

Diagnosing peanut allergy with skin prick and specific IgE testing

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Background: Food allergy is common in childhood. It has been suggested that the magnitude of a skin prick test or specific IgE result can improve diagnostic usefulness, but this has been addressed in only a few tertiary challenge-based studies.

Objective: To determine the predictive value of a wheal ≥ 8 mm or serum specific IgE ≥ 15 kU_A/L for clinical allergy and investigate whether results are generalizable.

Methods: All subjects, up to 16 years of age, who had been investigated with a peanut or tree nut food challenge were eligible for the study. Subjects were referred from either a tertiary allergy clinic or a community birth cohort. All subjects with a history suggestive of food allergy were offered a challenge unless there were features of anaphylaxis. Details of challenges were prospectively recorded. Results were modeled by using logistic regression.

Results: There was a total of 161 peanut challenges. Recent skin prick (longest wheal diameter) and specific IgE data were available for 135 and 136 challenges, respectively. The results suggest that a skin prick result ≥ 8 mm and a specific IgE ≥ 15 kU_A/L have predictive values of 95% (95% CI, 76.2% to 99.9%) and 92.0% (74.0% to 99.0%), respectively, for a positive challenge. Age, the type of nut, and referral pattern of the subject did not appear to alter this relationship.

Conclusion: These data suggest that a skin prick result ≥ 8 mm or a specific IgE ≥ 15 kU_A/L have a high predictive value for clinical allergy to peanut and that these cutoff figures appear generalizable to different populations of children undergoing an assessment for peanut allergy. (*J Allergy Clin Immunol* 2005;115:1291-6.)

Key words: Food allergy, children, skin prick testing, specific IgE, positive predictive value

Food allergy is very common in the pediatric population, with 8% of infants affected by type I hypersensitivity to foods.¹ Currently, the only reliable means of diagnosing food allergy is by graded challenge.² This is a time-consuming investigation for both the family and the multidisciplinary allergy team and exposes the child to the risk of anaphylaxis. A clinical history of a food allergy has only a 50% positive predictive value for clinical

Abbreviation used

ALSPAC: Avon Longitudinal Study of Parents and Children

allergy.³ Allergy tests, such as skin prick and serum specific IgE testing, detect only sensitization to allergen. It has been suggested that the magnitude of a skin prick testing or specific IgE result can improve the diagnostic usefulness of these tests.⁴⁻⁶ Specifically, a wheal of at least 8 mm or a specific IgE of at least 15 kU_A/L has been reported as having a 95% positive predictive value for clinical allergy as diagnosed by a food challenge.^{4,5} Not all studies agree with these figures, possibly because of the different subject groups, different commercial allergens, or serum specific IgE assays.⁷⁻¹⁰ Unfortunately, there are few studies addressing this issue, and they have used specific, often tertiary, patient groups or specific allergy tests. It therefore remains to be seen whether these results can be generalized to other groups of children with allergy and other means of assaying levels of specific IgE against food allergens.⁶ In this study, we have examined the ability of skin prick and serum specific IgE testing to predict presence of food allergy to peanuts, the most common childhood food allergen. To maximize the generalizability of the results, we included consecutive challenges from a tertiary allergy clinic and a community birth cohort.

METHODS

Subjects

Data from all food challenges to peanut at St Mary's Hospital were included in the study. Subjects undergoing challenges either were referred from the pediatric allergy clinic at St Mary's Hospital with suspected food allergy (January 1995 to July 2000) or were subjects from a large cross-sectional birth cohort (Avon Longitudinal Study of Parents and Children [ALSPAC]¹¹) with a positive skin prick test result and either a possible previous reaction or no history of having consumed the food (May 1997 to October 2002). At this time, any child with a history suggestive of food allergy to peanuts was offered a challenge regardless of the test results unless there was a history of anaphylaxis. Subjects had to have skin prick or serum specific IgE data available from the 2 years preceding the food challenge to be included in the study. Six children with inconclusive open challenges, which could not be repeated as a blind procedure, were excluded. The study protocol was approved by the local research ethics committee.

Skin prick and serum specific IgE testing

Skin prick testing was performed on the volar side of the forearm by using positive control (histamine dihydrochloride 10 mg/mL),

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TABLE I. Details of the peanut challenges*

	All challenges (n = 161)	Challenges with skin prick test results (n = 135)	Challenges with specific IgE results (n = 136)
Mean age at challenge in y	7.0 (1.0-16.4)	7.3 (1.5-16.4)	6.9 (1.0-16.4)
Median age of onset of symptoms in mo	24 (11-48)	23 (11-48)	24 (12-48)
Median number of reactions	2 (1-3)	2 (1-3)	2 (1-3)
Male sex	87 (54.0%)	71 (52.6%)	75 (55.2%)
Cohort			
St Mary's (hospital)	121 (75.2%)	98 (72.6%)	104 (76.5%)
ALSPAC (community)	40 (24.8%)	37 (27.4%)	32 (23.5%)
Other atopic problems			
Asthma	71 (44.7%)	57 (42.9%)	63 (47.0%)
Eczema	63 (39.6%)	49 (36.8%)	55 (40.7%)
Perennial allergic rhinitis	20 (12.7%)	17 (12.9%)	16 (11.9%)
Seasonal allergic rhinitis	43 (27.0%)	34 (25.6%)	35 (25.9%)
Time to reaction			
<5 min	33 (32.7%)	29 (34.5%)	24 (28.2%)
5-60 min	64 (63.4%)	51 (60.7%)	59 (69.4%)
61-120 min	3 (3.0%)	3 (3.6%)	2 (2.4%)
>120 min	1 (1%)	1 (1.2%)	0 (0.0%)
Food challenge result			
Positive	83 (51.6%)	67 (49.6%)	74 (54.4%)
Negative	78 (48.4%)	68 (50.4%)	62 (45.6%)

*Details of all challenges and those for which skin prick or serum specific IgE data are available. Results are presented as numbers (%), medians (interquartile range), or averages (range). The groups are not significantly different.

negative control (50% glycerol and 50% buffered saline), the potential food allergen (ALK-Abelló, Hørsholm, Denmark),¹² and single-headed lancet (ALK-Abelló). Skin reactions were recorded after 15 minutes. The test was repeated if the valid positive (≥ 3 mm wheal) and negative (no response) control results were not obtained. The size of the wheal was determined as the longest diameter. Testing was postponed if subject had used once-a-day antihistamines or prednisolone within the previous week. Serum specific IgE was measured by using the Pharmacia CAP method (Uppsala, Sweden). Not all subjects had both skin prick and serum specific IgE testing.

Food challenges

Children were admitted to the ward for the food challenge. The challenge started at 0.25 g, and increasing doses were given at 20-minute intervals until there were definite signs of a type I hypersensitivity reaction (for example, angioedema, urticaria, wheeze, or stridor) or 15 g had been ingested. The majority of challenges used an open protocol, but where there were only subjective symptoms, the challenge was repeated by using a double-blind protocol. In the event of no reaction, subjects were encouraged to eat the food at home on a daily basis for the next week. Written, informed consent was obtained from all families before food challenges.

Analysis

The positive predictive values and 95% CIs for clinical allergy associated with a wheal of at least 8 mm or a specific IgE level of at least 15 kU_A/L were calculated. The relationship between the skin prick test wheal diameter and the challenge result was modeled with a logistic regression analysis. The effect of age, time between testing and challenge, case mix (hospital or community cohort), and type of challenge were examined by adding each in turn to the logistic regression model. The likelihood ratio test was used to determine whether each improved the model. Likelihood ratios are presented for each level of skin prick or specific IgE result. This process was

repeated with the specific IgE data. STATA version 6 (StataCorp, College Station, Tex) was used for the statistical analysis.

RESULTS

Skin prick testing

A total of 157 subjects underwent 161 peanut challenges (Table I). Skin prick testing data were available for 135 (83.9%) challenges (Table I). There were no clinical or demographic differences between children with and without skin prick test data (Table I). The median time between skin prick testing and challenge was 1.7 (interquartile range, 0-7.2) months. The positive predictive value for clinical allergy of a wheal diameter of at least 8 mm was 94.4% (95% CI, 72.7% to 99.9%) with a specificity of 98.5% (Table II). As expected for a high cutoff point of 8 mm, the negative predictive value was only 57.3% and sensitivity 25.4%. The receiver operator curve characteristics are presented in the Journal's Online Repository (see Fig E1 at www.mosby.com/jaci). Logistic regression modeling suggested that the probability of clinical allergy for a specific wheal diameter was the following:

$$\frac{1}{e^{1.61 - (0.628 \times \text{wheal diameter})} + 1}$$

This relationship is shown in Fig 1. Adding variables for age, time between testing and challenge, where the subject was referred from, or type of challenge to the logistic regression model did not improve the model. The lack of influence of these variables on the positive predictive value for a positive challenge of a 8-mm cutoff point is illustrated in Table III.

TABLE II. Results of food challenge by skin prick test result*

Skin prick test result (mm)	Challenge result		Total number	Likelihood ratio
	Positive (%)	Negative (%)		
0	7 (13.2)	46 (86.8)	53	0.15
1	2 (40.0)	3 (60.0)	5	0.68
2	8 (57.1)	6 (42.9)	14	1.35
3	6 (50.0)	6 (50.0)	12	1.01
4	7 (70.0)	3 (30.0)	10	2.37
5-7	20 (87.0)	3 (13.0)	23	6.77
≥8	17 (94.4)	1 (5.6)	18	17.25
Total	67 (49.6)	68 (50.4)	135	—

*Likelihood ratios represent the likelihood of a skin prick test of a given wheal size in subjects with positive challenges vs the likelihood of a similar skin prick test result in subjects with negative challenges.

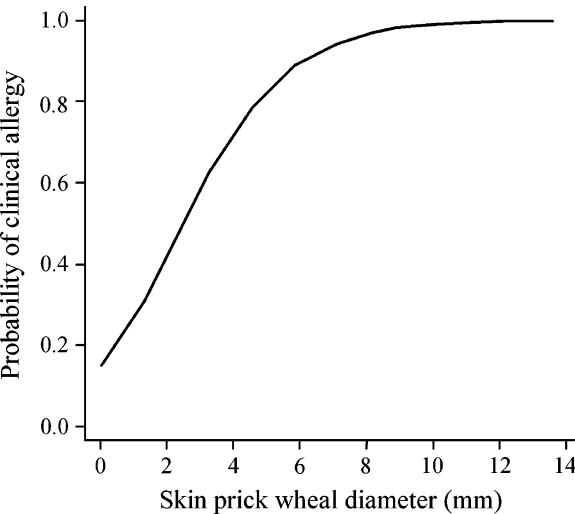


FIG 1. Predicted relationship between skin prick test result and challenge for peanuts. The logistic regression coefficient was 0.615 (95% CI, 0.411 to 0.818) and constant -1.60 (95% CI, -2.19 to -1.01). The area under the receiver operator curve was 0.86.

Serum specific IgE

Specific IgE data were available for 136 (84.5%) peanut challenges. There were no clinical or demographic differences between children with specific IgE data and those without (Table I). The median time between specific IgE testing and challenge was 0.0 (interquartile range, 0.0-1.6) months. The specific IgE data are tabulated in Table IV with results divided according to class of reaction. The positive predictive value for clinical allergy of a specific IgE of a 15-kUA/L cutoff point was 91.3% (72.0% to 99.0%) with a specificity of 96.8%. The negative predictive value was only 53.0% and sensitivity 28.4%. The receiver operator curve characteristics are presented in the Online Repository (see Fig E2 at www.mosby.com/jaci). The probability of clinical allergy for a specific IgE result was given by the following:

TABLE III. The effect of population, age, and time between testing and challenge on the predictive ability of skin prick testing*

Group	Skin prick test result (mm)	Challenge result	
		Number positive (%)	Number negative (%)
All subjects	<8	50 (42.7%)	67 (57.3%)
	≥8	17 (94.4%)	1 (5.6%)
Where			
St Mary's	<8	38 (40.9%)	55 (59.1%)
	≥8	5 (100.0%)	0 (0.0%)
ALSPAC	<8	12 (50.0%)	12 (50.0%)
	≥8	12 (92.3%)	1 (7.7%)
Age			
<7 y	<8	26 (41.9%)	36 (58.1%)
	≥8	3 (75.0%)	1 (25.0%)
≥7 y	<8	24 (43.6%)	31 (56.4%)
	≥8	14 (100.0%)	0 (0.0%)
Time between test and challenge			
<6 mo	<8	33 (41.2%)	47 (58.8%)
	≥8	14 (93.3%)	1 (6.7%)
6-24 mo	<8	17 (46.0%)	20 (54.0%)
	≥8	3 (100.0%)	0 (0.0%)
Type of challenge			
Double-blind	<8	12 (48.0%)	13 (52.0%)
	≥8	12 (92.3%)	1 (7.7%)
Open	<8	38 (41.3%)	54 (58.7%)
	≥8	5 (100.0%)	0 (0.0%)

*Figures in **bold** represent the positive predictive value of a wheal of at least 8 mm for a clinical allergy in each of the subgroups analyzed.

$$\frac{1}{e^{-0.202 - (0.502 \times \text{Ln}[\text{specific IgE}])} + 1}$$

where $\text{Ln}(\text{specific IgE})$ is the natural logarithm of the serum specific IgE level. This relationship is illustrated in Fig 2. Adding variables for age, time between testing and challenge, where the subject was referred from, or challenge type to the logistic regression equation did not improve the model. The lack of an effect of these variables on the positive predictive value for a positive challenge of a 15-kUA/L cutoff point is illustrated by Table V.

DISCUSSION

Previous studies have suggested that the magnitude of a skin prick test or specific IgE result can improve the diagnostic utility of these tests.^{4-6,13} We have presented data from a group of more than 100 children from both an allergy clinic and a community sample that demonstrate that a skin prick test ≥ 8 mm or a specific IgE ≥ 15 kUA/L have a high predictive value for clinical peanut allergy. With this high cutoff value, both the negative predictive value and sensitivity of the test were, as expected, relatively low. This means that although a positive result is very useful to rule in a diagnosis of clinical allergy, a

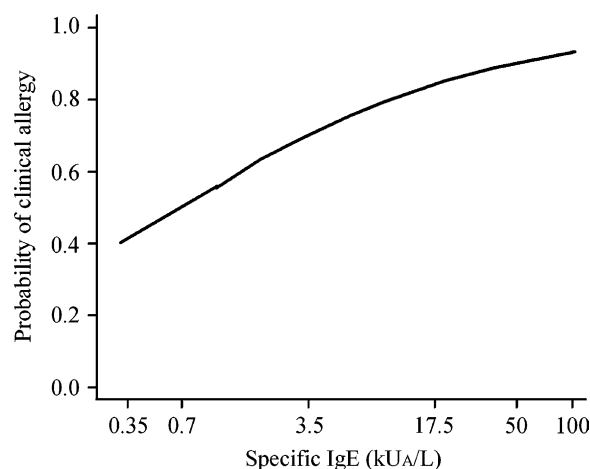
TABLE IV. Results of food challenge by serum specific IgE result*

Specific IgE result (kU _A /L)	Challenge result		Total number	Likelihood ratio
	Positive	Negative		
<0.35 (class 0)	15 (27.8%)	39 (72.2%)	54	0.32
0.35-0.69 (class 1)	5 (41.7%)	7 (58.3%)	12	0.60
0.7-3.4 (class 2)	19 (73.1%)	7 (26.9%)	26	2.27
3.5-17.4 (class 3)	16 (69.6%)	7 (30.4%)	23	1.92
17.5-49.9 (class 4)	10 (90.9%)	1 (9.1%)	11	8.38
50-99.9 (class 5)	1 (100.0%)	0 (0.0%)	1	∞
≥100 (class 6)	8 (88.9%)	1 (11.1%)	9	6.70
Total	74 (54.4%)	62 (45.6%)	136	—

*Likelihood ratios represents the likelihood of a specific IgE result of a given value in subjects with positive challenges vs the likelihood of a similar specific IgE result in subjects with negative challenges.

result of less than 8 mm or 15 kU_A/L does not rule out the diagnosis. These data also suggest that these predictive values are generalizable to both tertiary and community populations, do not appear to be dependent on the time lag between testing and challenge to a 2-year interval, and are applicable to both young and old children (Tables III and V). Unfortunately, even with more than 100 challenges, the number of positive challenges in each subgroup becomes very small. As in previous studies, this limits the ability of this study to make definitive statements about particular subgroups. For example, there were only 2 children younger than 2 years old, and it is therefore possible that the predictive equations for these young children differ from the data we present (Tables II and IV; Figs 1 and 2). A previous study has suggested that in this age group, smaller wheal sizes have a 95% positive predictive value for clinical allergy.⁴ Additional studies focusing on these younger children are required, or data from different groups must be collated.

Sporik et al⁴ have presented data on 95 subjects undergoing an open peanut challenge. The subjects in this study were similar in age, but they were tested with a different skin prick test solution (Dome-Hollister-Stier, Spokane, Wash). A third of their group had wheal diameters of 8 mm or more, and the positive predictive value for clinical allergy was 100% (calculated 95% CI, 91% to 100%). Rancé et al⁷ have performed skin prick testing and double-blind peanut challenges on 363 children who presented to their allergy clinic with a suspected food allergy. In their cohort, a wheal of at least 8 mm using commercial extract (Allerbio, Paris, France) had a 90% (95% CI, 74% to 98%) positive predictive value for clinical allergy (Rancé, personal communication, April 2004). One possible explanation for the differences in predictive values in the published data is the absence of

**FIG 2.** Predicted relationship between specific IgE and challenge for peanuts. The logistic regression coefficient was 0.521 (95% CI, 0.328 to 0.713) and constant 0.209 (95% CI, -0.163 to 0.581). The area under the receiver operator curve was 0.77.

any data on CIs. We have calculated CIs for the cohorts of Sporik et al⁴ and Rancé et al⁷ from their published data. Once these 95% CIs are taken into account, our results fit in well with the data from both these groups,^{4,7} with a skin prick test diameter of at least 8 mm having approximately a 95% predictive value for clinical allergy. The different results in these studies can also potentially be explained by the different specific skin prick testing solutions, lancets, and measurement techniques.⁶ In particular, we recorded wheal size by measuring the longest wheal diameter rather than a more time-consuming method such as taking the mean of longest diameter and the one at right angles to it. Despite this, we reach conclusions similar to those of the previous studies.

Sampson and Ho⁵ have demonstrated that a specific IgE value of 15 kU_A/L (Pharmacia CAP) had a 95% (calculated 95% CI, 71% to 100%) positive predictive value for peanut allergy in a study of 41 children who all underwent double-blind challenge.⁵ This was a highly selected group of children with suspected food allergy who all had eczema. In a further study by this group, 100 children with suspected food allergy were evaluated; only a proportion had eczema.¹⁴ In this study, the 15-kU_A/L cutoff point had a 100% positive predictive value for peanut allergy. However, because of ethical considerations, only 2% of those diagnosed with peanut allergy underwent a food challenge. The data we present were collected at the time when all children with a history suggestive of food allergy to peanuts were offered a challenge. Now that these cutoff points have gained general acceptance, it may be difficult to justify the use of a double-blind, placebo-controlled food challenge with children above the predictive value. One approach that has been successfully used to overcome this ethical issue is to address the reverse question of whether a patient with a

TABLE V. Effect of population, age, and time between testing and challenge on the predictive ability of serum specific IgE testing*

Group	Specific IgE result (kU _A /L)	Challenge result	
		Number positive (%)	Number negative (%)
All subjects			
<15		53 (46.9%)	60 (53.1%)
≥15		21 (91.3%)	2 (8.7%)
Where			
St Mary's	<15	41 (44.6%)	51 (55.4%)
	≥15	11 (91.7%)	1 (8.3%)
ALSPAC	<15	12 (57.1%)	9 (42.9%)
	≥15	10 (90.9%)	1 (9.1%)
Age			
<7 y	<15	29 (45.3%)	35 (54.7%)
	≥15	8 (88.9%)	1 (11.1%)
≥7 y	<15	24 (49.0%)	25 (51.0%)
	≥15	13 (92.9%)	1 (7.1%)
Time between test and challenge			
<6 mo	<15	45 (46.4%)	52 (53.6%)
	≥15	16 (88.9%)	2 (11.1%)
6-24 mo	<15	8 (50.0%)	8 (50.0%)
	≥15	5 (100.0%)	0 (0.0%)
Type of challenge			
Double-blind	<15	9 (45.0%)	11 (55.0%)
	≥15	10 (100.0%)	0 (0.0%)
Open	<15	37 (46.8%)	42 (53.2%)
	≥15	4 (100.0%)	0 (0.0%)

*Figures in **bold** represent the positive predictive value of a specific IgE result of at least 15 kU_A/L for a clinical allergy in each of the subgroups analyzed.

result below the cutoff point has outgrown an allergy.¹⁵ Rancé et al⁷ have examined the predictive values of specific IgE (Pharmacia CAP; Uppsala, Sweden) for clinical allergy. They demonstrated that a result of at least 15 kU_A/L had a 90% (95% CI, 82% to 96%) positive predictive value (Rancé, personal communication, April 2004). Again, once the 95% CIs are considered, the results of both Sampson and Ho⁵ and Rancé et al⁷ are very similar to our data.

The generation of 95% positive predictive values for skin prick tests and serum specific IgE has improved the treatment of our patients. Unfortunately, data from the ALSPAC cohort would suggest that only a quarter of sensitized children have a wheal of at least 8 mm to peanut (unpublished data, June 2004). This means that there is an immunological grey area in which we can not be 95% certain that a subject is clinically allergic or 99% certain that they are not allergic.⁶ It may be possible to reduce the number of subjects who fall within this area by using both skin prick and specific IgE testing. Rancé et al⁷ demonstrated that a skin prick test result of at least 16 mm or a serum specific IgE of at least 57 kU_A/L has a 100% positive predictive value for clinical allergy and identified a quarter of the subjects with allergy in their cohort. Hill et al¹⁶ have demonstrated that combining skin prick testing and serum specific IgE results can reduce the

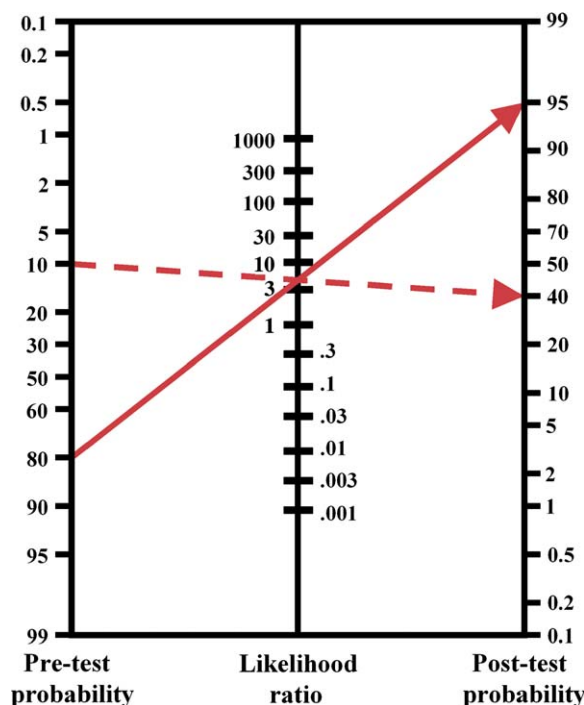


FIG 3. Normogram for generating posttest probabilities from likelihood ratios. The use of likelihood ratios is demonstrated by 2 clinical examples. Copyright © 1975 Massachusetts Medical Society. Adapted 2005 with permission from Fagan TJ. Normogram for Bayes's theorem. *N Engl J Med* 1975;293:257.

need for food challenges to make a diagnosis. However, when we combined the skin prick and serum specific IgE results, the positive predictive value and sensitivity were unchanged (data not shown).

When subjects fall within this immunological grey area, a probability of clinical allergy can still be calculated for each specific skin prick diameter (Fig 1) or serum specific IgE result (Fig 2).¹⁴ However, this probability must be interpreted in the light of the certainty of clinical allergy on the basis of the clinical history (pretest probability). Such an approach is aided by the generation of likelihood ratios (Tables II and IV) that can be used to predict the (posttest) probability of clinical allergy on the basis of the clinical history (pretest probability) and skin prick test or serum specific IgE result using a nomogram⁶ (Fig 3). Unlike positive predictive values, likelihood ratios are not affected by the prevalence of the disease.⁶ The use of likelihood ratios can be demonstrated by considering 2 clinical presentations. First, consider a child with a history of twice developing urticaria immediately after ingesting peanuts (pretest probability, 80%) and 5-mm wheal (likelihood ratio, 6.77). This result can be regarded as diagnostic, because as the nomogram indicates that the posttest probability of allergy is more than 95% (arrow, Fig 3). Second, consider a 5-mm wheal in an asymptomatic child with a peanut allergic sibling (pretest probability of 10%). The skin prick test result is less clinically useful because the posttest probability is 40%, well within the diagnostic

grey zone (*interrupted arrow*, Fig 3). Likelihood ratios can be used in a similar way with serum specific IgE results. In this way, likelihood ratios enable us to interpret skin testing or specific IgE results within the subject's clinical context, maximizing the available diagnostic information.⁶

We have presented data to demonstrate that a skin prick test of at least 8 mm or a serum specific IgE of at least 15 kU_A/L can accurately predict clinical allergy in subjects with a suggestive history in both a tertiary allergy clinic and community cohorts. By using likelihood ratios generated from this data it is possible to use the strength of a subject's history and the skin prick or specific IgE results to determine the probability that the subject has clinical allergy. This will improve the clinical decision making for individual subjects, particularly in deciding whether a food challenge is required to substantiate or refute a diagnosis of food allergy. Their use by family practitioners, pediatricians, and allergists should reduce the need for children with possible food allergy to undergo a diagnostic food challenge. It is important that we now extend this work to generate similar data for tree nuts and other foods to ensure that we can generalize these results to other foods.

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