

Allergy Immunotherapy in the Primary Care Setting

Integrating National Practice Standards to Promote Safe Delivery

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Allergy immunotherapy (AI) is frequently administered outside of the prescribing allergist's office in the primary care setting. Errors in this therapy can result in a wide variety of problems, ranging from local reactions to death. Proper documentation and instructions from the prescribing allergist's office as well as forms designed for complete and accurate documentation of therapy are vital components of safe administration. This article presents findings from a review of AI records in a primary care setting. Problems in documentation that could contribute to errors are examined and related to national standards of practice. Suggestions for process improvement are outlined.

Key words: *allergy immunotherapy, primary care, process improvement, safety*

ALLERGEN IMMUNOTHERAPY was first used in 1911, and is currently accepted as a safe treatment for allergic rhinitis, asthma, and insect venom allergy. It is often administered in the primary care setting rather than in the prescribing allergist's office as a result of influences of managed care. While allergy immunotherapy (AI) is considered a safe therapeutic regimen, it can be associated with allergic reactions including local pain and swelling, asthma attack, reactions requiring hospitalization, anaphylactic shock, and death. Currently, there are published practice parameters to guide healthcare professionals who administer the AI. This article describes current safety concerns related to this therapy; discusses the current practice parameters of the American College of Allergy, Asthma, and Immunology (ACAAI)

and the standards for safe communication of medication orders of the Institute for Safe Medication Practices (ISMP) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as they relate to this therapy; identifies common pitfalls in AI administration orders; and suggests methods to improve this therapy in the primary care setting.

BACKGROUND

Medication errors in healthcare are currently an area of intense study. After the 2000 release of the Institute of Medicine's report *To Err Is Human: Building a Safer Health System*, the national healthcare spotlight fell squarely on this issue. The report estimated that medication errors accounted for approximately 7000 deaths per year in the United States.¹ When the financial costs of malpractice suits and the system costs of treating the resultant conditions of medical errors are considered, the impetus for change is clear. Medication safety practices in the primary care setting must be addressed separately from those of the inpatient setting.

Allergy immunotherapy administration can be wrought with error. A recent survey of

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allergists showed that in their offices, there were administration errors, which resulted in a variety of reactions ranging from local reactions to death, in up to 74% of the responding offices in the past 5 years.² Presuming that the typical allergist's office staff is more experienced in AI administration than that of a primary care physician's office, the implications of potential for errors in the primary care setting are alarming.

The most troubling adverse effect of the AI, of course, is mortality. For the period from 1990 to 2001, the rate of fatal reactions to AI injections was reported as 1 in 2.5 million injections.³ While this rate represents a decrease in fatal reactions from the previous 4 years, 1 in every 2 million injections during the period from 1985 to 1989,⁴ it is significantly higher than the oft-cited report from the Allergen Products Manufacturers Association of 1 in 63 million injections. When the numbers of all adverse events are tallied, the frequency is staggering. Reports show that systemic reactions occur in 0% to 83% of patients.⁵

Risk factors associated with severe reactions include "errors in dosage, failure to reduce the dosage after a longer than scheduled interval, administration of the wrong extract, inadvertent intravenous administration, failure to postpone injection because of infection or asthma exacerbation, failure to observe patients for the appropriate length of time, [and] failure to adhere to guidelines for established contradictions," among others.^{6(p147)} In addition, one third of the fatal reactions to the AI between the years 1990 and 2001 were related to late (≥ 5 minutes) administration of epinephrine.³

Most of these risk factors are directly related to human error and as such have the potential to be prevented. In fact, AI administration errors, such as incorrect dose and wrong extract, were responsible for many of the deaths in the past 20-year period.⁶ With this in mind, it becomes clear that the staff who administers this therapy must be thoroughly trained and provided with precisely defined orders for administration. Highlighting these areas of potential error and parallel-

ing them to the current standards of practice suggest areas of weakness in the system of this therapy that must be addressed in the primary care setting.

CURRENT STANDARDS OF PRACTICE

The current practice parameters available from the ACAAI were published in 2003. In addition, JCAHO standards are updated annually to reflect new Ambulatory Care National Patient Goals.⁷ These 2 agencies' standards of practice, in addition to those of the ISMP, should be integrated into the primary care practitioners' AI delivery as an initial step in reducing administration errors.

While the complete practice parameter from the ACAAI should be obtained and reviewed by every primary care office that delivers the AI, this article focuses on the specific items that relate to the AI within this setting. It should be noted that the practice parameters of the ACAAI state that the preferred site for this therapy is in the prescribing allergist's office.⁸ However, they also indicate that in cases when the patient is not at high risk for a systemic reaction, that patient may receive this therapy under the supervision of another physician, specifically, "appropriately trained physician and personnel."^{8(p25)} Training recommendations for AI techniques are described fully within ACAAI practice parameters.⁸

With this caveat understood, the ACAAI in the Summary Statement 50 makes the following recommendations regarding AI administration in the primary care setting:

1. The physician and the staff should be trained in resuscitation, and there should be easy access to resuscitative equipment and medications.
2. The physician and the staff should determine prior to delivery of the AI if the patient is experiencing factors that would increase the risk of a systemic reaction. Such factors include current medications such as β -blockers, poorly controlled asthma, allergy symptoms, or allergy season.

3. The physician and the staff should be able to properly adjust the dose as "clinically indicated."^{8(p25)} It is the responsibility of the prescribing allergist to provide properly labeled vials, precise directions about the dosage schedule of both build-up and maintenance therapy, and specific instructions for dosage adjustments related to new vials, seasonal exposure to allergens, missed injections, and prior reactions.
4. The physician and the staff should treat reactions to the AI immediately and report those reactions to the prescribing allergist. The patient may be required to continue the AI under the direct supervision of the prescribing allergist.⁸

With regard to JCAHO standards, there are annually updated patient safety goals for ambulatory practice that include improving the accuracy of patient identification, effectiveness of communication among caregivers, and safety of using medications, and reconciling medications across the continuum of care accurately and completely.⁷

The ISMP published a table of dangerous abbreviations and dose expressions most often associated with misinterpretation and patient harm as reported in its *Medication Errors Reporting Program*. A steady stream of reported errors due to misinterpreting a handful of dangerous dose expressions and abbreviations led the ISMP to recommend abandoning the use of these items for almost 3 decades. Included on this list was the expression of a decimal dose without a leading zero, and zeros "trailing" after decimal points.⁹ This was one of the first medication safety issues ever published by the ISMP over 25 years ago. Yet today, misinterpretation doses expressed with decimal points continue to cause mistakes. Table 1 presents a summary of the current pertinent JCAHO, ISMP, and ACAAI standards of practice as they relate to the AI in the primary care setting.

INTERNAL RECORD REVIEW

The Johns Hopkins Community Physicians is a multicenter primary care practice lo-

cated in Maryland. This service provides over 400,000 primary care visits annually at 15 sites. In the year 2004, there were 3492 visits to this practice for the AI. For this report, records of 31 patients receiving this therapy in the year 2004 were randomly selected and then reviewed for inadequacies in allergists orders that relate to the current JCAHO, ISMP, and ACAAI standards described above. There were 21 allergists practices represented in the records reviewed.

Examples of deficiencies in orders and administration forms that are directly addressed by the JCAHO, the ACAAI, and the ISMP included no consent form, only one patient identifier, unclear dosing schedules, no instructions or ambiguous instructions related to dosage modifications for missed doses, no instructions related to dosage modification for local reactions, local reactions not described in concrete terms, systemic reactions not defined, protocols related to a systemic reaction not given, and no specific dosage modification schedule following a systemic reaction (Table 2). While ACAAI practice parameters do not specify separate instructions for local versus systemic reactions, these records were evaluated on both types of reaction independently. Inadequacies that related to the understandability of orders included failure to label the dose with a unit of measurement (milliliters). Other problems that related to basic medication order safety included no date on the order, no allergist's signature on the order, and no space for the medical personnel who administers the AI to sign off each given dose. Precise operational definitions are presented in Table 2.

None of the records selected were problem free. In fact, the lowest number of inadequacies in any record was 4, and the mean number per record was 7.39 (SD = 1.94). The frequency of each problem type is presented in Table 2.

The most frequently occurring problem was a missing informed consent in the documents sent to the primary care provider. The ACAAI specifically requires documentation of informed consent and a consent form.⁸ The

Table 1. JCAHO, ACAAI, and ISMP standards applicable to allergy immunotherapy*

Required action	
JCAHO 2005 Ambulatory Care National Patient Safety Goals	
Patient identification	The orders must state that at least 2 identifiers for each patient are required whenever administering medications
Reconcile medications	1. The healthcare provider must document medications that each patient is currently taking 2. The healthcare provider must communicate medications completely to the next care provider
ACAAI practice parameters	
Summary Statement 50: Technical training in the AI of personnel	1. The care provider must use 26- or 27-gauge needle and correct SQ injection technique 2. The care provider must properly store AI extracts 3. The care provider must recognize early signs of anaphylaxis and has the ability to administer emergency medications
Summary Statement 50: Theoretical training of AI personnel	1. The care provider must understand factors that increase risks of systemic reactions including concomitant β-blocker use, poorly controlled asthma, and allergy symptoms 2. The care provider must withhold doses of the AI if patient displays any of these risk factors
Summary Statement 50: Proper documentation from the prescribing allergist	1. The allergist must provide vials that are labeled with 2 patient identifiers, a general description of contents, concentration, and expiration date 2. The allergist must supply a dosage schedule for build-up and maintenance of the AI with precise directions related to dose adjustments 3. The allergist must provide a consent form and vaccine administration form 4. The allergist must provide instructions related to treating reactions in case they occur
Summary Statement 50: Immediate response to systemic reactions	1. The care provider must provide immediate emergency treatment for systemic reactions 2. The care provider must refer the patient back to the prescribing allergist for evaluation
Summary Statement 47: Informed consent and proper documentation	1. Immunotherapy consent form must include the contents of the extract 2. The allergist must provide either a written consent form or document verbal consent in the medical record
ISMP dangerous abbreviations	
Do not use trailing zeros	<i>Example:</i> 5 mg, never 5.0 mg
Use leading zeros for doses less than 1 measurement unit	<i>Example:</i> 0.3 mg, never .3 mg

*JCAHO indicates Joint Commission on Accreditation of Healthcare Organizations; ACAAI, American College of Allergy, Asthma, and Immunology; ISMP, Institute for Safe Medication Practices; and AI, allergy immunotherapy.

Table 2. Errors and percentage of records with each type of error

Errors*	% of records with error
No consent form	94
Dose administration record does not provide space to clearly identify the medical personnel who administered the serum	87
The allergist's order is ambiguous when instructions for missed doses are present	68
The allergist's order is not signed by the allergist	58
The allergist's order contains trailing zeros in dose measurements	58
The allergist's order contains only one patient identifier	58
The allergist's order for the dosing schedule is not clear when a dosing schedule is included	55
The allergist's order is not dated	45
Definition of term "systemic reaction" is not given	42
Neither the dose administration record nor the order contains the specific contents of the vial	32
Specific protocols for the treatment of a systemic reaction are not given	35
A dosage modification schedule following a systemic reaction is not given	35
The size of induration is not specified in millimeters when instructions for local reactions are available	26
The allergist's order does not give the unit of measurement for the dose	16
The allergist's order does not contain instructions for dosage modifications related to missed doses	16
The allergist's order does not contain instructions for dosage modifications related to local reactions	16
The allergist's order does not contain leading zeros in dose measurements	6

*Definitions for each error are available from the authors.

second most frequent problem was the lack of a signature by the person who administered the dose. Often initials were used, but this is not an acceptable means of signature if there is no signature box on the page. Other problems noted in the records were the allergist's orders not being dated or signed.

In addition, other common problems were ambiguous orders related to dosage adjustments after missed doses and unclear dosing schedules, which represent a failure to meet the standard of precise directions set forth by the ACAAI. These problems are particularly concerning when considered within the context that the AI is often delivered by unlicensed personnel who may not be compe-

tent to make a clinical judgment about dosing, given the ambiguity. Similarly, when the allergist's orders fail to give the unit of measurement for the dose, when the dose measurements contain trailing zeros, or when the description of local reactions are not in concrete terms such as "millimeters of induration," the healthcare provider is placed in a situation where the directions are not easily interpreted. Practice parameters of the ACAAI, under the requirement of proper documentation from the prescribing allergist, address this requirement of precision of directions.⁸

Another error that conflicts with the proper documentation mandate of the ACAAI

is the failure of allergists to provide documents that list the contents of the vials. While the ACAAI approves of abbreviations, especially when space is limited, no other form of labeling can substitute for the fully written contents.⁸ Finally, more than half of the records failed to have at least 2 patient identifiers on the orders and/or administration forms. This error represents a direct failure to meet JCAHO standard of patient identification.

Clearly, these randomly selected records demonstrate that the practice of the AI in the primary care setting continues to be an area prone to risk of medical error. Adding to this risk is the fact that a given office staff can treat patients from multiple referring allergists, each with unique problem-prone dosing schedules and documentation inadequacies.

IMPROVEMENT SUGGESTIONS

The practice of the AI in this setting continues to be less than 100% compliant with JCAHO and ACAAI practice standards. This noncompliance increases the potential for errors in its administration. Considering that these errors can be associated with adverse events for patients including hospitalization and/or death, this area of practice must be carefully modified and monitored. Specifically, the documents from the allergists' offices should be improved and standardized, specific training should be instituted for personnel responsible for this therapy, and careful monitoring of records should be instituted. If an allergist's office fails to provide proper documentation, that office should be called for clarification.

The ACAAI provides a sample AI administration form and a complete list of standards for AI documentation in the "Practice parameter," published in 2003.⁸ This practice parameter benefits the allergist and primary care providers by establishing a precise standard of care and documentation. The sample form provided by the ACAAI does not include a signature box but should. This practice parameter is a national standard.¹⁰ An organizational

Table 3. Checklist for incoming allergist documentation

The documentation must include

- signed consent forms
- space for administering personnel to sign full name
- precise delivery instructions including schedule of delivery, directions for dosage rescheduling after missed doses, directions for dosage rescheduling after a reaction (local or systemic)
- complete definitions of local and systemic reactions and instructions for treatment of these reactions
- local reactions defined in terms of millimeters
- two patient identifiers
- allergist's signature and date
- unit of measurement for doses, no trailing zeros, leading zeros in place as necessary
- specific contents of the vials

policy that this therapy can only continue with proper documentation promotes safer practice. However, recognizing that the documentation is not complete takes a trained eye. Nurses can use a checklist to ensure proper documentation (Table 3).

Since the primary care setting is an environment with both licensed and unlicensed personnel, training should be designed to address the learning needs of all healthcare providers involved in the AI. Registered nurses may be in the best position to review the incoming documentation from allergists' offices to ensure that it is complete and meets national standards.

Unlicensed staff, who frequently administer the AI, should be given specific training. This group must fully understand the documentation on the medication record, how to interpret a dosing schedule, how to assess patient status both prior to and after receiving AI injections, how to deliver an AI injection, how to measure a local reaction, and how to recognize and react to systemic reactions. After the initial training, it may be helpful to have

annual refresher courses that incorporate new practice standards. Including documentation prompts and patient-screening prompts in the AI patient record may also aid in proper AI delivery.

A final step in reducing AI errors is vigilant monitoring of the practice. Periodic chart reviews not only promote proper charting practices but also provide a window into the daily delivery of service. The findings of this report are a result of a randomized chart review done for performance improvement purposes. Chart reviews provide insight into AI problems that are specific to each practice. When chart reviews are done, it is necessary for the reviewer to have a full understanding of the AI. Reviewers must be held to the same rigor of training as other staff associated with its delivery. In the event that overwhelming inadequacies in instructions, forms, and documentation threaten patient safety, a change in policy requiring patients to be seen in their allergist's office for continued therapy may be warranted.

The Johns Hopkins Community Physicians has had a long-standing policy that incorporates accepted safe standards for AI administration. Practice administrators made many attempts to solicit compliance with this policy

from the various allergists in the referring network but met with limited success. Therefore, the leadership of the Johns Hopkins Community Physicians, in the interest of patient safety, made the decision to phase out AI service at our primary care offices. Patients were referred back to allergists for immunotherapy.

CONCLUSION

As long as the AI continues to be delivered in the primary care setting, it will be vitally important for all the involved health-care providers to be familiar with the standards of practice that relate to this therapy. As this report demonstrates, it continues to be an area of high potential for medication error. Considering that it is often delivered by unlicensed staff, the responsibility for training and monitoring lies with nurses, administrators, and physicians. Taking proactive steps to prevent errors is necessary, and knowing what types of errors typically occur in allergists orders and documentation can help to target this pursuit. Considering the potential for serious reactions and even death associated with improper administration, these errors must be addressed and rectified to protect patient safety.

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