Self-Reported Anxiety Symptoms Among Patients With a Systemic Allergic Reaction to the COVID-19 Vaccine

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Background

- Sparse evidence suggests that patients experience anxiety related to allergic reactions.[1]
- Individuals with a history of allergic disorders display higher rates of mental health (MH) disorders, such as anxiety and depression.[2]
- There are currently limited options for those who had an allergic reaction (CoFAR grade 2 or 3) to the first dose of the mRNA COVID-19 vaccine to receive a second vaccine dose.[3]

Aims

- In a sample of individuals who experienced a systemic allergic reaction to the COVID-19 mRNA vaccine, we aimed to:
  - Describe self-reported MH history, current MH symptoms, and anxiety levels during a placebo-controlled administration of the second dose.
  - Describe the acceptability of inquiring about mental health symptoms as part of the study.

Methods

C-L Psychiatrist Role:

- IRB required that C-L psychiatrists monitor anxiety regarding study participation.

Sample:

- Sub-analysis of a NIAID longitudinal study (NCT04977479); a convenience sample of adults who experienced a systemic allergic reaction (CoFAR grade 2 or 3) to the first dose of the COVID-19 mRNA vaccine.

Setting:

- Participants received the placebo-controlled vaccine at the NIH ICU, a virtual psychiatric interview prior to the study visit, and completed online surveys before, during, and after vaccination.

Measures/Clinical Information:

- **Mental Health History Questionnaire**
- **Generalized Anxiety Disorder (GAD-7)**
- **State-Trait Anxiety Inventory (STAI)**
- **Patient Health Questionnaire (PHQ-9)**
- **Anxiety Ratings (0-10)**
- **Questionnaire about study acceptability**

Data Analysis:

- Descriptive analyses identified sample demographics, MH history, and anxiety.
- Aggregate somatic responses to the placebo-controlled vaccine are provided.
- Acceptability of the mental health questionnaires is also reported.

Results

Table 1: Participant Demographics

Demographics	Total (N = 16)	Mental Health History (N = 10, 62.5%)
Gender:		
Female	15 (93.8%)	10 (100.0%)
Male	1 (6.2%)	-
Race:		
White	13 (81.3%)	8 (80.0%)
Asian	2 (12.5%)	1 (10.0%)
Black	1 (6.2%)	1 (10.0%)
Ethnicity:		
Hispanic/Latino	5 (31.2%)	3 (30.0%)
Mean Age: (Range: 18-93)	44.8 [11.6]	41.2 [10.5]

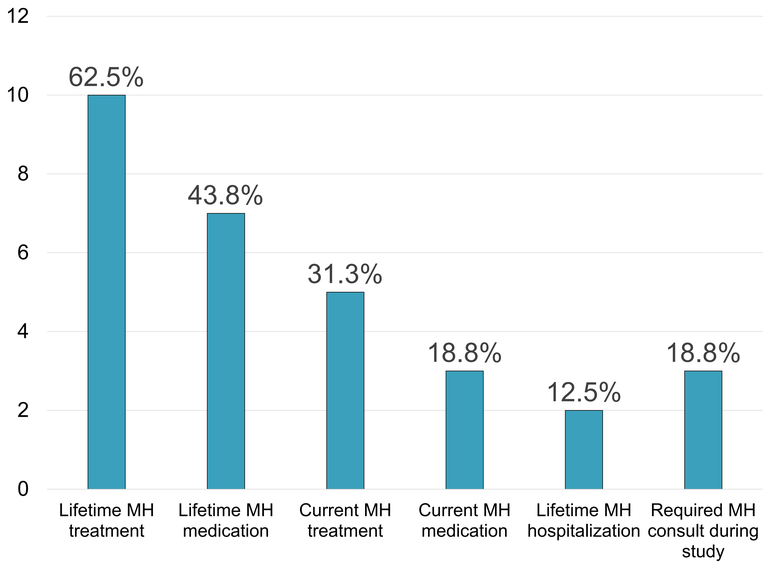


Figure 1: Self-Reported Mental Health History (N=16)

Table 2: Mental Health Symptoms at Baseline

	GAD-7	STAI (State)	STAI (Trait)	PHQ-9
Mean [SD]	2.7 [2.6]	29.8 [9.6]	30.8 [8.6]	2.75 [2.0]
Range	0-7	20-48	20-50	0-6
Clinically significant cutoff scores	>10	>40	>40	>10
Number of individuals above cutoff	-	3	3	-

Acceptability of Mental Health Surveys: Of the 14 individuals who completed follow-up surveys, 12 (85.7%) indicated it was appropriate and important to ask about MH as part of this study.

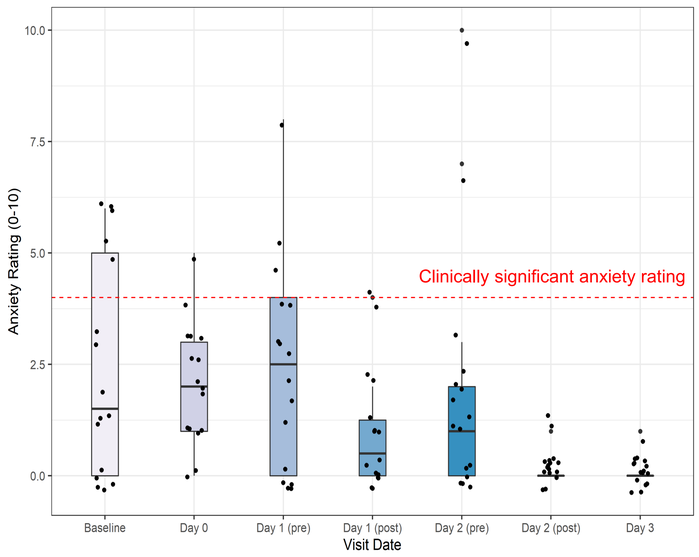
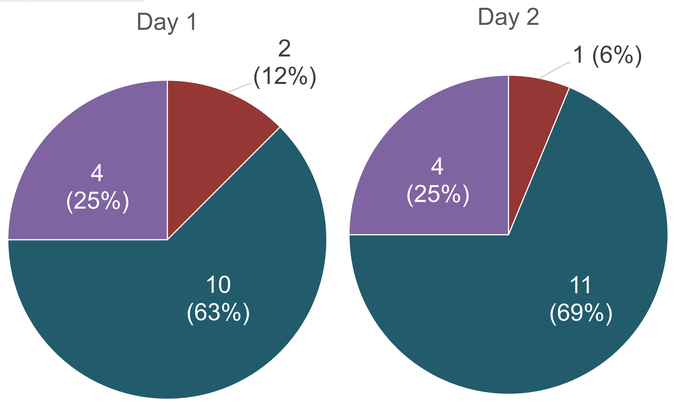


Figure 2: Anxiety Ratings During ICU Visit (N=16)



- **Non-allergic somatic symptoms**: numbness, tingling, throat tightness, difficulty swallowing, dizziness, hypertension, tachycardia
- **Signs of allergic reaction**: post-nasal drip, cough, SOB, hypotension, pruritis, flushing
- **Asymptomatic**

Figure 3: Reactions to Both Vaccine and Placebo (Blinded Data, N=16)

Discussion

- Individuals with previous allergic reactions to the COVID-19 vaccine reported relatively low and transient anxiety symptoms upon receiving the placebo-controlled doses.
- Despite low self-reported MH symptoms, most individuals experienced somatic symptoms after receiving both the vaccine and placebo doses.
- Most participants (10/16) had ever been treated by a mental health professional.
- Baseline MH symptoms, assessed through multiple validated measures, were not elevated beyond typical population norms for most participants.
- 3 patients received psychiatric consultation during the protocol period for psychological distress.
- Most participants approved of the MH surveys, suggesting inquiring about MH as part of an allergy trial is not particularly distressing or burdensome.

Limitations

- The study includes a small sample size (N=16), limiting analytical power.
- Laboratory markers of allergic reactions (e.g., tryptase) were not available for this analysis.
- The supportive ICU setting may not generalize to community health settings where vaccines are administered.

Conclusions

- Controlled administration of a second COVID-19 vaccine dose after a severe allergic reaction was tolerable, regardless of past MH history and anxiety.
- Despite low self-reported anxiety, 75% of participants reported somatic symptoms to placebo and vaccine, suggesting integrated care with C-L psychiatrists may be useful during a vaccination clinical trial.

References

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