Allergen immunotherapy found to pose no risk of infection

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A team of Massachusetts General Hospital (MGH) investigators has found no evidence of infections related to administration of allergy immunotherapy, the common practice of injecting minimal quantities of allergens beneath the skin to reduce the allergic response. Although there has never been a concern about the sterility of the preparations used in these "allergy shots," the organization that sets standards for the quality and safety of medications and other products has proposed revised guidelines that place allergen immunotherapy (AIT) in the same category as more risky preparations intended for intravenous or spinal administration.

"Our analysis of 10 years of data from large allergy practices at Massachusetts General Hospital and Brigham and Women's Hospital - covering approximately 135,000 individual injections administered to about 3,250 patients—finds no incidence of infection related to those injections," says Aidan Long, MD, clinical director of the Allergy and Clinical Immunology Unit in the MGH Division of Rheumatology, Allergy and Immunology and senior author of the report published online in the *Journal of Allergy and Clinical Immunology*. "This confirms that the sterile practices used in the preparation of allergy shots at our hospitals and at most clinical allergy practices do not pose an infectious risk for patients."

The report notes that the safety record of AIT goes back more than 100 years and that the practices used are different from those of pharmacy compounding, which has recently come under scrutiny because of a

meningitis outbreak tied to contaminated spinal injections prepared by a particular compounding center. That and other incidents may be behind the guideline changes proposed by the U.S. Pharmacopeia (USP), which would place allergen extracts in the same category as compounds prepared for injection into the circulatory system or the cerebrospinal fluid. The current study was prepared to provide data supporting the response to the proposed changes from several allergy and immunology specialty organizations.

In on-site pharmacies at MGH, Brigham and Women's Hospital (BWH) and other major hospitals, the allergen extracts used in AIT are individually prepared for each patient. Independent allergy practices may prepare them in their offices using the same sterile techniques used in hospitals, and existing USP standards placed allergen extracts in a separate category because their infectious risk was perceived to be extremely low.

"AIT is truly a disease-modifying treatment that diminishes the intensity, frequency and severity of symptoms, as well as reducing the need for medications. There are no equivalent therapies for allergic diseases—including seasonal allergies, asthma, and potentially life-threatening hypersensitivity to insect stings," says Long, who is an associate professor of Medicine at Harvard Medical School. "While there was no evidence in the literature to suggest that a problem existed, but we wanted to look at a larger data set to confirm the widely held belief in the lack of infectious problems related to AIT,"

The MGH-led study analyzed data from the Research Patient Data Registry of Partners Healthcare—a Boston-based system that includes MGH, BWH, several community hospitals and a network of more than 6,000 physicians—covering all AIT injections administered at two major allergy practices at the hospitals from 2005 through 2015. Using the electronic medical record, they were able to identify any patients

receiving AIT during those years who also were treated for an infection at any Partners-affiliated practice during the week after their injection. While there were 86 episodes of patients being treated for infection during that time—out of 3,242 patients - no soft-tissue infections were at the site of the injection, and no systemic infections could be attributed to AIT.

Long explains, "While it would be technically possible for hospital pharmacies to meet the proposed USP guidelines, doing so would require significantly more manpower, space and work. It is unlikely that any individual allergy practice not allied to a pharmacy would ever be able to meet the specifications, and given the current reimbursement rates, the additional costs would not be feasible for any active allergist inside or outside a hospital. The net effect would be the disappearance of subcutaneous allergen immuotherapy."

While the official commentary period for the proposed changes to USP guidelines—which are typically adopted by the U.S. Food and Drug Administration—have ended, Long has been informed that the agency is still holding discussions with the allergy community and accepting additional information. He and his colleagues plan to continue those discussions, including presentation of the data in this report.

More information: Diana S. Balekian et al. Allergen Immunotherapy: No Evidence of Infectious Risk, *Journal of Allergy and Clinical Immunology* (2016). DOI: 10.1016/j.jaci.2016.03.021

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