

Incorrect allergy injections: Allergists' experiences and recommendations for prevention

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There are several reports of fatalities caused by allergen immunotherapy and skin testing. Patients have been reported who have received incorrect allergy injections. These could put them at risk for anaphylactic reaction and a possible fatality. We performed a survey to determine allergists' experiences with incorrect injections and to identify opportunities for prevention. This study was endorsed by the American Academy of Allergy, Asthma and Immunology and the Joint Council of Allergy, Asthma and Immunology. We conducted an e-mail survey of 1717 allergists, asking whether they knew of an incorrect injection administered within the last 5 years in their offices. An incorrect injection is an injection given to the wrong patient or a correct patient receiving an injection of an incorrect dose. Fifty-eight percent of responders reported an event in which a patient had received an injection meant for another patient. Seventy-four percent of responders reported that patients had received an incorrect amount of vaccine. The effect on patients ranged from local reactions to one fatality. Specific reasons given for the incorrect injections were patient name similar to that of another patient with incorrect name check and nurse error resulting in an incorrect dose. We conclude that allergy injections are a potential safety concern. There are a variety of prevention strategies that could be implemented to reduce or eliminate this risk, such as improved nurse training in the administration of allergy injections and compliance with the recommendations in the "Allergen Immunotherapy: A Practice Parameter" for use of patient-specific vials, standardized dosage sheets, and implementation of triple-checking of identity to make sure the correct patient is receiving the correct injection. (*J Allergy Clin Immunol* 2004;113:1117-21.)

Key words: Patient safety, medical error, anaphylaxis

With the publication in 2000 of the report "To err is human,"¹ the issue of patient injury as a result of medical

care became an important item on the public health care agenda. Indeed, 42% of the public reported they had experienced an error with their own care or the care of a family member.² An adverse event is defined as an injury caused by medical management rather than by the underlying condition of the patient.¹ Several studies have demonstrated that approximately 1% of hospitalized patients might experience injury as a result of negligent medical care.^{3,4} No comparable studies of preventable errors in ambulatory care, particularly in the outpatient allergy setting, exist.

Allergen immunotherapy is effective for the treatment of allergic rhinitis,⁵ allergic bronchial asthma,⁶ and anaphylactic reactions to hymenoptera venoms^{7,8} and has been an available treatment for more than 100 years. It is generally considered to be a very effective therapy. There have been reports in the past of fatalities caused by allergy injections, and these are usually attributed to anaphylactic reactions.^{9,10} Nonfatal systemic reactions caused by allergy immunotherapy have also been described.^{11,12} Generally, there are few reports of injuries caused by allergy testing or treatment. Given the lack of information about adverse events in outpatient allergy clinics, our goals in this study were as follows: (1) to determine allergists' experiences with incorrect injections and (2) to identify opportunities for improvement.

It is generally recognized that medical errors frequently involve systemic errors in addition to human errors.¹³ Preventing errors and improving safety for patients requires a systems approach to modify the conditions that contribute to error. The recently published "Allergen Immunotherapy: A Practice Parameter"¹⁴ focused, in part, on correcting potential systemic errors in the provision of allergy vaccine immunotherapy. Our recommendations endorse and elucidate those recommendations that fall within the scope of this article. Our other recommendations focus on the interface between human and systemic errors. Although we certainly do not recommend that human errors be ignored, we do believe that elimination of as much systemic error as possible will result in a large reduction in human error because we believe much human error is facilitated by faulty systems.

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TABLE I. Wrong-patient injections

No. of wrong-patient injections	Response (%)	Total response (n)
1-3	44.3	211
4-7	10.7	51
10	0.8	4
>10	1.9	9
None	42.2	201

There were a total of 479 respondents.
Statistics are based on 476 respondents (3 skipped).

METHODS

One thousand eight hundred fifty-seven e-mails (with one follow-up e-mail) were sent to a merged American Academy Of Allergy, Asthma and Immunology and Joint Council of Allergy, Asthma and Immunology e-mail list. We had 140 returned because of incorrect e-mail addresses, and therefore we effectively sent 1717 e-mails. The e-mail had a link to a secure Web site where physicians could input responses. The Web site ensured that we were unable to obtain any identifier data for responding physicians. No patient identifier data were asked for or received. The secure Web site was set up to allow for only one response from a computer to prevent contamination of the responses.

We defined a wrong injection as an injection given to a wrong patient or a correct patient receiving an incorrect dose (either incorrect concentration or incorrect volume). The questionnaire asked the following question: "For the last 5 years, approximately how many incorrect allergy injections have been given to your patients? An incorrect allergy injection is defined as an injection given to a wrong patient or a correct patient who received an incorrect dosage or volume."

We were also interested in determining the type of reaction caused by an incorrect allergy injection. The survey provided for a range of responses: local reaction only, systemic reaction with no hospitalization, systemic reaction with either emergency department care or hospital admission, or death.

The first responder identified numbers of different types of reactions to injections that we thought represented a factitious response, and we eliminated this response from the study.

This study was submitted to the Institutional Review Board of the Harvard School of Public Health, who determined it to be exempt from institutional review board review.

RESULTS

Fifty-seven percent of respondents reported at least one wrong injection given to their patients in the past 5 years. The breakdown of the number of wrong-patient injections given in that time period is found in [Table I](#). Most respondents reported 1 to 3 wrong-patient injections.

Seventy-four percent of respondents reported at least one incorrect-dose injection given to their patients in the past 5 years. The breakdown of the number of incorrect-dose injections is found in [Table II](#).

Seventy-nine percent of respondents responded to the question asking for a description of the reaction that resulted from an incorrect injection. The reactions ranged from local reaction only to death. The specific breakdown of the type of reactions is found in [Table III](#). The greatest

TABLE II. Incorrect-dose injections

No. of incorrect-dose injections	Response (%)	Total response (n)
1-3	42.3	200
3-7	19.9	94
10	4.9	23
>10	7.2	35
None	25.8	122

There were a total of 479 respondents.
Statistics are based on 473 respondents (6 skipped).

TABLE III. Types of reactions resulting from an incorrect allergy injection (numbers are approximations only)

Type of reaction	No. reported
Local reaction only	1128
Systemic: no hospital care	443
Systemic: emergency department care	59
Systemic: admission to hospital	24
Death	1

numbers of reactions were local reactions without systemic reactions.

DISCUSSION

Our survey results show that administration of incorrect injections continues to occur in allergy clinics. The reporting of 24 systemic reactions requiring admission to the hospital, along with one death, make it clear that reactions to allergy injections can be serious. We believe that most of these incorrect injections are preventable.

This study was designed to determine only whether incorrect allergy injections are given in allergy clinics. It was not meant to determine the frequency of incorrect injections in an allergy clinic because the occurrence of any incorrect injection is sufficient to identify a preventable medical error. We asked about the type of reaction to determine whether reactions to incorrect allergy injections posed a serious risk to patients and not to quantify numbers.

Although not easily comparable because allergy vaccine is a biologic administered by a physician in an outpatient setting as an injection, it is reasonable to look at preventable drug errors and see whether we can learn anything about prevention. There are very few studies of adverse drug events in ambulatory patients. One recent study by Gandhi et al¹⁵ surveyed 661 outpatients and found that 20 of 162 reporting adverse drug events had a drug reaction caused by preventable error. There were no deaths or apparent serious reactions except for one case of jaundice. The principle recommendation was physician and patient education and improved communication between provider and patient. These 2 principles form the basis for many of the recommendations that follow, which are intended to decrease wrong-patient and incorrect-dose errors, as well as monitoring errors.

There are a number of studies that have looked at the safety of allergen immunotherapy.^{8-10,16-18} None of these studies was designed specifically to look at errors in the administration of allergy vaccine. Errors in administration were reported, but no evaluation of the role of systemic error was made, and no recommendations were offered to correct systemic faults. On the basis of the high number of errors found in our survey, this study attempts to make systemic recommendations for error prevention. We have drawn our recommendations from "Allergen Immunotherapy: A Practice Parameter"¹⁴ and from personal experience in evaluating systemic errors, as well as the patient safety literature. The practice parameters were endorsed by the American Academy of Allergy, Asthma and Immunology; the American College of Allergy, Asthma and Immunology; and the Joint Council of Allergy, Asthma and Immunology and are, as far as possible, evidence based. Although the guidelines offer an appropriate disclaimer that not all recommendations will be appropriate for all patients, we believe that with rare exception, the recommendations covering the technical aspects of allergy vaccine immunotherapy are appropriate for all patients receiving allergy injections.

RECOMMENDATIONS

The following recommendations, which will be discussed below, are based primarily on "Allergen Immunotherapy: A Practice Parameter"¹⁴ and supplemented by the patient safety literature, Joint Commission on Accreditation of Healthcare Organizations guidelines, and experiences of the authors:

1. Annual continuing medical-nursing education for physicians and nurses in safe administration of allergen immunotherapy should be required.
2. All vials should be patient specific, and off-the-board treatment with common vials of vaccine should be discontinued.
3. Standardized forms, as recommended in "Allergen Immunotherapy: A Practice Parameter,"¹⁴ should be adopted by all allergy practices.
4. Three identity checks should be used before a patient is given an allergy injection, and patients should only be called into a room by their first and last names.
5. The individual who draws up an injection must be the one who administers the injection, and no injection should be drawn up until the patient who will receive the injection is in the room.
6. Only one patient receiving allergy injections should be in the room where injections are administered at any one time.
7. All patients should be advised to wait 20 to 30 minutes after an allergy vaccine injection.
8. Physician office staff must report all incorrect injections immediately and all near-miss episodes as soon as it is practicable. Near-miss reporting should be done in a nonpunitive environment.

The above recommendations are further discussed in the following sections.

1. Physician and nurse education

Annual physician and nurse continuing medical-nursing education regarding patient safety as it relates to allergen immunotherapy should be required for board certification and recertification and for continued employment as an allergy nurse. This education must focus on the technical and administrative components of allergen immunotherapy. Specifically, it must address injection techniques, management of doses, and adjustment for changes in clinical status or a systemic type of reaction to the last injection. It should have as its goal maintenance of technical skills. This education could be carried out in each office, at local or national meetings, or by using electronic media instruction programs. Targeted continuing medical education requiring risk management education is required for relicensure in Massachusetts. It is likely that this requirement will spread with the current emphasis on patient safety. This recommendation is in line with current thinking.

2. Patient vials of allergy vaccines

In accordance with the practice parameters,¹⁴ we endorse the recommendation that patient-specific vials of allergen vaccines not be shared among patients (off-the-board treatment). The practice parameters specifically state that "vials of allergen vaccine should be prepared individually for each patient to enhance individualization of therapy, reduce the risk of allergen cross-contamination and *reduce the risk of error in administration* [emphasis added]."¹⁴ This proposal is wholeheartedly endorsed. With the advent of standardized extracts for cat, dust mite, and grass pollens, the higher the noted concentrations, the stronger the vaccine for these allergens. The notation for weight versus volume mixtures of the other allergy vaccine extracts implies the higher the number (ie, 1:1000, 1:10,000), the weaker the vaccine. This is inherently confusing and might lead less experienced personnel to administer an incorrect-dose injection. Individual vials for each patient should help to eliminate this problem. Although it is technically possible for an error to be made in the mixing of the vaccine, this risk should be substantially less than the risk of an error in drawing up each individual vaccine dose at each visit, as occurs in the off-the-board approaches. The person mixing vaccine vials is usually in a quiet laboratory area when performing this procedure. There is substantially less distraction in this procedure than there is for the nurse in a room with a patient who is trying to concentrate only on drawing up the injection correctly.

3. Standardized forms

The practice parameter¹⁴ recommends a series of standardized forms. Specifically, they have created recommended forms for immunotherapy vaccine

administration. Use of this form will require the individual administering the injection to ask about current clinical status and reactions to previous injections each time a patient is seen for an injection. This should eliminate many of the problems suggested by the Lockett et al⁹ and Reid et al¹⁰ studies of injections being given when specifically contraindicated because of an acute change in patient status or a prior reaction to an injection. The vaccine prescription and label form should help to ensure that the correct concentration of vaccine is used. Standardized injection doses for all patients as advised should also decrease incorrect-dose administration experiences. Continuing education annually for those who prepare vials of vaccine should ensure that the basic product used for immunotherapy in each clinical practice is mixed correctly. Use of standardized forms and procedures will facilitate patient transfer from one allergist to another because of insurance change or a move of residence.

4. Identity checking

No patient should be called into a room for their injection by using the patient's first name only, no matter how familiar the person administering the injection is with the patient. Patients must always be called into a room by using a first and last name, and a second identifier should be used as well. This is consistent with current Joint Commission on Accreditation of Healthcare Organizations' recommendations.¹⁹ Both identity checks should be used every time a patient is called in for an injection. We believe 3 identity checks should be used for an injection and strongly recommend the first 3 of the 4 following. The fourth could be used if you wished an additional safeguard.

- A. Have the patient confirm that the name on the vaccine vials is the name of the patient to receive the injection.
- B. Have the patient confirm that the name on the vaccine administration form is the name of the patient to receive the injection.
- C. Have the patient identify his or her date of birth or medical record number and check to make sure it conforms with the number in the record of the patient to receive the immunotherapy injection.
- D. An additional identity check could be a current photograph of the patient that would be compared with the patient. This will not replace the first 3 recommendations above.

5. Drawing up and administering the injection

The person who draws up the injection must be the same person as the one who administers the injection. Although there are no studies supporting this recommendation, it seems reasonable to conclude that the fewer persons involved in administering immunotherapy injection, the less chance there is for error. No injections should be drawn up unless the patient is in the room with the person who will administer the injection and has done all of the above recommended identity

confirmations. Some patients prefer the injection to be drawn up before they come into the injection room. This opens a route for possible incorrect injections, and therefore we believe this should not be allowed. It seems clear that the fewer distractions for the nurse giving the injection, the less chance there is for error.

6. Only one patient who is to receive an injection should be in the injection room at any one time.

It is not uncommon for family members or friends to come together to get their immunotherapy. Allowing 2 patients who are to receive injections into the injection room at the same time and having both records in the room at the same time increases the risk of one of them getting an incorrect injection and should not be allowed.

7. Waiting after the injection

We strongly affirm the recommendation of the practice parameter¹⁴ that the patients wait 20 to 30 minutes after an injection. Some physicians might choose to enforce this requirement by timing each patient's wait, whereas others might use an honor system. Either approach is acceptable. We would point out that patients who have long waits to get a shot are less likely to wait the required duration after an injection. Patients must be made aware that failure to wait after an injection has been associated with unattended fatalities in the medical literature.⁹

8. Near-miss reporting

All physicians should require of their staff that they be immediately informed of any incorrect injections given in their office and should deal with this in an appropriate, nonpunitive way. The Institute of Medicine has recommended that voluntary systems for reporting near misses be implemented.¹ A near miss is defined as an error that resulted in no harm. Their aim is "to identify and remedy vulnerabilities in systems before the occurrence of harm." There is evidence that confidential reporting systems by house staff were more effective in uncovering potential injuries than chart review.²⁰ Allergy physicians should implement near-miss, nonpunitive, confidential (if possible) reporting to assist in their ongoing surveillance of their offices to ensure continued safe allergy practices. It should be made clear that, confidential or not, the goal of reporting is to identify and improve faulty systems or practices that lead to errors. Reporting gives the best chance for identifying problems before an injury occurs and should strongly be encouraged by each allergist.

CONCLUSION

The high percentage of allergists who indicated that incorrect injections are being administered confirms the impression that we have a system-based safety problem that should be amenable to systems correction. The recommendations made in this report focus mainly on the newly adopted "Allergen Immunotherapy: A Practice

Parameter.”¹⁴ The stated goal of the allergy practice parameters is to improve the uniformity and standardization of immunotherapy practice. Standardization is a basic tenet of improving systems to ensure safety. The implementation of these recommendations across the field of allergy and immunology could substantially reduce medical errors in immunotherapy administration. In particular, recommendations for individual treatment vials with accompanied immunotherapy schedules and forms for recording immunotherapy schedules should be adopted as soon as possible. Once this has been done broadly in allergy, its effect on patient safety can be quantitatively examined. Implementation of the recommendations of our specialty into each allergist’s office creates a real opportunity for us to standardize our medical practices as a specialty. At the same time, we, as a specialty, can become leaders in implementing procedures to reduce the risk of medical error.

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