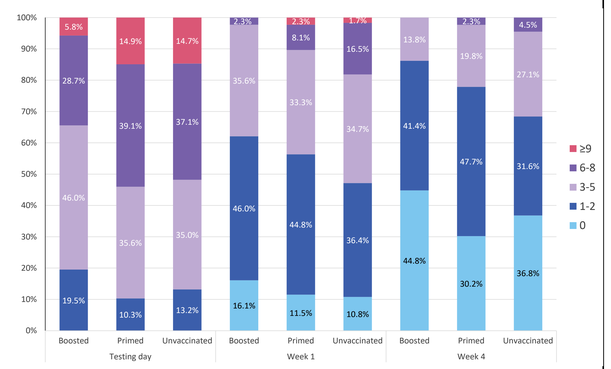
- The most common symptoms were systemic/respiratory, and the most persistent one was fatigue (**Table 2**).
- Compared to Primed and Unvaccinated, the Boosted cohort had lower mean number of symptoms (SD):
  - On testing day, Boosted reported 4.7 (2.5) symptoms versus 5.7 (2.4) and 5.6 (2.7) in Primed and Unvaccinated, respectively (p=0.01).
  - At Week 1, Boosted reported 2.1 (1.6) symptoms versus 2.7 (2.2) and 3.2 (2.4) in Primed and Unvaccinated (p=0.0013).
  - At Week 4, Boosted reported 1.0 (1.2) symptoms versus 1.5 (1.5) and 1.7 (1.9) in Primed and Unvaccinated (p=0.005).
- In the Boosted cohort, four and six out of twelve symptoms were less often reported on testing day and Week 1, respectively, with largest differences observed for fever, chills, muscle/body aches.
- Three out of eight symptoms were less often reported by Boosted at Week 4, with largest differences for headache, diarrhea, and loss of taste/smell (**Table 2**).
- Boosted had lower total symptom burden (p<0.005) across all time points (**Figure 1**).

Table 2. Prevalence of Acute Symptoms by Vaccination Status and Time

	Testing day				Week 1				Week 4			
	Boosted	Primed	Unvaccinated	P-value	Boosted	Primed	Unvaccinated	P-value	Boosted	Primed	Unvaccinated	P-value
Number of symptoms, mean (SD)	4.7 (2.5)	5.7 (2.4)	5.6 (2.7)	0.010	2.1 (1.6)	2.7 (2.2)	3.2 (2.4)	0.001	1.0 (1.2)	1.5 (1.5)	1.7 (1.9)	0.005
Systemic symptoms	70 (80.5%)	76 (88.4%)	178 (90.4%)	0.064	48 (55.2%)	48 (55.8%)	119 (67.6%)	0.066	34 (39.1%)	49 (57.0%)	79 (50.6%)	0.056
Fever	22 (25.3%)	35 (40.7%)	93 (47.2%)	0.002	0 (0.0%)	3 (3.5%)	11 (6.3%)	0.032	0 (0.0%)	0 (0.0%)	1 (0.7%)	1.000
Chills	27 (31.0%)	48 (55.8%)	113 (57.4%)	0.000	1 (1.2%)	4 (4.7%)	20 (11.4%)	0.005	-	-	-	
Muscle or Body Aches	36 (41.4%)	52 (60.5%)	117 (59.4%)	0.011	5 (5.8%)	17 (19.8%)	49 (27.8%)	0.000	10 (11.5%)	18 (20.9%)	38 (24.5%)	0.052
Headache	51 (58.6%)	62 (72.1%)	140 (71.1%)	0.081	17 (19.5%)	23 (26.7%)	63 (35.8%)	0.020	10 (11.5%)	18 (20.9%)	39 (25.2%)	0.040
Fatigue	48 (55.2%)	56 (65.1%)	125 (63.5%)	0.325	41 (47.1%)	37 (43.0%)	94 (53.4%)	0.258	28 (32.2%)	42 (48.8%)	65 (41.9%)	0.081
Respiratory symptoms	86 (98.9%)	84 (97.7%)	180 (91.4%)	0.013	63 (72.4%)	65 (75.6%)	132 (75.0%)	0.871	32 (36.8%)	35 (40.7%)	76 (48.7%)	0.165
Shortness of Breath	6 (6.9%)	13 (15.1%)	29 (14.7%)	0.155	14 (16.1%)	16 (18.6%)	45 (25.6%)	0.160	13 (14.9%)	13 (15.1%)	32 (20.6%)	0.412
Cough	65 (74.7%)	63 (73.3%)	141 (71.6%)	0.854	34 (39.1%)	51 (59.3%)	92 (52.3%)	0.025	21 (24.1%)	19 (22.1%)	46 (29.7%)	0.385
Sore Throat	53 (60.9%)	50 (58.1%)	104 (52.8%)	0.399	15 (17.2%)	17 (19.8%)	28 (15.9%)	0.739				
New/Recent Loss of Taste or Smell	7 (8.1%)	13 (15.1%)	22 (11.2%)	0.339	6 (6.9%)	19 (22.1%)	36 (20.5%)	0.011	5 (5.8%)	14 (16.3%)	32 (20.6%)	0.009
Congestion or Runny Nose	69 (79.3%)	72 (83.7%)	134 (68.0%)	0.010	44 (50.6%)	35 (40.7%)	84 (47.7%)	0.398	-	-	-	
GI symptoms	17 (19.5%)	20 (23.3%)	69 (35.0%)	0.013	7 (8.1%)	12 (14.0%)	28 (15.9%)	0.211	3 (3.5%)	3 (3.5%)	17 (11.0%)	0.029
Nausea or Vomiting	7 (8.1%)	11 (12.8%)	31 (15.7%)	0.210	4 (4.6%)	7 (8.1%)	14 (8.0%)	0.586	-	-	-	
Diarrhea	14 (16.1%)	15 (17.4%)	51 (25.9%)	0.102	3 (3.5%)	6 (7.0%)	20 (11.4%)	0.081	3 (3.5%)	3 (3.5%)	17 (11.0%)	0.029

RESULTS (continued)

Figure 1. Distribution of Number of Acute Symptoms by Vaccination Status and Time



CONCLUSIONS

- **Participants boosted with BNT162b2 reported fewer acute symptoms and lower disease symptoms burden than those unvaccinated or primed during both the acute phase of the infection and up to Week 4, reaffirming the value of being up-to-date with COVID-19 vaccination.**

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Disclosures

M.D.F., J.C.C., A.Y., K.E.A., T.M.P., M.B.A., L.P. , SMCL are employees of Pfizer and may hold stock or stock options of Pfizer. B.A. and X.S. are employee of CVS Health and hold stock of CVS Health.

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