

Standardized outcome measures proposed for asthma clinical research

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A consortium of federal agencies and nongovernmental organizations has published a report proposing a set of common measures and datacollection methods for use in asthma clinical research. Asthma Outcomes in Clinical Research: Report of the Asthma Outcomes Workshop, which appears as a supplement to the March 2012 issue of the *Journal of Allergy and Clinical Immunology*, resulted from a meeting organized by the National Institutes of Health, the Agency for Healthcare Research and Quality and the Merck Childhood Asthma Network, Inc., with additional support for the publication from the U.S. Environmental Protection Agency. NIH contributors were the National Institute of Allergy and Infectious Diseases; the National Heart, Lung, and Blood Institute; the Eunice Kennedy Shriver National Institute of Child Health and Human Development; and the National Institute of Environmental Health Sciences.

NIH-funded research has led to many improvements in the management and treatment of asthma, a chronic lung condition that affects more than 25 million people in the United States. However, asthma clinical research has lacked a common set of outcomes, measures used by researchers to assess a disease during the course of a study. This lack of standardization has made it difficult to compare results between individual studies and to share data across studies, thus hindering the progress of asthma research.

The report identifies standard definitions and methodologies for measuring seven groups of outcomes that are important in asthma



clinical studies: symptoms, exacerbations (asthma attacks), biomarkers (biological substances that indicate disease state), lung function, quality of life, <u>asthma control</u> questionnaire results, and health care utilization and costs. By using the same set of outcome measures in asthma clinical studies, researchers will be able compare their results more efficiently. This proposed standardization across asthma studies promises to enhance the development of prevention and treatment strategies and lead to improvements in the quality of asthma care.

Based on the recommendations of the report, NIH and other federal agencies will require the inclusion of the proposed outcomes in future government-funded asthma clinical research.

Provided by National Institutes of Health

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