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Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109
Submitted electronically to publiccomments@icer-review.org

To Whom It May Concern:

The Asthma and Allergy Foundation of America (AAFA) applauds the Institute for Clinical and Economic Review (ICER) for its decision to ask patients with asthma about their experience with the disease to inform its newest report. As ICER notes in its Patient Guide to Open Input, assessing patient experience is imperative to creating a report that supports the policies and guidelines that are meaningful to patients with asthma. As the leading patient organization for people with asthma and allergies and the oldest asthma and allergy patient group in the world, AAFA appreciates the opportunity to provide ICER with insight into the experiences of patients with asthma.

In 2017, AAFA published “My Life With Asthma,”¹ a national, three-part study about asthma in the United States. AAFA surveyed several populations including caregivers of adults with asthma and healthcare professionals who care for adults with asthma. Perhaps most relevant to ICER’s request for comment are the 804 U.S. adult patients living with asthma who AAFA surveyed for this study. These survey responses have deepened AAFA’s understanding of the burden of asthma – especially severe asthma – on patients, caregivers, and healthcare professionals. These data are important for ICER to consider as it begins drafting a new report. We have summarized the survey’s key findings below. For further information, please see the full report attached to this letter.

Disease Experience

AAFA’s survey included a total of 804 adult respondents living with asthma. Of these, 185 had “severe uncontrolled” asthma. These respondents reported experiencing symptoms of asthma such as chest tightness, cough, shortness of breath, or wheezing more than two times per week; waking up during the night because of coughing or other asthma symptoms more than once per week; using a rescue or “quick-relief” inhaler more than two times per week; or having at least two asthma attacks that required them to take a steroid pill by mouth in the past 12 months. In addition, these 185 respondents reported either that a doctor or nurse had told them they had severe asthma, and that they had used a combination inhaler, an anti-IgE biologic agent, or an anti-IL-5 biologic agent in the past 12 months for their asthma. Another 619 respondents had asthma that was defined as “not severe uncontrolled.”

¹ Asthma and Allergy Foundation of America, “My Life With Asthma: Survey Overview (2017).
www.aafa.org/media/my-life-with-asthma-in-2017-survey-findings-report.pdf.



Among those with severe uncontrolled asthma, more than half of respondents reported that they experienced asthma symptoms more than once a day.² Other respondents with asthma reported less frequent asthma symptoms; however, more than a quarter reported asthma symptoms more than two times per week, and nearly one in ten reported daily asthma symptoms.³

Respondents with severe uncontrolled asthma frequently end up in the emergency room. Eighteen percent reported one visit to the ER in the past 12 months, and an additional 42 percent reported two or more ER visits over the same time period.⁴ Meanwhile, 28 percent of other respondents with asthma reported at least one ER visit in the past 12 months.⁵

Day-to-Day Life

The majority of those with severe uncontrolled asthma said they were scared and burdened by their condition.⁶ More than two-thirds said it prevents them from living the life they want to live and more than three quarters said their asthma is always in the back of their mind.⁷ Close to half (44 percent) felt like asthma ruins their life.⁸

Other respondents with asthma were less likely to report similar day-to-day impacts of asthma on their lives, but there were still significant portions of respondents who were scared by their asthma and burdened by their asthma, as well as prevented from living the life they want to live.⁹

Impact on Family and Caregivers

Sixty percent of those with severe uncontrolled asthma and 31 percent of other respondents with asthma reported that their conditions scare their loved ones.¹⁰ Almost half of respondents with severe uncontrolled asthma reported their condition was a burden to their family.¹¹

These responses mirror those reported by caregivers of adults with asthma. Our survey included 109 US adult caregivers of adults diagnosed with asthma, 26 of whom cared for someone with

² Asthma and Allergy Foundation of America, “My Life With Asthma: Survey Overview (2017). 5. www.aafa.org/media/my-life-with-asthma-in-2017-survey-findings-report.pdf.

³ *Ibid*

⁴ Asthma and Allergy Foundation of America, “My Life With Asthma: Survey Overview (2017). 6. www.aafa.org/media/my-life-with-asthma-in-2017-survey-findings-report.pdf.

⁵ *Ibid*

⁶ Asthma and Allergy Foundation of America, “My Life With Asthma: Survey Overview (2017). 7. www.aafa.org/media/my-life-with-asthma-in-2017-survey-findings-report.pdf.

⁷ *Ibid*

⁸ *Ibid*

⁹ *Ibid*

¹⁰ *Ibid*

¹¹ *Ibid*



severe asthma.¹² Seventy-seven percent of caregivers for those with severe asthma reported being scared by their charge's condition, as were 29 percent of the caregivers who care for someone whose asthma was not severe.¹³ Nearly one in three caregivers of those with severe asthma reported feeling burdened by their charge's condition.¹⁴

The majority of respondents with asthma reported that it affects their relationships with their families followed by relationships with spouses/significant others, friends, and colleagues/co-workers. Only 17 percent of respondents with severe uncontrolled asthma and 38 percent of other respondents with asthma that reported their condition had no effect on their personal relationships.¹⁵

Impact on Ability to Work, Exercise, Care for Family

Respondents with severe uncontrolled asthma were much more limited in their daily activities than others with asthma. Forty percent of respondents in the former category reported extreme limitations on their activities, compared to respondents in the latter category who were most likely to report minor limitations (39 percent).¹⁶ Nearly three quarters of respondents with severe uncontrolled asthma and half of other respondents with asthma missed at least one day of work in the past 12 months, but severe uncontrolled asthma was much more likely to cause extended absences from work (41 percent missed over 10 days of work) than other asthma (only 9 percent missed over 10 days of work).¹⁷ When at work or school, a majority of respondents in both categories reported at least one day in the past 12 months when tasks were difficult to perform because of asthma, though severe uncontrolled asthma was more highly associated with difficulty performing tasks.¹⁸

Thoughts on Treatments

Respondents with severe uncontrolled asthma were generally less satisfied with current asthma medicines than those with not severe uncontrolled asthma. More than one in three in the former category reported being somewhat or very unsatisfied compared to only 14 percent of the latter.¹⁹

¹² Asthma and Allergy Foundation of America, "My Life With Asthma: Survey Overview (2017). 16. www.aafa.org/media/my-life-with-asthma-in-2017-survey-findings-report.pdf.

¹³ Asthma and Allergy Foundation of America, "My Life With Asthma: Survey Overview (2017). 17. www.aafa.org/media/my-life-with-asthma-in-2017-survey-findings-report.pdf.

¹⁴ *Ibid*

¹⁵ Asthma and Allergy Foundation of America, "My Life With Asthma: Survey Overview (2017). 10. www.aafa.org/media/my-life-with-asthma-in-2017-survey-findings-report.pdf.

¹⁶ Asthma and Allergy Foundation of America, "My Life With Asthma: Survey Overview (2017). 12. www.aafa.org/media/my-life-with-asthma-in-2017-survey-findings-report.pdf.

¹⁷ Asthma and Allergy Foundation of America, "My Life With Asthma: Survey Overview (2017). 13. www.aafa.org/media/my-life-with-asthma-in-2017-survey-findings-report.pdf.

¹⁸ *Ibid*

¹⁹ *Ibid*



When choosing asthma treatment options, both types of respondents said effectiveness and cost were the two most important factors.²⁰

Compliance with asthma treatment was similar across both groups: around one in four respondents always used their asthma treatments as prescribed by their doctor or nurse.²¹ Each of the top three reported reasons for not using asthma treatments dealt with cost. The most common reason among both groups was that respondents could not afford treatment, followed by the treatment being too expensive and lack of insurance coverage for the treatment.²² Respondents with severe uncontrolled asthma were more likely to report that their asthma treatments were not covered by their insurance plan compared to other respondents with asthma.²³

The theme of cost as a major barrier is consistent with responses from healthcare providers. Of the 215 healthcare providers surveyed (these included physicians, physician assistants, nurses, nurse practitioners, and respiratory therapists with primary specialties in allergy/immunology, pulmonology, primary care, family medicine, and internal medicine),²⁴ 74 percent said cost and coverage of treatment was the biggest barrier to controlling moderate-to-severe asthma in adult patients.²⁵

Compliance was impacted by effectiveness (or lack thereof) among respondents with severe uncontrolled asthma; for other respondents with asthma, side effects of treatments were a major concern.²⁶

While respondents with severe uncontrolled asthma were more knowledgeable about biologic drugs for asthma, few respondents overall reported significant knowledge of these new treatments.²⁷ Biologic treatment can be life changing and greatly improve quality of life for patients with asthma,²⁸ but are out of reach for many due to cost. AAFA receives requests every day for financial assistance to help cover treatment because many patients fall into the gaps between insurance and patient assistance.

²⁰ Asthma and Allergy Foundation of America, "My Life With Asthma: Survey Overview (2017). 14. www.aafa.org/media/my-life-with-asthma-in-2017-survey-findings-report.pdf.

²¹ *Ibid*

²² *Ibid*

²³ *Ibid*

²⁴ Asthma and Allergy Foundation of America, "My Life With Asthma: Survey Overview (2017). 21. www.aafa.org/media/my-life-with-asthma-in-2017-survey-findings-report.pdf.

²⁵ Asthma and Allergy Foundation of America, "My Life With Asthma: Survey Overview (2017). 29. www.aafa.org/media/my-life-with-asthma-in-2017-survey-findings-report.pdf.

²⁶ Asthma and Allergy Foundation of America, "My Life With Asthma: Survey Overview (2017). 14. www.aafa.org/media/my-life-with-asthma-in-2017-survey-findings-report.pdf.

²⁷ Asthma and Allergy Foundation of America, "My Life With Asthma: Survey Overview (2017). 15. www.aafa.org/media/my-life-with-asthma-in-2017-survey-findings-report.pdf.

²⁸ McCracken, Jennifer, Julia Tripple, and William J. Calhoun. "Biologic therapy in the management of asthma." *Current opinion in allergy and clinical immunology* 16, no. 4 (2016): 375.



Other Relevant Publications on Patient Experience

While not unpublished, AAFA would like to point towards several studies regarding the experiences of individuals with asthma. One comprehensive review of the literature found that patients with asthma prefer treatments that increase days without symptoms, but would be willing to sacrifice some treatment outcomes (specifically, the number of days without symptoms) for higher convenience and fewer side effects.²⁹ Many studies continue to show low adherence to inhaler based-asthma management and significant barriers to proper adherence.^{30,31,32} Other studies highlight that other factors, such as Body Mass Index (BMI), age, mental health status, and time since diagnosis can impact patients' ability to manage their asthma and adhere to appropriate therapies.^{33,34} Additionally, research shows that there is underuse of asthma medication among racial and ethnic minorities in the United States, due in part to issues such as cost and whether or not they are insured; one study of adults aged 50-64 found that African American adults were significantly more likely to have uncontrolled asthma than Whites, and that adults in the age cohort with cost limitations were significantly more likely to have limitations of activity.^{35,36}

Previous research shows that optimal asthma control remains elusive for many living with this condition. Biologic therapies have the potential to produce better outcomes for patients who suffer from moderate-to-severe asthma. AAFA has received testimonials from several patients who have used a biologic, describing the impact it has had on their lives. They have used words like “revolutionary” and “miraculous.” Quality of life has been greatly improved, as evidenced by stories of being able to “walk, dance, sing”, or being able to “visit friends with cats.” These personal accounts remind us of what is important to our patients, and what kind of outcomes they are hoping for.

²⁹ Bereza, Basil G., et al. "Patient preferences in severe COPD and asthma: a comprehensive literature review." *International journal of chronic obstructive pulmonary disease* 10 (2015): 739.

³⁰ Price, D., Harrow, B., Small, M., Pike, J. and Higgins, V., 2015. Establishing the relationship of inhaler satisfaction, treatment adherence, and patient outcomes: a prospective, real-world, cross-sectional survey of US adult asthma patients and physicians. *World Allergy Organization Journal*, 8(1), p.1.

³¹ Braido, F., Chrystyn, H., Baiardini, I., Bosnic-Anticevich, S., van der Molen, T., Dandurand, R.J., Chisholm, A., Carter, V. and Price, D., 2016. “Trying, but failing”—the role of inhaler technique and mode of delivery in respiratory medication adherence. *The Journal of Allergy and Clinical Immunology: In Practice*, 4(5), pp.823-832.

³² Jahedi, L., Downie, S.R., Saini, B., Chan, H.K. and Bosnic-Anticevich, S., 2017. Inhaler Technique in Asthma: How Does It Relate to Patients' Preferences and Attitudes Toward Their Inhalers?. *Journal of aerosol medicine and pulmonary drug delivery*, 30(1), pp.42-52.

³³ Loerbroks, Adrian, et al. "Determinants of patients' needs in asthma treatment: a cross-sectional study." *NPJ primary care respiratory medicine* 26 (2016): 16044.

³⁴ Scott, Lyne, et al. "Factors affecting ability to achieve asthma control in adult patients with moderate to severe persistent asthma." *Journal of Asthma* 53.6 (2016): 644-649.

³⁵ McQuaid, E.L., 2018. Barriers to medication adherence in asthma: the importance of culture and context. *Annals of Allergy, Asthma & Immunology*.

³⁶ Urbstonaitis, R., Deshpande, M. and Arnoldi, J., 2018. Asthma and health related quality of life in late midlife adults. *Research in Social and Administrative Pharmacy*.



AAFA also supports the use of biologics because they are more targeted to different “types” of asthma than previous classes. Xolair (omalizumab), Nucala (mepolizumab), Dupixent (dupilumab), Cinqair (reslizumab), and Fasentra (benralizumab) have different indications and provide options for patients based on their specific kind of asthma. These treatments may also be an attractive alternative to frequent use of oral corticosteroids for patients with frequent exacerbations. As one patient writes, “I cannot be on prednisone much longer, it is making me miserable.” Biologics may offer fewer side effects.

However, these medicines can be very expensive and AAFA also hears from patients expressing their difficulty and frustration with the high cost of biologic treatment. One patient writes “It was difficult to get my insurance to cover the Xolair. I’m concerned if I stop the Xolair but then need to restart it that my insurance will give me problems again. I have not been well enough to get my allergy shots.” Another writes, “The Xolair did not lower my eosinophils but the Nucala helped until my funding program ran out so I had to stop it.” Despite the promise of biologics, if they are cost-prohibitive for the majority of the population, their overall impact will be minimal. Cost is also one of the major factors correlated to poor medication adherence; if patients cannot consistently afford their treatments, they will not be able to consistently use them. In addition to cost, access to treatment may also be affected by the availability of reliable transportation to get to the medical office. If only specific demographics have access to biologics, asthma disparities may potentially broaden for some like those of low socioeconomic status, or older adults. While AAFA supports biologics as a promising class of drugs to improve asthma outcomes, we urge ICER to consider cost structure and issues of affordability.

Conclusion

AAFA will continue to report on and advocate for people with asthma and allergies. We are eager to continue to provide input to ICER to ensure that the needs and preferences of patients with asthma are appropriately taken into consideration within any larger push for policy development and/or change.

Thank you for providing us with the opportunity to share our experiences as well as the experiences of those for whom we represent. Should you have any questions, please contact me at 202-974-1231 or kmendez@aafa.org.

Sincerely,

Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America