

compared with females, and this pattern reverses after the onset of puberty. Omalizumab, an IgE antibody, is an effective treatment for allergic asthma, but sex-specific responses have not been studied in detail.

Methods: Post hoc analysis examined data from randomized, placebo-controlled IA05 trial of omalizumab treatment (52 weeks; 75–375 mg sc every 2–4 weeks; N=627; 6 to <12 years, ie children) and open-label, single-arm PROSPERO study (NCT01922037; 48-weeks; N=801; ≥12 years ie adolescents/adults (n=732 ≥18 years); both included patients with moderate-severe allergic asthma.

Results: In IA05/PROSPERO, baseline characteristics of mean age and IgE levels were similar for female and male participants (females 8.4/47.8 versus males 8.6/46.2 years; IgE levels females 463.2/560.3 versus males 472.8/615.0 IU/mL). Asthma exacerbation rates following omalizumab treatment were similar for females and males. In IA05 (children), asthma exacerbation rates were: females - placebo 0.74 versus omalizumab 0.46, males - placebo 0.55 versus omalizumab 0.43, and the interaction test of effect of sex on omalizumab response was not significant (p=0.4821). In PROSPERO (adolescents/adults), asthma exacerbation rates in females were 0.74 versus males 0.77 (p=0.787). Overall safety reported previously for IA05, Lanier JACI 2009;124:1210–6 and PROSPERO, Casale JACI:IP 2019;7(1):156–64.

Conclusions: Despite differences in asthma between females and males, we found no evidence that the effect of omalizumab in children was dependent on sex, and no evidence that the rate of exacerbations was dependent on sex following omalizumab initiation in adolescents/adults.

P092

IMPROVEMENTS IN SELECT PATIENT-REPORTED OUTCOMES ARE SIMILAR ACROSS DIFFERENT OMAUZUMAB DOSING REGIMENS

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Introduction: For patients with asthma, the dose/frequency of omalizumab is determined by bodyweight and pretreatment IgE levels. Since patients who fall outside the dosing table are treated with omalizumab, we assessed patient-reported outcomes (Asthma Control Test [ACT], Global Evaluation of Treatment Effectiveness [GETE], Work Productivity and Activity Impairment [WPAI-Asthma]) stratified by where they fell on the omalizumab dosing table.

Methods: This post hoc analysis examined data from the open-label, 48-week, PROSPERO study (NCT01922037; N=801, ≥12 years with asthma initiated on omalizumab by physician-assessment). For this analysis, subgroups are those who (i) fall within the recommended dosing table (n=506), (ii) fall into the section of the approved dosing table where not enough clinical data was available to make dose recommendations (defined as 'insufficient data to recommend a dose'; n=72), or (iii) fall outside the dosing table (not in (i) or (ii) and with IgE <30 or >700IU/mL and/or weighing <30 or >150kg; n=209).

Results: Patient characteristics were similar between groups, with the expected exception of total IgE. Improvement in ACT was similar for all groups (mean±SD CFB Month 12: (i) 4.3±5.3, (ii) 5.5±4.9, (iii) 4.5±4.9). At Month 12, GETE was rated by most patients as good/excellent ((i) 76.4% (ii) 82.1% (iii) 75.3%). Improvement in WPAI % activity impairment was similar for all groups (mean±SD CFB Month 12 (i) -20.4±33.0 (ii) -26.1±34.6 (iii) -20.1±30.6). Overall safety in Casale JACI:IP 2019;7(1):156–64.

Conclusions: Select patient-reported outcomes improved regardless of whether patients fell inside or outside the omalizumab dosing table for asthma.

P093

REDUCTIONS IN EXACERBATIONS OF SEVERE ASTHMA PATIENTS TREATED WITH BENRALIZUMAB – ZEPHYR 3

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Introduction: Eosinophilic asthma is the most common phenotype of severe asthma. This study aimed to evaluate the impact of benralizumab, which is approved for severe eosinophilic asthma, on asthma exacerbations.

Methods: Using claims and laboratory data from a large US health plan, this retrospective cohort study described the exacerbation rates of patients initiating benralizumab between 11/01/2017 and 07/31/2021. Patients =12 years old with an asthma diagnosis, =12 months of insurance enrollment pre- and post-initiation, =2 pre-initiation exacerbations, and =2 doses of benralizumab were included.

Results: 506 patients met the inclusion criteria. The patients were 69% female, had a mean (SD) age of 52 (14) years, and were seen primarily by allergists/immunologists (39%) and pulmonologists (34%). Of the 506 patients, 223 (44%) were persistent users (=6 doses) post-initiation; the mean (SD) number of doses was 5 (2.2). After initiating benralizumab, patients had a 62.5% reduction in the annual exacerbation rate (3.2 vs. 1.2, p<.001). Patients with pre-initiation blood eosinophil (bEOS) counts of <300 cells/μL showed similar reductions (53.1% [3.2 vs. 1.5], p <.001) as did patients with bEOS of=300 cells/μL (71.9% [3.2 vs. 0.9], p <.001). A similar decline in annual exacerbation rate was observed for bEOS <150 cells/μL (53.1% [3.2 vs. 1.5], p <.001 and bEOS =150 cells/μL (68.8% [3.2 vs. 1.0], p <.001).

Conclusion: Patients had significantly fewer asthma exacerbations overall and across blood eosinophil count thresholds after initiating benralizumab. These findings demonstrate that benralizumab is an effective add-on treatment option for patients with severe eosinophilic asthma.

P094

LIABILITY: A MISUNDERSTOOD BARRIER TO STOCK ALBUTEROL IMPLEMENTATION IN ILLINOIS SCHOOLS

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Introduction: Asthma in children is common and disproportionately impacts Black and Latinx children. School stock inhaler programs are a policy solution to improve reliever access for children with respiratory symptoms. Legislation and implementation are lacking, in part, because of liability concerns.

Methods: We conducted a legal analysis of Illinois Public Act 100-0726 (PA) or "Stock Asthma Rescue Medication in Schools" to assess liability concerns. Qualitative interviews of key stakeholders in stock albuterol/relievers were conducted.

Results: PA 100-0726 allows schools to stock and administer undesignated asthma relievers, namely albuterol, in the event of respiratory distress. Public Act 100-0726 states that if stock albuterol is administered "in good faith" that there would be "no liability, except for willful and wanton conduct", and the schools, districts, employees, agents, prescribers "are to incur no liability or professional discipline, except for willful and wanton conduct, as a result of any injury arising from the use of . . . undesignated asthma medication." A recent systematic review of liability verbiage of stock inhaler laws demonstrate that IL's wording is strong, making liability an extremely unlikely occurrence. Nevertheless, in seven of twenty (35%) key stakeholder interviews (i.e., nurses, clinicians, administrators, etc.), difficulty obtaining prescriptions for stock inhalers was cited as an implementation barrier (Table 1). Liability concerns were one reason for the inability to secure prescriptions.

Conclusion: Stock inhaler laws improve access to asthma medications in schools for children with respiratory distress. In Illinois, liability concerns are overestimated. This problem could be addressed through additional regulation and education of providers and their insurers.

Table 1: Presence and Absence of “Provider Refused to Prescribe Medication” Code in Qualitatively Coded Stock Albuterol Stakeholder Interviews

Interview	Presence of “Provider Refused to Prescribe Medication” Code
State Advocacy Group 1	No
National Advocacy Group 1	Yes
State Government Organization 1	Yes
Health Department 1	No
State Advocacy Group 2	No
National Advocacy Group 2	No
Urban School District 1	Yes
State Advocacy Group 3	Yes
State Advocacy Group 4	Yes
Suburban School District 1	No
Suburban School District 2	No
Urban School District 2	No
Suburban School District 3	No
Suburban School District 4	Yes
Rural School District 1	No
Urban School District 3	No
Rural School District 2	No
Suburban School District 5	Yes
Pharmaceutical Company 1	No
Suburban School District 1 (Second Interview)	No

P095

USING AREA DEPRIVATION INDEX TO ASSESS RACIAL DISPARITIES IN ASTHMA AMONG CHILDREN WITH FOOD ALLERGY

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Introduction: Previous studies have shown significant racial disparities in food allergy (FA) phenotype and outcomes. Our study sought to understand if higher rates of asthma in African American (AA) children with FA were driven by differences in individual and community-level socioeconomic status (SES), regardless of race.

Methods: We analyzed data from FORWARD, which is a prospective, multicenter cohort study investigating the natural history of pediatric atopy. A validated, multi-component area deprivation index (ADI) was used to estimate patient exposure to low SES at the local census block group level. Higher ADI is associated with greater socioeconomic disadvantage.

Results: Of the 700 children in this study, 51% were non-Hispanic White, 37% AA, and 12% Hispanic. The mean ADI across the analytic sample was 37.7 (95% CI: 35.6–39.7). The highest mean ADI (51.5) was seen among AA patients when compared to non-Hispanic White (mean ADI of 24.2) and Hispanic (mean ADI of 41) patients ($p < .0001$). The mean ADI was 43.3 in children with asthma as opposed to 31.8 in those without asthma ($p < .0001$). Asthma was more common among AA children [OR=2.76 (95% CI: 1.77–4.29)] after adjusting for household income, respondent educational attainment, child gender, and recruitment site.

Conclusion: Our data shows that higher ADI is independently associated with higher odds of asthma among children with FA. These findings demonstrate the role of socioeconomic deprivation in the development of asthma among children with FA. This is especially important considering the obstacles associated with socioeconomic deprivation that hinder appropriate management of asthma.

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SHORT-ACTING BETA2-AGONIST USE REDUCTION AMONG PATIENTS WITH UNCONTROLLED ASTHMA USING A RELIEVER DIGITAL SYSTEM

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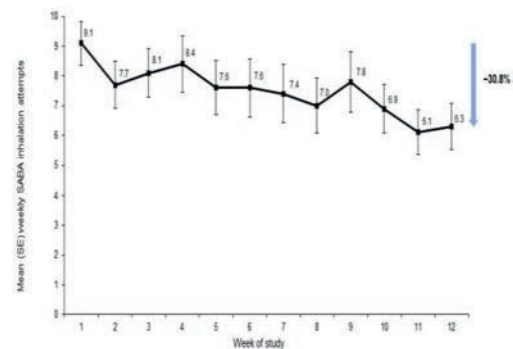
Introduction: Frequent use of short-acting beta₂-agonist (SABA) indicates poor asthma control. Participants in CONNECT1 (NCT03890666) used the Reliever Digital System (RDS), which consists of an albuterol Digihaler that transmits data wirelessly to a mobile application and synchronizes with a web-based Dashboard. This exploratory analysis evaluated SABA use among participants with uncontrolled asthma using the RDS.

Methods: In this 12-week study, 333 eligible participants (≥ 13 years old with suboptimal asthma control [Asthma Control Test (ACT) score < 19]) were randomized to the RDS (N=167) or SoC (N=166). Exploratory outcomes included mean weekly SABA usage and mean weekly number of SABA-free days during the 12-week study period, as well as the number of participant-healthcare professional interactions (office visits/phone calls) that were due to increased SABA use, as identified from the Dashboard in the RDS group.

Results: In participants using the RDS (n=135), the weekly average daily SABA inhalations decreased (from 9.1 at Week 1 to 6.3 at Week 12) and the weekly average SABA-free days increased (from 3.4 at Week 1 to 4.6 at Week 12) over the 12-week study period (Figure). Furthermore, out of the 85 interactions in the RDS group, 32 (37.6%) were due to increased SABA use.

Conclusion: SABA use decreased over 12 weeks among participants using the RDS. The SABA use data recorded by the RDS may provide clinically meaningful information to facilitate physician-patient discussions and guide interventions to improve asthma control and reduce reliever need.

Figure. Mean weekly SABA use over the 12 study weeks in the RDS group



RDS, Reliever Digital System; SABA, short-acting beta₂-agonist; SE, standard error

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EFFECTIVENESS OF A MAINTENANCE AND RELIEVER DIGITAL SYSTEM TO IMPROVE ASTHMA CONTROL

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Introduction: In the Maintenance and Reliever Digital System (MRDS), Digihaler integrated inhalers (fluticasone propionate/salmeterol and albuterol Digihalers) transmit data wirelessly to a mobile application, which synchronizes with a Digital Health Platform to store and transfer data to a web-based Dashboard. This allows patients and clinicians to track and