

The need for standardizing the aeroallergen immunotherapy missed-dose adjustment protocol

To the editor:

Our National Societies have published comprehensive standards for the provision of allergen immunotherapy (AIT) in primary care providers' offices and other health services facilities¹ and have excellent training material available for guiding the safe administration of AIT in remote facilities.^{2,3} However, there is no standard adjustment protocol for missed AIT doses.^{1,4} Even our parameters offer only an example protocol not based on retrospective or prospective studies.¹ This omission burdens nonspecialty health care facilities with a multitude of provider-specific instructions and harbors the potential for practitioner error and patient harm.⁴

Of the 16 missed-dose adjustment protocols used in the institution on which this study is based, 50% calculate the late interval from the last dose received, while the other half calculate from the missed scheduled dose. Forty-one percent of adjustments are based on volume (e.g., "reduce by 0.1 mL"), 35% are based on "steps" (e.g., "go back 2 doses"), and 24% require calculating the reduced dose (e.g., "reduce by 25%"). Sixty-nine percent of providers use a single adjustment protocol, and 31% require different adjustment protocols for build-up and maintenance-level therapies. Studies show the more complex or inconsistent a process, the more likely it is that errors will result.⁵

Distribution analysis of the dose adjustments for each missed-dose interval during the build-up and maintenance phases of the 16 studied protocols is shown in Fig. 1. For consistency, all protocols were adjusted to the interval beginning with the missed dose ("days late") and for "step changes." The immunotherapies involved were aqueous extracts from major suppliers dosed in accordance with standard guidelines.¹ Notably, neither dosing nor adjustments were associated with an inordinate number of significant reactions.

The allergy community is doing an excellent job of educating the general population and the primary care provider about allergic disease and the role of immunotherapy in its effective management. As a result, allergy shots given outside allergists' offices (e.g., edu-

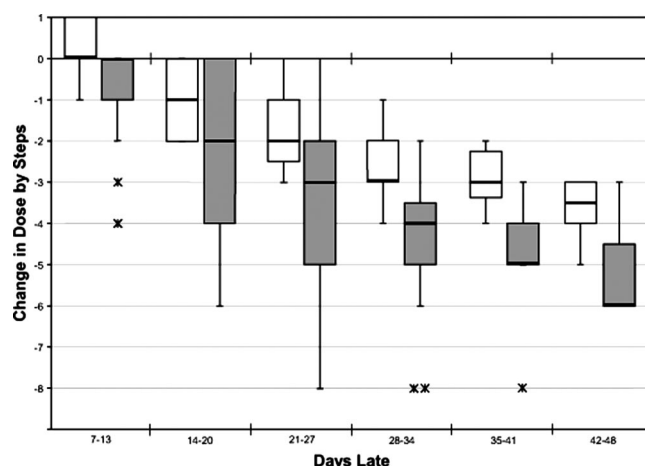


Figure 1. Dose adjustment variation for missed-dose intervals during build-up (unshaded) and maintenance (shaded) phase AIT of 16 adjustment protocols. +1 = advance dose, 0 = repeat last dose, -1 = number of doses to reduce. Boxes represent the 25th to 75th percentile (interquartile range [IQR]); whiskers represent the 5th to 95th percentile; horizontal bar represents the median (50th percentile); and the asterisk represents an outlier >1.5 IQR.

cational institutions, state and federal health facilities, and primary care providers' offices) are increasing. Efforts toward educating the allergist, the primary care provider, and the patient as to what constitutes safe practice in AIT are ongoing. A generic, standard missed-dose adjustment protocol for use by remote facilities being neither overly conservative so as to result in unnecessary shots that delay (re)attaining effective maintenance-level therapy, nor overly aggressive so as to compromise patient safety would further these patient safety efforts.

This pilot observational study suggests a simple protocol based on interval adjustments falling within the interquartile range reflecting the adjustments used by 50% of today's protocols would be safe and is possible. Establishing this process feasibility, a stepwise reduction (reduce 1 dose/week late) beginning at 3 weeks late for build-up and 1 week late for maintenance falls within the interquartile ranges of the 16 protocols studied.

A universal missed-dose adjustment protocol would reduce the potential for provider error and immunotherapy-associated patient harm in facilities providing

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AIT from multiple allergists. Distribution analysis of a specialty-wide adjustment protocol survey would facilitate the development of a statistically significant foundation for this needed standard.

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Availability of the combination of formoterol and budesonide in the United States of America

Dear Editor:

A recent comprehensive review entitled “Pharmacoeconomic review of medical management of persistent asthma”¹ published in the March–April 2008 issue of *Allergy and Asthma Proceedings* contained an inaccurate statement regarding the availability of the combination of formoterol and budesonide (Symbicort, AstraZeneca LP) in the US. Specifically, it stated “This last combination also has been approved by the US Food and Drug Administration and will be available on the market shortly.” We respectfully request that your readership be made aware that Symbicort (a combination of for-

moterol and budesonide) has been available as a pressurized metered-dose inhaler in the US since June 25, 2007.

REFERENCE

1. Cheng JWM, and Arnold RJG. Pharmacoeconomic review of medical management of persistent asthma. *Allergy Asthma Proc* 29:109–122, 2008.

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