



The Peanut Allergy Burden Study: Impact on the quality of life of patients and caregivers

Anna Nowak-Wegrzyn^{a,b}, Steven L. Hass^c, Sarah M. Donelson^{d,*}, Dan Robison^d, Ann Cameron^e, Martine Etschmaier^e, Amy Duhig^e and William A. McCann^f

ABSTRACT

Background: Peanut allergy (PA) places significant burden on peanut-allergic individuals and their families, yet limited research in the United States has quantitatively examined the impact on peanut-allergic individuals and their families' health-related quality of life (HRQoL). The Peanut Allergy Burden Study (PABS) aimed to quantify the impact of PA on the general and disease-specific HRQoL of children, adolescents, and adults with PA, as well as caregivers of children with PA.

Methods: A cross-sectional survey design was employed to examine the real-world impact of PA in children, adolescents, and adults with PA, and caregivers of children with PA.

Results: Of 153 adult patients, 102 adolescents, and 382 caregivers of peanut-allergic children (n = 382), 6.8% and 24.8% of participants indicated being dissatisfied or somewhat dissatisfied, respectively, with current approaches to avoid or prevent PA reactions. Approximately two-thirds of patients and caregivers indicated that PA interferes at least somewhat with daily living. In terms of general HRQoL, adolescents, adult patients, and caregivers indicated that mental/psychosocial health was more problematic than physical health. PA patients and caregivers indicated worse HRQoL in all domains compared to healthy samples, and worse overall HRQoL, psychosocial, emotional, and social functioning than a sample of chronically ill patients. Results from the allergy-specific HRQoL measures showed that adolescents experienced greater impairment in overall HRQoL due to PA and in allergen avoidance and dietary restriction than adults.

Conclusion: PA negatively affects the general and PA-specific HRQoL of both patients and caregivers. The high emotional and psychosocial burden, in particular, demonstrates significant unmet need for patients with PA and their caregivers. Future work on treatment and preventive options to improve HRQoL for PA patients, particularly adolescents and their families, is needed.

Keywords: Peanut allergy, Food allergy, Quality of life, Health-related quality of life, Burden

INTRODUCTION

Epidemiological data estimate that food allergy affects up to 10% of the United States (US)

population and has been increasing in prevalence in the last few decades.¹ Peanut allergy (PA) is the most prevalent food allergy in the United States

^aNYU Grossman School of Medicine at Langone Health, New York, NY, USA
^{*}Corresponding author. 8000 Marina Blvd, Suite 300, Brisbane, CA 94C5-1884, USA E-mail: sdonelson@aimmune.com
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and is on the rise, particularly in children.¹ A 1997 survey conducted in the United States reported a PA prevalence of 0.4%, whereas a US survey administered between 2015 and 2016 reported a prevalence of 2.2%, translating into a dramatic 5-fold increase in prevalence.^{2,3} Recent studies have estimated that about 1.6 million children aged 1–17 years and over 4 million adults in the United States are affected by PA.^{3,4}

Individuals with PA who are exposed to peanuts, even trace amounts, can develop allergic reactions that impact the skin, respiratory, gastrointestinal, and cardiovascular systems, ranging in both severity (ie, mild, moderate, or severe) and time to onset (ie, immediate or delayed).⁵ Exposure can result in anaphylaxis, a life-threatening reaction requiring immediate treatment with injectable epinephrine.⁵ The standard of care for PA is the avoidance of foods with peanuts and carrying injectable epinephrine. With the first treatment for PA approved by the US Food & Drug Administration (FDA) in January 2020,⁶ and other treatments under investigation, this may be changing.⁷ Despite efforts to avoid peanuts, accidental peanut exposure may still occur due to mislabeled or unclear food labels, cross-contamination, consumption of foods less known for containing peanuts, and unawareness of food ingredients (eg, at a restaurant or social event).^{5,7}

Individuals with PA and their families must be vigilant about exposure to peanuts in a variety of settings. Living with PA presents day-to-day challenges and places significant burden on individuals with PA and their families. Accidental exposures to peanut are difficult to avoid, as peanuts can be hidden in various foods or contaminate meals prepared by others, and the severity of an allergic reaction to the peanut exposure is unpredictable.⁸ Individuals with PA and caregivers must engage in time-consuming tasks in an effort to avoid accidental exposure (eg, reading labels, preparing separate meals, etc.) and may avoid activities (eg, social gatherings, eating at restaurants, airplane travel) altogether when risk is unknown, which may result in increased anxiety about accidental peanut exposure and negatively impact health-related quality of life (HRQoL).⁷ HRQoL encompasses several aspects of overall quality of life that affect an individual's health. The US Centers for Disease Control and

Prevention (CDC) define HRQoL as including “physical and mental health perceptions (eg, energy level, mood) and their correlates – including health risks and conditions, functional status, social support, and socioeconomic status.”⁹ Connecting this definition to peanut-allergic individuals, HRQoL would refer to the perception of the condition's and treatment's effect on mental, emotional, physical, and social functioning.

A limited research base has examined the effect of PA on HRQoL. Studies conducted in Europe found decreased HRQoL among children with PA.^{7,10,11} These studies found that the majority of participants with PA indicated that PA affected their daily activities and that social activities and relationships were main drivers of PA impact on HRQoL.^{10,11} A US study showed that children with food allergies (including PA) incurred substantial direct medical costs due to outpatient and emergency department (ED) visits and hospital stays, and that their families had even greater out-of-pocket costs due to their food allergy.¹² Although these studies have led to important insights, the effect of PA on HRQoL has been understudied in the United States. Furthermore, a comprehensive assessment of child, adult, and caregiver HRQoL has not been gathered. For instance, treatment satisfaction has not yet been examined, leaving out crucial information of potential unmet needs that may affect PA individuals' HRQoL.

To add to the relatively sparse work done to date, a large survey study, the Peanut Allergy Burden Study (PABS), was conducted to investigate the real-world experience of individuals with PA in the United States. Given that PA may have a differential impact based on age and caregiver status, adolescents, adults, and caregivers of children with PA were included in the current study.

METHODS

Study design and procedure

A cross-sectional survey was designed to examine the real-world impact of PA in peanut-allergic adolescents, adults, and caregivers of peanut-allergic children. The study was reviewed and approved by the Solutions institutional review

board (IRB). Participants were recruited using Lightspeed, a market research company with a US panel of 1.3 million individuals, which emailed panel participants inviting them to participate in the survey. Those who completed the screening questions and met the inclusion criteria were invited to complete the full survey online. The survey consisted of demographic questions, questions about medical and treatment history related to PA, food allergy, and general HRQoL measures, along with questions about resource utilization and productivity, and took approximately 20-30 min to complete. Caregivers completed an additional measure on the burden to themselves and the family due to PA. Participants, including adolescents, gave informed consent to be in the overall research panel and then gave informed consent to voluntarily opt-in to complete this survey. For adolescents, a caregiver also provided consent for the adolescent to participate. Results from the resource utilization and productivity questions will be reported in a separate manuscript, as well as the PA medical and treatment history questions; therefore, those measures will not be described in the current manuscript. Study participants were compensated with "award points" that could be redeemed for gift certificates, merchandise, or cash.

Study participants

Participants first completed a screening questionnaire emailed to Lightspeed panel members in order to assess their eligibility for the study. Inclusion criteria for the adolescent and adult samples included: (a) aged 13-17 years (adolescent sample) or 18-55 years (adult sample); (b) self-reported physician-diagnosed PA; (c) required use of medication or medical care to treat a reaction to peanut or patient/caregiver always carries emergency medication; (d) agree completely or very much that they avoid being around peanuts; and (e) English-speaking US resident. Inclusion criteria for the caregiver sample included: (a) primary caregiver or shared caregiver responsibility for at least 1 child aged 1-17 years with a caregiver-reported physician-diagnosed peanut allergy; (b) child resides in the same household; (c) child required use of medication or medical care

to treat a reaction to peanut or patient/caregiver always carries emergency medication; (d) agree completely or very much that they avoid being around peanuts; and (e) English-speaking US resident. Recruitment quotas were set to ensure an approximate 50:50 male to female ratio of peanut allergic children, adolescents, and adults but this quota did not apply to caregiver gender. Additionally, age quotas were set for the adult and caregiver samples to ensure a broad age perspective, such that 50% of peanut allergic adults were between the ages of 18 and 25, and no more than 25% of caregivers had children between the ages of 1 and 3. Potential respondents were excluded who did not meet the inclusion criteria or once gender or age quotas had already been met. The response rate was 97% for adolescents, 96% for adult patients, and 93% for caregivers.

MEASURES

Treatment satisfaction

Treatment satisfaction was assessed using bespoke questions on overall satisfaction, with preventive care and treatment for reactions, as well as satisfaction questions pertaining to each specific treatment method, including epinephrine autoinjector, steroids, bronchodilators, antihistamines, oral immunotherapy, and epicutaneous immunotherapy. Each question was answered on a 5-point Likert scale from "not at all satisfied" to "extremely satisfied." Treatment satisfaction questions were administered to all samples.

12-item Short-Form Health Survey - version 2 (SF-12v2)

The SF-12v2 is a validated, 12-item measure of general HRQoL in adults in the past month. For all SF-12v2 health domain scales and component summary measures, a score of 50 anchors to the population mean, such that scores below indicate worse and scores above indicate better health compared to the population mean.¹³ The SF-12v2 provides a Physical Component Summary and a Mental Component Summary score. In addition, 8 domains of health are assessed: physical functioning, role - physical, bodily pain, general health,

vitality, social functioning, role - emotional, and mental health.¹⁴ The SF-12v2 was administered to the adult patient and caregiver samples.

Pediatric Quality of Life Inventory 4.0 (PedsQL)

The PedsQL is a validated, 23-item instrument that measures HRQoL in healthy children and adolescents, as well as those with acute and chronic health conditions.¹⁵ The measure consists of Generic Core scales, which were designed to measure the core dimensions of health as delineated by the, as well as role (school) functioning.⁹ There are 4 multidimensional scales: Physical Functioning (8 items), Emotional Functioning (5 items), Social Functioning (5 items), and School Functioning (5 items), as well as 3 summary scores: Physical Health Summary Score (8 items), Psychosocial Health Summary Score (15 items), and Total Scale Score (23 items). Each question is answered on a 5-point Likert scale from "never" to "almost always" and scored on a scale from 0 to 100, such that lower scores indicate worse HRQoL. The PedsQL was administered to the adolescent sample.

Food Allergy Quality of Life Questionnaire (FAQLQ)

The FAQLQ is a validated HRQoL measure specific to food allergy and is available in age-appropriate self-report forms. The adolescent sample received the FAQLQ-Teenager Form (FAQLQ-TF; 13-17 years) and the adult patient sample received the FAQLQ-Adult Form (FAQLQ-AF; ≥ 18 years). The FAQLQ-TF contains 23 items and 3 domains (Allergen Avoidance and Dietary Restrictions, Risk of Accidental Exposure, and Emotional Impact), and the FAQLQ-AF contains 29 items and 4 domains (the same 3 domains of the adolescent instrument, with the addition of a Food Allergy Related Health domain).¹⁶⁻¹⁹ Each question on the FAQLQ is scored on a 7-point Likert scale, with a range of 1 (no impairment) to 7 (maximal impairment). Higher scores on the FAQLQ indicate greater impairment in HRQoL.

The Food Allergy Quality of Life Questionnaire - Parent Form (FAQLQ-PF) and the Food Allergy Quality of Life Questionnaire - Parent Form

Teenager (FAQLQ-PFT) measure the degree to which a caregiver thinks that his/her child's HRQoL is affected by food allergy. The FAQLQ-PF is for caregivers with children aged 1-12 years who have a food allergy and consists of 30 items representing 3 domains (Emotional Impact, Food Anxiety, Social and Dietary Limitations). The FAQLQ-PFT is for caregivers with children aged 13-17 years who have a food allergy and contains 27 items and comprising the same 3 domains as the FAQLQ-PF. Each question on the FAQLQ-PF and FAQLQ-PFT is answered on a 7-point Likert scale, with a score range of 1 (no impairment) to 7 (maximal impairment) and higher scores indicating greater impairment in HRQoL.

Food Allergy Independent Measure (FAIM)

The Food Allergy Independent Measures (FAIM) corresponds with the FAQLQ-TF and FAQLQ-AF and both consist of 6 items. Four items of the self-report FAIM comprise an Expectation of Outcomes measure regarding the perceived chance of accidental exposure to allergens and what will happen following accidental exposure. The remaining 2 questions deal with how many products must be avoided because of their food allergy and the impact on their social life. It was developed to establish the construct validity of the FAQLQ.²⁰

The FAIM for caregivers with children aged 1-12 years consists of 8 items that measure the Caregiver Expectation of Outcomes and the Child Expectation of Outcomes. The Caregiver Expectation measures the caregiver's perceived expectation of the child's chance of accidental exposure to allergens and what will happen to the child following accidental exposure, whereas the Child Expectation measures what the caregiver thinks of the child's perceived expectation of the chance of accidental exposure to allergens and what the child thinks will happen following accidental exposure. The FAIM for caregivers with children aged 13-17 years consists of only the 4 items that measure Caregiver Expectation of Outcomes. All versions of the FAIM use a 7-point Likert scale, with a score range of 1-7, with higher scores indicating greater impact of PA.

Food Allergy Quality of Life - Parental Burden (FAQL-PB)

The FAQL-PB is a 17-item measure that assesses the degree to which a child's food allergy limits the caregiver's/family's choices and activities, as well as the caregiver's emotional distress in the past week due to their child's food allergy.²¹ The FAQL-PB uses a 7-point Likert scale, with a score range of 1 (not troubled) to 7 (extremely troubled). Higher scores on the FAQL-PB scale indicate greater caregiver burden.

Statistical analyses

Demographic and clinical data were analyzed using descriptive statistics. The 3 cohorts—adolescents, adults, and caregivers—were evaluated

separately using percentages for categorical variables and mean, median, standard deviation (SD), and/or range (as applicable) for continuous variables. For general HRQoL, norms from previously published large samples^{13,22} were examined for comparison purposes.

RESULTS

Demographic characteristics

There were 102 adolescents, aged 13-17 years, with a mean age of 14.6 years (SD = 1.3), and the adolescent sample was 55.9% male and 62.8% white (Table 1). There were 153 adult patients, aged 18-55 years, with a mean age of 31.3 years (SD = 11.7), who were 34.6% male and 64.1%

Characteristic		Adolescents (N = 102)	Adult Patients (N = 153)	Caregivers (N = 382)
Age (years), mean (SD)		14.6 (1.3)	31.3 (11.7)	37.5 (9.7)
Age of caregiver's child (years), mean (SD)		-	-	8.6 (4.7)
	1-3 years, n (%)	-	-	81 (21.2%)
	4-6 years, n (%)	-	-	60 (15.7%)
	7-12 years, n (%)	-	-	147 (38.5%)
	13-18 years, n (%)	-	-	94 (24.6%)
Sex, n (%)	Male	57 (55.9%)	53 (34.6%)	153 (40.1%)
	Female	45 (44.1%)	100 (65.4%)	229 (60.0%)
Hispanic, Latino, or Spanish ethnicity, n (%)	Yes	21 (20.6%)	38 (24.8%)	85 (22.3%)
	No	81 (79.4%)	115 (75.2%)	297 (77.8%)
Race, n (%)	White	64 (62.8%)	98 (64.1%)	265 (69.4%)
	Black/African-American	19 (18.6%)	23 (15.0%)	76 (19.9%)
	Asian	5 (4.9%)	12 (7.8%)	23 (6.0%)
	American Indian or Alaska Native	2 (2.0%)	3 (2.0%)	5 (1.3%)
	Mixed race	10 (9.8%)	10 (6.5%)	5 (1.3%)
	Other	1 (1.0%)	5 (3.3%)	7 (1.8%)
	Prefer not to answer	1 (1.0%)	1 (0.7%)	0 (0.0%)

Table 1. Demographic characteristics of PABS participants Key: PABS - Peanut Allergy Burden Study

Characteristic, n (%)		Adolescents (N = 102)		Adult Patients (N = 153)		Caregivers (N = 382)	
		n	%	n	%	n	%
Satisfaction with preventive care	Not at all satisfied	1	0.9%	5	3.2%	8	2.0%
	Not very satisfied	4	3.9%	11	7.1%	20	5.2%
	Somewhat satisfied	29	28.4%	53	34.6%	110	28.8%
	Very satisfied	47	46.0%	48	31.3%	160	41.8%
	Extremely satisfied	21	20.5%	36	23.5%	84	21.9%
Satisfaction with treatment for reactions	Not at all satisfied	0	0.0%	7	4.5%	6	1.5%
	Not very satisfied	3	2.9%	9	5.8%	19	4.9%
	Somewhat satisfied	23	22.5%	36	23.5%	99	25.9%
	Very satisfied	47	46.0%	63	41.1%	156	40.8%
	Extremely satisfied	29	28.4%	38	24.8%	102	26.7%
Satisfaction with epinephrine autoinjector ^a	Patients with epinephrine autoinjector experience	77	-	89	-	231	-
	Not at all satisfied	1	1.3%	2	2.2%	1	0.4%
	Not very satisfied	2	2.6%	5	5.6%	4	1.7%
	Somewhat satisfied	8	10.3%	18	20.2%	30	12.9%
	Very satisfied	24	31.1%	32	35.9%	81	35.0%
	Extremely satisfied	42	54.5%	32	35.9%	115	49.7%
Satisfaction with steroids ^a	Patients with steroid experience	52	-	71	-	162	-
	Not at all satisfied	0	0.0%	1	1.41%	5	3.0%
	Not very satisfied	1	1.9%	5	7.04%	1	0.6%
	Somewhat satisfied	16	30.7%	23	32.3%	34	20.9%

	Very satisfied	20	38.4%	24	33.8%	73	45.0%
	Extremely satisfied	15	28.8%	18	25.3%	49	30.2%
Satisfaction with bronchodilator ^a	Patients with bronchodilator experience	48	-	82	-	174	-
	Not at all satisfied	1	2.0%	3	3.6%	3	1.7%
	Not very satisfied	2	4.1%	11	13.4%	6	3.4%
	Somewhat satisfied	12	25.0%	22	26.8%	39	22.4%
	Very satisfied	21	43.7%	23	28.0%	75	43.1%
	Extremely satisfied	12	25.0%	23	28.0%	51	29.3%
Satisfaction with antihistamines/over-the-counter medications ^a	Patients with antihistamine/OTC experience	81	-	137	-	323	-
	Not at all satisfied	1	1.2%	15	10.9%	10	3.1%
	Not very satisfied	4	4.9%	15	10.9%	16	4.9%
	Somewhat satisfied	27	33.3%	30	21.9%	81	25.0%
	Very satisfied	24	29.6%	40	29.2%	121	37.4%
	Extremely satisfied	25	30.8%	37	27.0%	95	29.4%
Satisfaction with oral immunotherapy ^a	Patients with oral immunotherapy experience	21	-	49	-	112	-
	Not at all satisfied	1	4.7%	3	6.1%	1	0.8%
	Not very satisfied	0	0.0%	5	10.2%	5	4.4%
	Somewhat satisfied	9	42.8%	15	30.6%	24	21.4%
	Very satisfied	5	23.8%	15	30.6%	36	32.1%
	Extremely satisfied	6	28.5%	11	22.4%	46	41.0%

(continued)

Characteristic, n (%)	Adolescents (N = 102)		Adult Patients (N = 153)		Caregivers (N = 382)	
	n	%	n	%	n	%
Satisfaction with epicutaneous immunotherapy ^a	18	-	50	-	106	-
Patients with epicutaneous immunotherapy experience						
Not at all satisfied	1	5.5%	4	8.0%	3	2.8%
Not very satisfied	2	11.1%	4	8.0%	6	5.7%
Somewhat satisfied	5	27.7%	13	26.0%	19	17.9%
Very satisfied	6	33.3%	13	26.0%	43	40.6%
Extremely satisfied	4	22.2%	16	32.0%	35	33.0%

Table 2. (Continued) PA treatment satisfaction Key: PABS – Peanut Allergy Burden Study. a. Responses among those with experience using that form of therapy

white. There were 382 caregivers, aged 19–66 years, with a mean age of 37.6 years (SD = 9.7), and the caregiver sample was 40.1% male and 69.4% white. The age of the caregiver's child ranged from 1 to 17 years old, with a mean age of 8.69 years (SD = 4.7); 21.2% were aged 1–3 years, 15.7% were aged 4–6 years, 38.5% were aged 7–12 years, and 24.6% were aged 13–17 years.

Treatment satisfaction

When asked about their satisfaction with current approaches to avoid or prevent PA reactions, 4.8% of adolescents, 10.3% of adult patients, and 7.2% of caregivers stated that they were “not at all satisfied” or “not very satisfied”, and 28.4% of adolescents, 34.6% of adult patients, and 28.8% of caregivers reported that they were “somewhat satisfied” (Table 2). Satisfaction with treatment for PA reactions was similar, with 2.9% of adolescents, 10.3% of adult patients, and 6.4% of caregivers indicating they were “not at all satisfied” or “not very satisfied”, and 22.5% of adolescents, 23.5% of adult patients, and 25.90% of caregivers stated that they were “somewhat satisfied”. When reported by treatment type, the highest proportion of participants reported being “very satisfied” or “extremely satisfied” with injectable epinephrine, with percentages ranging from 71.8% to 85.6%, while the highest proportion of participants reported being “not at all satisfied” or “not very satisfied” with epicutaneous immunotherapy (weighted average: 11.6%) and antihistamines/over-the-counter medications (weighted average: 11.0%).

Interference with day-to-day life

When asked about the extent to which living with PA limits day-to-day life, 26.5% of adolescents, 31.4% of adult patients, and 34.3% of caregivers indicated that PA interferes with day-to-day life either “very much” or “completely,” and 42.2% of adolescents, 37.9% of adult patients, and 35.3% of caregivers indicated that PA interferes with day-to-day life “somewhat.” Importantly, 79.4% of adolescents reported that fear of experiencing a reaction affected their emotional well-being at least “somewhat.”

Domain	PABS Adolescents ^a (N = 102)			MID
	Mean (SD)	P-value (vs Healthy Sample ^b)	P-value (vs Chronically Ill Sample ^b)	SEM
Total	69.4 (2s3.0) ^{c,d,e}	<0.001	0.045	4.3
Physical	75.4 (29.4) ^c	<0.001	0.180	6.6
Psychosocial	66.2 (23.4) ^{c,e}	<0.001	0.035	5.3
Emotional	61.3 (26.7) ^c	<0.001	0.004	8.9
Social	69.6 (27.7) ^c	<0.001	0.021	8.3
School	69.6 (27.7) ^c	<0.001	0.804	9.1

Table 3a. General self-reported HRQoL (PedsQL)

General HRQoL

The results for general HRQoL, as measured by the PedsQL, for the adolescent sample are shown in Table 3. Out of the 4 scales, adolescents rated Emotional Functioning (mean = 61.4, SD = 26.7) as the worst and Physical Functioning (mean = 75.4, SD = 29.4) as the best. Of the 2 summary scores, adolescents rated Psychosocial Health as the worst (mean = 66.2, SD = 23.4) and Physical Health as the best (mean = 75.4,

SD = 29.4). The total score and all subscale scores were all significantly different and below the minimal important difference (MID) from the mean of a healthy US sample.²² The total score, Psychosocial Health, Emotional Functioning, and Social Functioning scores were also significantly different than the scores of a chronically ill sample that consisted of children whose parents reported 1 or more of the following chronic conditions: asthma, diabetes, attention deficit

Domain	Adults (N = 153)		Caregivers (N = 382)	
	Mean (SD)	P-value ^g	Mean (SD)	P-value ^g
Physical Functioning	43.7 (13.1)	<0.001	46.3 (12.5)	<0.001
Role - Physical	35.2 (12.2)	<0.001	32.2 (12.5)	<0.001
Bodily Pain	43.3 (13.6)	<0.001	42.7 (14.1)	<0.001
General Health	36.2 (12.8)	<0.001	34.3 (12.0)	<0.001
Role - Emotional	28.4 (15.0)	<0.001	25.5 (14.9)	<0.001
Vitality	45.6 (11.3)	<0.001	44.8 (10.8)	<0.001
Mental Health	36.4 (9.9)	<0.001	34.1 (10.3)	<0.001
Social Functioning	32.1 (12.5)	<0.001	29.0 (12.6)	<0.001
Physical Component Summary	43.7 (8.9) ^h	<0.001	44.2 (9.1) ^h	<0.001
Mental Component Summary	32.3 (14.1) ^h	<0.001	28.8 (14.8) ^h	<0.001

Table 3b. General self-reported HRQoL (SF-12v2)^f Key: HRQoL - health-related quality of life; MID - minimal important difference; PABS - Peanut Allergy Burden Study; PedsQL - Pediatric Quality of Life Inventory; SD - standard deviation; SEM - standard error of measurement; SF-12v2 - 12-item Short-Form Health Survey - version 2. a. None of the mean scores in our samples were 1 SD (per the chronically ill population's SD) below the chronically ill sample (consisting of children whose parents reported 1 or more of the following conditions: asthma, diabetes, attention deficit hyperactivity disorder, depression or "other") b. In Table 3a, US norms for the adolescent sample were retrieved from Varni and colleagues (2003) and were also used for statistical testing²² c. Mean score > MID lower than the healthy population's mean d. Mean score > MID lower than the chronically ill population's mean e. Mean score > 1 SD (per the healthy population's SD) below the healthy sample f. In Table 3b, for the adult and caregiver samples, a score >50 or <50 suggested better or worse mental and physical health, respectively, than the population mean¹³ g. For statistical testing, 2009 US general population SF-12v2 standard 4-week recall form normative data were used¹³ h. Group-level mean summary score > MID (3 T-score points) lower than in the US general population normative sample¹³

Domain	Adolescents (N = 102) Mean (SD)	Adult Patients (N = 153) Mean (SD)	P-value
FAQLQ			
Total	5.0 (1.8)	4.6 (1.4)	0.030
Allergen Avoidance and Dietary Restriction	5.0 (1.3)	4.6 (1.4)	0.025
Emotional Impact	4.9 (1.3)	4.7 (1.5)	0.272
Risk of Accidental Exposure	5.0 (1.3)	4.7 (1.4)	0.114
Food Allergy-Related Health	-	4.4 (1.64)	-
FAIM			
Total	4.3 (1.2)	4.1 (1.2)	0.192
Expectation of Outcomes	4.3 (1.4)	4.2 (1.5)	0.587
Product Avoidance	4.6 (1.1)	4.3 (1.4)	0.056
Social Impact	3.9 (1.5)	3.6 (1.5)	0.118

Table 4. Allergy-specific quality of life – self-report *Table 4 Notes:* The MID of HRQoL questionnaires with a 7-point scale was approximately 0.5;¹⁹ none of mean score comparisons for adolescents and adults exceeded that threshold. For statistical testing, the adolescent and adult patient samples were compared. Key: FAIM - Food Allergy Independent Measures; FAQLQ - Food Allergy Quality of Life Questionnaire; MID - minimal important difference; HRQoL - health-related quality of life; SD - standard deviation

hyperactivity disorder, depression or “other”.²² The total (mean = 69.4, SD = 23.0) and psychosocial scores (mean = 66.2, SD = 23.4) were also 1 SD or more below the mean of the healthy sample of 5079 children in the United States (see [Table 3a](#)). Furthermore, as seen in [Table 3b](#), the total score was also below the MID from the mean of a chronically ill sample of 574 children in the United States.

General HRQoL for the adult patient and caregiver samples were measured by the SF-12v2. In both the adult patient and caregiver samples, all domains of HRQoL were significantly different than a US normative sample and were below the population mean of 50.¹³ For both the Physical and Mental Component Summary scores, the mean scores were significantly different than a US normative sample and more than the MID (3 T-score points) below the population mean of 50, indicating that both physical and emotional health for the adult patient and caregiver samples are significantly worse than the general population.¹³ Similar to the adolescent sample, both the adult patient and caregiver samples had

lower Mental Health Component Summary scores (adults: mean = 32.3, SD = 14.1; caregivers: mean = 28.8, SD = 14.8) than Physical Health Component Summary scores (adults: mean = 43.7, SD = 8.9; caregivers: mean = 44.2, SD = 9.1).

Allergy-specific quality of life

For the adolescent sample, mean (SD) scores on the FAQLQ-TF were 5.0 (1.2) for FAQLQ-TF total, 5.0 (1.3) for Allergen Avoidance and Dietary Restriction, 4.9 (1.3) for Emotional Impact, and 5.0 (1.3) for Risk of Accidental Exposure ([Table 4](#)). Given that the scale ranges from 1 (minimal impairment) to 7 (maximum impairment), results showed that the adolescents with PA sample experienced substantial impairment in HRQoL due to PA.

In the adult patient sample, mean (SD) scores on the FAQLQ-AF were 4.6 (1.42) for FAQLQ-AF total, 4.69 (1.46) for Allergen Avoidance and Dietary Restriction, 4.78 (1.5) for Emotional Impact, 4.7 (1.4) for Risk of Accidental Exposure, and 4.4 (1.6) for Food Allergy-Related Health. Like the

	FAQLQ-PF						FAQLQ-PFT
	Caregiver's child aged 1-3 years (N = 81)		Caregiver's child aged 4-6 years (N = 60)		Caregiver's child aged 7-12 years (N = 147)		Caregiver's child aged 13-17 years (N = 94)
	Mean (SD)	P-value	Mean (SD)	P-value	Mean (SD)	P-value	Mean (SD)
FAQLQ Domain							
Total	4.39 (1.86)	0.969	4.76 (1.67)	0.170	4.61 (1.72)	0.308	4.40 (1.45)
Emotional Impact	4.15 (1.94)	0.827	4.66 (1.68)	0.102	4.50 (1.78)	0.195	4.21 (1.64)
Food Anxiety	4.42 (2.01)	0.766	4.83 (1.75)	0.224	4.82 (1.65)	0.115	4.50 (1.46)
Social	4.65 (1.90)	0.509	4.81 (1.71)	0.214	4.59 (1.79)	0.598	4.48 (1.43)

	FAQLQ-PF		FAQLQ-PFT
	Caregiver's child aged 1-12 years (N = 288)		Caregiver's child aged 13-17 years (N = 94)
	Mean (SD)	P-value	Mean (SD)
FAIM			
Caregiver Expectation	4.29 (0.98)	0.589	4.37 (1.32)
Child Expectation ^a	4.22 (1.11)	-	

Table 5. Allergy-specific quality of life – caregiver-report Key: FAIM - Food Allergy Independent Measures; FAQLQ - Food Allergy Quality of Life Questionnaire; FAQLQ-PF - Food Allergy Quality of Life Questionnaire - Parent Form; FAQLQ-PFT - Food Allergy Quality of Life Questionnaire - Parent Form Teenager; MID - minimal important difference; HRQoL - health-related quality of life; SD - standard deviation. Notes: The MID of HRQoL questionnaires with a 7-point scale was approximately 0.5.¹⁹ None of the mean score comparisons for any domain differed between groups by more than 0.5 points. Statistical testing from this table represents results when compared to FAQLQ and FAIM scores of caregivers whose children were aged 13-17 years. a. The Child Expectation score was only reported for caregivers of children aged 1-12 years because the FAIM does not ask child expectation questions for FAQLQ-PFT

adolescent sample, patients from the adult sample experienced impairment in HRQoL due to PA and results from the FAIM indicate substantial concern over serious health risks due to their PA. Statistical testing showed that adolescents had significantly worse scores for total FAQLQ ($P = 0.030$) and the Allergen Avoidance & Dietary Restriction subscale ($P = 0.025$). None of the differences between adolescents and adult patients were substantially different, as measured by the MID of HRQoL questionnaires with a 7-point scale of 0.5 points.¹⁹

Results from the adolescent and adult patient samples on the FAIM corroborate findings from the FAQLQ-TF and FAQLQ-AF, with mean scores on each question being in the middle of the scale and showing impairment. Over half of the adolescents and adult patients thought that there was at least a fair chance that they would accidentally eat something to which they were allergic (adolescents: 71.6%, adults: 61.4%), have a severe reaction if they accidentally ate something to which they were allergic (adolescents: 78.4%, adults: 74.5%), die from eating something to which they were allergic (adolescents: 58.8%, adults: 62.8%), and not be able to effectively deal with an allergic reaction (adolescents: 65.7%, adults: 58.8%). These Expectation of Outcomes, Product Avoidance and Social Impact scores from the FAIM were not significantly different between adolescents and adult patients.

The results for children's PA-specific HRQoL are reported by caregivers of children of the following age groups: 1-3 years (FAQLQ-PF), 4-6 years (FAQLQ-PF), 7-12 years (FAQLQ-PF), and 13-17 years (FAQLQ-PFT). Results from the FAQLQ-PF showed that caregivers of children in each age group perceive that the HRQoL of their children as impaired due to PA (Table 5). There were no significant differences between caregivers of children 13-17 years and caregivers of any other age group, and there were also no differences between the groups that exceeded the minimal important difference (MID) of 0.5. Within each age group, the lowest domain score was seen for Emotional Impact.

Results from the FAIM Caregiver Expectation of Outcomes scale (Table 5) indicate that personal concern over the health risk of PA among caregivers of children aged 13-17 years

(mean = 4.2, SD = 0.9) was not significantly different ($P = 0.589$) than concern among caregivers of children aged 1-12 years (mean = 4.3, SD = 1.3). For caregivers of children aged 1-12 years, the Caregiver Expectation of Outcomes score (mean = 4.2, SD = 0.9) was similar to the Child Expectation of Outcomes score (mean = 4.2, SD = 1.1), indicating that the caregiver's perceived expectation of the child's chance of accidental exposure is similar to the caregiver's opinion of the child's perceived expectation of the chance of accidental exposure.

Caregiver burden

Caregivers had an average score of 3.8 (SD = 1.8) on the FAQL-PB, indicating that on average, caregivers experienced some emotional distress due to their child's PA and that the caregiver's/family's choices and activities were somewhat limited in the past week.

DISCUSSION

The current study demonstrated that PA imposes a daily burden on adolescents, adult patients, and caregivers, negatively affecting allergy-specific, as well as general HRQoL. Approximately two-thirds of adult patients, adolescents, and caregivers of individuals with PA indicated that PA interferes at least "somewhat" with daily living. PA seems to affect mental health/emotional functioning more than physical health and functioning, likely due to having to restrict social interactions to avoid contamination or accidental exposure. This suggests that interventions could improve HRQoL for PA patients. Although most participants indicated that PA interferes with their daily activities, only 6.8% of participants were dissatisfied with current approaches to avoid or prevent PA reactions, which may be partially because there were no FDA-approved treatments for PA available prior to January 2020 and during the conduct of this survey. However, an additional 24.8% of participants were only "somewhat satisfied" with current approaches to avoid or present PA reactions, indicating that these patients may have needs that are not currently being addressed by the available approaches. Findings that PA interferes with daily activities, social functioning and emotional

functioning are consistent with previous studies of food allergies overall.²³ In terms of general HRQoL, all 3 samples (adolescents, adult patients, and caregivers) indicated that mental/psychosocial health was more problematic than physical health. When compared to a healthy sample, adolescents, adult patients and caregivers indicated worse HRQoL in all domains. Statistical significance testing revealed that the overall HRQoL in this sample of adolescents with PA was worse than that of a sample of children with chronic health conditions, such as asthma or diabetes, for the total HRQoL score, psychosocial health, emotional functioning and social functioning, although none of the specific domain scores exceeded the MID, indicating that they may not be clinically different from children with chronic health conditions. Results from this study are consistent with results of a European study that was conducted showing that children with PA had decreased HRQoL compared to children with chronic diseases. In that study, children with PA reported higher fear of potential hazards in their environment, lower ability to participate fully in physical activities, and higher worry when being away from home.⁷ These findings are consistent with previous research showing that caregivers of children with PA report their child's physical and emotional HRQoL as lower than that of healthy children, thus corroborating that children and families appear to experience high levels of caregiver stress and child anxiety, which can affect HRQoL.²⁴

Results from the allergy-specific HRQoL measures indicated that adolescents experience significantly worse impairment than adult patients in overall allergy-specific HRQoL and for allergen avoidance and dietary restriction. This finding may be due to the fact that adults have had more time to adjust their lifestyles due to PA and have been able to determine how to successfully avoid peanut exposure both by navigating dietary restrictions and negotiating social interactions that include food. However, when using the MID of HRQoL questionnaires with a 7-point scale, this difference between adolescents and adult patients was not significant. Previous research has suggested that adolescents are at greater risk of adverse events related to food allergies as their autonomy develops.²³ More research is needed to

clarify differences in HRQoL between adolescents and adult patients. Additionally, the variation in HRQoL impairment among caregivers of various developmental age groups was minimal, despite previous research on food allergies in general indicating that caregivers of younger children reported a more negative impact on family activities.²³ Findings from the current study were consistent with previous research showing that caregivers consistently reported being bothered by social limitations resulting from their child's food allergy and the fear of allergen exposure outside the home.^{23,25} The PABS is the first study to systematically gather quantitative data, including a wide range of data from adolescents, adults, and caregivers, on the impact of PA on HRQoL in the United States. Another strength of the study is the use of validated food allergy-specific and general HRQoL scales. There are several limitations of this study, including the reliance on self-report measures for the adolescent and adult cohorts, which may be subject to social desirability bias, response bias, misinterpretation of questions, and inability to accurately assess questions. The study also utilized observer reported measures from caregivers, which has inherent limitations in that they are asked to report on how another feels or functions, which may be subject to bias. Another limitation is that the normative sample from the PedsQL is based on a study conducted from 2001 to 2003.²² Given differences in sociodemographic and cultural characteristics over time, there may be differences between this normative sample and a more current normative sample. Additionally, despite efforts to balance the enrollment, there may be some demographic, disease history or treatment imbalances that would influence the interpretation of the data. The current study did not collect information on sociocultural information, such as household income and education level, that could impact HRQoL. Future studies should examine the impact of these variables. Patients with PA may also have other conditions, including allergic diseases such as asthma or allergic rhinitis, that may affect HRQoL, and thus, results of the current study may not reflect solely the impact of PA. Another limitation is that the inclusion criteria of PA diagnosis for the study is self-reported, and therefore, not verified by a physician. Finally, results may be biased

due to the inclusion criteria for the study. Since one of the inclusion criteria was that participants either required medication or medical care because of a peanut reaction, or that the participant or caregiver always carries emergency medication in case of accidental peanut exposure, results may not be generalizable to all individuals with PA, particularly for those in whom avoidance of peanuts is a successful strategy or who may be less sensitive to very small amounts of peanut. Another inclusion criterion was that participants avoid being around peanuts, which may have excluded individuals with PA who are not as worried about their PA or who have learned to cope better with their PA, so the population in this study may represent one that has more impaired HRQoL and may not be generalizable to all individuals with PA.

CONCLUSION

In conclusion, PA detrimentally affects not just the patient but the patient's caregiver and family, as well. Further studies are needed to determine how to best address the individual patient and caregiver/family burden, especially the high emotional and psychosocial burden, experienced due to PA. Adolescent patients, in particular, may be at greater risk for impaired HRQoL. Some real-world studies have shown that treatments, such as immunotherapy and epinephrine, can improve HRQoL in patients and caregivers with food allergies,^{23,25-28} and an open-label extension study of the Phase 3 PALISADE trial for PALFORZA showed improvements in self-reported PA-specific HRQoL at 28 and 56 weeks beyond the first year of treatment.²⁹ However, real-world evidence is lacking regarding a PA treatment that allows patients to maintain a high level of physical and emotional functioning. Treatments that can prevent or lower the risk of reactions to peanuts would improve HRQoL for these patients and may be life-changing for individuals with PA and their families. Given the recent approval of PALFORZIA for the treatment of PA by the US Food and Drug Administration, it remains to be seen whether this therapy will be able to improve the HRQoL burden for this patient population and their caregivers in a real-world setting.

Abbreviations

FAIM, Food Allergy Independent Measure; FAQL-PB, Food Allergy Quality of Life-Parental Burden; FAQLQ, Food Allergy Quality of Life Questionnaire; FAQLQ-AF, Food Allergy Quality of Life Questionnaire-Adult Form; FAQLQ-PF, Food Allergy Quality of Life Questionnaire-Parent Form; FAQLQ-PFT, Food Allergy Quality of Life Questionnaire-Parent Form Teenager; FAQLQ-TF, Food Allergy Quality of Life Questionnaire-Teenager Form; HRQoL, health-related quality of life; MCID, minimal clinically important difference; MID, minimal important difference; PA, peanut allergy; PABS, Peanut Allergy Burden Study; PedsQL, Pediatric Quality of Life Inventory 4.0; SD, standard deviation; SEM, standard error of measurement; SF-12v2, 12-item Short-Form Health Survey-version 2; US, United States

Ethics statement

The study was reviewed and approved by an institutional review board. All research was conducted in accordance with the 1964 Declaration of Helsinki and its later amendments.

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Availability of data statement

The data that support the findings of this study, which are captured in the current article, are available from the corresponding author upon reasonable request.

Consent for publication

All authors have reviewed this manuscript and consent to its publication.

Author contributions

Anna Nowak-Wegrzyn: Supervision; writing, review, and editing.

Steven L. Hass: Conceptualization, methodology, validation, formal analysis, investigation, supervision, writing, review, and editing; visualization.

Sarah M. Donelson: Supervision, writing, review, and editing; visualization and project administration.

Dan Robison: Conceptualization, methodology, writing, review, and editing; funding acquisition.

Ann Cameron: Conceptualization, methodology, validation, formal analysis, investigation, data curation, writing (original draft); writing, review, and editing.

Martine Etschmaier: Conceptualization, methodology, validation, investigation, writing (original draft); writing, review, and editing; visualization and project administration.

Amy Duhig: Conceptualization, methodology, validation, writing, review, and editing.

William A. McCann: Conceptualization, methodology, supervision, writing, review, and editing.

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Dan Robison: Employee of Aimmune Therapeutics; holds Aimmune stock options/restricted stock options.

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Author details

^aNYU Grossman School of Medicine at Langone Health, New York, NY, USA. ^bDepartment of Pediatrics, Gastroenterology and Nutrition, Collegium Medicum, University of Warmia and Mazury, Olsztyn, Poland. ^cH.E. Outcomes, LLC, Los Angeles, CA, USA. ^dAimmune Therapeutics, Brisbane, CA, USA. ^eXcenda, LLC, Palm Harbor, FL, USA. ^fAllergy Partners P.A., Asheville, NC, USA.

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