



The mental health burden of food allergies: Insights from patients and their caregivers from the Food Allergy Research & Education (FARE) Patient Registry

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ABSTRACT

Background: Food allergies impose a large psychosocial burden, including mental, emotional, and social aspects, on both patients and their caregivers. Patients, caregivers, and their families often experience anxiety, isolation, and fear around food allergies.

Objective: To assess the real-world mental health burden of food allergies, using the Food Allergy Research & Education (FARE) Patient Registry (NCT04653324).

Methods: Self-reported data from patients with food allergies, and their caregivers, were analyzed from the FARE Food Allergy History and Mental Health Concerns surveys. Odds ratios were also calculated as a measure of association between patient food allergy characteristics and the likelihood of having mental health concerns or a formal mental health diagnosis.

Results: The FARE Patient Registry included 1680 patients/caregivers. Anxiety (54%) and panic (32%) were the most common emotions that patients reported as a result of eating the food that produced an allergic reaction. About two-thirds of patients reported mental health concerns related to food allergies (62%), including anxiety after an allergic reaction, anxiety about living with food allergies, and concerns about food avoidance. Caregivers also experienced fear for the safety of their children, and often sought mental health care to cope with worry related to caring for patients with food allergies. The likelihood of having food allergy-related mental health concerns was increased for patients experiencing more than 1 reaction per year (OR 1.68–1.90) and was lowered for patients having a formal mental health diagnosis (OR 0.43). Caregivers filling out the FARE survey for pediatric patients (OR 4.03) and experiencing food allergy-related mental health concerns (OR 2.36) were both significant predictors for having a formal mental health diagnosis.

Conclusion: Our study highlights a continuing unmet need for mental health screening and support as part of the management of patients with food allergies.

Keywords: Food hypersensitivity, Mental health, Anxiety, Caregivers, Food allergy, Anaphylaxis

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INTRODUCTION

Food allergies impose a large psychosocial burden, including mental, emotional, and social aspects, on both patients and their caregivers.¹⁻³ A population-based survey of adults with food allergies (N = 6207, living in the United States) assessed the psychosocial burden of food allergies using the validated Food Allergy Independent Measure (which assesses expectation of adverse food allergy-related outcomes in multiple contexts, extent of avoidance, and perceived social limitations), and found substantial impacts based on expectation of outcomes and effects on socializing.⁴ In addition, patients often experience heightened emotions, especially anxiety, around living with food allergies, food avoidance, and the potential for exposure and severe reactions.^{5,6} Children with food allergies may face additional challenges, including bullying and social isolation at school.⁷⁻⁹ Furthermore, food allergies can also affect family life, with many caregivers living in fear that their child's life is threatened by severe allergic reactions.¹⁰ Caregivers may also experience feelings of anxiety and isolation, which could affect their mental health.¹¹

Although the psychosocial burden of food allergies is evident from these studies, assessing the full and current extent of this burden can be challenging due to its multi-faceted and evolving nature. The patient-reported and caregiver-reported data available from the Food Allergy Research & Education (FARE) Patient Registry provides a unique perspective on current patient experiences that may also contribute to the holistic management of food allergies. The objective of this study was to use the FARE Patient Registry to assess the mental health characteristics of patients with food allergies, and their caregivers. FARE captures real-world, voluntary, patient/caregiver-reported data, using a series of surveys.¹²

METHODS

Cross-sectional data regarding patient experiences were obtained prospectively via online surveys of patients and their caregivers enrolled in the FARE Patient Registry: A Registry for the Food Allergy Community (NCT04653324). Informed

consent was obtained from patients prior to the completion of the surveys.

For the current analysis, data were collected between May 2017 and March 2021 and there were an estimated >13,000 registry participants at the time of data analysis. De-identified data from patients aged <1 to >80 years were used in this analysis. The patient inclusion criteria were completion of the online survey (N = 6166), United States residency, reporting ≥ 1 food allergy, reporting age at diagnosis, and completion of the mental health concerns survey. Patients with a single food allergy with discordant data were removed from the analysis (for example, if the patient reported having a peanut allergy, but actually selected milk in the specific list of allergens, the data were excluded from the analysis). Given the data were collected during the COVID-19 pandemic, we also stratified data by completion of survey pre-COVID-19 and during COVID-19 (January 2020 or later).

Data were obtained from the Food Allergy History, Food Allergy Reactions, and Mental Health Concerns surveys in the FARE Patient Registry, which were administered once per registry participant. Patients and/or their caregivers completed a survey assessing their mental health concerns related to food allergies, and levels of mental health screening and care. A caregiver was defined as either a parent or legal guardian. For each survey question, patients were given a list of selections to choose from or were asked to specify "other" responses when the most relevant response option was not available. Excerpts from the FARE surveys are provided in the Supplementary Methods.

For predictors of mental health concerns and a formal mental health diagnosis, the odds ratio (OR [95% CI]) was calculated as a measure of association between patient food allergy characteristics and the likelihood of having mental health concerns or a formal mental health diagnosis. P values were calculated using the generalized linear model function in R for a binomial regression model (Wald test). Each variable was compared with a reference group: frequency of allergic reactions per year (compared with less than 1 reaction per year); single food allergy (compared with multiple food allergies); mild/severe/very severe reaction severity (compared with moderate

reaction severity); experienced food allergy-related mental health concerns (compared with no mental health concerns); formal mental health diagnosis (compared with no mental health diagnosis); not admitted/unsure of admission to medical facility (including hospital, intensive care unit, urgent care, and emergency room; compared with admission to facility for an allergic reaction); survey completed by parent/legal guardian (compared with survey completed by self); non-White race (compared with White race); and female (compared with male). Significantly associated characteristics are shown in the results section.

RESULTS

Patient characteristics

From the FARE Patient Registry, 1680 patients with food allergies who completed the mental health survey were included in the study cohort (Table 1 and Warren et al.¹³), including 55% pediatric patients (923/1680, aged <1-17 years). Most patients in the study were White (79%), and over half were female (61%). Most adult patients filled out their own survey (89%; 675/757), whereas most pediatric patients needed a caregiver to fill out the survey on their behalf (97%; 898/923).

Concerns reported by patients

Anxiety and panic were the most common emotions that patients reported as a result of

eating the food that produced an allergic reaction (Fig. 1). Common emotions experienced by patients were similar between peanut, tree nut, egg, and milk allergens (Supplementary Fig. 1), as well as before and during the COVID-19 pandemic (Supplementary Fig. 2).

About two-thirds of patients reported mental health concerns related to food allergies (62%; 1035/1680), including anxiety after an allergic reaction and anxiety about living with food allergies (Fig. 2A). Mental health concerns were more prevalent in patients with multiple food allergies compared with single food allergies (Supplementary Fig. 3), but were similar between peanut, tree nut, egg, and milk allergens (Supplementary Fig. 4), as well as before and during the COVID-19 pandemic (Supplementary Fig. 5). Adult patients were more likely to report experiencing anxiety around food allergies than pediatric patients (Supplementary Fig. 6). Adults were also more likely to report additional concerns than pediatric patients, related to underestimating the severity of their allergies (28%, 212/757) and panic attacks (24%, 182/757).

Concerns reported by caregivers

Common concerns that were reported by over half of all caregivers were fear of trusting others with their child and fear for the safety of their child (Fig. 2B). Mental health concerns were more prevalent in caregivers of patients with multiple food allergies compared with single food

Characteristic, n (%) ^a	Patients with food allergies (n = 1680)
Female	1025 (61)
White	1321 (79)
Adult patients (≥18 y)	757 (45)
Pediatric patients (0-17 y)	923 (55)
Duration of disease ^b , y, mean (SD)	12 (12)
Completed survey during COVID-19 pandemic ^c	415 (25)
FARE survey respondent	
Self	700 (42)
Parent	907 (54)
Other caregiver	73 (4.3)

Table 1. Characteristics of patients with food allergies COVID-19, coronavirus disease 2019; FARE, Food Allergy Research & Education; y, years. ^aUnless stated. ^bDuration of disease was calculated as the age at survey completion minus the age at diagnosis for each patient. ^cDuring or after January 2020.

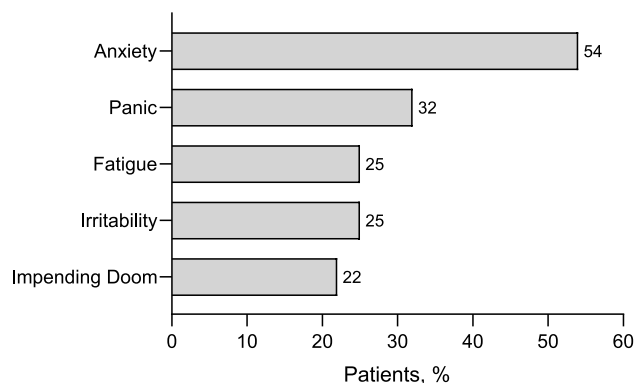


Fig. 1 Common emotions experienced by patients with food allergies (n = 1680). Response to the survey question, “Choose the EMOTIONAL/BEHAVIORAL symptoms that the participant developed as a result of eating the food or foods that produce an allergic reaction. (Select all that apply)”

allergies (Supplementary Fig. 3), and were similar before and during the COVID-19 pandemic (Supplementary Fig. 5B). Many caregivers sought mental health care for themselves to cope with worry related to caring for patients with food allergies (23%; 226/980).

Drivers of mental health concerns

There were several significant predictors of mental health concerns in patients with food allergies (Fig. 3). Experiencing a higher number of reactions per year was associated with an increased likelihood of mental health concerns (1-3 reactions per month, OR 1.90 [95% CI: 1.23, 2.93]; 2-3 reactions per year, OR 1.78 [95% CI: 1.32, 2.40]; and ≥ 1 reaction per week, OR 1.68 [95% CI: 1.02, 2.74]; compared with less than 1 reaction per year). Other significant predictors of mental health concerns were having a single food allergy (compared with multiple food allergies), not being admitted to the hospital (compared with hospital admission for an allergic reaction), a parent/other caregiver completing the FARE survey (compared with patient completing the survey), and being in a racial or ethnic minority group (as compared with people of White race). Characteristics associated with a decreased likelihood of mental health concerns were being a female participant (OR 0.63 [95% CI: 0.49, 0.80]; compared with male) and having a formal mental health diagnosis (OR 0.43 [95% CI: 0.33, 0.55]; compared with no diagnosis).

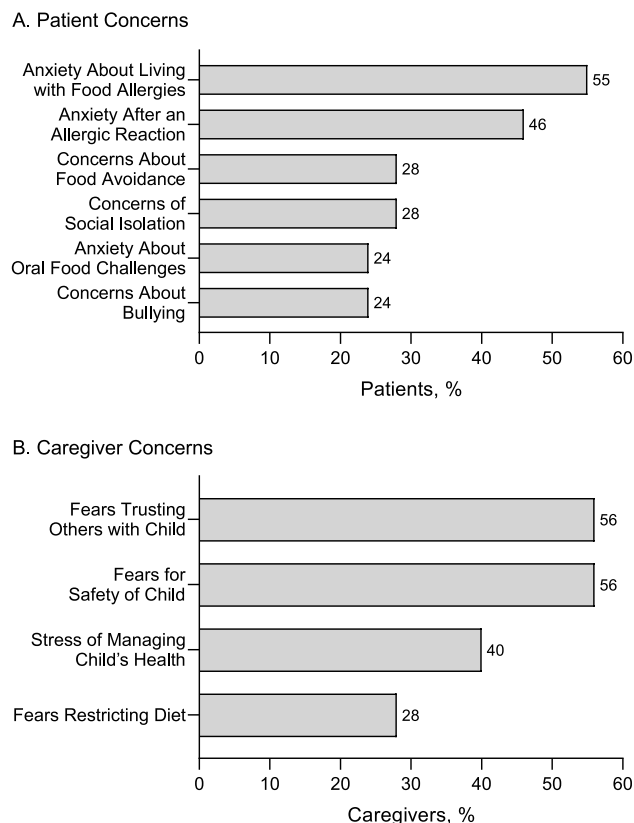


Fig. 2 Food allergy-related mental health concerns of patients with food allergies and their caregivers (n = 1680 participants, including n = 980 caregivers). A. Patient response to the survey question, “What types of mental health concerns related to food allergy has the participant experienced? (Select all that apply).” B. Caregiver response to the survey question, “What types of mental health concerns related to food allergy has the participant experienced? (Select all caregiver only responses that apply)”

Mental health screening and diagnosis

In the FARE Patient Registry, 30% of patients (512/1680) were previously diagnosed with a mental health disorder. Of note, types of mental health disorders were not specified in the questionnaire. One-third of patients indicated that they would like to be screened for mental health concerns related to food allergies (Fig. 4). However, fewer than 1 in 10 patients reported being screened during any previous food allergy appointment (Fig. 4). Of patients who were screened for mental health concerns related to food allergies, most patients were asked informal questions about their mental health during the food allergy appointment, and less than one-quarter of patients were assessed by a mental health professional during the food allergy appointment.

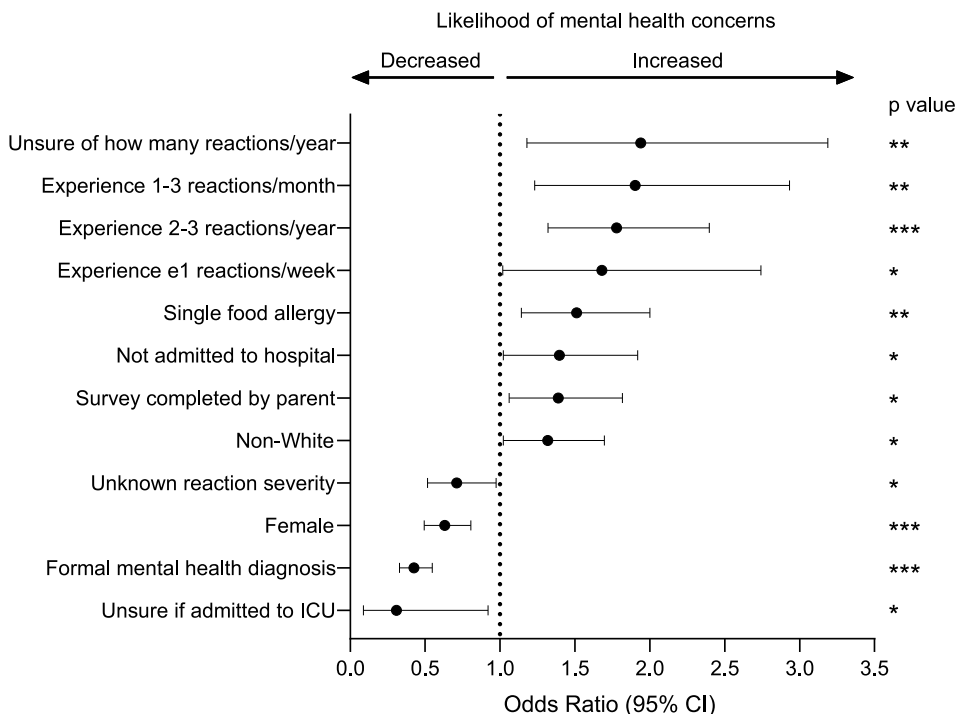


Fig. 3 Odds ratio (95% CI) of patient demographic and food allergy characteristics and their association with food allergy-related mental health concerns (n = 1680). An OR >1 indicates that the characteristic is associated with an increased likelihood of mental health concerns. An OR <1 indicates that the characteristic is associated with a decreased likelihood of mental health concerns. All OR are defined as the likelihood of having mental health concerns compared to a reference group: higher or unsure of frequency of allergic reactions (compared with less than one reaction per year); single food allergy (compared with multiple food allergies); not admitted to hospital (compared with admission to hospital for an allergic reaction); unsure of admission to the intensive care unit (ICU; compared with admission to ICU for an allergic reaction); survey completed by parent (compared with survey completed by self); unknown reaction severity/did not answer question (compared with moderate reaction severity); non-White race (compared with White race); formal mental health diagnosis (compared with no mental health diagnosis); and female (compared with male). Significantly associated characteristics are indicated as *p < 0.05, **p < 0.01, and ***p < 0.001

There were several predictors for a formal mental health diagnosis in patients with food allergies (Fig. 5); for example, a parent/other caregiver filling out the survey (OR 4.03 [95% CI: 3.04, 5.37], compared with patient completing

the survey) and experiencing food allergy-related mental health concerns (OR 2.36 [95% CI: 1.84, 3.05], compared with no mental health concerns) were associated with having a formal mental health diagnosis. In addition, having a single food

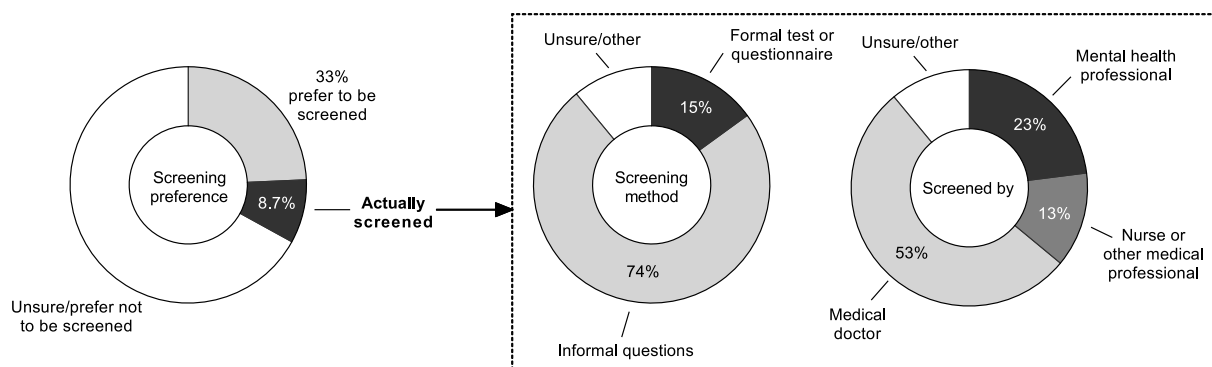


Fig. 4 Mental health screening of patients with food allergies (n = 1680). Response to the following survey questions: "Has the participant ever been screened or assessed for food allergy-related stress or mental health concerns during an allergy appointment?"; "Would the participant like for an allergist or pediatrician to screen for mental health concerns related to food allergy?"; "How was the participant screened or assessed?"; and "Who conducted the screening or assessment?"

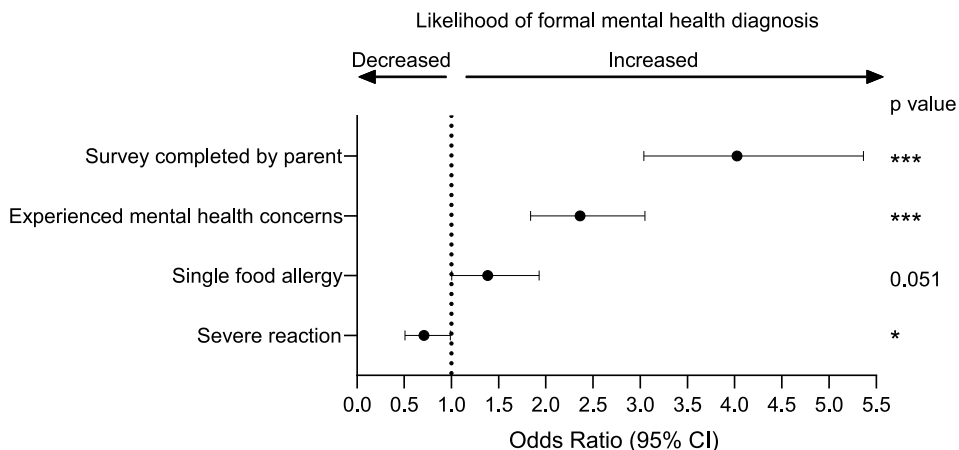


Fig. 5 Odds ratio (OR [95% CI]) of patient demographic and food allergy characteristics and their association with a formal mental health diagnosis (n = 1680). An OR >1 indicates that the characteristic is associated with an increased likelihood of a formal mental health diagnosis. An OR <1 indicates that the characteristic is associated with a decreased likelihood of a formal mental health diagnosis. All OR are defined as the likelihood of having a formal mental health diagnosis compared to a reference group: survey completed by parent (compared with survey completed by self); experienced food allergy-related mental health concerns (compared with no mental health concerns); single food allergy (compared with multiple food allergies); and severe reaction (compared with moderate reaction severity). Significantly associated characteristics are indicated as *p < 0.05 and ***p < 0.001

allergy was also a predictor for mental health diagnosis (OR 1.38 [95% CI: 1.00, 1.93], compared with multiple food allergies; p = 0.051). Severe reactions were associated with a decrease in formal mental health diagnosis (OR 0.71 [95% CI: 0.51, 0.99], compared with moderate reaction severity).

DISCUSSION

Our analysis of data from FARE Patient Registry, the largest, most comprehensively phenotyped registry of patients with food allergies in the United States, provides unique insights into the mental health status of patients with food allergies and their caregivers. Our findings indicate that food allergy-related mental health concerns, including anxiety, panic, and fear, are generally in agreement with previous studies and support that the psychosocial burden of food allergies is a widespread concern.^{4,6-8,10,11,14-16} In addition, we found that experiencing more than 1 reaction per year may drive mental health concerns in patients and their caregivers, suggesting these patients may benefit from additional mental health care. Our data also show that both single and multiple food allergies are associated with the likelihood of experiencing food allergy-related mental health concerns, suggesting that anyone with food allergies is at a greater risk. Thus, our study highlights a continuing unmet need for mental health

awareness as part of the management of all patients with food allergies.

This study supports the need for mental health screening for patients with food allergies. Although one-third of patients reported a previous or current mental health disorder, fewer than 1 in 10 patients reported being screened for mental health concerns. Currently, however, there is a lack of mental health support available for patients with food allergies.^{17,18} With mental health services often in high demand, many patients and caregivers may find it difficult to access mental health screening and support. Of note, we found that patients reporting a formal mental health diagnosis were less likely to report food allergy-related mental health concerns. Together, our analysis highlights the importance of having a clear path for referral of patients to a specialist mental healthcare provider if indicated in initial screening tests.

Several management strategies have been suggested that could improve the mental health of patients with food allergies and their caregivers, and we have listed some for consideration. Patients and caregivers should be provided with adequate information to manage severe food-allergic reactions (including proper use of epinephrine autoinjectors and availability of emergency medical services) and potential mental health concerns.^{1,10} In addition, empowering

parents/caregivers and building self-efficacy through education and support groups may decrease fear around food allergies,^{8,19-21} although levels of empowerment may differ between parents/caregivers.²² For children with food allergies, counseling and discussions with parents/caregivers and school officials could help to alleviate concerns of bullying and social isolation at school.^{1,9,23} In clinical practice, assessment tools including the Food Allergy Independent Measure (FAIM), the Pediatric Food Allergy Quality of Life Questionnaire (PFA), the Scale of Food Allergy Anxiety (SOFAA), and the Scale of Psychosocial Factors in Food Allergy (SPS-FA) could be used to formally assess mental health status and identify patients for referral to a mental health specialist.^{1,4,24} With the help of a psychologist, cognitive behavioral therapy, a currently understudied area of research for food allergies, could be used as an intervention to improve patient and caregiver mental health concerns.²⁴⁻²⁶ Finally, certain treatments such as oral immunotherapy^{16,27,28} could reduce food allergy symptoms and reactions in patients, and potentially decrease mental health concerns.

There are several limitations of this study. Given that the FARE Patient Registry is voluntary, the data may be reflective of the type of patient/caregiver responding to a registry request and may not be representative of all patients with food allergies. For example, although the current composition of the registry over-represents patients of White race relative to the general food-allergic population,²⁹ non-White race was a factor that increased the likelihood of mental health concerns in the FARE cohort. However, racial, ethnic, and socioeconomic data were not captured adequately in FARE to permit further analysis. Data in the FARE Patient Registry are self-reported or reported by a parent or caregiver on behalf of a child and, therefore, could be subject to bias. In addition, caregivers may have over- or under-reported their child's food allergy-related concerns - for example, survey completion by a parent/legal guardian was a key factor that increased the likelihood of mental health concerns and a formal mental health diagnosis. Of note, the FARE Mental Health Concerns survey asks questions on typical concerns, such as worry, stress, anxiety, or sadness about food

allergy, but should not be used for diagnosis of mental health disorders. Finally, this study took place in part during the COVID-19 pandemic; however, no additional survey questions were added in FARE to capture this information.

In conclusion, our findings from the FARE Patient Registry confirm the significant psychosocial burden of food allergies and identify drivers of food allergy-related mental health concerns. Importantly, FARE and its network of clinicians recognize these mental health concerns.^{18,30} Our concurrent analysis from the FARE Patient Registry identified the overall burden of food allergies, which may also help in understanding the needs of patients with food allergies.¹³ We encourage clinicians to screen for potential mental health concerns in patients and their caregivers and discuss options for professional mental health support if needed. Shared decision-making approaches may be useful in deciding on the right mental health care strategy for food allergy-related concerns.³¹

Abbreviations

CI, confidence interval; COVID-19, coronavirus disease; FAIM, Food Allergy Independent Measure; FARE, Food Allergy Research & Education; ICU, intensive care unit; OR, odds ratio; PFA, Pediatric Food Allergy Quality of Life Questionnaire; SD, standard deviation; SOFAA, Scale of Food Allergy Anxiety; SPS-FA, Scale of Psychosocial Factors in Food Allergy; y, years.

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Author contributions and consent for publication

TBC, CW, SG, RS, RW, AI, AS, and RG conceived the study, interpreted the results, and prepared the manuscript. RS, RW, and AS analyzed the data. All authors critically reviewed the manuscript, approved the final draft, and provided their consent for publication.

Ethics approval

Informed consent was obtained from patients prior to the completion of the surveys.

Data availability

Data supporting this study are included within the article and/or supporting materials.

Role of the sponsor

Genentech, Inc. was involved in the study design, data analysis, and preparation of the manuscript.

Declaration of competing interest

Thomas B. Casale is a consultant and speaker bureau member for Genentech, Inc.; is a consultant for Novartis Pharmaceuticals Corporation; and acted as chief medical adviser for FARE at the time of data acquisition. Christopher Warren received institutional research funding from FARE, the National Institutes of Health, and the Sunshine Charitable Foundation. Sachin Gupta, Robert Schuldt, Rongrong Wang, Ahmar Iqbal, Arpamas Seetasith are employees of Genentech, Inc. and stockholders in Roche. Ruchi Gupta received research grant support from Allergy and Asthma Network, FARE, Genentech, Inc., Melchiorre Family Foundation, National Confectioners Association, NIH, Stanford Sean N. Parker Center for Allergy Research, Sunshine Charitable Foundation, Thermo Fisher Scientific, UnitedHealth Group, and Walder Foundation; is a medical consultant/adviser for FARE, Genentech, Inc., and Novartis; and has ownership interest in Yobee Care, Inc.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.waojou.2024.100891>.

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