# Harmonized outcome measures for use in asthma patient registries and clinical practice



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**Background: Asthma, a common chronic airway disorder, affects an estimated 25 million persons in the United States and 330 million persons worldwide. Although many asthma patient registries exist, the ability to link and compare data across registries is hindered by a lack of harmonization in the outcome measures collected by each registry.**

**Objectives: The purpose of this project was to develop a minimum set of patient- and provider-relevant standardized outcome measures that could be collected in asthma patient registries and clinical practice.**

**Methods: Asthma registries were identified through multiple sources and invited to join the workgroup and submit outcome measures. Additional measures were identified through literature searches and reviews of quality measures and consensus statements. Outcome measures were categorized by using the Agency for Healthcare Research and Quality's supported Outcome Measures Framework. A minimum set of broadly relevant measures was identified. Measure definitions were harmonized through in-person and virtual meetings.**

**Results: Forty-six outcome measures, including those identified from 13 registries, were curated and harmonized into a minimum set of 21 measures in the Outcome Measures Framework categories of survival, clinical response, events of interest, patient-reported outcomes, resource utilization, and experience of care. The harmonized definitions build on existing consensus statements and are appropriate for adult and pediatric patients.**

**Conclusions: The harmonized measures represent a minimum set of outcomes that are relevant in asthma research and clinical practice. Routine and consistent collection of these measures in registries and other systems would support creation of a national research infrastructure to efficiently address new questions and improve patient management and outcomes. (J Allergy Clin Immunol 2019;144:671-81.)**

***Key words:*** *Asthma, patient registry, outcome measure, patient outcome, data standard, common data element, harmonization*

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Asthma is a common chronic airway disorder that affects an estimated 25 million persons, including 6 million children, in the United States, and 330 million persons worldwide.[1-3] In 2015, 1.7 million emergency department (ED) visits and 11 million physician's office visits listed asthma as the primary diagnosis.[1] Asthma can be fatal in some cases.[4] The economic burden of asthma, including absenteeism and mortality, is estimated at $81 billion per year in the United States.[5]

Although asthma cannot be cured, effective treatments are available to control symptoms and reduce the risk of future exacerbations. In recent years, new treatments have become available for severe asthma[2] and specific asthma phenotypes,[6] and new tools, such as electronic inhaled medication sensors and digital health management programs, are available to support medication adherence and patient self-management.[7-9] With these advances have come new questions about how to personalize asthma treatment to improve individual patient outcomes across disease phenotypes.[10] Questions also remain about the long-term effects of available treatments and the most effective

*Abbreviations used*
ED: Emergency department
EHR: Electronic health record
OMF: Outcome Measures Framework
PRO: Patient-reported outcome

methods for addressing racial, ethnic, and socioeconomic disparities in asthma outcomes.[11-13]

It is critical to build a robust infrastructure to consistently and efficiently collect high-quality data on outcome measures that are relevant to patients and clinicians as part of routine clinical practice to address these questions and improve patient outcomes. Longitudinal observational studies, such as patient registries, already capture a wealth of data on asthma treatment patterns and outcomes and could serve as the foundation of this infrastructure. A patient registry is defined as "an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure and that serves one or more pre-determined scientific, clinical, or policy purposes."[14] As observational studies, patient registries capture data that reflect routine clinical practice.

Linkage of data across registries and related data collection efforts would offer the opportunity to address new research questions efficiently, drawing on large populations of diverse patients. However, because each effort has unique objectives and methodologies, they often focus on different outcome measures. Even when the same outcome is captured (eg, exacerbation), different definitions of the measure can be used, reflecting the lack of harmonization of outcome measure definitions across professional societies and research-funding agencies. These variations make linkages and comparisons across data sources challenging, reducing the utility of these resources for answering new research questions.

To address these issues, the US Department of Health & Human Services, led by the Agency for Healthcare Research and Quality and in collaboration with the US Food and Drug Administration and the National Library of Medicine, has supported the development of the Outcome Measures Framework (OMF). The OMF is a conceptual model for classifying outcomes that are relevant to patients and providers across most conditions.[15] The OMF is designed to serve as a content model for developing harmonized outcome measures in specific disease areas; the framework was developed with input from more than 400 stakeholders and refined through analyses of outcome measures used in existing registries.

Our goal was to develop a minimum set of standardized outcome measures for use in asthma patient registries and clinical practice in the United States. The objectives were to (1) test the utility of the OMF for categorizing asthma outcomes and for supporting harmonization of outcomes across treatment pathways; (2) identify a minimum set of outcome measures that could be captured in asthma patient registries and clinical practice; (3) agree on harmonized definitions for each outcome in the minimum measure set; and (4) map the harmonized definitions to standardized terminologies to support consistent implementation and collection of the outcome measures within electronic health records (EHRs) as part of routine clinical practice.

## METHODS

Existing asthma registries and asthma-related data collection efforts were identified through a multistep process, including searches of the Registry of Patient Registries[16] and ClinicalTrials.gov[17]; reviews of the Qualified Clinical Data Registries list maintained by the Centers for Medicare and Medicaid Services, Post-Marketing Commitment studies listed on the US Food and Drug Administration Web site, and projects funded by the Patient-Centered Outcomes Research Institute; and searches of the published medical literature using PubMed and Google Scholar and the "gray literature," including conference abstracts.

All identified registries meeting definitional criteria for a patient outcomes–focused registry[14] and collecting data in the United States were invited to participate as voluntary members of the registry workgroup. In addition, a stakeholder group, including clinicians, researchers, and representatives from medical specialty associations, health systems, community health centers, regulatory agencies, funding agencies, payers, patient advocacy organizations, measure developers, and measure-endorsement organizations, was formed.

Outcome measure specifications were obtained from the participating registries, the published literature, and additional resources, such as the Core Outcome Measures in Effectiveness Trials Initiative database[18] and the National Quality Forum database.[19] The registry workgroup met virtually and in person 5 times over a 6-month period to develop the harmonized measures.

First, the group categorized all identified measures using the OMF categories of survival, clinical response, events of interest, patient-reported resource utilization, and experience of care. Within each category, measures representing similar concepts were identified and grouped accordingly. Workgroup members rated the priority of each measure concept, and the workgroup used the weighted average of the ratings as a basis for the development of the minimum measure set. The minimum measure set is intended for use as a core set of outcomes that will be collected in all future asthma registries and would also be suitable for use in clinical practice; some studies might collect additional outcomes using other definitions to meet specific purposes. For each measure in the minimum set, definitions were reviewed, and detailed comparisons highlighting differences in definitions were prepared. Through iterative meetings, the workgroup discussed the clinical significance of and reasons for the differences and possible approaches to harmonization (eg, recommending use of an existing definition or modifying an existing definition to incorporate concepts from other definitions) until consensus was reached.

The combined registry workgroup and stakeholder group met to reach consensus on the minimum measure set and harmonized narrative definitions. Clinical informaticists mapped these narrative definitions to standardized terminologies (primarily the International Classification of Diseases–10th Revision and SNOMED-CT) to produce a library of common data definitions suitable for implementation within EHRs. For each measure, the recommended reporting period, initial population for measurement, outcome-focused population, and data criteria and value sets were defined. Where possible, existing common data elements and value sets were used. The narrative definitions and standardized definitions were posted for public comment. After public comment, the measure set was finalized.

## RESULTS

Twenty-one registries were identified, and 13 registry sponsors agreed to participate. Participating registries represented multiple purposes, patient populations, and care settings (Table I).[20-32] Five participating registries focus on severe asthma, whereas the others capture data on patients with mild, moderate, or severe asthma. Three participating registries enroll pediatric patients only, 5 enroll adults only, and 3 enroll adults and children. Table E1 in this article's Online Repository at www.jacionline.org describes registries that declined to participate. The registries that declined are similar to the participating registries in terms of

**TABLE I.** Participating registries

| Registry name | Sponsoring organization | Primary purpose | Patient population |
|---|---|---|---|
| Longitudinal Observational Study of Severe Asthma[20] | NHLBI | To compare patients with severe asthma, patients with mild or moderate asthma, and healthy volunteers; to study the progression and outcomes of the disease; and to gain a better understanding of pathogenic mechanisms that differentiate severe asthma from mild-to-moderate asthma | Patients aged ≥18 y with severe, moderate, or mild asthma and healthy volunteers; estimated enrollment is 600 participants. |
| The Genetics of Severe Asthma in Children[21] | Connecticut Children's Medical Center | To examine whether a child's *ADRB2* genotype is associated with development of a near-fatal asthma exacerbation | Patients aged 4-18 y with asthma who are admitted to the hospital with an exacerbation or who have not been admitted to the hospital with an exacerbation and healthy control subjects |
| Washington University Severe Asthma Research Program III[22] | Washington University School of Medicine | To better understand the basis of airway remodeling in patients with severe asthma and how remodeling changes over time using a well-characterized cohort of adult and pediatric patients with severe asthma | Patients aged ≥6 y with severe asthma, well-controlled asthma, and healthy control subjects |
| CAPriCORN Asthma Survey[23] | Chicago Area Patient-Centered Outcomes Research Network (CAPriCORN) | To determine how patients are affected by asthma and other health conditions | Children and adults with asthma identified from EHRs from 10 institutions participating in the network |
| Vitamin D, Steroids, and Asthma in African American Youth (AsthMaP2)[24] | Children's Research Institute | To examine the contribution of vitamin D to disparities in the chronic control and acute severity of asthma. The overall goal of this study is to provide critical epidemiologic/molecular information that will inform the interpretation of ongoing and impending randomized clinical trials of vitamin D supplementation in asthmatic patients, especially with regard to urban African American youth with asthma. | Patients aged 6-20 y with physician-diagnosed asthma |
| CSP #595—Pulmonary Health and Deployment to Southwest Asia and Afghanistan[25] | Veterans' Affairs | To assess the association of airborne exposures encountered during deployment with current measures of respiratory health among US military veterans who served in Iraq (March 2003–December 2011) and Afghanistan (October 2001-present) | US military veterans who served in Iraq and Afghanistan |
| AAAAI Allergy, Asthma, and Immunology Quality Clinical Data Registry[26] | AAAAI | To provide a practice improvement tool and a CMS-approved registry option for the Merit Based Incentive Payment Schedule (MIPS) reporting program under the Medicare Access and CHIP Reauthorization Act (MACRA) | Patients seen by physicians specializing in allergy/immunology for routine clinical care |
| Mechanisms of Response to Diesel Exhaust in Subjects With Asthma[27] | University of Pennsylvania, Rutgers University | To determine the acute effect of diesel exhaust inhalation on airway inflammation and AHR in subjects with mild-to-moderate stable asthma by using noninvasive measures | Adults aged 18-55 y with a history of mild-to-moderate asthma |

*(Continued)*

**TABLE I**. *(Continued)*

| Registry name | Sponsoring organization | Primary purpose | Patient population |
|---|---|---|---|
| MN Community Measurement[28] | MN Community Measurement | To accelerate improvements in health by publicly reporting health care information, including information about asthma in children and adults, from health care providers in Minnesota | Children and adults seen by physicians in Minnesota for routine clinical care for asthma |
| A Longitudinal Prospective Observational Study of the Characteristics, Treatment Patterns and Health Outcomes of Individuals with Severe Asthma[29] | AstraZeneca, Duke University | To describe the epidemiology and medical management of US adults with severe asthma who have not achieved control with high-dose inhaled corticosteroid therapy and additional controllers | Adults with severe asthma who did not achieve control with high-dose inhaled corticosteroid therapy with additional controllers and/or require systemic corticosteroid or mAb therapy |
| Immune Interactions in Severe Asthma[30] | University of Pittsburgh | To obtain human lung samples by means of bronchoscopy from a range of asthmatic patients and healthy control subjects to address questions related to mechanisms for development of the complex immune processes observed in the lungs | Patients with severe asthma, patients with mild-to-moderate asthma, and healthy control subjects |
| Pediatric Asthma Registry[31] | Children's Health Foundation | To identify children with asthma, assign an asthma severity classification per NHLBI guidelines, and enter encounter-based updates on key clinical actions and measures to support improved patient management and outcomes | Children with asthma treated by pediatricians who participate in the Children's Health Foundation collaboration |
| Bronchial Thermoplasty in Severe Persistent Asthma (PAS2)[32] | Boston Scientific Corporation | To demonstrate durability of the treatment effect and to evaluate short-term and longer-term safety profiles of the Alair System in the United States in the intended use population (patients aged ≥18 y with severe persistent asthma) | Patients aged ≥18 y with severe persistent asthma receiving bronchial thermoplasty treatment |

*AAAAI*, American Academy of Allergy, Asthma & Immunology; *AHR*, airway hyperresponsiveness; *CMS*, Centers for Medicare and Medicaid Services; *NHLBI*, National Heart, Lung, and Blood Institute.

number of patients enrolled, patient populations, and areas of focus.

Thirteen stakeholders participated, representing patient advocacy organizations (the Asthma and Allergy Foundation of America, COPD Foundation, and Allergy & Asthma Network), professional societies (the American Thoracic Society; American Academy of Allergy, Asthma & Immunology; and American College of Chest Physicians), industry (Propeller Health), health systems (Montefiore), the National Institute of Allergy and Infectious Diseases, the National Library of Medicine, and the National Quality Forum.

Forty-six outcome measures were identified from registries and other sources and curated according to the OMF. Of these, 17 (37%) were categorized as resource utilization, such as asthma-related ED visits or hospitalizations. The remaining measures were categorized as patient reported (30%), clinical response (20%), events of interest (7%), survival (4%), and experience of care (2%). The project team identified 10 consensus statements with relevant outcome measure definitions for asthma.[33-42]

Twenty-one measures are included in the minimum measure set. The minimum measure set is intended to be feasible to collect in all registries, and therefore burden of collection and reporting are important considerations. These measures are suitable for use in both adult and pediatric patients with asthma. Measure definitions and sources are listed in Table II; the rationale for selection of the measures and definitions is described below. It is important to note that these measures are intended to track patient outcomes over time to support patient management, inform clinical decision making, and facilitate clinical research. Although it is possible that these measures could be adapted for use in quality measurement programs, the measures presented here are not intended for use as measures of quality. In addition, some measures appear in multiple categories to reflect the importance of the measure in different contexts. For example, hospitalization is included in the "events of interest" category because it is a significant event from a patient perspective and in the "resource utilization" category because of the cost implications. The inclusion of a measure in multiple categories does not imply duplicate data collection but rather a different way of viewing the same data.

## Survival

Asthma-related death, the single survival measure included, is relatively rare and might be difficult to capture in some circumstances, such as when a registry patient is lost to follow-up or when the cause of death cannot be ascertained. Despite these

**TABLE II.** Asthma minimum measure set and harmonized definitions

| OMF category | Outcome measure | Definition |
|---|---|---|
| Survival | Death (asthma related) | Death from asthma reported in 12-month intervals |
| Clinical response | Exacerbation | Exacerbations of asthma are episodes characterized by an increase in symptoms of shortness of breath, cough, wheezing, or chest tightness and decrease in lung function (ie, they represent a change from the patient's usual status that is sufficient to require a change in treatment). An exacerbation includes any of the following:<br>1. Prescribed systemic steroids (defined as ≥2 days of oral steroids or a steroid injection) or increasing the oral steroid dose from the baseline dose<br>2. An asthma-related hospitalization, ED visit, urgent care center visit, or unscheduled office visit requiring prescription of systemic corticosteroids<br>3. Documentation by provider of acute asthma exacerbation |
| Clinical response | Change in asthma control (adults - age ≥12 y) | *Measurement tools*<br>1. ACT<br>● Not well controlled: ≤19<br>● MID: Increase in score ≥3 points<br>2. ACQ<br>● Not well controlled: ≥1.5<br>● MID: Decrease in score ≥0.5 points<br>3. ATAQ<br>● Not well controlled: ≥1<br>● MID: Decrease in score ≥1 point<br>*Improvement in asthma control:*<br>Change from not well controlled to controlled OR change representing ≥ MID improvement in control<br>*Worsening of asthma control:*<br>Change from controlled to not well controlled OR change representing ≥ MID decrease in control<br>*Stable level of asthma control:*<br>Patient remains stable throughout the measurement period (controlled or not well controlled) OR does not demonstrate a change in score representing ≥ MID<br>Reported in 12-month intervals<br>*Notes: Patient scores (as opposed to "controlled" vs "uncontrolled" only) on the selected measurement instrument should be recorded to permit future analyses. Where multiple measurements are available, the first and last measurement in the 12-month measurement period should be used.* |
| Clinical response | Change in asthma control (pediatrics - <12 y) | *Measurement tools*<br>1. TRACK<br>● Not well controlled: ≤79<br>● MID: Increase of ≥10 points<br>2. C-ACT<br>● Not well controlled: ≤19<br>● MID: Increase of ≥2 points<br>3. ATAQ<br>● Not well controlled: ≥0<br>4. ACQ<br>● Not well controlled: ≥1.5<br>● MID: Decrease of ≥0.5 points<br>*Improvement in asthma control:*<br>Change from not well controlled to controlled OR change representing MID) improvement in control<br>*Worsening in asthma control:*<br>Change from controlled to not well controlled OR change representing MID decrease in control<br>*Stable level of asthma control:*<br>Patient remains stable throughout the measurement period (controlled or not well controlled) OR does not demonstrate a change in score representing the MID<br>Reported in 12-month intervals<br>*Notes: Patient scores (as opposed to "controlled" vs "uncontrolled" only) on the selected measurement instrument should be recorded to permit future analyses. Where multiple measurements are available, the first and last measurement in the 12-month measurement period should be used.* |

*(Continued)*

**TABLE II**. *(Continued)*

| OMF category | Outcome measure | Definition |
|---|---|---|
| Clinical response | Prebronchodilator indices (prebronchodilator $FEV_1$ and FVC percent predicted and $FEV_1$/FVC ratio) | Change in measurements over 12-month period<br>The goal is to have 2 measurements in a 12-month period. Two measurements within a 24-month period are also acceptable if 2 measurements within 12 months are not available.<br>*Notes: Recommended for patients aged ≥5 y. Use first and last measurement if more than 2 measurements are available in 12-month period.* |
| Clinical response | Change in asthma controller medication use | Measured by patient/caregiver self-report, physician report, prescription fill, or electronic medication monitoring<br>Preferred asthma controller medications are inhaled corticosteroids. Although long-acting bronchodilators alone are not, combination inhaled corticosteroid and long-acting β-agonist medications are considered controller medications. Additional controller medications include leukotriene modifiers, long-acting muscarinic antagonists, and immunomodulators. |
| Clinical response | Change in quick-relief asthma medication use | Measured by patient/caregiver self-report, physician report, prescription fill, or electronic monitoring<br>Preferred asthma quick-relief medications are SABAs, such as albuterol. An additional quick-relief medication includes ipratropium bromide. |
| Events of interest | Systemic corticosteroids for asthma | Defined as a prescription for systemic steroids filled within 7 days of a health care visit for asthma (ie, with an ICD-10 code associated with asthma) and counted as number of events per patient in a 12-month reporting period. |
| Events of interest | Asthma-specific ED visits | Defined as number of ED visits per patient in the 12-month reporting period |
| Events of interest | Asthma-specific hospital admission | Defined as the number of hospital admissions caused by asthma per patient in the 12-month reporting period |
| Events of interest | Near-fatal asthma | Asthma exacerbation associated with severe respiratory compromise requiring intubation or noninvasive positive-pressure ventilation (to prevent it from progressing to a fatal asthma exacerbation).<br>*Note: use of high-flow nasal cannula in pediatrics is not considered "positive-pressure ventilation" for the purposes of defining near-fatal asthma.* |
| Events of interest | Medication-related adverse events | Adverse events related to asthma medications |
| Patient reported | Asthma control | Patient with a diagnosis of asthma whose asthma was optimally controlled during the measurement period, as defined by achieving both of the following:<br>● Asthma well controlled, as defined by the most recent asthma control tool result available during the measurement period<br>AND<br>● patient not at increased risk of exacerbation, as defined by <2 ED visits and/or hospitalizations caused by asthma in the last 12 months |
| Patient reported | Medication adherence | Measured by patient/caregiver self-report, physician's report, prescription fill, or electronic medication monitoring |
| Patient reported | Asthma-specific quality of life | Asthma-specific quality of life should be measured by using a brief, validated, publicly available instrument that is appropriate for the population of interest. |
| Patient reported | General quality of life | General quality of life should be measured by using a quality-of-life instrument that is validated and commonly used (eg, PROMIS Global 10 and VR-12). |
| Resource utilization | Missed school days/missed work days | *Missed school days:*<br>● Patient has had ≥1 missed school days caused by asthma in the past 12 months<br>OR<br>● Number of days missed from school (preferably days missed because of asthma).<br>*Missed work days:*<br>● Caregiver has had ≥1 missed days of work caused by their child's asthma in the past 12 months or patient has missed ≥1 days of work because of his or her own asthma<br>● Use Work Productivity and Activity Impairment Questionnaire (WPAI) to count work absence days. |
| Resource utilization | Asthma medication ratio | Calculated as the number of canisters of asthma controller medication dispensed during the measurement year divided by the number of canisters of total asthma medications dispensed (controllers plus relievers) during the measurement year. |
| Resource utilization | Unscheduled visits to primary care physician's office/visits to urgent care center/ED visits/ hospital admission for asthma | Unscheduled visits to primary care physician's office/visits to urgent care center/ED visits/ hospital admission for asthma counted as number of visits per patient in the 12-month reporting period. |

*(Continued)*

**TABLE II**. *(Continued)*

| OMF category | Outcome measure | Definition |
|---|---|---|
| Resource utilization | Treatment-related resource utilization | All resource utilization (as measured by cost) related to treatment or management of asthma, including hospitalizations, ED visits, urgent care center visits, office visits, medications, and other costs |
| Experience of care | Patient satisfaction with care | Patients with high care satisfaction, as measured by a brief, validated, publicly available instrument |

*ACQ*, Asthma Control Questionnaire; *ACT*, Asthma Control Test; *ATAQ*, Asthma Therapy Assessment Questionnaire; *C-ACT*, Childhood Asthma Control Test; *FVC*, forced vital capacity; *ICD-10*, International Classification of Diseases–10th Revision; *MID*, minimal important difference; *PROMIS*, Patient-Reported Outcomes Measurement Information System; *SABA*, short-acting β-agonist; *TRACK*, Test of Respiratory and Asthma Control in Kids; *WPAI*, Work Productivity and Activity Impairment Questionnaire.

difficulties, the workgroup recommends capturing asthma-related deaths when feasible in concordance with the National Institutes of Health consensus statements on asthma outcomes.[40]

## Clinical response

Six clinical response measures are included in the minimum set. Exacerbation was identified as an important outcome, but multiple definitions have been developed through consensus-based efforts[37,41,42] and by individual registries. Of note, the definitions use different criteria to identify treatments that are indicative of an exacerbation (eg, any change in treatment or any use of systemic corticosteroids or an increase in maintenance dose or use for ≥3 days). The harmonized definition includes prescribed systemic steroids (defined as ≥2 days of oral steroids or a steroid injection) or an increase in a maintenance dose of steroids to reflect potential variability in practice patterns. Treatment-seeking behavior, such as hospitalizations, visits to the ED or urgent care centers, or unscheduled office visits resulting in a prescription for systemic corticosteroids, are also indicative of an exacerbation and are included in the harmonized definition. Lastly, the workgroup included "documentation by a provider of acute asthma exacerbation" to capture exacerbations that are managed through contact with the provider but that do not result in a new prescription for systemic corticosteroids (eg, an exacerbation in a pediatric patient managed with a short-acting β-agonist).

Similar to exacerbations, measurement of asthma control is central to understanding clinical response in asthmatic patients. Validated asthma control instruments are widely used in research, quality improvement efforts, and clinical practice and have established cutoff values for asthma control and minimal clinically important differences. Building on existing quality measures[43] and consensus statements,[33] the workgroup recommended capturing improving, worsening, and stable levels of asthma control for adults by using the Asthma Control Test, Asthma Control Questionnaire, or Asthma Therapy Assessment Questionnaire. For children less than 12 years of age, the workgroup recommends the Test for Respiratory and Asthma Control in Kids, Childhood Asthma Control Test, Asthma Therapy Assessment Questionnaire, or Asthma Control Questionnaire. Other instruments were considered but not included because they lacked validated cutoffs or minimal clinically important differences or because the necessary use fees would pose a burden to registries.

Lung function, as measured based on prebronchodilator percent predicted $FEV_1$, forced vital capacity (as a percentage), and $FEV_1$/forced vital capacity ratio, was included in the minimum measure set. Most registries capture this as a secondary outcome measure, and workgroup participants noted challenges ranging from the difficulty of measuring lung function in young children to the lack of availability of equipment and trained personnel at some community health centers. However, the group emphasized that lung function is important to measure for patient treatment and management purposes. The measure is included in the minimum set, but additional work is needed to understand variability in measuring this outcome and to identify resource- and training-related barriers that should be addressed to improve measurement.

Two clinical response measures are included to track changes in medication use over time as correlates for asthma control. Change in asthma controller medication use and change in quick-relief medication use should be tracked by patient/caregiver self-reports (average daily use over the past 2 weeks), physician reports, prescription fills, or electronic monitoring. Each of these sources of information has strengths and limitations, and the selection of the most appropriate method or methods will depend on the purpose and design of the registry or other data collection effort. Further work is needed to develop a validated and reliable method for obtaining average daily use over the past 2 weeks.

## Events of interest

Five events of interest are captured in the minimum measure set: systemic corticosteroids for asthma, ED visits for asthma, hospitalizations for asthma, near-fatal asthma exacerbations, and asthma medication–related adverse events. Although there is some overlap between the events of interest and other categories (clinical response and resource utilization), the workgroup identified these as important events to track individually because of their effect on patients. The definitions for these measures were taken from participating registries, with 1 exception. After extensive discussion and 2 virtual activities, the workgroup agreed to modify the definition of near-fatal asthma from the Severe Asthma Research Program to reduce the complexity of the definition and to clarify how to apply the definition in pediatric populations. The harmonized definition for near-fatal asthma is "an asthma exacerbation associated with severe respiratory compromise requiring intubation or noninvasive positive-pressure ventilation (to prevent it from progressing to a fatal asthma exacerbation). Note, use of high-flow nasal cannula in pediatrics is not considered 'positive-pressure ventilation' for the purposes of defining near-fatal asthma."

## Patient-reported outcomes

Asthma is a lifelong chronic disease, and patient-reported outcomes (PROs) are important to help understand the effect of asthma on a patient's quality of life and the patient's experience with treatment. The registry workgroup and stakeholders both

expressed strong interest in capturing PROs but did not identify a validated instrument that is publicly available, sensitive to change over time, and sufficiently brief to allow for routine use in clinical practice. Identifying an instrument that would be relevant across patient populations and registries was also noted as a challenge. Further work is needed in this area to develop, validate, and implement asthma-specific PROs that are meaningful to clinicians and patients.

The workgroup recommended measuring general quality of life by using a validated and commonly used instrument, such as the Patient-Reported Outcomes Measurement Information System (PROMIS) Global 10 or the Veterans RAND 12 Item Health Survey (VR-12), to facilitate comparisons of burden across diseases.

The workgroup included a measure of asthma control in the patient-reported category, reflecting the fact that asthma control instruments are largely based on patient-reported data. In comparison to the "change in asthma control" measure included in the clinical response category, this measure captures patients who have maintained asthma control through the measurement period, as indicated by achieving a well-controlled score on the most recent asthma control instrument result and having fewer than 2 ED visits, hospitalizations, or both in the last 12 months. This measure is already captured by some participating registries as a quality measure.[43]

Lastly, the workgroup included medication adherence in the patient-reported category. Medication adherence is not a direct patient outcome, but adherence affects key patient outcomes. Tracking adherence over time and attempting to understand the factors that influence adherence for an individual patient are important for increasing adherence and improving patient outcomes.

## Resource utilization

Resource utilization measures capture the cost of care for a specific condition and are typically calculated by using existing data sources (EHR and claims data). In asthmatic patients cost drivers include hospitalizations, ED visits, urgent care visits, office visits, and medications. Absenteeism from school and work are also important factors when considering the overall economic burden of asthma. The workgroup recommends measuring asthma-related unscheduled visits to the primary care provider's office, urgent care center, ED, or hospital. The workgroup recommends measuring all resource utilization related to treatment or management of asthma to capture the burden of medications and regular visits with a care provider. These measures focus on individual health resource consumption. Family costs are an important issue in asthmatic patients and could be captured as a supplemental measure. It is important to note that these measures are intended to track resource utilization and are not intended for use as indicators of quality.

In addition to treatment-related use, the workgroup recommends measuring missed school days and/or missed work days for both patients and caregivers of patients with asthma. The Work Productivity and Activity Impairment Questionnaire is recommended as a validated tool for measuring absenteeism from work related to a health problem. However, further work is needed to develop a corollary tool for measuring missed school days.

Lastly, the workgroup recommends measuring the asthma medication ratio, which was calculated as the number of canisters of asthma controller medication dispensed during the measurement year divided by the number of canisters of total asthma medications dispensed (controllers plus relievers) during the measurement year.[44] The workgroup cautioned that this measure is most useful in patients with persistent asthma (as opposed to patients with intermittent asthma) and might be problematic in pediatric patients, in whom multiple quick-reliever medication prescriptions can be filled for use in different locations (eg, home, school, camp, and daycare).

## Experience of care

Measures of experience of care, unlike the outcome measures discussed above, do not capture the disease-related outcomes of treatment for an individual patient. Instead, these measures capture the patient's perspective on the process of receiving treatment. These measures might be useful for helping providers understand issues encountered by patients during treatment, such as communication challenges. Asthma is a chronic condition that affects a diverse patient population, and patients express different needs regarding the education and support necessary to manage their asthma appropriately.[45] Understanding patients' satisfaction with care might help providers build stronger partnerships with patients. However, more work is needed to develop a validated and publicly available instrument that is meaningful to patients and clinicians and could be recommended for broad use in registries and in clinical practice.

## Characteristics

In addition to defining the minimum measure set, the workgroup identified asthma-specific characteristics of the participant, disease, and provider for which there is published evidence showing a correlation with patient outcomes (Fig 1); these characteristics are important to consider for risk adjustment when measuring asthma outcomes. Further work is needed to recommend specific approaches for risk adjustment for each outcome measure included in the minimum measure set.

## Standardized library

Narrative definitions were translated into standardized terminologies to facilitate implementation within EHRs. Some challenges were encountered in translating the text definitions produced by the workgroup into standardized definitions and value sets. Of note, several outcome measures focus on change over time, such as change in medication dosage or change in pulmonary function over a 12-month period. These measures require multiple measurements in data representations. The workgroup recommended using the first and last measurement within the parameter of "interval of interest" (generally 12 months).

Related to the outcomes occurring outside of the clinical setting (eg, missed work/school days), condition-specific instruments, standard terminology, or both representing the instruments might not exist. The same challenge applies to PROs and patient-reported activities (eg, medication adherence). In addition, although missed work or school days can be captured within the EHR setting, there is no reliable way to assert that the missed days are caused by asthma (as opposed to another condition).

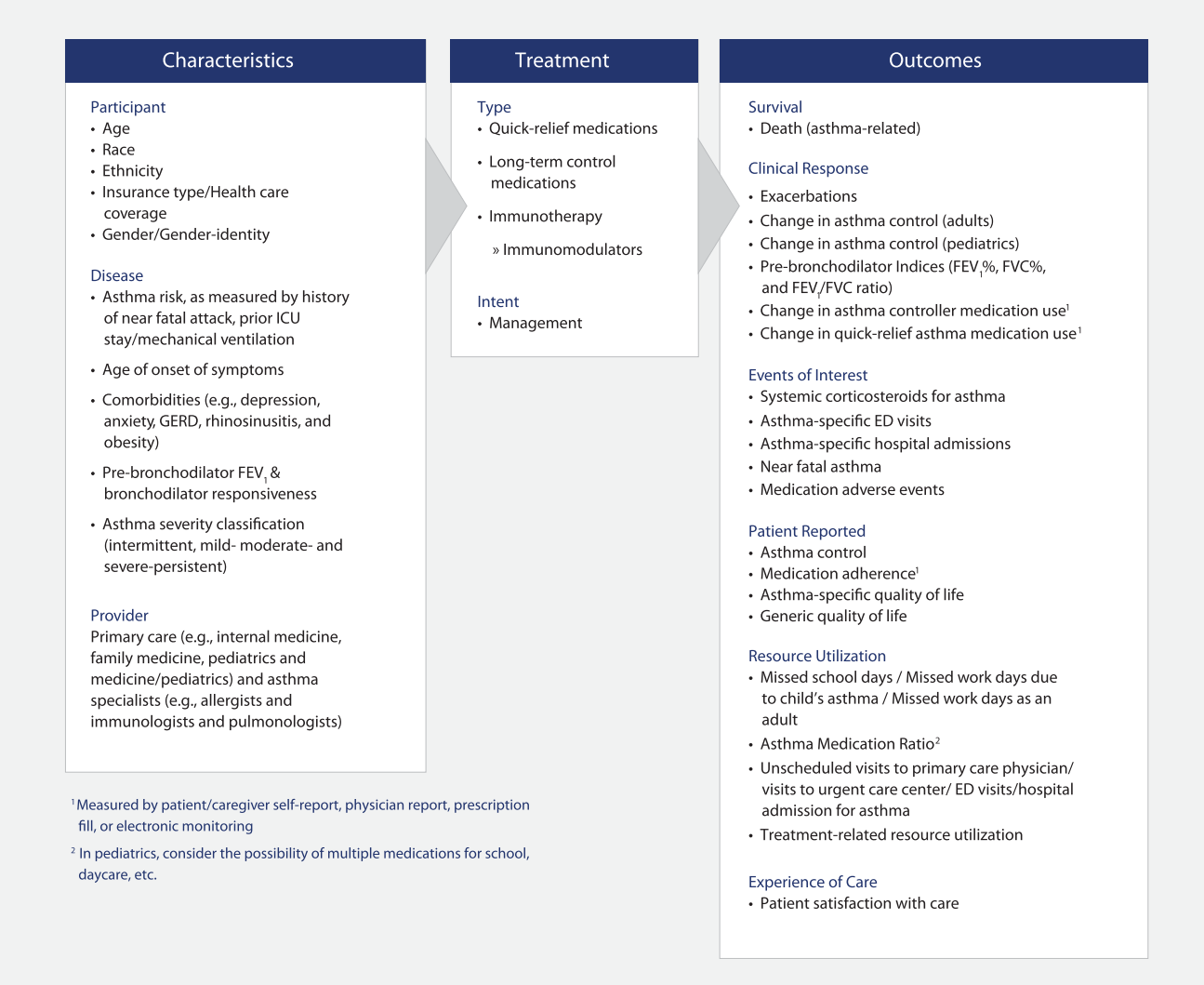


**FIG 1.** The OMF, as completed for asthma characteristics and outcomes. The OMF depicts the minimum set of outcome measures recommended by the workgroup *(right column)*, as well as the key characteristics of the participant, disease, and provider that should be captured to support risk adjustment *(left column)*. Treatments of interest are listed in the *center column*. *FVC*, Forced vital capacity; *GERD*, gastroesophageal reflux disease; *ICU*, intensive care unit.

## DISCUSSION

This initiative builds on other efforts to harmonize outcomes measurement in asthmatic patients[40,41] and expands on those efforts in 2 important ways. First, some efforts have focused on harmonizing asthma outcomes for use in clinical trials and observational research studies, but these outcomes do not always reflect the outcomes that are meaningful and feasible to capture in routine clinical practice across a wide range of provider types and practice settings.[40] The OMF standardized outcome measures for asthma are designed for use in a wide range of routine clinical practice settings, as well as in research studies. These measures acknowledge and, where possible, address variations in clinical practice across the United States, such as differences in the duration of systemic corticosteroid use after an exacerbation (3 vs 2 days) and challenges related to obtaining spirometric measurements in some practice settings. The measure definitions were also modified, where necessary, to apply to both pediatric and adult patients.

Second, other harmonization efforts generally have not addressed the informatics components of the definitions, such as how the data could be captured in and extracted from an EHR. This is an important and major challenge for new registries and other research projects. For example, the ability to expand pragmatic clinical trials, such as those conducted in PCORnet, is highly dependent on EHR-derived outcomes with standard definitions. Key goals of standardization are to reduce duplicate data collection (and therefore data collection costs) by harmonizing data requirements across the learning health care system and to increase the utility of registry data for improving patient outcomes and facilitating shared decision making. The OMF effort includes development of standardized definitions that could be implemented within an EHR as a core component. The potential limitations of EHR-derived data were considered during the measure harmonization process; for example, some measures (exacerbation and resource utilization) group together unscheduled physician's office visits and urgent care center visits because

of the difficulty of distinguishing between these types of visits in some EHR data.

The clinical implications for use of standardized outcome measures across patient registries and clinical practices are 2-fold. First, use of the harmonized measures provides clinicians with access to consistently defined measures that are useful for informing clinical decision making and important to patients and caregivers. A major barrier to providing optimal multidisciplinary team–based care for pediatric and adult patients with asthma is a lack of standardized clinical measures. The use of standard definitions and the ability to easily extract these important clinical data from various sections of the EHR (eg, medication tab for controller, quick-relief, and oral steroid use; encounter tab for hospitalizations, ED visits, urgent care, asthma specialist, and primary care visits; review flowsheet for asthma control tool scores; procedure tab for spirometric results; laboratory test tab for IgE and eosinophil counts; and letters section for asthma action plans) into a central location would allow primary care physicians and asthma specialists to better communicate about and tailor treatment for individual patients. For patients with difficult-to-control and severe asthma, it would allow asthma specialists to more efficiently and accurately assess a patient's asthma phenotype and in turn optimize selection of treatment. Use of a standardized minimum measures set also enables more efficient identification of high-risk patients across large health care systems and facilitates the targeting of additional resources to this group.

In addition, standardized measures provide a foundation for understanding treatment patterns and outcomes for all asthmatic patients on a population health scale. Capturing the same outcomes consistently across health systems and within different registries would create a national data infrastructure that could be leveraged to efficiently monitor patient outcomes, identify areas for improvement, and address new research questions.

The minimum measure set has several limitations. First, consistent capture of the minimum measure set across providers, patients, and care settings will be challenging. For some of the measures, necessary data are not currently captured as part of routine clinical care in all care settings. For example, a registry might be unable to determine whether a patient's death was due to asthma. Lung function might not be measured in some care settings, and many providers do not capture quality-of-life measures (either general or disease-specific measures) as part of routine care for asthmatic patients. Even when a measure is captured routinely (eg, exacerbation), it is difficult to consistently extract the same data from different systems. Development of standardized measure definitions is intended to help address both types of practical limitations by making it easier for providers to codify these data elements within the EHR to capture the data and to facilitate automated extraction of the data for multiple uses (eg, quality reporting, clinical research, and population management). Utility of standardized measurement at the population level for benchmarking, quality improvement, and population management is well established in health care. The minimum measure set described here builds on that foundation with a set of measures that are useful at both the population level and the individual patient level.

Although implementing the measure set in new registries should reduce burden, a major barrier to use in existing registries is mapping existing data to the new measures and updating registry infrastructure. This requires substantial resources, and in some cases mapping existing data to the new measures might not be feasible. A pilot implementation of the measure set would be valuable to demonstrate the feasibility of capturing the measures consistently across care settings and the utility of the measures in terms of reducing data collection burden and providing useful information to inform clinical decision making. In addition, asthma is a heterogeneous disease, and the measures here do not cover all special circumstances (eg, cardiovascular support for anaphylactic shock). These measures are intended to cover the most broadly relevant patient outcomes, and discussion of all special circumstances in asthma care are beyond the scope of this measure set.

Additional work is also needed to determine how best to incorporate PROs into asthma research and practice. Although some registries captured information on asthma-related quality of life, the workgroup did not identify a tool that was considered appropriate for use in routine clinical practice across care settings and patient populations. Consistent collection of PROs within registries would provide important information on quality of life as it relates to asthma management and treatment.

Lastly, effective governance is necessary for sustainability of the minimum measure set. Regular review and updates are necessary to ensure that the measures continue to reflect current clinical practice. A transparent governance structure is also needed to develop processes for monitoring implementation of the measure set and setting and monitoring benchmarks for success.

The 21 harmonized measures represent a minimum set of outcomes that are relevant in asthma research and multiple clinical practice settings. Consistent collection of these measures in registries and other systems would support the creation of a national research infrastructure to efficiently address new questions and improve patient management and outcomes.

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**Key messages**

- **Asthma patient registries collect a wealth of data on asthma treatment patterns and outcomes, but the ability to compare, link, and aggregate data across registries and other systems is hindered by variability in the selection and definition of outcome measures.**
- **Consistent and routine collection of a minimum set of 21 standardized outcome measures that are relevant to asthmatic patients, providers, and other stakeholders would create the foundation for a national research infrastructure that could efficiently address new questions and improve patient management and outcomes.**

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**TABLE E1.** Invited registries that declined to participate

| Registry name | Sponsoring organization | Primary purpose | Reason for declining to participate |
|---|---|---|---|
| Characterization of Adults for Asthma Microbiome Research Studies (CAARS) | University of Michigan | To characterize adult subjects regarding their history of allergy and asthma, clinical manifestations of asthma, and exposures and conditions that might influence asthma severity and control | Registry outcomes are not clinically focused. |
| American Lung Association Airways Clinical Research Centers | American Lung Association | Network of clinical research centers dedicated to asthma and COPD treatment research | Did not respond to invitations. |
| Tri State Physician Hospital Organization Asthma Improvement Initiative and Outcomes | Tri-State Physician Hospital Organization | To improve the quality of care and outcomes for children with asthma in the region through collaboration among community-based physicians, hospital-based physicians, and Cincinnati Children's Hospital Medical Center | Time commitment |
| Pediatric Physicians' Organization at Children's (PPOC) Asthma Program | Pediatric Physicians' Organization at Children's | To improve patient outcomes and quality of care in children with persistent asthma | Scheduling conflicts |
| Characterizing Asthma Sputum Elasticity in the UCSF Severe Asthma Research Program (CAESAR) | University of California, San Francisco | To characterize subjects in terms of their sputum phenotype<br>The purpose of this study is to learn more about the effect of having abnormally elastic sputum on asthma severity by comparing subjects with both severe and mild-to-moderate asthma with healthy control subjects. | Does not capture clinical patient outcomes |
| Severe Asthma Research Program, University of Virginia (SARP3) | University of Virginia, NHLBI | To better understand the basis of airway remodeling in patients with severe asthma and how remodeling changes over time by studying a well-characterized cohort of patients with severe asthma by using a multidisciplinary state-of-the-art-approach | Time commitment; in addition, the SARP3 project is represented by another registry in the workgroup. |
| Observational Study of Obstructive Lung Disease (NOVELTY) | AstraZeneca | To investigate patients' characteristics, treatment, burden of illness, and underlying disease mechanisms in patients with asthma and/or COPD by using a multicounty, multicenter, prospective, longitudinal study design | Time commitments and stage of registry (had not started recruitment at time of invitation) |
| Colorado Pediatric Collaborative Asthma Patient Registry | Colorado Pediatric Collaborative | To track, monitor, and improve the health of asthmatic patients | Time commitment and change in registry personnel |

*COPD*, Chronic obstructive pulmonary disease; *NHLBI*, National Heart, Lung, and Blood Institute.