

Review of National Insurance Claims Gives Insight into the Use and Misuse of Allergen-Specific, In Vitro Diagnostic Tests

TO THE EDITOR:

In the diagnosis of human allergic disease, the two most popular classes of allergen-specific diagnostic tests are percutaneous testing, in the form of skin prick or skin puncture tests, and in vitro diagnostic (IVD) testing performed on blood (1, 2). The main allergen-specific IVD test is allergen-specific IgE.

Practice guidelines from the American Academy of Asthma, Allergy and Immunology, and the American Academy of Pediatrics discourage the use of IgG immunoassays (CPT 86001), IgE screening assays that do not identify specific allergens (CPT 86005), and broad, indiscriminate batteries of allergen-specific IgE (sIgE) tests. While sIgE testing (CPT 86003) can be clinically useful, these guidelines encourage the use of a targeted test selection strategy that incorporates a patient's clinical presentation, history, and pretest probabilities (3–5). Large sIgE

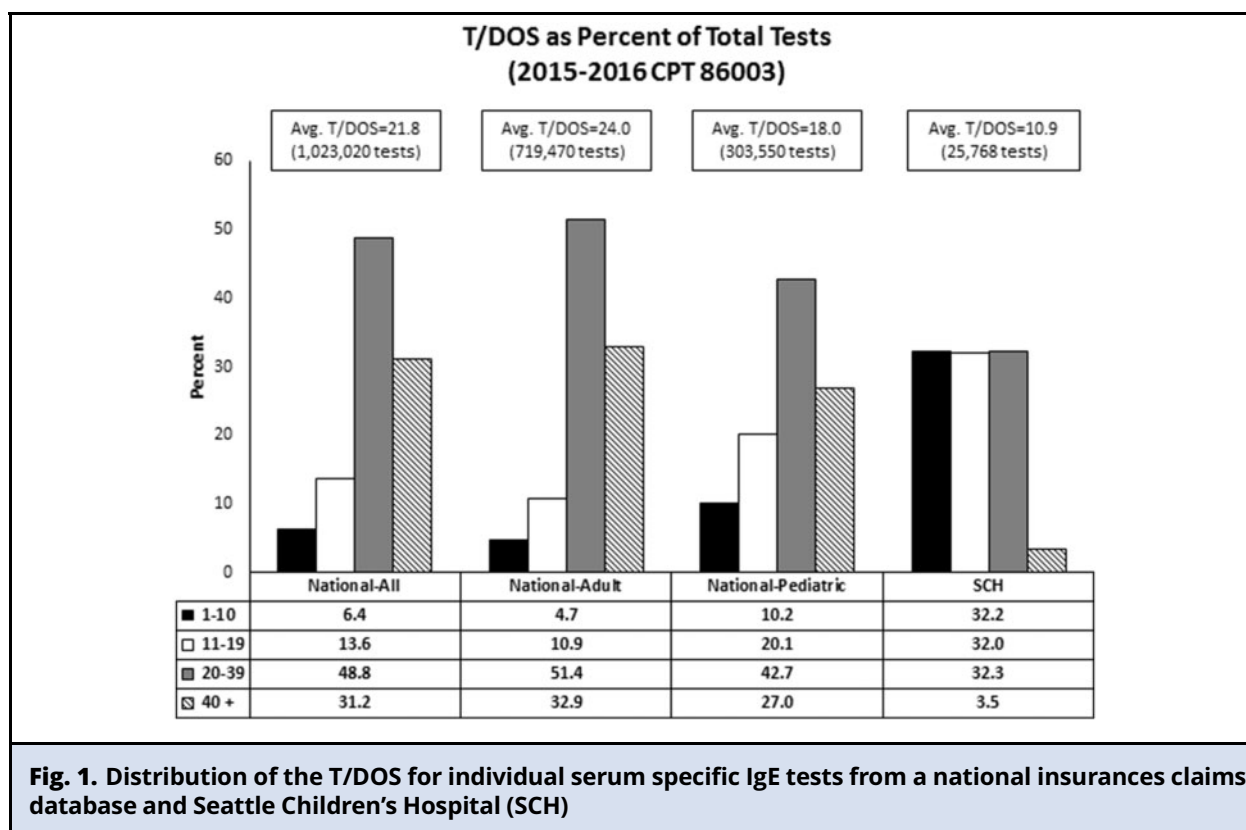
workups without a clear clinical indication for allergy generate false positive results that patients and providers may mistakenly interpret as evidence of clinically significant allergy adding undue anxiety, lifestyle/diet limitations, and cost for follow-up testing and treatments.

Using the metric of tests per date of service (T/DOS) we performed a cross-sectional analysis of claims for outpatient allergy testing from a national insurance claims database for the calendar years 2015 and 2016 using CPT codes 86001, 86003, and 86005. This dataset represents 5.25 million commercially insured patients in 11 states and includes testing from >500 clinical laboratories. Outpatient test results from a tertiary pediatric care center that provides reference lab services (SCH; Seattle Children's Hospital, Seattle, WA) were included for comparison. This study was approved by the Seattle Children's Institutional Review Board. To our knowledge, this is the first published report comparing the average size of allergy test workups between a national dataset and a laboratory focused on improving test utilization.

Our findings suggest that test misutilization and over utilization may be common. With a total of 96 086 IgG tests and

37.9 T/DOS in the national data set, the continued use of IgG testing suggests there is still some disregard for accepted clinical practice. While not as common, the 1633 IgE screening test claims (CPT 86005) in the national data set are still surprising. The distribution of T/DOS of sIgE tests are shown in Fig. 1. Of particular concern is that 80% of the workups from the national data set are for ≥ 20 T/DOS. This improves slightly to 70% when we consider only the pediatric patients. For comparison, workups from pediatric patients processed through the SCH laboratory improve this number by almost half (36%). We believe this difference is due to two primary factors: (a) the majority of SCH orders are placed by allergy specialists; and (b) the laboratory actively promotes laboratory stewardship by providing limited-order sets designed in consultation with allergy specialists. Combined, these data illustrate that there is likely wide variation in the size of workups nationally and that there are significant opportunities to improve allergy test utilization.

What is an appropriate size for the diagnostic workup? Current guidelines do not give an evidence-based threshold for each type of allergy workup. In general, it is considered



good practice to avoid large screening panels and favor a focused workup guided by the history and physical exam. For example, in food allergy the recommendation is no more than 14 allergens for the initial workup since eight allergens account for 95% of food allergy (2). A recent examination of ordering practices at SCH, showed that there were broad differences in ordering practices by specialty. For some specialties (allergy, gastroenterology, dermatology) small T/DOS reflected targeted diagnostic strategies, while others

(pediatrics, naturopaths, and generalists) did not (6). This may be true for the national dataset as well.

While it is difficult to speculate on the financial impact of over-testing, national payors continue to limit reimbursement by capping the number of allergen tests covered per date of service. The resulting unreimbursed claims add to the patient financial burden. In addition to the financial implications of over-testing for patients and third-party payers, unnecessary testing increases the number of false positive results and

additional follow-up as testing is expanded to incorporate allergens of low pretest probability.

We think it is reasonable for individual practices, health systems, and insurers to review current practice and implement rational policies and procedures designed to improve allergy test utilization. Key outcomes of these interventions would be to stop the ordering of sIgG testing and sIgE screening panels and reduce the indiscriminate ordering of sIgE tests. This will focus clinicians around the allergens that are

most likely, reduce financially wasteful and medically unnecessary testing, and improve patient care.

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Expression of Daratumumab and Elotuzumab Migration by Capillary Electrophoresis Relative to Transferrin Improves Precision of Their Identification

TO THE EDITOR:

The response to therapy in patients with multiple myeloma (MM) may be followed by observing the change in the concentration of the monoclonal protein (M-protein) produced by the neoplastic cells. Complete remission requires an absence of the M-protein in serum protein electrophoresis (SPEP), urine protein electrophoresis, and immunofixation (1). The widespread use of the US Food and Drug Administration-approved therapeutic IgGκ monoclonal antibodies (t-MAbs) daratumumab and elotuzumab for the treatment of patients with MM has complicated the clinical laboratory's role in following patients with an IgGκ M-protein because the detection of these t-MAbs on SPEP could be misinterpreted as residual disease in a patient who, in fact, had