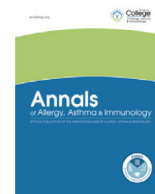




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MOC-CME Review

Unnecessary food allergy testing by primary care providers Ethical implications for the specialist

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Key Messages

- Serum specific immunoglobulin (Ig)E tests can be useful in the diagnosis of IgE-mediated food allergy by demonstrating the presence of sensitization; however, they should not be considered diagnostic of food allergy without clinical correlation, given their poor positive predictive value and inability to reliably predict clinical reactivity.
- The use of multiple food allergen panels has been associated with the misdiagnosis of food allergy, leading to unnecessary dietary avoidance and higher health care costs.
- Most food allergen panels are ordered by primary care providers, who may be unaware of the added costs and potential harms associated with panel testing.
- Specialists have an ethical responsibility to provide education and expertise to other providers, and they should use all opportunities to exercise this responsibility.
- Clinical practices that are thought to be unethical or incompetent should be reported to the appropriate state medical board.

Clinical Vignette

After completing her fellowship in allergy and immunology, Dr. X accepted an appointment in an academic position at a tertiary care pediatric hospital. Many of the patients Dr. X sees for evaluation of food allergy have undergone serum specific IgE testing before their allergy consultation. As time goes on, Dr. X begins to notice a concerning trend in patients referred from Dr. Y, a primary care provider who has been practicing in the community for over 20 years. Dr. X is worried that many of Dr. Y's patients have undergone clinically unwarranted extensive serum specific IgE testing with panels of multiple food allergens. In many instances, families were instructed to

avoid all foods against which the patient was found to have detectable serum specific IgE, even if these were foods that were previously tolerated in their diet. Although Dr. X has included comments in her communications to Dr. Y recommending against ordering panel testing for the assessment of possible food allergy, Dr. Y continues to regularly order them and uses the results to direct dietary avoidance. Dr. X is concerned that Dr. Y may cause patient harm through management decisions that are inconsistent with currently accepted clinical practices and published guidelines. What should Dr. X do?

Introduction

This clinical vignette raises questions about clinical and ethical considerations that can arise when physicians order tests they may not have the knowledge to interpret, and the ethical responsibilities of the specialist in those situations. In this case, we are discussing the use of a laboratory test by clinicians that has a significant risk of

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overestimating food allergy, and the ethical considerations for a specialist who knows of a provider overusing this test. In this article, we discuss the clinical issues related to the use of serum specific IgE testing, and then explore the ethical conundrum that the specialist must navigate.

Clinical Considerations

This vignette highlights a challenge commonly faced by many allergy and immunology specialists: inappropriate use of serum specific IgE testing and its contribution to the misdiagnosis of food allergies. In the 2014 update on food allergy, the Joint Task Force on Practice Parameters acknowledged the role of specific IgE testing:

Summary Statement 23: The clinician should use specific IgE tests (skin prick tests, serum tests, or both) to foods as diagnostic tools; however, testing should be focused on foods suspected of provoking the reaction, and test results alone should not be considered diagnostic of food allergy. [Strength of recommendation: Strong; B Evidence]

The parameters go on to issue a cautionary statement that “the clinician should be aware that a relatively small number of foods are responsible for the majority of IgE-mediated food reactions, and therefore panel testing to a large number of allergens should not be conducted.”¹ Although primary care providers may not read the allergy and immunology practice parameters, a similar warning against indiscriminate use of specific IgE tests was included in the National Institute of Allergy and Infectious Disease’s food allergy guidelines.² Effort has been made to disseminate these guidelines and to ensure their implementation; however, the practicing allergist continues to encounter overuse of specific IgE testing in clinical practice.

Allergy skin prick tests and serum specific IgE testing show evidence of sensitization to a particular protein, but imperfectly correlate with food allergy as diagnosed by the gold standard, an oral food challenge. In population studies looking at National Health and Nutrition Examination Survey data, 17% of people demonstrated sensitization to a major food allergen, but only 2.5% had clinical reactivity consistent with food allergy.³ The poor positive predictive value of serum IgE tests is highlighted by the fact that only 33% of peanut-sensitized and 55% of egg-sensitized infants showed oral food challenge—proven food allergy.⁴ In a large cohort of siblings of children with food allergies whose pretest probability of having food allergy is higher than the general population, 53% demonstrated sensitization to at least 1 food but had no clinical symptoms concerning for food allergy.⁵ These results highlight the significant number of false-positive tests that a provider may expect to encounter when ordering specific IgE levels that are not guided by a history suggestive of an IgE-mediated food reaction.

In nearly all situations, the use of a multiple food allergen panel will result in obtaining specific IgE levels for uncommon/unlikely triggers or foods that are not implicated by the clinical history, and a growing body of evidence has shown that this translates into higher health care costs. Bird et al⁶ looked at all new patients seen by a single provider at a tertiary-care, food allergy referral center over the course of a year and found that a standard panel of food-specific IgE tests had been previously ordered in 35% of all visits.⁶ The authors estimated that the panel testing across all visits resulted in a total avoidable cost of nearly \$79,000. A study by Stukus et al⁷ comparing the use of food allergy panels by pediatric care providers (PCPs) versus allergists found that PCPs ordered 79% of food panels and that the longer the PCPs were from their residency training the more likely they were to use panel testing.⁷ Driven in large part by the use of multiple allergen panels, the cost of specific IgE testing obtained by

PCPs was nearly twice as much as the cost of testing performed by an allergist.

Beyond the associated health care costs, inappropriate panel testing can be potentially harmful to the patient, if it results in unnecessary dietary modification. In the study by Bird et al, fewer than one third of patients who previously underwent allergy testing even required evaluation for an IgE-mediated food allergy.⁶ Additionally, nearly half of the patients who underwent panel testing had altered their diet based on provider recommendation before seeing the allergist. In situations in which testing was warranted, patients were avoiding an average of 4.8 foods, but 90% were able to add at least 1 food back into their diet on further evaluation. Dietary modification because of presumed food allergy can also place a child at risk for nutritional deficiencies and potential growth problems.⁸ In some extreme cases, severe malnutrition has been reported as the result of unnecessary avoidance from misdiagnosed food allergy.⁹ Beyond the impact on diet, recognizing the psychosocial impact on families when a child is diagnosed with or perceived to have a food allergy is important. A growing body of evidence shows that a food allergy diagnosis has a profound impact on the quality of life of children, adolescents, and their families.¹⁰ Therefore, inappropriate measurement of food-specific IgE levels has potentially significant impacts on patient health and well-being, but what is the ethical responsibility of the specialist in this situation?

Ethical Considerations

Physicians agree to adhere to a set of ethical guidelines intended to underlie their decisions and interactions with patients. Of these, the core principle of *nonmaleficence*, or “do no harm,” forbids providers from recommending ineffective or unnecessarily dangerous tests or therapies. The guideline of *beneficence* requires physicians to weigh the risks and benefits of a given intervention and only take action when a net benefit for the patient is believed to be the result. Because patients rely on physicians to provide sound advice and act in their best interest, physicians have a fiduciary responsibility to recommend the course of action that is most likely to improve the patient’s well-being.¹¹ Although these principles are taught in medical school and emphasized throughout medical training, their application in clinical practice is subject to individual interpretation.

In the vignette, Dr. X ponders the principles of *nonmaleficence* and *beneficence* while considering Dr. Y’s continued reliance on multiple food allergen panels for the evaluation and diagnosis of suspected food allergy, even when not clinically warranted. Although the act of drawing blood does not pose significant risks to the patient, potential for harm from extensive and likely unnecessary dietary avoidance is present. Beyond significant nutritional and psychosocial ramifications, there is the theoretical concern that removal of a tolerated food from the diet of a person sensitized to that food may result in the development of a clinical hypersensitivity on re-exposure to the food. Therefore, indiscriminately ordering specific IgE tests (and acting on the results) violates the principle of *nonmaleficence*—not only because the patient may have secondary nutritional and psychosocial issues, but also because they could develop a disease (true food allergy) that they did not have before. So what could a specialist do to prevent this violation of the principle of *nonmaleficence*?

As specialists who have undergone specific training on the diagnosis and treatment of food allergy, we have an obligation to disseminate our knowledge to primary care providers. The American Medical Association’s Code of Medical Ethics states, “A physician shall continue to study, apply and advance scientific knowledge, maintain a commitment to medical education, [and] make relevant information available to patients, colleagues, and the public.”¹² Sharing our scientific knowledge to professional colleagues is important and necessary

as allergists; a survey of primary care providers showed that only 28% felt comfortable interpreting laboratory tests used to diagnose food allergies.¹³ Given her knowledge of the American Medical Association's Code of Medical Ethics, Dr. X continues to provide education to Dr. Y through professional communications but notices no change in his testing and management strategy. At one point, she even decided to call Dr. Y to discuss the appropriateness of specific IgE testing. During the call, Dr. Y defends his use of the food allergy panels and refers to the fact that his patients have never complained of this practice, and he insists physician self-determination protects his ability to practice medicine as he sees fit, even if it does not adhere to expert opinion guidelines.

Frustrated by her inability to change Dr. Y's beliefs and behaviors, Dr. X wonders whether bringing her concerns to the attention of a regulatory authority would be appropriate. If so, whom would she contact and under what grounds could she file a complaint? In a hospital setting, the chief of service or chief of staff would ultimately have the ability to regulate a physician's behavior. As a physician in private practice, Dr. Y is not under such a regulatory hierarchy, but he is bound to the obligations of his state's medical board. Each state's medical licensing board defines the standards of professional conduct for physicians and nurse practitioners. Although unprofessional conduct has no universally agreed upon definition, the Federation of State Medical Boards identifies one form of unprofessional conduct as failure to meet the standard of care.¹⁴ Similarly, the American Medical Association's Code of Medical Ethics states, "A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence."¹² When professional guidelines recommend the targeted use of specific IgE testing and avoidance of multiple food allergen panels, does continued use of these panels constitute a failure to meet the standard of care? After all, Dr. Y's behavior is not directly and immediately putting the patient at risk as compared with an impaired surgeon or a physician who administers toxic concentrations of drugs. In the current example, the primary care provider may be providing substandard care (especially as measured by the specialist's view), but Dr. X recognizes that she has seen numerous patients from other providers whom she also felt had inappropriately used panel testing. As a result, Dr. X decides that Dr. Y's actions do not constitute clinical incompetence or a significant deficiency in character that warrants a formal complaint with the state medical board.

Even though she did not think Dr. Y's behavior was unprofessional, does Dr. X have another obligation to decrease the use of tests that have been associated with higher health care costs? Many of Dr. X's patients have public insurance, so the added cost of diagnostic tests and subsequent evaluation are borne in part through taxpayer money. The American Medical Association's Code of Medical Ethics' Opinion on Physician Stewardship states that physicians should "Choose the course of action that requires fewer resources when alternative courses of action offer similar likelihood and degree of anticipated benefit compared to anticipated harm for the individual patient but require different levels of resources."¹⁵ Rather than focusing on the individual behavior of Dr. Y, Dr. X decides to concentrate her attention on the health care delivery system. She reaches out to the information technology team at the hospital where she works to see whether anything can be done to improve the situation. Together, they change the electronic health record so that any provider

attempting to order panel testing will be informed that routine use of food allergen panels is not recommended and that individual serum IgE tests are available and should be correlated with history before being ordered. In addition, Dr. X contacts the laboratory that performs serum specific IgE testing to begin discussions with them about the appropriate use of the test and ways to share this information with other health care providers. This approach incorporates the idea of beneficence (doing the best good for the entire community) and is aligned with the American Medical Association's Code of Medical Ethics. Most importantly, these are interventions that fit with the expected responsibilities of the specialist: providing education and support to the primary care providers so that they will have the knowledge needed to order the appropriate test, and to ensure the best possible outcome for their patients.

This vignette and discussion demonstrate an issue that specialists often encounter in their practice, the inappropriate ordering of laboratory tests. Hopefully, this discussion has shed insight into the ethical responsibilities that a specialist has to provide education for primary care physicians. By sharing their knowledge and expertise, a specialist can ensure that primary care physicians will be equipped with a better understanding of how to provide ethically proper care for their patients. In this case, that would involve a more judicious and appropriate ordering of specific IgE tests. This route of action is a win-win-win for all involved—the specialist is recognized for their expert knowledge, the provider is given additional education, and together this sharing of information leads to a more appropriate treatment plan and improved outcome for the patient.

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