

# PROs

Patient Reported Outcomes

# Assessing and Measuring the Patient Experience of Severe, Uncontrolled Asthma

PROs can measure patient symptoms and health-related quality of life to support clinical studies and help guide clinical decision-making<sup>1-5</sup>

PROs are often different than physician measured outcomes; understanding where these differences lie can help physicians better communicate with their patients<sup>1</sup>

PROs are increasingly recognized as important measures of disease by regulatory bodies<sup>6,7</sup>

In recent surveys of patients with asthma, patients reported experiencing frequent symptoms that affect their daily lives<sup>8-11</sup>

## Select PRO Measures

	Duration Measured	What Is Measured	Scoring	Clinical Use	MCID	Limitations
ACQ-6 <sup>12-15</sup>	Previous 1 week	Degree of asthma control that occurs with or without need for treatment (7 items)	Rated from 0 (no impairment) to 6 (maximum impairment for symptoms and rescue medication use)	Evaluates asthma control including nocturnal waking. Thresholds for control $\leq 0.75$ and uncontrolled $> 1.5$	0.5 points	Not designed to differentiate between daytime and night time asthma control and may be influenced by type of administration (self-administered vs interviewer administered)
AQLQ(S)+12 <sup>16-18</sup>	Previous 2 weeks	Quality of life, including symptoms, activity limitations, emotional function, and environmental stimuli (32 items)	Rated from 7 (not impaired at all) to 1 (severely impaired)	Measures patient quality of life change over past 2 week interval	0.5 points	May be influenced by type of administration (paper vs electronic)
ASD <sup>19,20</sup>	Mean daily score; past 7-day average	Symptoms (10 items: 5 daytime and 5 night time)	Items scored from "0" (no symptom, no nighttime awakening, or no activity limitation) to "4" (very severe symptom, unable to sleep, or extreme activity limitation)	Captures patient experience with asthma in real time	0.5–0.6 points on mean 7-day scores. Reduction of 2 to 3 ASD-based symptomatic days	Reliance on patient compliance with twice daily recording of entries in diary
SGRQ <sup>21-23</sup>	Previous 1, 3, or 12 months	Quality of life; includes 3 domains: symptoms, activity limitations, and impact on quality of life (50 items)	Scores from 0 to 100, with higher scores indicating more limitations	Measures impact on overall health, daily life, and perceived well-being	4 units	Less well validated in severe asthma
EQ-5D-5L <sup>24-27</sup>	Current day	Index has 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression and 5 levels: no, slight, moderate, severe, and extreme problems; additional VAS rates health on a scale of "best health you can imagine" to "worst health you can imagine"	For index, 5-digit number for all dimensions converted to a number from 1 (best health) to a negative number (worse than death health state), with 0 equal to death; VAS scored 0 to 100, with lower numbers indicating worse health	Measures patient's current health state	0.037–0.069	Limited sensitivity to small changes in asthma control



Efforts to use PRO measures in patient care—to track patient-specific outcomes and to assess the quality of patient-centered outcomes—are in need of broader validation and acceptance.<sup>28</sup> PROs should be considered an important component of assessing a patient's experience with asthma.

ACQ, Asthma Control Questionnaire; AQLQ(S)+12, Standardized Asthma Quality of Life Questionnaire for 12 Years and Older; ASD, Asthma Symptom Diary; EQ-5D-5L, European Quality Of Life 5 dimensions 5 levels; MCID, minimum clinically important difference; PRO, patient reported outcomes; SGRQ, St. George's Respiratory Questionnaire; VAS, visual analog scale.

1. Stahl E. *Respir Med.* 2000;94:735-741.
2. Davis SQ, et al. *Ann Allergy Asthma Immunol.* 2009;102:455-461.
3. Shen Q, et al. *J Allergy Clin Immunol Pract.* 2021;9:400-409.e1.
4. Corren J, et al. *Ann Allergy Asthma Immunol.* 2021;126:187-193.
5. Teeter JG, Bleecker ER. *Chest.* 1998;113:272-277.
6. United States Department of Health and Human Services, Food and Drug Administration. December 2009. [www.fda.gov/media/77832/download](https://www.fda.gov/media/77832/download) (Accessed 11 July 2024).
7. European Medicines Agency, Patient Experience Data in EU Medicines Development and Regulatory Decision-Making. 17 October 2022. [https://www.ema.europa.eu/en/documents/other/executive-summary-patient-experience-data-eu-medicines-development-and-regulatory-decision-making-workshop\\_en.pdf](https://www.ema.europa.eu/en/documents/other/executive-summary-patient-experience-data-eu-medicines-development-and-regulatory-decision-making-workshop_en.pdf) (Accessed 11 July 2024).
8. Ambrose CS, et al. *Pragmat Obs Res.* 2020;11:77-90.
9. Katsaounou P, et al. *ERJ Open Res.* 2018;4:00076-2018.
10. Kritikos V, et al. *NPJ Prim Care Respir Med.* 2019;29:43.
11. Price D, et al. *NPJ Prim Care Respir Med.* 2014;24:14009.
12. American Thoracic Society. [www.thoracic.org/members/assemblies/assemblies/srn/questionnaires/acq.php](http://www.thoracic.org/members/assemblies/assemblies/srn/questionnaires/acq.php) (Accessed 11 July 2024).
13. Honkoop PJ, et al. *Prim Care Respir J.* 2013;22:284-289.
14. Juniper EF, et al. *Respir Med.* 2005;99:553-558.
15. Juniper EF, et al. *Respir Med.* 2006;100:616-621.
16. Juniper EF, et al. *Respir Med.* 2009;103:932-934.
17. Juniper EF, et al. *Health Qual Life Outcomes.* 2005;3:58.
18. Wyrwich KW, et al. *Respir Med.* 2011;105:698-712.
19. Globe G, et al. *J Allergy Clin Immunol Pract.* 2016;4:60-6.e4.
20. Globe G, et al. *J Patient Rep Outcomes.* 2019;3:22.
21. American Thoracic Society. [www.thoracic.org/members/assemblies/assemblies/srn/questionnaires/sgrq.php](http://www.thoracic.org/members/assemblies/assemblies/srn/questionnaires/sgrq.php) (Accessed 11 July 2024).
22. Jones PW. *Eur Respir J.* 2002;19:398-404.
23. Nelsen LM, et al. *Respir Med.* 2017;126:32-38.
24. EQ-5D-5L User Guide 2019. September 2019. <https://euroqol.org/publications/user-guides/> (Accessed 11 July 2024).
25. Hernandez G, et al. *PLoS ONE.* 2018;13:e0202624.
26. McClure NS, et al. *Value Health.* 2017;20:644-650.
27. Szentes BL, et al. *BMC Pulm Med.* 2020;20:168.
28. Herman E, et al. *J Allergy Clin Immunol Pract.* 2019;7:1771-1777.