



Letter

Errors in allergen immunotherapy administration: A systems assessment

Allergen immunotherapy (AIT) is a widely implemented effective treatment for a myriad of atopic diseases ranging from hymenoptera venom allergy to allergic rhinitis and allergic asthma. Although the mechanisms of allergen immunotherapy have been extensively studied, the process of administration and potential for error has less clearly been reported in the literature.

The most comprehensive investigation of AIT administration errors was published by Aaronson and Gandhi in 2004¹ as a retrospective survey of practicing allergists' recognition of administration errors. The survey questionnaire focused on incorrect dosing and, to a lesser extent, administration to the wrong patient. Seventy-four percent of responders reported at least 1 incorrect-dose injection given to their patients over a 5-year span.¹ The conclusion of this report was that allergy injections pose a potential safety concern and a system-based safety problem based on the high percentage of allergists reporting incorrect injections.¹ Amin et al found that 25% of near fatal reactions to AIT were associated with dosing errors, highlighting the importance of error assessment.²

Medical errors often involve system errors in conjunction with human errors.³ With this in mind, we sought to identify common factors that contribute to AIT administration errors at our institution by combining a review of reported errors from 2009 to 2011 in conjunction with an in-depth analysis of AIT administration. Errors were defined as any AIT administration that deviated from the prescribed dosing schedule.

First, we mapped our process of AIT administration at our institution with the assistance of a quality systems expert (B.J.W.), by identifying all steps in the process, the steps in the process in which decision-making occurred, and the steps that involved documentation directly into the electronic medical record. We attempted to identify a baseline administration error rate based on AIT-administering nurse recall of administration errors of immunotherapy from January 1, 2009 to January 31, 2010. After January 2010, a reporting protocol was instituted in which AIT administration errors were immediately reported with a no-penalty standardized report form completed at the time of the event, which included details regarding the dose given, error type, and any circumstances thought to have contributed to the error. Initial review of reported errors reported in first 6 months of 2010 identified 5 errors out of 3,193 injections (1 in 638 or 0.2%).

We further sought to verify the validity of the reporting protocol by conducting an audit of AIT administered under the reporting protocol from January 1, 2011 to June 30, 2011. During this period a total of 3,277 AIT injections were given. Two errors were reported via the reporting protocol previously described. Immunotherapy records were reviewed independently by 2 investigators with

expertise in AIT, and a uniform consensus was reached regarding classification as an error. With this method, 2 additional errors were detected (in addition to the 2 previously detected errors). Thus, the reporting protocol alone revealed an error rate of 1 in 1,638 injections (0.06%), and additional patient record review found an error rate of 1 in 819 injections (0.1%).

The most frequent error types occurred in patients ($n = 5$) on an atypical dosing protocol, (defined as a buildup or maintenance schedule, which diverged from our standardized protocol), and in patients ($n = 4$) who required changes in immunotherapy bottles. In our practice, vials are 5 mL in total volume, and a new bottle is mixed every 6 to 10 months. Immunotherapy doses are initially not reduced for a new bottle (AIT extract composition identical to patient's previous bottle, including constituents, manufacturer, lot number, and concentration), are reduced to 50% of the scheduled dose for a new lot (AIT extract composition identical to patient's previous bottle, with the exception of new lot number by manufacturer), and are reduced to 25% of the scheduled dose for new company (AIT extract composition identical to the patient's previous bottle, with the exception of extract manufacturer). The errors did not include any wrong patient administrations or any adverse events for patients. Table 1 summarizes all errors identified.

The main limitation of this report is that AIT administration process maps may differ considerably in other practices. Although the national AIT guideline recommendations are followed in our practice, the interpretation and implementation of these guidelines may differ in other practices. A second limitation of this study is related to the infrequency with which administration errors occur;

Table 1
Summary of Errors Identified

Year	Age	Sex	Error type
2009	9	M	Change in immunotherapy bottle ^a
2009	45	F	Change in immunotherapy bottle
2010	29	F	Atypical dosing protocol (honeybee buildup different from vespid)
2010	45	F	Change in immunotherapy bottle
2010	34	M	Subsequent dose given prematurely
2010	6	F	Subsequent dose given prematurely
2010	9	M	Atypical dosing protocol (Outside provider extract & build schedule)
2010	55	F	Atypical dosing protocol (Vespid buildup different from honeybee in patient receiving both)
2011	28	M	Atypical dosing protocol (Cluster protocol, new nurse unfamiliar with protocol)
2011	46	F	Atypical dosing protocol (Outside provider extract and build schedule resulting in suboptimal maintenance dosing)
2011	55	F	Presenting late for venom immunotherapy different from aeroallergen
2011	32	F	Incorrect documentation of dose

^aPatient also on an atypical dosing protocol.

Disclosures: Authors have nothing to disclose.

Funding Sources: Funding provided by Mayo Foundation.

a higher-volume AIT practice may yield a larger number of errors, allowing for a more powerful analysis.

In conclusion, we found that AIT administration errors occur between 0.1 and 0.2% in our practice and that the rate depends on the reporting mechanism. We identified 2 common situations that increased error rates for AIT administration based on our analysis: atypical dosing protocols and bottle changes.

In attempts to eliminate the latter as a source of errors, we since have implemented a standard reduction in scheduled dose by (50%) for any new extract (new bottle or new lot), with the goal of reducing administration errors.

Sujan Patel, MD
Kari L. Rossow, PA-C
Brandon J. Williams, MHA, CSSBB

James T. Li, MD, PhD
Matthew A. Rank, MD
Mayo Clinic
Rochester, Minnesota
patel.sujan@mayo.edu

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