

Defining quality metrics and improving safety and outcome in allergy care

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Background: The delivery of allergy immunotherapy in the otolaryngology office is variable and lacks standardization. Quality metrics encompasses the measurement of factors associated with good patient-centered care. These factors have yet to be defined in the delivery of allergy immunotherapy. We developed and applied quality metrics to 6 allergy practices affiliated with an academic otolaryngic allergy center.

Methods: This work was conducted at a tertiary academic center providing care to over 1500 patients. We evaluated methods and variability between 6 sites. Tracking of errors and anaphylaxis was initiated across all sites. A nationwide survey of academic and private allergists was used to collect data on current practice and use of quality metrics.

Results: The most common types of errors recorded were patient identification errors ($n = 4$), followed by vial mixing errors ($n = 3$), and dosing errors ($n = 2$). There were 7 episodes of anaphylaxis of which 2 were secondary to dosing errors for a rate of 0.01% or 1 in every 10,000 injection visits/year. Site visits showed that 86% of key safety

measures were followed. Analysis of nationwide survey responses revealed that quality metrics are still not well defined by either medical or otolaryngic allergy practices. Academic practices were statistically more likely to use quality metrics ($p = 0.021$) and perform systems reviews and audits in comparison to private practices ($p = 0.005$).

Conclusion: Quality metrics in allergy delivery can help improve safety and quality care. These metrics need to be further defined by otolaryngic allergists in the changing health care environment. © 2014 ARS-AAOA, LLC.

Key Words:

allergic rhinitis; asthma; allergen immunotherapy; quality care; health care reform; guidelines; outcome assessment

How to Cite this Article:

Lee S, Stachler RJ, Ferguson BJ. Defining quality metrics and improving safety and outcome in allergy care. *Int Forum Allergy Rhinol.* 2014;4:284-291.

Allergic rhinitis (AR), a risk factor for asthma, is one of the most common chronic conditions in the United States and continues to be a prevalent health problem. Allergen immunotherapy (AIT) is the only potential cure for AR and preventative intervention for asthma.^{1,2} Treatment is provided largely through subcutaneous immunotherapy (SCIT) in the United States, although sublingual immunotherapy (SLIT) is an emerging therapeutic option.³ Approximately 10 million patients are treated annually

with SCIT,⁴ provided in the offices of both otolaryngologists and medical allergists. The impetus for this study originated from the need to standardize allergy delivery in the University of Pittsburgh Medical Center network of otolaryngic allergy clinics, the examination of current guidelines in allergy practice, and the realization that quality metrics yet need to be defined in the current era of health care reform.

The Affordable Care Act (ACA) signed in 2010 has put into place far-reaching health care reforms that will continue to implement significant changes over the next several years. A prevalent theme is to improve quality while lowering costs. Several programs have been signed into law that call for quality care and encourage outcomes research. A few examples include the development of Accountable Care Organizations that provide incentives to better coordinate care, improve quality, and reduce cost. The ACA has also developed the Patient-Centered Outcomes Research Institute, which is expected to receive an estimated \$3.5 billion through 2019 to encourage research priorities that will focus on patient decision making and comparative effectiveness. Finally, the ACA will also modify reimbursement

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Potential conflict of interest: B.J.F. and R.J.S. are consultants for Teva, and B.J.F. is on the advisory board for MEDA.

Received: 20 September 2013; Revised: 12 November 2013; Accepted: 7 December 2013

DOI: 10.1002/alr.21284

View this article online at wileyonlinelibrary.com.

algorithms by linking payment to quality outcomes and by the year 2015 a new provision will tie physician payments to the quality of care provided.

Currently health care providers are required to report on areas such as patient satisfaction, surgical process of care, 30-day mortality, and appropriate use of medical imaging. The Agency for Healthcare Research and Quality, 1 of 12 agencies within the U.S. Department of Health and Human Services (USDHHS), delineates quality metrics in clinical performance as the degree to which a provider can competently and safely deliver the appropriate clinical service to the patient within an optimal time period. Quality measures can be defined by process, access, and outcome measures. Other characteristics include structure, efficiency measures, and patient experience metrics such as performance on Press-Ganey surveys.

Currently quality measures do not exist for the treatment of allergy patients and there is a need to develop appropriate metrics that assess and correlate with outcomes. The goal of this study was to conduct a systemwide evaluation of current practice, determine areas for improvement, and develop quality metrics in allergy delivery.

Materials and methods

This work was conducted at the University of Pittsburgh Medical Center (UPMC). The UPMC allergy delivery system was comprised of a network of 6 outpatient clinics individually providing testing, vial formulation, and immunotherapy to approximately 1500 patients. Existing problems included variability in training of staff, resulting in inconsistencies and variability in delivery of allergy care. There was a need for comprehensive didactic and practical training as well as routine assessment. In addition, errors were reported but not consistently tracked or analyzed. Incidence of anaphylaxis was not known and patient outcome was not assessed consistently. As a result a systemwide approach to improving safety and quality in the allergy delivery system was conducted and on a departmental level, quality metrics were developed for reporting on a quarterly basis. Quality metrics for allergy delivery were conceptualized based on process and outcome measures.

Process measures: increasing safety in allergy delivery

An initial Allergy Quality Initiative Round Table was convened with all staff stakeholders including physicians, technicians, nurses, and managers. From the initial meeting, deficiencies and 5 core areas of improvement were identified:

1. Need for routine and ongoing systems review with evaluation of current practice and adherence to existing practice parameters;
2. Standardization of training and assessment;
3. Reduction of errors in mixing, allergy administration, and documentation;

4. Improved communication with data entry, access, and relevance of the electronic medical record;
5. Reporting and review of errors/anaphylaxis.

Outcome measures: effect on patient care

A quality improvement project focusing on efficacy of allergy treatment on patient outcome was also initiated. A need to routinely and rigorously assess patients on immunotherapy was apparent. A questionnaire was developed for patients undergoing immunotherapy including perceived benefit of immunotherapy, experience with local reactions, medication scores, validated symptom scores (Rhinosinusitis Quality of Life Questionnaire), and effect on asthma control (Asthma Control Questionnaire). This information is currently collected at the initiation of allergy immunotherapy and on a monthly basis.

Nationwide practices: Where do we stand?

In order to assess whether quality measures were being used among allergy practices in the United States, an online survey was developed to collect data from academic and private allergists from both medical and otolaryngic allergy training backgrounds. A total of 130 physicians were invited to participate in the survey (Table 1). SPSS statistical software was utilized for analysis (IBM, Armonk, NY). A chi-square test of goodness-of-fit was performed to determine if there was a statistically significant difference in practices comparing medical vs. otolaryngic allergists and academic vs private practices.

Results

Development of quality measures

In order to conduct a systems review, routine audits and site visits were performed. Assessment was conducted via a checklist including maintenance of allergy supplies/equipment, use of appropriate documentation, and anaphylaxis preparedness (Table 2). Training was standardized with the development of modules for compounding personnel. An online competency training module was created as well as a curriculum for biweekly allergy teleconference across allergy satellites for continued education.

Reduction of human error in compounding and providing allergy immunotherapy was evaluated and the decision was made to implement a centralized mixing program. Two-person vial verification was instituted in which 2 technicians confirmed accuracy of each vial. Protected mixing time was reinforced and supported by administration. In addition, physician oversight was facilitated by modification of the electronic medical record interface to allow for improved access to allergy patient information. The Epic interface was customized to display results of testing, mixing, and allergy administration on a "Synopsis" screen. Vial testing was implemented for any patient starting injections from a new vial.

TABLE 1. Survey questions of medical and otolaryngic allergists

Question	Response choices
Do you provide allergy shots or skin testing as part of your practice?	Yes, No; If No, your survey is complete
Do you make your own allergy vials for SCIT?	Yes, No
Do you make your own allergy vials for SLIT?	Yes, No
If you practice allergy in more than one location, are allergy vials made at multiple locations or centralized?	Centralized, Multiple locations, Not applicable I only practice in one location
Which of the following allergy tests do you perform, mark all applicable:	In vitro (blood test), Skin prick test, Intradermal dilutional testing, Nasal provocation, Patch skin testing for contact allergy, Don't do allergy testing
Do you perform anaphylaxis mock drills?	Yes, No
If yes, how often do you perform mock drills?	One time in 2 or 3 years, Yearly, Every 3 months, Monthly
Do you have an emergency anaphylaxis box or cart?	Yes, No, Don't know
Do you know where your emergency kit is?	Yes, No, No, but the nurse knows
How do you verify patient and vial are correct, check all applicable:	One person verification, Two person verification, Three person verification, Bar code
Does the patient have to verify their vial?	Yes, No
Do you verify the formulation of each vial with the allergy technician or nurse before/after it is mixed?	Yes, No
How long do you recommend patients wait after a shot?	No wait unless they have risk factors such as asthma, 20 minutes, 30 minutes, Longer than 30 minutes
If patients don't wait what do you do?	They sign out against medical advice, Prescription and instructions on how to use epi-pen, Refuse to give shot or continue immunotherapy, Nothing, it's a free country
Do you differentiate between vials which are advancing and those at maintenance and if so how?	Yes, No; by: Color caps are different for vial type, Numbers are different, Other _____
Do you record near misses and adverse events?	Yes (please describe), No, Sometimes
Do you perform a systems review/chart audits/site visits to assess reasons for errors or adverse reactions	Yes (please describe), No, Usually, Hardly ever
Do you have quality metrics for your allergy practice?	Yes (please specify), No, Don't know
How many anaphylaxis episodes have you had in the last year from skin testing?	
How do you keep track of anaphylaxis episodes?	Electronic Database, Paper records, Don't record, Other (please describe)
How many anaphylaxis episodes have you had in the last year from SCIT?	
Do you allow home immunotherapy in certain situations?	Yes, No
If patients are doing home immunotherapy, do you prescribe and instruct on use of the epi-pen?	Yes, No
If you allow home immunotherapy have you had any patient report a serious adverse reaction?	Yes, No, Not applicable
About how many patients do you treat a year with SCIT?	
About how many patients do you treat a year with SLIT?	

SCIT = subcutaneous immunotherapy; SLIT = sublingual immunotherapy.

An anaphylaxis database was developed for analysis, surveillance, and prevention. Quality metrics included the incidence of anaphylaxis per site, errors, as well as performance on checklists for both chart audit and site visits.

For fiscal year 2013 (July 1, 2012 to June 30, 2013) approximately 30,000 vials were mixed and 10,000 allergy injections administered per year. Allergy injections administered at outside offices, facilities, and at home were not

TABLE 2. Example of checklist for allergy site visit

Equipment/protocols	Pass	Fail	Recommendations	Technician/manager initials
Epi-pen adult				
Epi-pen child				
Emergency drug box/crash cart				
Oxygen tank/mask/prongs				
Injectable steroids				
Skin prick screen trays				
Intradermal dilutional testing trays				
Patient vial expiration				
Patient vial management				
Antigen log book				
Antigen expiration				
Antigen management				
Emergency plan for testing				
Emergency plan for injections				
Emergency plan for vagal reactions				
MSDS logbook				
Allergy delivery protocol				
Bloodborne pathogens protocol				
Needle stick protocol/kit				

MSDS = material safety data sheet.

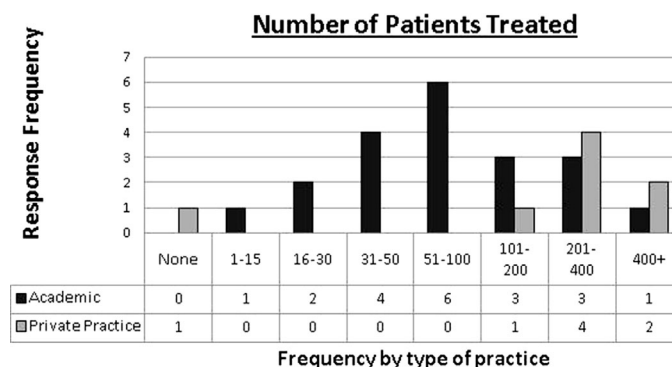
included in this analysis. The most common types of errors over the past 5 years included patient identification errors ($n = 4$), vial mixing errors ($n = 3$), and dosing errors ($n = 2$). There were 7 episodes of anaphylaxis of which 2 were secondary to dosing errors yielding a rate of approximately 0.01% or 1 in every 10,000 injection visits/year. Site visits showed that 86% of key safety measures were followed. Remediation was performed for deficiencies and chart audits and site visits were scheduled on a quarterly basis.

Differences between practice setting, and medical and otolaryngic allergists

Of the 130 medical and otolaryngic allergists invited to participate in the survey, 33 complete responses were obtained yielding a 25% response rate. The responders were comprised of 19 medical allergists and 14 otolaryngic allergists. There were 25 academic practices and 8 private practices, the majority of which treat from 30 to 400 patients (Fig. 1).

Most practices use in vitro testing (91%) and skin prick testing (94%) and only about half employ intradermal dilutional testing (51%) or patch testing (55%). The majority of practices provide SCIT and do not provide SLIT (57%) (Figs. 2 and 3). Eighty-four percent (84%) of responders indicated that their office mixes their own vials, usually

in 1 location (90%). Most practices differentiate between vials at maintenance or advancing (91%) using a color-coding system (76%) or numerical system (13%). Seventy-three percent (73%) of those surveyed indicated that patients were asked to verify their vials prior to injection, but 27% do not. Over 97% responders recommend patients to wait 20 to 30 minutes after injection with 54% of responders recommending the full 30 minutes. If patients refuse to wait the majority of practices require that the patient sign out against medical advice (42%) or do not give the

**FIGURE 1.** Number of patients treated with immunotherapy.

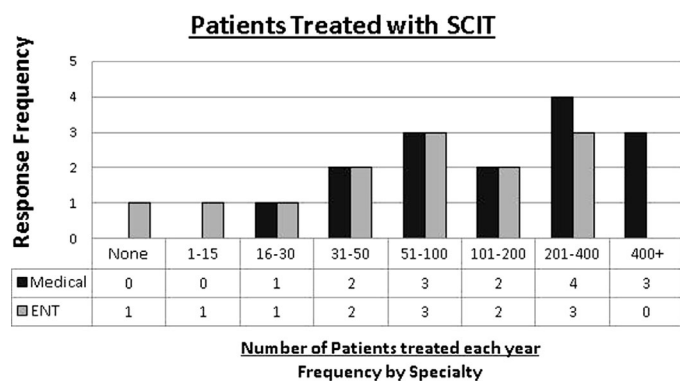


FIGURE 2. Number of patients treated with SCIT. SCIT = subcutaneous immunotherapy.

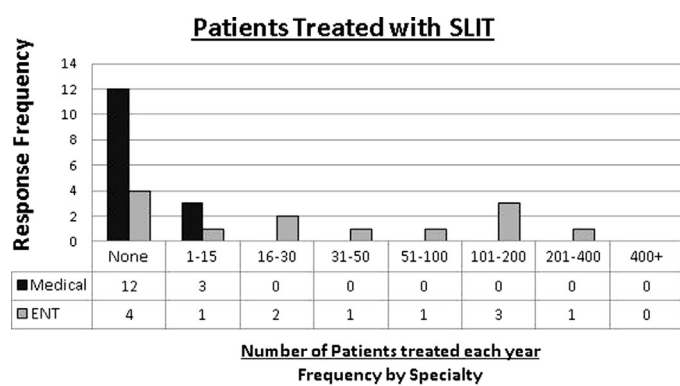


FIGURE 3. Number of patients treated with SLIT. SLIT = sublingual immunotherapy.

injection (35%). The majority of responders indicated that they screen for asthma prior to giving injections (87%) and the majority of responders perform anaphylaxis mock drills (60%) at least on a yearly basis (75%).

Medical allergists were more likely to verify vial formulation with staff than otolaryngic allergists ($\chi^2 = 4.765$, $df = 1$, $p = 0.029$) and academic practices were more likely to verify vial formulation in comparison to private practitioners ($\chi^2 = 3.857$, $df = 1$, $p = 0.050$) (Fig. 4). Approximately 60% of practitioners did not know how to define a quality metric for allergy and there was no statistically significant difference between medical and otolaryngic allergists. There was a significant difference, however, between academic and private practitioners with academic practices more likely to know how to define a quality metric for their practice ($\chi^2 = 5.333$, $df = 1$, $p = 0.021$) (Fig. 5). Half of responders perform systems reviews/audits to assess for errors and adverse reactions and in this group both medical and otolaryngic allergists were equally likely to perform systems reviews/audits but academic practices were statistically more likely to perform this type of review in comparison to private practices ($\chi^2 = 8.000$, $df = 1$, $p = 0.005$) (Fig. 6).

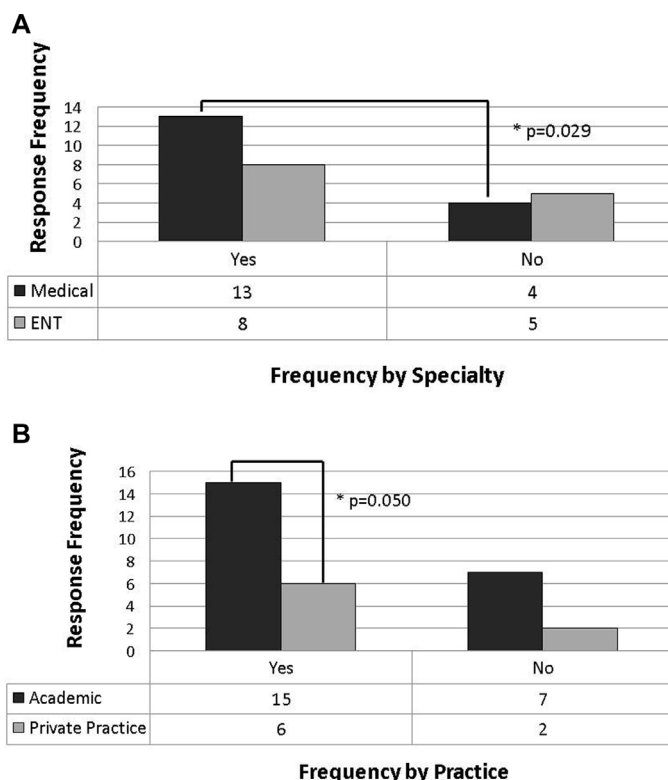


FIGURE 4. Verification of formulation of vials. (A) Medical allergists are more likely to perform verification. (B) Academic practitioners are more likely to perform verification.

Home immunotherapy

Approximately 40% of responders indicated that they provide home immunotherapy and of these 75% indicated that they have not had any patient report a serious adverse reaction. In the practitioners who allow home immunotherapy, 83% indicated no reports of adverse reactions in the past 5 years. All practitioners who provide home immunotherapy counsel patients on the use of injectable epinephrine. Of the adverse reactions seen, there was 1 response indicating an emergency room visit for possible anaphylaxis. No deaths were reported. Academic practitioners were more likely to not provide home immunotherapy in comparison to private practitioners ($p = 0.008$) and there was a trend for medical allergists to not provide this as an option compared to otolaryngic allergists ($p = 0.074$) (Fig. 7) although this was not statistically significant.

Discussion

The goal of this study was to implement a systemwide quality program to improve the safety, efficacy, and patient experience of allergy care in a tertiary academic center composed of a network of 6 allergy clinics. Five core areas of improvement mainly tied to processes including the need for standardized practice, training, improved interface with the electronic medical record, error reporting, and review were identified. The current practice of immunotherapy

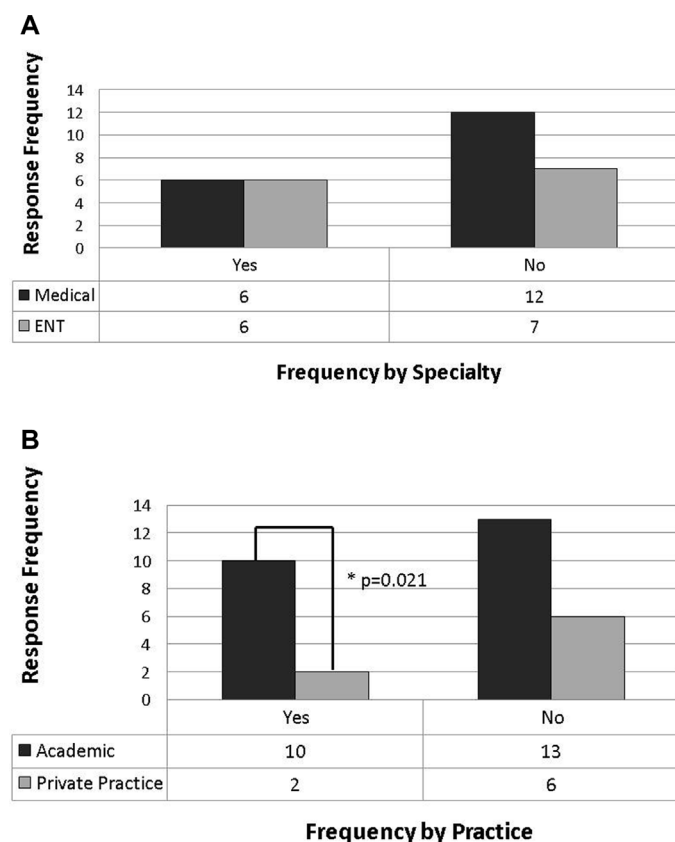


FIGURE 5. Knowledge of quality metrics. (A) There was no difference between medical and otolaryngic allergists. (B) Academic practitioners are more likely to know how to define a quality metric than private practitioners.

delivery involves a complex series of events that must take place accurately from initial testing, to compounding of allergen extracts into patient vials, and the administration of injections. Errors can occur at any of these junctures and standardized practice, meticulous attention to detail, and continuous review of the process is necessary to ensure safe delivery of care. The development of reportable measures is also important for ongoing evaluation and improvement. Safety measures including incidence of anaphylaxis and performance on a standardized checklist were initiated.

Although SCIT has shown to be a safe and effective treatment for allergic rhinitis and asthma, the risk of severe systemic reactions and mortality due to anaphylaxis still exist. Fatal reactions are estimated to occur in every 2.5 million injections (3.4 deaths/year) and near-fatal reactions in every 1 million injections (4.7 episodes/year).^{5,6} Factors that have been shown to contribute to fatalities include errors in dosing and administration of injections, delay or failure to administer epinephrine, inadequate post-injection waiting period, presence of asthma, and administration of injections in suboptimal settings.⁷ Fatal reactions, however, appear to be declining, with a recent survey of American Academy of Allergy, Asthma and Immunology and American College of Allergy, Asthma and Immunology members showing no fatalities from 2008 to 2011 for SCIT-related reactions. This decline was attributed to increased screening for asthma

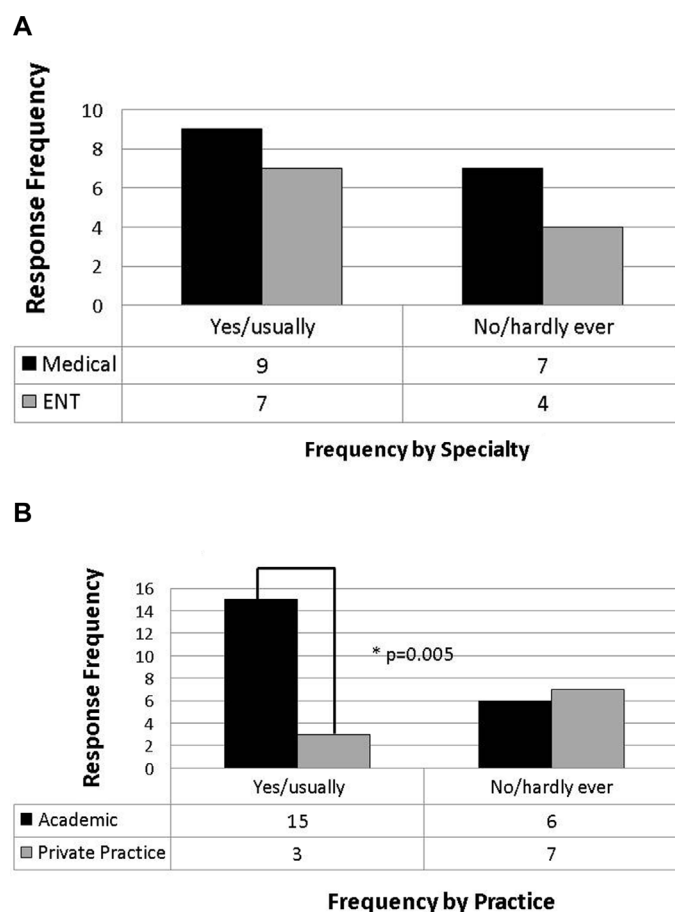


FIGURE 6. Performance of systems review/audits. (A) There was no difference between medical and otolaryngic allergists. (B) Academic practitioners are more likely to perform systems review/audits compared to private practitioners.

and dose adjustment during the pollen season.⁸ The anaphylaxis rate in our study of approximately 0.01% or 1 in every 10,000 injection visits/year is in line with this recently published survey, which reported approximately 0.4 to 2.6 moderate to severe systemic reactions per 10,000 injection visits. Tracking and analysis of systemic reactions is important but the standardization of training and delivery of allergy immunotherapy have been the most helpful in improving safety and quality.

The Joint Task Force on Practice Parameters has published clinical practice guidelines in the third update of the practice parameters on allergen immunotherapy.⁹ The practice parameters provide summary statements for allergen extract handling and administration based on available evidence but do not provide recommendations on quality metrics. The third update includes discussion on the use of the U.S. Pharmacopeia 797 allergen extract preparation guidelines as well as the guidelines developed by the Joint Task Force. Guidelines vary, however, and depend on practice setting. Currently there are no guidelines available from the American Academy of Otolaryngic Allergy.

The results from this study indicate that the majority of both medical and otolaryngic allergists do not yet know

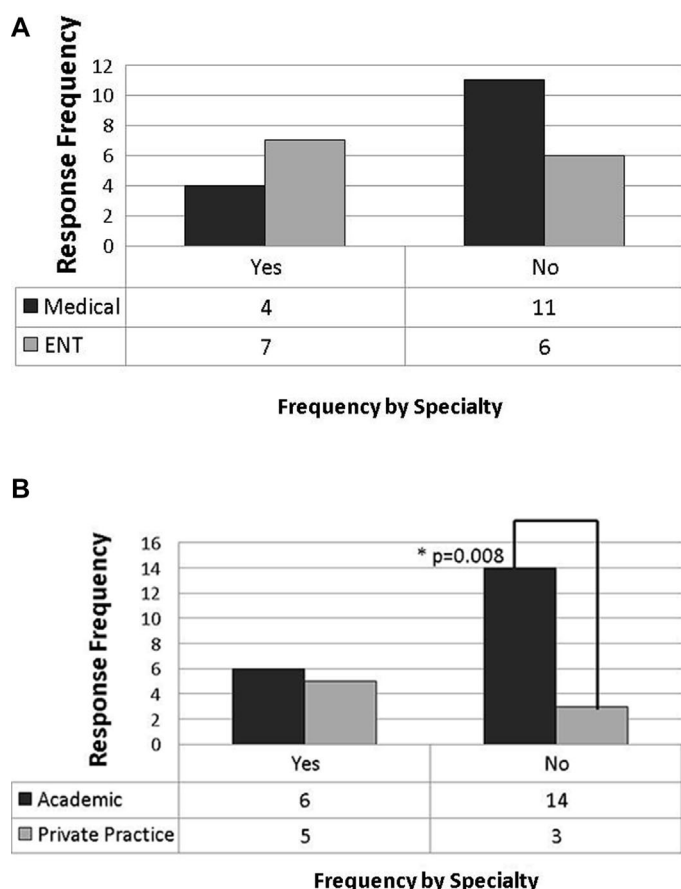


FIGURE 7. Home immunotherapy. (A) There was no difference between medical and otolaryngic allergists in provision of home immunotherapy. (B) Academic practitioners are more likely to not provide home immunotherapy in comparison to private practitioners.

how to define or use quality measures or perform systems reviews. If in existence, these initiatives appear to be more prevalent in the academic than the private practice setting. Although the majority of practitioners screen for asthma, perform vial verification, and ensure anaphylaxis preparedness, it appears that there are differences between medical and otolaryngic allergists as well as between academic and private practice settings. A limitation of our study, however, is the small population surveyed and the potential for variance in the responses.

Other quality metrics in development include rate of appropriate ordering of allergy testing by supervising physicians, rate of physician follow-up while on immunotherapy, and evaluation of patient outcome including medication usage, symptom, and asthma control. Although AIT is currently the only disease-modifying treatment available for allergic rhinitis, this treatment is still vastly underutilized with only 2% to 6% of potentially appropriate patients treated.¹⁰ With the increasing utilization of SLIT in the United States, more patients may be able to benefit from immunotherapy as a therapeutic option and measurement of quality will become even more relevant. Home immunotherapy was provided by approximately

40% of our responders and there was no statistical significance between medical and otolaryngic allergists although the data suggest that academicians and medical allergists are less likely to provide home immunotherapy as an option.

Quality measures of patient outcome and patient satisfaction are important in determining comparative effectiveness between treatment options. Studies examining quality outcomes between AIT and pharmacotherapy are needed but only possible with initiatives in place to develop and utilize these metrics rigorously. Interestingly, although measurements of processes and of patient outcomes are important, patient subjective experience with care is often found to be distinct and do not even correlate with outcome.¹¹ Therefore evaluation of not only processes and outcomes of care, but assessing patient experience is important in measuring quality.¹²

The USDHHS has developed a National Quality Metrics Clearinghouse with measures currently being used by agencies for reporting purposes.¹³ An example is the appropriate treatment for children with pharyngitis tracked via the Centers for Medicare and Medicaid Services. The numerator is the number of patients dispensed an antibiotic and who received a strep test for the episode. The denominator is all patients aged 2 to 18 with a diagnosis of pharyngitis. The development of quality metrics, however, is still in its infancy and quality metrics do not yet exist for allergy delivery.

Finally, efficiency measures have also recently attracted more attention as increasing cost of care and limited resources has burgeoned in the past decade. Reporting of quality measures will become increasingly important and tied to reimbursement as the transition occurs from a fee-for-service payment model to new systems tied to quality care. These measures can also direct consumer decisions and in the future, maintenance of certification of providers. Efforts are currently in place to use the electronic medical record for reporting of quality measures to payors and regulatory agencies. At the present time “meaningful use” measures can be used for incentive payments but by 2015, providers that do not participate in this effort will see reduction in reimbursement.

Over a decade ago the Institute of Medicine proposed a widespread reengineering of the health care system in their publication “Crossing the Quality Chasm: A New Health System for the 21st Century.”¹⁴ Six aims for improvement include safe, effective, patient-centered, timely, efficient, and equitable care. The charge to provide care that is tailored to the patient, evidence-based, and provided quickly without wasted resources is becoming even more relevant in the current health care climate.

Conclusion

Quality metrics including process, outcome, and patient satisfaction measures are important for providing safe and patient-centered care in the delivery of allergy

immunotherapy. In the current era of health reform, quality measures will become increasingly important and required of providers. Otolaryngic allergists must be versed in the discussion of quality metrics, cost-effectiveness, and patient outcome in order to participate in defining the future of allergy care for our patients. 🌐

Acknowledgments

We thank Dr. Andrej Petrov for his feedback on developing the online survey and John McCormick for statistical analysis and technical assistance.

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