

Physician Compliance with Updated Practice Parameters for Influenza Vaccination in Individuals with Egg Allergies

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What is already known about this topic? Since 2010, there have been significant changes to guidelines in providing trivalent seasonal influenza vaccine (TIV) to individuals with egg allergy, the most significant of which is that the vaccine is no longer contraindicated for individuals with egg allergy.

What does this article add to our knowledge? There has been successful implementation of guidelines in providing TIV to individuals with egg allergy. Fewer physicians withhold the vaccine, perform intradermal vaccine testing, multistep desensitization, or observe patients after vaccination for fewer than 30 minutes.

How does this study impact current management guidelines? There is strong acceptance of the TIV vaccination guidelines, despite evidence that some providers continue to perform vaccine skin testing unnecessarily, and minimal sentiment that TIV should be contraindicated in this population.

BACKGROUND: Significant recent changes to the recommendations in providing trivalent seasonal influenza vaccine (TIV) to individuals with egg allergy were made, but their implementation has not been studied.

OBJECTIVES: To investigate allergist-reported compliance with updated TIV administration guidelines for individuals with egg allergy.

METHODS: A 22-question electronic survey was distributed via e-mail to American Academy of Allergy, Asthma, and Immunology members (allergists), which queried practice styles and attitudes that pertain to TIV administration to individuals with egg allergy.

RESULTS: Only 1% of 895 respondents believed that TIV should be contraindicated for individuals with egg allergy, 3.8% reported not administering TIV to individuals with egg allergy, and 17% reported only administering TIV to individuals with mild egg allergy; 13.2% reported that risk-mitigating precautions (eg, vaccine skin testing, graded-dose challenges) were necessary. Postimplementation change compared with preimplementation change included less intradermal testing (30.6% vs 64.9%), less multistep desensitization (34.7% vs 65.3%), observing more patients for >30 minutes after vaccination (79.1% vs 20.9%), administering TIV despite positive TIV skin tests (65.4% vs 34.6%) (all $P < .001$), but no significant reduction in performing TIV prick skin testing (46.2% vs 53.8%). Factors associated with not performing TIV skin testing included reading the guidelines ($P = .028$), academic practice ($P < .01$), and fewer years in practice ($P < .01$). Only 48.6% agreed that TIV can safely be administered in the primary care setting to individuals with egg allergy, and only 41.9% advised their patients accordingly.

CONCLUSION: There were significant shifts in practice style over time concurrent with newly established guidelines, except for vaccine skin testing. Physician opinions are also concurrent with guideline changes. Although TIV administration guideline recommendations are being successfully implemented, greater adherence should be promoted. © 2013 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2013;1:602-7)

Key words: Trivalent seasonal influenza vaccine; Guideline implementation; Egg allergy

Influenza virus infection is a contagious respiratory illness for which effective vaccines are available.¹ The Centers for Disease Control (CDC) recommends that all persons 6 months of age and older should be vaccinated annually, particularly those at high risk for complications of infection, including those 6 months to 4 years of age and those with chronic pulmonary disease (including

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Abbreviations used

AAAAI- American Academy of Allergy, Asthma, and Immunology
ACAAI- American College of Allergy Asthma and Immunology
ACIP- CDC Advisory Committee on Immunization Practices
CDC- Centers for Disease Control
CI- Confidence interval
JTFFP- Joint Taskforce on Practice Parameters
OR- Odds ratio
TIV- Trivalent seasonal influenza vaccine

asthma).^{2,3} Because the manufacturing methods for the trivalent seasonal influenza vaccine (TIV) results in residual amounts of ovalbumin, a major egg allergen, there has been concern for the safety of TIV in individuals with egg allergy.^{4,5} Since 1998, the safety of TIV for various phenotypes of egg allergy has been reported, and, more recently, results of studies have demonstrated the safety of TIV in children with a history of severe allergic reactions to egg as well.⁶⁻¹⁵ Furthermore, the ovalbumin content ($\mu\text{g/mL}$) of TIVs from commonly used manufacturers has declined, and batch-to-batch variability of ovalbumin content has improved over the past decade.¹⁶⁻¹⁹

Based on accumulating evidence that the risk of allergic reaction to TIV is low for individuals with egg allergy, recent guidelines from the CDC Advisory Committee on Immunization Practices (ACIP) states that those with a history of a reaction no more severe than hives after egg ingestion can receive the TIV as a single dose with a 30-minute observation period at the primary care physician's office, and those with more severe egg allergy are advised to consult an allergy specialist before vaccination.² However, little is known about the implementation process and physician acceptance of such guidelines within the allergy community. This study assessed the early implementation of recent guideline changes in 2011 and 2012 by practicing allergists in providing TIV to individuals with egg allergy.^{2,18,20}

METHODS

In November 2012, a 22-question electronic survey was distributed via the e-mail distribution list of the American Academy of Allergy, Asthma, and Immunology (AAAAI) to approximately 4323 accounts. Electronic informed consent was obtained. Questions queried physician practice styles that pertained to TIV administration as well as knowledge and adherence to recent recommendations published by the Joint Taskforce on Practice Parameters of the AAAAI and American College of Allergy Asthma and Immunology (ACAAI), the AAAAI, the ACAAI, and the CDC. Multiple responses were allowed for selected questions. Selected member data were obtained directly from the AAAAI, which maintains a profile for each member who received the survey. No compensation was provided for participation in the survey. Potential participants were contacted up to 3 times in 30 days regarding unanswered survey invitations. Each participant was only allowed to access the survey once. Respondents were not required to answer every question, and skip logic was used to direct respondents around particular questions.

The outcomes were to assess physician-reported compliance and agreement with recommended AAAAI/ACAAI Joint Taskforce on Practice Parameters (JTFFP) guidelines on providing TIV to patients with egg allergy and to note any change to

TABLE I. Demographic data for the responding population

Trend*	No. (%)
Academic faculty (n = 619)†	142 (23)
Perform in-office food challenge (n = 619)	583 (94.2)
Pediatric board certification (n = 619)	375 (60.1)
Median years in practice (n = 619)	17 (—)
Fewer than 5 years in practice	136 (22)
Attending AAAAI meeting in past 3 years (n = 619)	559 (91.2)
Read medical literature at least monthly (n = 619)	539 (87)
Characteristics of worst observed reaction from providing TIV to individuals with egg allergy (n = 825)	
Never noted reaction	289 (35)
Local reaction only	221 (26.8)
Anaphylaxis	9 (1.1)
Administered epinephrine	41 (5)
Administered H1 antihistamine	248 (30)
Administered β -agonist	25 (3)
Do not provide TIV to individuals with egg allergy (n = 782)	30 (3.8)

*Respondents were not required to answer every question, and multiple responses were allowed for certain questions.

†Demographic data were available for 619 responding subjects, provided courtesy of the AAAAI from the membership profile database used to distribute the survey.

reported practice style over the past 2 seasons.²⁰ Specific areas of interest included if the physician chose to vaccinate any individuals with egg allergy, if risk-mitigating precautions were used (eg, vaccine skin testing, use of low-ovalbumin TIV preparation), the severity of patients' egg allergy that physicians chose to vaccinate versus withheld TIV, management of potential reactions, and attitudes toward the changes in the guidelines. Data were analyzed for descriptive statistics by using frequency analysis and cross-tabulation, and proportional analysis was conducted by using the χ^2 test and the Fisher exact test. A multiple logistic regression model was created to explore the relationship of guideline compliance and several covariates. All analyses were prespecified, without use of backward stepwise selection. An alpha level of .05 was used to denote statistical significance. Statistical analysis was performed by using Stata IC, Version 12 (Stata Corp, College Station, Tex). The study was deemed exempt from ongoing review by the University of Michigan Medical School Institutional Review Board.

RESULTS

A total of 895 members participated in the survey, for a response rate of approximately 20.2%. The characteristics of the responding population are shown in Table I. A total of 88.2% reported reading either the Joint Task Force 2011 practice parameter on providing TIV to individuals with egg allergy, the 2012 Adverse Reactions to Vaccines practice parameter, the ACIP/CDC Influenza Vaccination Guidance, or the specific guidance that pertain to administering TIV to individuals with egg allergy that were posted at www.aaaai.org in 2010 and 2011. Only 28.1% (n = 232) reported no longer having a specific office protocol for vaccinating individuals with egg allergy. There were no differences in the reported practices of performing vaccine skin testing, withholding TIV or restricting its administration in individuals with more severe allergy, administering

TABLE II. Changes in practice patterns in administering TIV to individuals with egg allergy, with dissemination of 2011-2012 practice parameter

Risk reduction measure	Total no. of respondents	No. (%) before 2011	No. (%) in 2011-2012	P value
Performed vaccine PST	467	251 (53.8)	216 (46.2)	.11
Performed vaccine ID	297	206 (69.4)	91 (30.6)	<.001
Observed ≥ 30 min	220	46 (20.9)	174 (79.1)	<.001
Observed for 15-30 min	385	28 (7.3)	357 (92.7)	<.001
Performed multistep (>2) desensitization if skin test positive	168	104 (61.9)	64 (38.1)	.003
Performed 2-step graded challenge if skin test positive	285	117 (41.1)	168 (58.9)	.003
Withheld TIV if skin test positive	188	123 (65.4)	65 (34.6)	.001
Performed graded challenge for any patient	484	156 (32.2)	328 (67.8)	<.001
Performed multistep (>2) desensitization for any patient	225	147 (65.3)	78 (34.7)	<.001
Used low-ovalbumin-containing TIV only	222	63 (28.4)	159 (71.6)	<.001
Used booster from the same lot as the initial TIV	160	70 (43.8)	90 (56.2)	.002

ID, Intradermal test; PST, prick skin test.

TIV by graded challenge, number of years in practice, or differences in postvaccination observation time when comparing those who observed a severe TIV reaction in the past versus those who did not have this experience.

Adherence to guidelines

Specific changes in practice style between the pre-2011 and 2011-2012 influenza vaccination seasons are shown in Table II. Compared with the pre-2011 season, significantly more physicians in private practice than in academic practice reported continuing to skin test to the vaccine in 2011-2012 (83.5 vs 16.5; $P = .001$). A logistic regression model was created to explore factors associated with performing vaccine skin testing (Table III). Interestingly, more recent AAAAI conference attendance (attendance within the past 3 years) was not associated with whether a physician provided TIV to individuals with egg allergy with "hives only" versus severe reactivity from egg ingestion.

There were 41% reporting that, for the 2011-2012 influenza vaccination season, they advised individuals with egg allergy with only hives from egg ingestion to receive TIV from their primary care physician, and 17.2% who advised all their patients with egg allergy (irrespective of severity) to do so (Figure 1). However, 60.1% reported that the primary care physician refused to provide TIV. Regarding guidance for the 2012-2013 season, 45.9% reported they would advise individuals with egg allergy with only hives from egg ingestion to receive TIV from their primary care physician, and 21.5% would advise individuals with egg allergy of any severity to receive TIV to do so.

There was a clear association with practice style and longer duration in practice, with using 2 sensitivity cut points ($>$ or < 5 years, and $>$ or < 10 years in practice). Significantly more individuals in practice longer than 5 years reported continuing to use vaccine prick skin testing (85.6% vs 14.3%; $P < .001$), intradermal vaccine testing (87.9% vs 12.1%; $P = .038$), and withholding the vaccine for a positive skin test (90.8% vs 9.2%; $P = .012$). Significantly more individuals in practice longer than 10 years reported continuing to use vaccine prick skin testing (69.9% vs 30.1%; $P = .001$), intradermal testing (76.9 vs 23.1; $P = .005$), and withholding the vaccine for a positive skin test (70.8 vs 29.2; $P = .041$). At a bivariate level, each additional year that a physician reported being in practice was significantly associated with a 4% increase in the odds of continuing to use vaccine skin testing (odds ratio 1.04 [95% CI, 1.02-1.06]; $P < .001$).

TABLE III. Factors associated with performing vaccine skin testing

Factors associated with performing vaccine PST	OR (95% CI)	P value
Read the guidelines for influenza vaccination	0.29 (0.1-0.87)	.028
Perform OFC in the office	1.48 (0.69-3.32)	.33
Academic practice	0.16 (0.05-0.55)	.004
Pediatrician	1.24 (0.57-2.65)	.58
Years in practice	1.04 (1.01-1.08)	.009
Attended AAAAI annual meeting in past 3 y	0.54 (0.23-1.31)	.17
Vaccinate any egg allergic individual	0.51 (0.2-1.33)	.17
Have a TIV protocol	0.47 (0.22-1.01)	.053

OFC, Oral food challenge; OR, odds ratio; PST, prick skin test.

Moreover, significantly more physicians who reported that they vaccinated individuals with egg allergy of any severity (compared with those with mild egg allergy) reported continuing to perform prick skin testing to the vaccine (77.3 vs 22.7; $P < .001$), perform intradermal vaccine testing (76.9% vs 23.1%; $P = .008$), use a graded challenge if the vaccine skin test was positive (85.1% vs 14.9%; $P = .005$), and reported withholding the vaccine for a positive vaccine skin test (67.7% vs 32.3%; $P = .004$). A logistic regression model was created to further explore the influences of various factors on the odds of providing vaccination to any individuals with egg allergy as opposed to only individuals with egg allergy with mild reactions (eg, hives only), shown in Table IV. Performing oral food challenges in the office and having read the guidelines for influenza vaccination were significantly associated with vaccinating an individual with egg allergy of any severity.

Physician opinions and attitudes

In addition, respondents were asked to rate their agreement with several facets of the most current JTFPP guidelines as of the time when taking the survey. Among 631 participants who responded to these questions, approximately 1% ($n = 6$) agreed that TIV should be contraindicated in individuals with egg allergy, and only 13.2% reported that precautions to mitigate risk were necessary. Specifically, 8.9% reported that vaccine skin testing is necessary in any patient with egg allergy, and 29% in individuals with severe egg allergy (Figure 2). Concerning

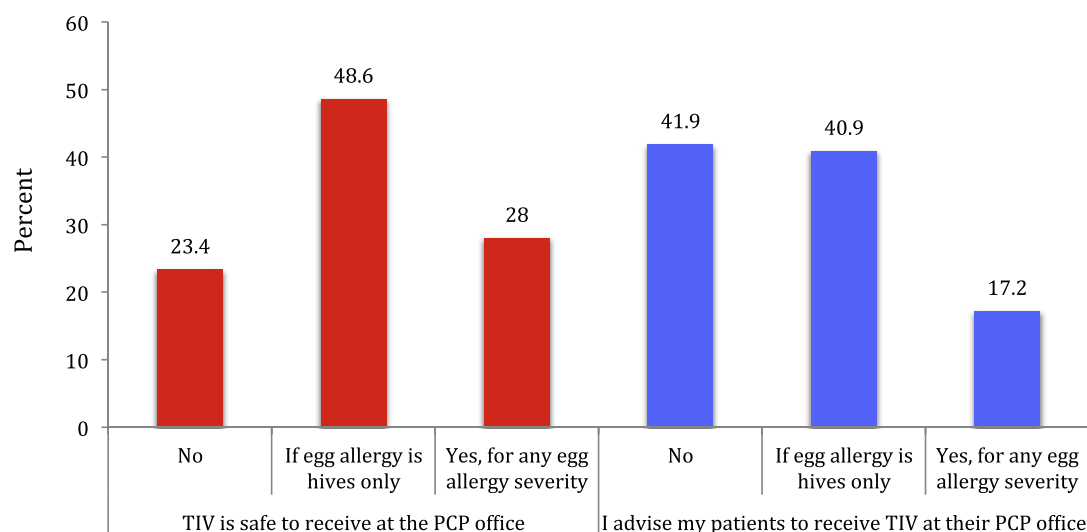


FIGURE 1. Provider reported practices regarding TIV administration in the primary care setting to individuals with egg allergy.

vaccine ovalbumin content, 20.3% agreed that low ovalbumin preparations (<1.2 $\mu\text{g/mL}$) are necessary, and 30% agreed that this was only necessary for individuals with severe egg allergy (Figure 2). Lastly, 23.4% thought that providing TIV to individuals with egg allergy in the primary care office was unsafe, 48.6% thought that this was safe for individuals with egg allergy with hives only, and 28% thought that this was safe for any individuals with egg allergy (Figure 1).

DISCUSSION

This present study is the first to investigate physician-reported compliance and agreement with guidelines for providing influenza vaccine to individuals with egg allergy. Guidance for vaccination has undergone significant evolution over the recent few years, and the JTFPP guidelines for this topic have been updated in both 2011 and 2012.^{18,20} Simultaneously, the ACIP and CDC have also updated their guidelines and removed any language specifically advising that individuals with egg allergy not receive TIV. Such precaution previously existed before August of 2011, including in the 2009 Red Book on Infectious Disease.^{2,4} Over the past 3 years, the AAAAI, ACAAI, and JTFPP guidelines statements have recommended a more aggressive approach to vaccinating individuals with egg allergy with TIV, based on a number of recently published studies that demonstrated that vaccine skin testing is not necessary, that a single-dose administration is safe, and that the vaccine can be provided to individuals with egg allergy of any severity.^{18,20} The guidelines have reflected these advances (Table V). Interestingly, most physicians have not actually had any of their patients react to TIV. Among those who have, very few have witnessed a severe allergic reaction to TIV in an individual with egg allergy, and very few reactions (5%) required treatment with epinephrine.

Adherence to guidelines

There were significant reported shifts in TIV vaccination practice for individuals with egg allergy reflective of guideline compliance. Specifically, when comparing reported behaviors pre-2011 to 2011-2012, there were significant decreases in the number of physicians who reported performing intradermal vaccine

TABLE IV. Factors associated with providing TIV to individuals with egg allergy, irrespective of underlying egg allergy severity

Factors associated with vaccinating an individual with egg allergy of any severity	OR (95% CI)	P value
Does not perform oral food challenges (reference)		
Perform open challenges	5.77 (1.27-26.1)	.023
Perform open and blinded challenges	8.56 (1.4-52.2)	.02
Academic practice	2.26 (0.59-8.73)	.236
Pediatrician	0.76 (0.32-1.84)	.539
Years in practice	1.01 (0.97-1.05)	.626
Read literature monthly or less	0.72 (0.29-1.78)	.475
Attended AAAAI annual meeting in the past 3 y	1.19 (0.43-3.31)	.741
Read the guidelines for influenza vaccination	4.24 (1.44-12.43)	.009
Have TIV protocol	1.32 (0.52-3.36)	.565
Lack of compliance with all practice parameter recommendations*	0.94 (0.67-1.31)	.701

OR, Odds ratio.

*Compliance measures included elimination of prick and intradermal skin testing to TIV, multistage desensitization, withholding vaccine because of the egg allergy or positive skin test, patient observation of at least 30 min after vaccine administration, and not strictly administering a booster vaccine dose from the same vaccine lot as the original.

testing, multistep (>2) desensitization to administer the vaccine, and withholding the vaccine for a positive test (Table I). As well, there was a significant increase in the proportion of physicians who reported that they observed patients for at least 30 minutes after vaccination. These are clear reflections of a change in practice style as recommended by the guidelines and, most importantly, reflect acceptance of the specific recommendation in place since 2010 that individuals with egg allergy not have the vaccine withheld.²⁰ There was a significant increase in the use of a 2-step graded challenge if skin testing was positive and in administering TIV in this manner for any individual with egg allergy. As well, there was a significant increase in the number of physicians who reported that they used a low-ovalbumin-containing vaccine. These behavioral modifications

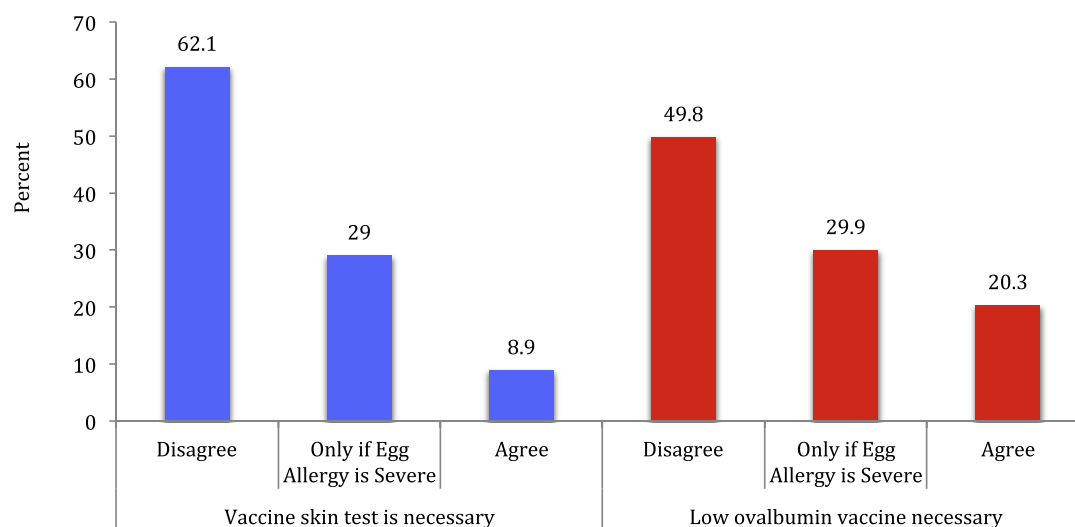


FIGURE 2. Provider opinion regarding vaccine skin testing and use of low-ovalbumin vaccine.

TABLE V. Summary of current recommendations (2012 practice parameter) for providing TIV to individuals with egg allergy

It is no longer recommended to withhold TIV because of egg allergy; egg allergy does not place patients at any increased risk compared with that of the general population without egg allergy.

All individuals with egg allergy age 6 mo or older who desire yearly seasonal influenza vaccination should receive the vaccine, irrespective of the underlying severity of the egg allergy (eg, individuals with severe egg allergy can safely receive TIV).

TIV can be safely administered in a single, age-appropriate dose.*

Vaccine skin prick testing, vaccine intradermal testing, 2-step graded challenge, or multistep desensitization are unnecessary, offer no risk mitigation, and, therefore, should no longer be performed.

Individuals with egg allergy who choose to receive TIV should do so in a medically supervised setting that is prepared to observe for, assess, and treat a potential allergic reaction or anaphylaxis to the vaccine (eg, a medical office as opposed to a pharmacy clinic).†

Individuals with egg allergy who receive TIV should be observed for 30 min afterward, similar to the JTFPP guideline recommendations for observation after subcutaneous immunotherapy.†

Individuals with egg allergy should only receive the injectable TIV and not LAIV (intranasal LAIV), pending ongoing evaluation of the safety of LAIV in individuals with egg allergy.

Certain individuals with egg allergy may be able to receive TIV in the primary care setting, depending on the provider's comfort.†

LAIV, Live attenuated influenza vaccine.

*For individuals younger than age 3 y who receive their initial TIV, a booster dose is still recommended, but both the primary and booster dose should be given as a single injection (eg, each individual injection does not have to be given as a graded challenge).

†Changes to these recommendations are currently under consideration for the 2013-2014 influenza vaccination season.

reflect compliance with the guidelines through the 2011-2012 season. All TIVs manufactured for use in the United States since 2010-2011 have ovalbumin concentrations of <1.2 µg/mL. In addition, the CDC and AAAAI/ACAAI published lists of these vaccines to facilitate choice.^{2,20}

There still is some residual hesitancy surrounding the specific recommendation for physicians to discontinue vaccine skin testing.²⁰ There was a nonsignificant decrease in the proportion of those who reported that they still skin tested, a trend that

could be viewed as in line with the practice parameter recommendations. However, the persistence of skin testing was even more pronounced among those in private practice, those in practice >5 years or in practice >10 years, and among those who vaccinated more individuals with severe egg allergy (when there also was evidence of persistence of intradermal skin testing). Our regression model denoted a 4% increase in the odds of performing vaccine skin testing for every year that a responder reported being in practice, an 84% lower odds for not skin testing if in academic practice, and (intuitively) a 71% lower odds for not skin testing if one has read the guidelines (Table IV). This would temper enthusiasm regarding guideline adherence in eliminating this particular risk-mitigation strategy. The time in practice has been identified as significantly associated with guideline compliance in other disciplines, although not universally.²¹⁻²³ Ample evidence in the past 3 years has shown that vaccine skin testing is neither sensitive for identifying patients at risk for a reaction, nor necessary to safely vaccinate an individual with egg allergy.^{10-13,15} Furthermore, guideline recommendations since 2010 have recommended this practice be dropped.¹⁸ Further work is needed to understand why this behavior persists because it is associated with increased costs, longer visits, and increased discomfort to patients, and is unnecessary.¹⁸

Physician opinions and attitudes

Nearly all responding allergists had read a recent guideline statement and provide TIV to individuals with egg allergy, including approximately 80% who provide TIV to individuals with severe egg allergy. Providing TIV to individuals with egg allergy of any severity was not significantly associated with the length of time in practice or the type of practice. More than 85% of respondents thought that any precautions to mitigate risk were unnecessary, yet there was a divide on the necessity of performing vaccine skin testing and the necessity to use low-ovalbumin vaccine preparations. Consensus is divided regarding the safety of vaccinating individuals with egg allergy in the primary care physician's office based on the underlying severity of the egg allergy, which is in accordance with both the 2011 and 2012 ACIP/CDC guidelines.² There is hesitancy to concur that this is

safe for individuals with more severe egg allergy as well as hesitancy to advise individuals with egg allergy to seek vaccination from the primary care physician. However, 2 recent studies specifically showed that egg allergy severity is not associated with increased odds of reacting to TIV.^{6,8} These opinions are important to continue to track longitudinally and compare with similar opinions from primary care physicians.

Limitations to the study include use of self-reported data from the physicians, recall bias, and only a 20% response rate, although, per communication with the AAAAI, typical response rates to AAAAI electronically distributed surveys run approximately 10% (S. Folstein, AAAAI, written communication, April 10, 2013). The survey was distributed to more than 4000 allergists through the AAAAI and, therefore, would also have selection bias against physicians without AAAAI membership. The survey was not previously validated, and guideline compliance was assessed over a relatively short period of time (2 seasons). Compliance with guidelines also is not a mandated activity, and patient acceptance of the guidelines in terms of patient permissiveness to submit to certain changes (eg, receiving the vaccine, not having skin testing, receiving either a single or a 2-step dose) was not assessed but could also significantly influence physician behavior.

In conclusion, this study demonstrated that physicians were, overall, adhering to most of the updated recommendations and guidelines in providing influenza vaccine to individuals with egg allergy. In the past 2 years, there is evidence of significant changes in practice style in how allergists provide TIV to individuals with egg allergy. The one notable exception was vaccine skin testing, although the type of practice (academic vs nonacademic) and time in practice significantly shifted the odds of performing this procedure. Physician opinions appeared to be in agreement with the changes to the guidelines as well. Thus, it appears that there is at least moderate implementation of the series of recommended changes in how to vaccinate individuals with egg allergy with TIV as specified in the JTFPP practice parameters. Further observation is needed, however, to monitor the longitudinal change in behaviors and to assess physician compliance and opinion regarding the changes as more time elapses from their implementation of these guidelines.

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