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Asthma Outcomes: Healthcare Utilization and Costs

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Abstract

Background—Measures of healthcare utilization and indirect impact of asthma morbidity are used to assess clinical interventions and estimate cost.

Objective—National Institutes of Health (NIH) institutes and other federal agencies convened an expert group to propose standardized measurement, collection, analysis, and reporting of healthcare utilization and cost outcomes in future asthma studies.

Methods—We used comprehensive literature reviews and expert opinion to compile a list of asthma healthcare utilization outcomes that we classified as core (required in future studies), supplemental (used according to study aims and standardized) and emerging (requiring validation and standardization). We also have identified methodology to assign cost to these outcomes. This work was discussed at an NIH-organized workshop in March 2010 and finalized in September 2011.

Results—We identified 3 ways to promote comparability across clinical trials for measures of healthcare utilization, resource use, and cost: (1) specify the study perspective (patient, clinician,

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payer, society), (2) standardize the measurement period (ideally, 12 months), and (3) use standard units to measure healthcare utilization and other asthma-related events.

Conclusions—Large clinical trials and observational studies should collect and report detailed information on healthcare utilization, intervention resources, and indirect impact of asthma, so that costs can be calculated and cost-effectiveness analyses can be conducted across several studies. Additional research is needed to develop standard, validated survey instruments for collection of provider-reported and participant-reported data regarding asthma-related health care.

Keywords

Asthma hospital admissions; asthma ED visits; asthma outpatient visits; asthma medication use; asthma intervention resource use; asthma study perspective

INTRODUCTION

Asthma clinical research lacks adequate outcomes standardization. As a result, our ability to examine and compare outcomes across clinical trials and clinical studies, interpret evaluations of new and available therapeutic modalities for this disease at a scale larger than single trial, and pool data for observational studies (eg, genetics, genomics, pharmacoeconomics) is impaired.[1] Several National Institutes of Health (NIH) institutes that support asthma research (the National Heart, Lung, and Blood Institute; National Institute of Allergy and Infectious Diseases; National Institute of Environmental Health Sciences; and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development), as well as the Agency for Healthcare Research and Quality, have agreed to an effort for outcomes standardization. This effort aims at (1) establishing standard definitions and data collection methodologies for validated outcome measures in asthma clinical research with the goal of enabling comparisons across asthma research studies and clinical trials and (2) identifying promising outcome measures for asthma clinical research that require further development. In the context of this effort, 7 expert subcommittees were established to propose and define outcomes under 3 categories—core, supplemental, and emerging:

- *Core outcomes* are identified as a selective set of asthma outcomes to be considered by participating NIH institutes and other federal agencies as requirements for institute/agency-initiated funding of clinical trials and large observational studies in asthma.
- *Supplemental outcomes* are asthma outcomes for which standard definitions can or have been developed, methods for measurement can be specified, and validity has been proven, but whose inclusion in funded clinical asthma research will be optional.
- *Emerging outcomes* are asthma outcomes that have the potential to (1) expand and/or improve current aspects of disease monitoring and (2) improve translation of basic and animal model-based asthma research into clinical research. Emerging outcomes may be new or may have been previously used in asthma clinical research, but they are not yet standardized and require further development and validation.

Each subcommittee used the recently published *American Thoracic Society (ATS)/European Respiratory Society (ERS) Statement: Asthma Control and Exacerbations—Standardizing Endpoints for Clinical Asthma Trials and Clinical Practice*[2] (hereafter referred to as the *ATS/ERS Statement*) as a starting point as a starting point and updated, expanded, or modified its recommendations as the subcommittee deemed appropriate. Each subcommittee produced a report that was discussed, modified, and adopted by the Asthma Outcomes Workshop that took place in Bethesda, Md, on March 15 and 16, 2010. The reports were revised accordingly and finalized in September 2011. The workshop's recommendations in regard to healthcare utilization and costs are presented in this article.

This work reflects the subcommittee's informed view of how healthcare and asthma intervention resources should be identified, measured, and reported, and the preferred methodology for valuing these measures so that cost or cost-effectiveness studies can be conducted as part of asthma clinical research. Measures of healthcare utilization and indirect impact of asthma morbidity (eg, work absences) are generally surrogates for direct indicators of intervention efficacy and asthma control, but they are commonly used to assess clinical interventions and assign costs. Despite their widespread use, however, the definitions of these measures rely primarily on consensus rather than on evidence-based study of their validity and reliability. Nevertheless, consistent methodology and reporting of these outcomes makes it possible to combine studies, thereby enlarging sample size and ensuring that cost estimates and cost-effectiveness analyses, for which these outcome measures are inputs, are comparable across studies.

The *ATS/ERS Statement* provides the foundation for the subcommittee's asthma outcomes recommendations. The *ATS/ERS Statement* focuses on outcomes directly related to asthma control. However, the central focus of the work of this subcommittee was to establish a more complete and uniform accounting of data elements without strict reference to their usefulness in assessing asthma control. In the first part of this article, we (1) present recommended measures of asthma healthcare utilization and resources, intervention-related resources (eg, personnel time), and other measures of asthma morbidity (work and school absences); and (2) recommend standard definitions and measurement approaches. In the second part, we articulate appropriate analytic methods for determining cost and cost-effectiveness. Another departure from the *ATS/ERS Statement* is the underlying assumption made in this article that the US health system is the predominant environment in which most studies subject to these NIH-based recommendations will take place and on which definitions of *healthcare utilization* and related terms will be based.

The Healthcare Utilization and Costs Subcommittee makes 3 overall recommendations, all of which promote comparability across studies. First, clearly specifying the study perspective (patient, clinician, payer, society) facilitates assessing and comparing published studies. Study perspective influences study design, data sources, participant recruitment and characteristics, and measurement and analysis methodologies. Evaluated outcomes may differ depending on the choice of perspective. The societal perspective is the broadest and helps minimize the risk that a study will determine an intervention to be cost-effective because it has overlooked negative consequences or significant costs for groups omitted from the analysis—or conversely, that an intervention appears not to be cost-effective

because benefits accruing to an omitted group are not considered.[3] For example, examining costs and outcomes averted from a payer perspective may lead to the conclusion that preventive medication is not cost-effective if only avoided emergency department (ED) visits and hospitalizations are considered, but that conclusion may be different if savings from reduced morbidity and improved quality of life (QOL) from the patient perspective have been included. Study perspective also may affect the strengths and limitations of studies. For example, hospitalizations and ED visits are likely to be represented differently in administrative data than they would be in self-reported data. Administrative data may reflect the payer perspective in which details on duration, diagnosis, and treatment are available, but event capture may be biased because of billing concerns; with self-reported data, the patient perspective may be better reflected, but event capture is affected by recall bias.

The second major recommendation is to standardize the measurement period. When measuring counts of events or days, study duration is a critical issue, and measurement periods of at least 12 months are ideal. Because adverse outcomes (eg, hospitalizations) may be relatively rare and/or seasonal, such events may be underrepresented or overrepresented in studies of less than a 12-month duration. We do not recommend extrapolating event counts and rates collected for shorter periods to a 12-month period. For prospective studies, including those spanning multiple years, event rates should be reported as annual rates. Retrospective studies using claims or encounter data also should, ideally, report annual rates.

Finally, the subcommittee recommends that healthcare utilization and other asthma-related events measured in clinical research studies be counted as “units, frequency, and duration of services provided.” This will enable investigators to apply a uniform cost per service to evaluate the costs of different studies or to combine results from several studies. Note that such cost studies are distinct from *cost-effectiveness analyses*, which are discussed in the final section of this article.

I. MEASUREMENT OF ASTHMA-SPECIFIC HEALTHCARE EVENTS AND RESOURCE UTILIZATION, INTERVENTION-RELATED RESOURCES, AND OTHER ASTHMA-RELATED EVENTS

A. Health Care Events and Resource Utilization

Definition and methodology for measurement—Collecting and reporting asthma-related events and resource utilization make it possible to compare events and outcomes across studies and to achieve a more complete and standardized accounting of resource use. Healthcare events include:

- Hospitalizations
- ED visits
- Unscheduled outpatient visits
- Scheduled (preventive) outpatient visits
- Subspecialist care

- Remote care

For the purposes of measuring healthcare utilization and cost, each healthcare event and occurrence of resource use (eg, short course of systemic corticosteroids) is considered an independent contribution, in contrast with defining an asthma exacerbation or episode of care, in which multiple healthcare events may be combined. Definitions and measurement methodologies for hospitalizations, ED visits, and outpatient visits are given below, followed by a section outlining specific details for each type of event.

Data sources—Data collection may be study specific or obtained from external sources (healthcare claims, encounter data from care organizations, electronic medical records, or existing datasets, such as the Medical Expenditure Panel Survey). The subcommittee endorses the recommendations made in the *ATS/ERS Statement* for data collection methods for outpatient visits and recommends a similar approach for all healthcare events whenever possible. These methods include standardized clinician-completed data collection forms, subject-completed forms near the time of the healthcare event, retrospective provider-completed forms and retrospective subject-completed forms (see Table V for examples of survey questions on asthma healthcare utilization from national surveys). For retrospective or observational studies, healthcare events for persons with asthma may be identified from administrative data, using an asthma diagnosis code listed in any position among the billing codes; the choice of position(s) will depend on study objectives. In general, diagnostic codes that are listed first represent the main reason for a visit or hospitalization. Data should be categorized as outlined below:

Clinician-reported data: Data captured for healthcare encounters and management may include (1) unscheduled outpatient visits for worsening asthma symptoms, (2) scheduled asthma visits, and (3) recommendations to obtain subspecialty consultation. The subcommittee recommends prospective data capture, using structured forms at the time of the clinical encounter. Researchers should specify the content of these forms and the timing of data collection.

Patient- or family-reported data: The conventional survey data collection method is respondent self-report of asthma healthcare events, using interviews (see Table V for sample survey questions from national health surveys) and respondent-completed questionnaires. A primary consideration in designing data collection instruments is recall period. A summary of early interviewing methodology studies demonstrated a typical “forgetting” curve in which the likelihood of failure to report an event grew with time.[4] Further, underreporting for “small impact” events (eg, a doctor visit) began earlier and was larger than for “big impact” events (eg, a hospital stay). To minimize recall bias, recall periods should be minimized—ideally 2 weeks for low-impact events, such as scheduled office visits, and ≤6 months for major events (hospitalizations).[4] For prospective studies with duration of at least 12 months but with periodic recall periods of shorter length, annual rates should be calculated on the basis of the recall period used (see Sullivan et al, 2007[5] for an example).

Retrospective studies relying on self-reported data may face a tradeoff between reporting annual event rates and long recall periods. For baseline data collection and for certain

outcomes in retrospective studies, a 12-month recall period may be justified, specifically for events that are rare (eg, hospitalizations)[6–9] or seasonal (eg, asthma school absences).

Administrative data sources (claims data, medical records, pharmacy data, and encounter data from managed care organizations): Events gathered from claims data are identified using a discharge diagnosis of asthma (International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9CM] codes beginning with 493). The coding position(s) used should be justified according to the research question (eg, using the primary coding position may be appropriate for assessing acute increase in asthma symptoms, whereas choosing asthma codes in any position may better capture a broader picture of healthcare resource use among persons with asthma). Pharmaceutical data are used to identify the name and strength of medications, dosing schedules, and dispensing events. Orders or prescriptions for asthma-specific long-term control medications such as inhaled corticosteroids or quick-relief medications such as short-acting β-agonists (SABAs) may be reasonably attributed to asthma care, depending on patient age and comorbidities. Asthma medications could be reported by drug class, such as long-acting β-agonists, SABAs, inhaled corticosteroids, leukotriene (LT)-modifying drugs, anti-IgE therapy, and systemic corticosteroids. However, costing medications requires data on individual compounds, because the products can vary in price, even within the same drug class. A listing of appropriate medications for people with asthma can be found at the National Committee for Quality Assurance Web site (http://www.ncqa.org/tabid/1091/Default.aspx). Systemic corticosteroid use (by tablet, suspension, or injection) for short duration, differentiated from the small subset of patients with asthma on chronic systemic corticosteroids, is an indicator of exacerbations and should be recorded as an annual event rate per patient. Antibiotics and short courses of high-dose inhaled corticosteroids are frequently prescribed for asthma exacerbations, and capture should be considered. To correctly attribute medication use to asthma care, researchers should specify *a priori* how they will exclude potential use of these medications for conditions such as chronic obstructive pulmonary disease (COPD), cystic fibrosis, and bronchiolitis.

Ascertainment and reporting—When reporting event counts, drawing inferences from summary statistics among groups can be problematic, given the fact that event count distributions are often skewed and have a large proportion of zeros. Sample size and data distribution should be evaluated to ensure that appropriate analysis measures are used.[10, 11] Providing the median and the interquartile range of count data, in addition to reporting the mean, gives greater insight into data distribution.[12] Another common approach is to report a dichotomous measure of the proportion of the group with no event versus any number of events. Dichotomization accounts for zeros but does not capture properties of the distribution, and should be used as an additional rather than a main indicator.

When healthcare event rates for a specified period are reported, the rates should be specific to the study population, and the appropriate study population or subgroup should be used as the denominator (ideally, the group at risk for the outcome being measured).[13–15] Denominators and populations must be described; when rates are compared among groups,

the denominators must be compatible. As discussed above, annual rates should be reported when the data support at least 1 year of follow-up.

Specific considerations for measurement of hospitalizations, ≤23-hour observations, and ED visits: Hospital length of stay and intensive care unit (ICU) days should be tabulated whenever possible. When these data are not available, average length of stay appropriate for the study population may be used, and sources must be specified. For hospitalizations collected from administrative data, a ≥24-hour length of stay is required. In addition, ≤23-hour observations should be explicitly included to avoid missing asthma healthcare utilization events, and should be counted separately from hospitalizations. When self-reported data are used, ≤23-hour observations will likely be captured as hospitalizations or ED visits. Investigators should specify how ≤23-hour observations are captured (ie, as hospitalizations or as ED visits).

To identify respiratory-related hospitalizations among patients previously diagnosed with asthma, other conditions may be included: pneumonia, influenza, and acute cardiopulmonary conditions. (ICD-9CM codes 422, 427–428, 460–466, 470–474, 480–487, and 490–519 have been used previously for this purpose.[16]) Capturing healthcare resource use for respiratory conditions that are closely related to asthma or that may result from complications of asthma helps to ensure comprehensive accounting. Respiratory-related outpatient and ED visits also may be collected to more completely represent morbidity that does not necessarily result in a hospitalization, using the same codes listed above. For all respiratory-related healthcare utilization visits captured, researchers should specify the coding positions used. The first and second positions may be a reasonable choice, although for outpatient visits, using all listed codes may be justified.

Hospital transfers and multiple bills for single hospitalizations may result in overcounting hospitalizations. Investigators should describe how hospital admission, readmission, and transfer are defined. For example, transfers may be identified by a new admission at a different hospital occurring within 24 hours after discharge. A new hospital admission within 7 days after discharge may be considered a readmission. Depending on study objectives, readmissions may be analyzed separately from admissions.

Special considerations for outpatient visits: If possible, outpatient visits should be identified either as scheduled (preventive) or unscheduled. Unscheduled visits can be considered a marker of poor asthma control; in contrast, scheduled visits may reflect optimal asthma management, because routine periodic review of disease control is a main component of recommended management.[17] Comprehensive scheduled health visits for patients previously diagnosed with asthma also may be included even without an asthma-specific diagnostic code due to the likelihood that asthma was addressed at these visits.

Currently, there is no standard methodology for distinguishing scheduled and unscheduled visits. The recommendation in the *ATS/ERS Statement* that a clinical definition be used—"an unscheduled patient-initiated visit resulting from worsening asthma symptoms"—remains the preferred option. If this definition cannot be used, another possible approach is categorizing primary care visits scheduled at least 72 hours in advance as scheduled care.

Often a scheduled visit may follow shortly after an unscheduled visit and may represent an attempt to reduce the need for future unscheduled visits. Although these scheduled follow-up visits also may result from worsening asthma symptoms, it may be appropriate to count them as scheduled care visits.

The criteria used to determine a scheduled care visit may differ according to the setting (pediatric vs adult ambulatory care) and should be specified. Additional study is needed to specify the criteria necessary for reliably distinguishing unscheduled care due to exacerbations from care for routine assessment and management.

Ideally, visits for subspecialty care should be measured separately from primary care visits since the 2 types of visits have different unit costs, but the same criteria should be used to categorize subspecialty visits: scheduled versus unscheduled visits. Allergists and pulmonologists are the subspecialists who are primarily involved in consultation related to asthma treatment.

Costs may be assigned to asthma outpatient visits by examining current procedural terminology (CPT) codes in administrative data. CPT codes for patient education and counseling are likely to be increasingly used because of growing attention to reimbursement for certified asthma educators and other staff involved in patient education. Whether patient education is a component of an intervention or occurs incidentally during healthcare encounters, its use should be documented to account for associated costs and potential impact on outcomes. Evaluation and management (E/M) codes beginning with 99 may be used to identify the level of service. For some services, more than 1 code may be applicable. For example, CPT codes 94010, 94060, and 94375 can be used to identify those visits where spirometry is performed. CPT codes also may be used to identify inhalation treatments given in the office (CPT code 94640) and pulse oximetry assessments (94760, 94761, and 94762). Medicare-adjusted allowable limits associated with these CPT codes may be used to assign a cost to these services if data on actual paid amounts are not available.

Specific considerations for patient-initiated remote visits: Patient-initiated remote care events such as e-mail or telephone consultation increasingly supplement traditional face-to-face encounters. The subcommittee encourages researchers to define methods for capturing and assigning costs to these emerging healthcare activities. Remote visit data are lacking from most healthcare claims and encounter datasets, but may increase with the use of electronic medical records. Further, costs are not well established for remote visits. Mean or median paid amounts per call for after-hours nurse triage services may be used as an estimate. Clinician and office staff time required to handle e-mail or telephone consultations may also provide a cost estimate. There are no known standardized survey instruments used in large studies to capture remote visit rates.

Medical and scientific value—Hospitalization is a theoretically avoidable and costly outcome for patients with asthma; hospitalization predicts those at highest risk for asthma-specific morbidity and mortality, and is potentially sensitive to the quality of ambulatory care and patient compliance with care.[18, 19] Similarly, ED visits may occur when there are barriers to high-quality ambulatory care. Scheduled primary care visits to assess and treat

asthma may improve the QOL for patients and reduce costly ED visits and hospitalizations, whereas unscheduled primary care visits are an important indicator of asthma exacerbations. Clinical consensus suggests that strategic use of asthma specialists may improve QOL for asthma patients and reduce costly ED visits and hospitalizations.[17] Increasingly, remote visits are used to manage asthma. The benefits of these consultations to enhance or replace office consultations remain an area of active investigation, as do the methods for capture and cost assignment.

Practicality of measurement and risk to the study population—Measurement of asthma-specific healthcare events and resource utilization is generally feasible and low risk, and this measurement presents low collection burdens, given routine claims and encounter data and a variety of survey instruments. As with any data on protected health information, maintaining participant confidentiality is of utmost importance.

Demographic considerations—Age, sex, race/ethnicity, socioeconomic status (SES), employment status, education, comorbidities, insurance coverage, and geographic factors may all affect asthma-specific healthcare utilization. Therefore, characteristics of the study population should be specified. The subcommittee recommends subgroup stratification whenever possible, to allow direct comparison of rates and costs among subgroups.

B. Intervention-Related Resources

The focus of this section is defining and measuring intervention-related resources, such as personnel time, that are not captured in healthcare claims and encounter data.

Definition and methodology for measurement—Collecting and reporting data on resource use related to the intervention enables comparisons among alternative interventions and full accounting of cost for the purposes of comprehensive comparative effectiveness research or meta-analyses. Research costs (design, implementation, procedures required for evaluation of intervention) should not be included. The use and cost of asthma interventions may not always be captured as part of the clinical trial or in healthcare claims or encounter data, and it is important to accurately capture this information. Examples include pharmaceuticals provided in physician offices, asthma teaching, allergy testing, allergen immunotherapy, pulse oximetry, spacing devices, nebulizers, spirometry, other pulmonary function testing, assessment of airway hyperresponsiveness or reversibility of obstruction, and smoking cessation. Time invested by both personnel and patients for treatment and travel also must be considered, and should be separable from those costs that are incurred to implement the research.

Information on use of asthma medication is available from most data sources, although the extent of information will vary.[2] Asthma medications used in an intervention may be categorized as long-term control or quick relief (or “rescue” or “relievers”). More specifically, asthma medications could be reported by drug class, such as inhaled corticosteroids, long-acting β-agonists, SABAs, LT-modifying drugs, anti-IgE therapy, and systemic corticosteroids. The subcommittee recommends that records of asthma medications used in the study intervention should capture the drug name, dose, and duration.

Supplies, equipment, and other required materials can often be tracked through an accounting system or other tracking system. Many of these items will frequently produce a record as part of their purchase and should be included in calculating the costs of the intervention. In addition to the direct resource use and cost of the intervention, there may be patient costs of the intervention that can be captured (eg, time spent for treatment and travel). Whether to include these resources and costs in an analysis will depend on the perspective of the analysis.

Personnel time can be the largest component of intervention resources and costs, but it is often difficult to measure. Several measurement approaches have been used to estimate the opportunity costs associated with interventions, including time-and-motion studies with direct observation, self-reported time logs, personnel interviews, and random work sampling.

Time-and-motion studies measure personnel time required for the intervention through direct observation and documentation of personnel activities.[20–26] It may not be necessary to observe entire days or shifts; a sampling of time periods can be used to estimate overall personnel requirements. The choice of the sampling timeframe is important, because personnel activities may change over the course of the intervention period and the sampling strategy should capture such changes. Time-and-motion studies have several limitations. They involve the high cost of trained observers; direct observation may lead to a Hawthorne effect of the personnel aware of the observation; and observers may have difficulty distinguishing between those activities that are related to the intervention and those that are not.

Self-reported time logs and personnel interviews require personnel to directly report on intervention time requirements. Although these 2 approaches are less expensive than time-and-motion studies, they also have limitations. Time logs are subject to the same limitations as daily diaries used to capture patient-reported outcomes. Both time logs and personnel interviews may be subject to recall bias, and both may fail to capture measures of personnel time as precisely as those from time-and-motion studies. However, in contrast to observers, personnel can differentiate intervention and nonintervention activities in time logs and interviews.

An alternative approach is random work sampling of personnel throughout an observation period by prompting them to report on current activities.[27–34] The samples are used to determine the amount of time spent in various activities; these estimates provide a basis from which overall time requirements can be estimated. The work-sampling approach does not require direct personnel observation, which may lessen any Hawthorne effect; it entails lower burden than complete activity logs; and it reduces recall bias because personnel report on their activities shortly after prompting.

Personnel time should be reported as personnel time per study participant per year of intervention (or relevant duration period).

Validity—Different methods for measuring personnel time may produce different outcomes. In some studies, time-and-motion studies and interviews resulted in similar estimates of overall time but substantially differed for categories of activities.[35] Other investigators indicate that self-reported work recall results in overestimation of the time spent in the activities perceived as important or necessary or activities that were disliked.[27] Further, without accurate distinction between research and usual clinical activities, self-reporting can lead to biased estimates of cost and cost-effectiveness.[27] Finally, it is necessary to have a large number of observations over a sufficient amount of time with the work sampling approach; otherwise the results may not be as precise as findings from a time-and-motion approach.[36]

C. Other Asthma-Related Events

Events that occur outside the healthcare arena also can contribute to asthma costs. Indirect costs from such nonmedical events as work and school absences are frequently used as indicators of asthma control and efficacy of interventions.[37] This section focuses on (1) work absence and productivity loss and (2) school absence and academic impact.

1. Work absenteeism and presenteeism

Definition and methodology for measurement: Absenteeism is the time missed from the workplace[38]; a "work absence day" for national health surveys is "a day in which a currently employed person 18 years of age or over missed more than half a day from a job or business."[39] Absenteeism data are predominantly collected via respondent self-report. Presenteeism is health-related productivity loss while at paid work.[38] Although presenteeism is currently not captured or reported in most studies, some studies suggest that it accounts for the majority of productivity loss from asthma.[37, 40]

The validated survey instrument most often used in asthma research to measure absenteeism and presenteeism is the nonproprietary Work Productivity and Activity Impairment Questionnaire (WPAI),[41] which produces 4 metrics: absenteeism (percentage of missed work time), presenteeism (reduced effectiveness while working), overall work productivity loss (absenteeism and presenteeism), and impairment in other activities (see http://www.reillyassociates.net/WPAI_General.html). The WPAI has a general version, as well as condition-specific versions (including 1 for asthma).

Absenteeism has been reported as total counts, mean number of days, rates, and the proportion of study participants with at least 1 absence day. Like healthcare events, summary statistics for counts should include the mean, median, and interquartile range. Similarly, 12-month rates should be presented using appropriate denominators (eg, those employed). The WPAI collects missed work time in hours and provides a summary measure of the percentage of missed work time in the previous 7 days. Therefore, the subcommittee recommends including the WPAI measure of percentage of missed work time due to asthma symptoms, in addition to counts of absence days. As discussed above, for events, extrapolation of a 7-day period to a longer period is not recommended. Rather, periodic administration of the WPAI would allow for comparison of WPAI percentage of missed work times at different periods (see Chen et al, 2008[40] as an example).

Range of values: The range of the percentage of work impairment varies with asthma severity[40] and control,[42] but there are few comparisons with the range of impairment within the general population. Work absence days differ significantly between groups with and without asthma, and by characteristics of participants with asthma (eg, weight status, sex, level of asthma control).

Repeatability and responsiveness: Scores from the allergic disease version of the WPAI were found to have acceptable reliability (internal consistency/reproducibility) for work performance and attendance.[43, 44]

All 4 metrics from the asthma-specific WPAI have been found to be sensitive to differing levels of asthma control in descriptive cross-sectional and longitudinal studies.[40, 42] WPAI-allergic disease scores for overall work impairment tracked 2-week symptom severity and were judged responsive to clinically meaningful changes in allergy symptoms.[44]

Validity: The construct validity of the general and asthma-specific WPAI has been established for overall work productivity (absenteeism and presenteeism), using general health perceptions,[41] asthma control, and asthma-specific QOL.[40, 42] Predictive validity of WPAI work impairment scores for asthma healthcare utilization at 12-month follow-up also has been demonstrated.[40]

Associations: Work absence assessed using the asthma-specific WPAI discriminated between controlled and uncontrolled asthma.[5] Asthma-specific WPAI scores also predicted work cessation, ED visits, and hospitalizations at 12 months but was poorly correlated with lung function.[40]

Practicality and risk: The WPAI and other self-report instruments have low respondent burden and cost. Administration of the WPAI by an interviewer improved data quality (providing a lower rate of missing responses).[41] Although interviewer administration may add significantly to the cost and burden of data collection, this is the recommended data collection method, especially if data collection for this instrument can be combined with other interviewer-mediated data collection.

Demographic considerations: Employment status necessarily limits the portion of the study sample included in work productivity measures. Type of employment (eg, the number and difficulty of physical tasks involved[41]) also may bias the sensitivity of a work impairment measure. Demographic characteristics, such as SES and health literacy, also may be associated with differences in sensitivity and recall bias.[45, 46] As with measures of healthcare utilization, the subcommittee recommends stratification of results by demographic and work-related characteristics when possible.

2. School absences and academic impact—Most published studies find no overall differences in measures of academic achievement between students with and without asthma, but have reported differences for subpopulations of children with severe symptoms or with contributing factors, such as low SES.[47] Measures of academic outcomes have received scant attention, but preliminary evidence suggests that teacher ratings of

performance and standardized test scores are the preferred emerging outcome measures for inclusion in clinical studies. More evidence is required to determine whether weak evidence of a link between asthma status and academic performance reflects lack of sensitivity of existing measures, lack of focus on academic outcomes likely to be affected by better disease control, or negligible effect of asthma management on academic performance.

Definition and methodology for measurement: Academic impact of asthma has been measured primarily with retrospectively reported school absence days. Self-report has well-known limitations, and school records may be limited because the records may not separate absences due to asthma and may not count an early dismissal as an absence when an ill child is sent home. Ideally, studies should focus on absences due to asthma. Comparisons of overall absences can be made among study groups, assuming that, in the case of a clinical trial, the participants have been adequately randomized or, in other studies, that participant groups are comparable. As with healthcare events, the subcommittee recommends that summary statistics for counts include the mean, median, and interquartile range, and that rates be reported for 12-month periods. The WPAI can be used to collect a school impairment measure for older children (including both absenteeism and presenteeism) akin to that for work impairment.[40]

Beyond school absence, the most commonly used academic outcome measures for children with asthma have been student grades, standardized test scores, and parent and teacher ratings of performance[47]; however, none of these has been widely accepted by the research community. Therefore, the subcommittee's recommendations for use of 2 of these additional metrics—teacher ratings and standardized test scores— are based on established validity and ease of use:

- The most frequently used instrument for teacher ratings, the Teacher Report Form (TRF) of the Child Behavior Checklist (http://www.aseba.org/products/forms.html), obtains teachers' reports of children's academic performance, adaptive functioning, and behavioral/emotional problems. TRF scores are reported pre- and post-intervention and/or by comparing group means.
- Standardized test scores can be obtained from the school district at predetermined intervals. However, there is no widely recognized instrument or measurement to ensure comparability across studies and cohorts.

Both of these metrics are considered emerging outcomes by the subcommittee.

Responsiveness: Responsiveness has not been determined for teacher ratings or standardized test scores, although 1 study reported changes over a 4-year period in teacher reports of performance among children with low asthma severity. However, children whose asthma conditions improved during this time showed little or no change in teacher reports.[48]

Validity: The construct validity of the asthma-specific WPAI for self-reported school impairment has been measured for asthma control and asthma-specific QOL.[40] The TRF also has established validity. Although validity of standardized test scores is generally not

reported, the scores are norm referenced, criterion referenced, or both, and are likely to have been extensively tested before adoption by school districts or state education systems.[47]

Associations: School absence has been shown to be sensitive to asthma severity.[49] School impairment asthma-specific WPAI scores also have been shown to be sensitive to asthma severity, control, and unscheduled office visits, but not to ED visits or hospitalizations.[40] Sensitivity of teacher ratings or standardized test scores to clinical factors or interventions is not well established.[47] Improvements in asthma severity were not related to changes in TRF scores over time.[48] Standardized test scores showed few differences between children with and without asthma.[50]

Practicality and risk: Teacher ratings can be used more frequently than standardized tests, which are available only at predetermined intervals. Further, standardized test scores require resources to maintain confidentiality, given their importance and meaning in settings outside the research study. Collection of standardized test scores and teacher ratings may present a high burden if patients are recruited across school districts and multiple entities must grant permission for data collection and analysis. Teachers also must be blinded to the study objectives.[47]

Demographic considerations: Although the majority of children with asthma have not been found to experience adverse academic outcomes, certain subpopulations appear at higher risk: those with low SES and those with greater severity of asthma.[48, 51–53] More research is needed to fully examine these relationships.

II. COST AND COST-EFFECTIVENESS ANALYSIS

The section below provides an overview of methods for assigning value to measured units of healthcare utilization, other intervention-related resources, and other outcomes that contribute to the direct and indirect costs of asthma interventions and morbidity. An important consideration across all types of resources when valuing an intervention is distinguishing between those activities that relate to research and those that are part of the intervention. Under most circumstances the research activities should not be included in estimating the overall cost of the intervention. The subsequent section reviews recommended methods for conducting cost-effectiveness analyses of asthma interventions.

A. Valuing Healthcare Events and Resources

The specified perspective of the analysis should guide valuation methodology and contribute to transparent reporting of resources and costs. A broader societal perspective will, at minimum, include costs of lost productivity, as well as direct healthcare costs. Some decision makers may want assurances that all cost implications have been considered; however, others may find more focused perspectives (eg, payer) more pertinent. Therefore, the subcommittee recommends providing disaggregated information on the resource units and costs of an intervention.[3]

Healthcare events—Costs of asthma healthcare events may be estimated using an average unit cost for the healthcare event type. Charges, costs, or payments for in-office

asthma treatments (nebulizer treatment, corticosteroid administration), assessments (eg, pulse oximetry, spirometry), and testing (skin prick testing and spirometry) should be tabulated separately when possible. The subcommittee strongly recommends using paid amounts rather than charges or billed amounts because they are closer approximations of cost.

However, paid amounts may not always adequately represent true costs—for example, in settings where unreimbursed care may be common. Standard sources of cost estimation (eg, Medicare Physician Fee Schedule,[54] Red Book Drug Topics, hospital cost-to-charge ratio[55]) are available for situations where study- or institution-specific payments may not be available. Disclosure of unit cost sources is encouraged. The presentation of cost estimates should include a table of the independent cost for each included healthcare event.

Intervention-related resources—Measurement of all intervention-related resource costs is an important component of estimating the cost-effectiveness of interventions. Many resources can be captured from administrative data; however, examples of studies that include resources not captured from administrative data are those evaluating the cost-effectiveness of planned asthma care interventions (nursing personnel),[56] counseling (social worker personnel),[57] and remediation of environmental exposures (equipment such as high efficiency particle arrestor [HEPA] filters).[58]

Perspective and timeframe—The perspective and timeframe of the analysis are important when considering measurement and valuation of intervention-related resources. The perspective defines which costs are necessary to capture. Perspectives may be specific to healthcare payers, insurers, employers, healthcare institutions (eg, hospitals), clinicians, and patients, or may be more general when considering costs to society. Each of the perspectives may result in capturing and valuing different intervention components. For example, from a societal perspective, all costs associated with an intervention must be captured; in contrast, from a healthcare payer perspective, services for which the payer does not pay should be excluded. The timeframe of the analysis is an important consideration for capturing costs. The costs of the intervention may vary with time—for example, costs that were high when the intervention was initially implemented may fall as providers become more familiar with it. Alternatively, the costs of the intervention may increase over time as the intervention is scaled to full capacity.

To estimate overall intervention costs, personnel time must be valued in monetary terms. The most common approach is to use average wage rates by age, sex, and position type, an approach recommended by the US Panel on Cost-Effectiveness in Health and Medicine.[59] The analysis perspective may alter the choice of wage rates or other cost estimates. For example, if the analysis were conducted from a hospital perspective and the intervention were provided by hospital employees, it would be appropriate to include cost estimates of those personnel, including benefits and administrative costs.

The valuation of nontime costs should reflect market prices.[59] Ideally, the unit costs should reflect the average price in the location where the intervention will be implemented, and

therefore may reflect local, regional, or national prices. Travel costs can be valued using the federal travel reimbursement rate.

Time and travel costs for patients should be considered, especially from a societal viewpoint. Patient travel costs can be captured through patient reporting logs or surveys or by use of a standard mileage rate for distance from the patient's residence to the healthcare site. Patient time spent for travel and treatment can be measured in several ways, including a gender-specific dollar amount for employed patients and assignment of the minimum wage or national average wage for home healthcare workers for unemployed or retired patients.[60]

Events outside the healthcare arena (work and school absences)—Valuation of work absence days is estimated using gender-specific dollar amounts applied for lost hours/days of work.[5] Although estimating the cost of work presenteeism is possible using the WPAI, no validated methods exist.[37] Missed school days for children are typically valued as the lost work of a parent caring for the child and calculated using a gender-blended pay rate.

B. Cost-Effectiveness Analyses

Economic evaluations of medical interventions are now routinely carried out by academic researchers, the healthcare industry, and healthcare payers, with the objective of informing clinical guidelines, research priorities, or coverage and reimbursement decisions. This trend reflects increasing interest in knowing whether interventions represent good value for the money in an environment of constrained resources. Use of health economic tools facilitates decision making by clearly identifying the relevant interventions, transparently evaluating the perspectives and inputs of the strategies, and modeling uncertainty and "what if" scenarios. The following section presents an overview of economic evaluations. Due to the complexities of cost analyses, it will be important for intervention studies that have a cost hypothesis to include the appropriate investigator expertise to select the appropriate tools and methods for resource use measurement and cost analysis. There are a number of published sources on methods for undertaking economic evaluations of medical technology.[61, 62] These texts detail accepted methodology for identifying, measuring, and valuing healthcare and non-healthcare resources as part of good research practice. There is a great deal of robust debate on these methods, but experts have generally embraced a common set of principles and approaches.[59]

In brief, economic evaluation in health care can be defined as the explicit comparison of 2 or more interventions designed to improve health outcomes in terms of their costs and consequences. For asthma, this may mean that a clinical trial has been designed to test the effectiveness of 2 medications in reducing the frequency of exacerbations in uncontrolled disease. A number of forms of economic evaluation exist, but the predominant methodology is cost-effectiveness analysis (CEA). In CEA, analysts are interested in estimating resource use and costs for patients in each of the intervention groups and comparing the costs with observed differences in outcome.

To estimate the incremental cost-effectiveness ratio (ICER), analysts and many end users prefer the quality-adjusted life year (QALY) outcome in the denominator of the ICER because it allows comparisons across interventions and disease states. In the asthma

economic evaluation literature, some have previously argued that the symptom-free day or asthma control day be used to define the denominator of the ICER.[63] An important reason for this recommendation is that the utility value necessary to estimate the QALY is very difficult to ascertain in disease states that are predominately pediatric or adolescent. However, methods for estimating utility values in diverse populations are improving, and decision-making bodies responsible for resource allocation have codified the QALY as the required denominator for the ICER. For these reasons, the subcommittee recommends using the QALY for all future cost-effectiveness evaluations in asthma.

Transparency and clarity are necessary to effectively present cost-effectiveness analyses. The need for and value of transparency is widely recognized and can provide some protection against the negative effects of bias and error. Users of CEA need to be able to understand all steps in the analytic process to improve their understanding of the key factors and variables in the model and its limitations.[64] Therefore, the subcommittee encourages researchers to focus efforts on the clarity and transparency of results and to provide detailed descriptions that explain the flow and combination of data. All calculations should be explained in a simple, straightforward manner to allow individuals with no economics background to comprehend the analysis. This information and all references to unit costs and external data sources should be accessible to reviewers.

A complete report of the cost-effectiveness analysis should use the following format: (1) introduction/background, (2) methods, (3) results, (4) limitations, and (5) discussion. Below are the minimum recommended figures and tables for reporting asthma cost-effectiveness analyses. These minimum requirements have been adapted from the 2010 US managed care guidelines for submission of economic evaluation data to support coverage and reimbursement,[65] and are consistent with other reporting criteria for CEA.

- **Figure 1**. Provide a figure displaying either the patient flow (for randomized controlled trials) or the structure of the economic evaluation model (eg, a decision tree or Markov model). A simplified schematic diagram may be used for ease of presentation, but a detailed figure also should be included.
- Table 1. Provide a table listing all the analytic inputs, including estimates of resource use, costs, and outcomes. Provide a range of values on which sensitivity analyses are based for each input.
    - Include references in the table for all inputs, including ranges.
    - Note in the table estimates that lack direct supporting evidence.
- Table 2. Provide an explicit list of analytic assumptions, including assumptions about the interventions under comparison, clinical events, patient management, and costs.
- Table 3. Present the disaggregated results in a table (eg, cost-consequence,[66] with costs presented separately from health outcomes). Data presented in this format are more easily understood and interpreted by decision makers. The following specific data should be presented for each intervention:

- Projected clinical events (eg, exacerbations)
- Estimates of life expectancy and quality-adjusted life expectancy
- Total healthcare costs
- Cost of implementing therapy and the resulting cost offsets
- ICERs

- **Figure 2**. Present 1-way sensitivity analyses on all analytic inputs in a figure (eg, tornado diagram) or a table.
  - Clearly present the inputs or assumptions that drive the difference in (1) costs, (2) effects, and (3) incremental cost-effectiveness.
  - When appropriate, present multiway (eg, 2-way, best/worst case scenario, probabilistic, or bootstrapped) sensitivity analyses.

FUTURE DIRECTIONS

The subcommittee identified 4 priority topics for additional research:

1. **Development of survey instruments**. Analysts sometimes rely on poorly validated convention and historical documents from national surveys to elicit measures of healthcare utilization from patients and providers. Development of standardized and validated survey instruments for prospective and retrospective data collection for asthma healthcare and other asthma-related events, for both provider-reported and participant-reported data, would greatly improve comparability between studies and potentially increase the quality of data collected. A possible resource for such an effort is the collection of national surveys used for health surveillance (see Table V).
2. **Development of methods to measure intervention resources**. There are many interventions (eg, education, case management) for which counting units is not straightforward. Further, no standard valuation methods currently exist for many aspects of the burden of asthma (eg, productivity loss from presenteeism, impact of asthma on academic achievement). Methods to more comprehensively measure intervention resources and outcomes, as well as to assign value to a broad range of resource use and morbidities, will allow a fuller accounting and better understanding of treatments, outcomes, and consequences.
3. **Development of methods to evaluate long-term asthma costs**. Currently, the long-term benefit and risk consequences of interventions and outcomes are not well understood or typically captured in clinical research. This includes measurement of long-term impact of asthma (eg, disability and lost lifetime earning potential) and its treatment (eg, long-term consequences of chronic medication use). Methodology for evaluating the lifetime course and cost of asthma and its treatment could potentially improve accounting of costs, as well as highlight intervention areas in need of additional focus.

4. Development of methods for capturing and reporting data from electronic medical records and electronic patient diaries is another emerging need that promises both complexity and added value.

Additional recommendations for future research and methods development include:

1. For primary care asthma visits, there is a need to investigate the distinction between scheduled (preventive) versus unscheduled (urgent care) visits, taking into account population differences. Similarly, when evaluating medications, making a distinction between long-term control (preventive) medications and quick relief (rescue) medications may help better classify resources used to prevent morbidity versus those used as consequence of an acute increase in asthma symptoms.
2. The use of patient-initiated remote care via telephone, e-mail, and other media is an emerging area of importance. Additional research is needed to guide both capture and cost estimation of remote care.

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Abbreviations

ATS	American Thoracic Society
BRFSS	Behavioral Risk Factor Surveillance Survey
CEA	Cost-effectiveness analysis
CPT	Current procedural terminology
E/M	Evaluation and management
ED	Emergency department
ERS	European Respiratory Society
ICD-9CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ICER	Incremental cost-effectiveness ratio
ICU	Intensive care unit
ISAAC	International Study of Asthma and Allergies in Childhood
LT	Leukotriene

MEPS	Medical Expenditure Panel Survey
NHANES	National Health and Nutrition Examination Survey
NHIS	National Health Interview Survey
NIH	National Institutes of Health
NSCH	National Survey of Children's Health
QALY	Quality-adjusted life year
QOL	Quality of life
SABA	Short-acting β-agonist
SES	Socioeconomic status
SLAITS	State and Local Area Integrated Telephone Survey
TRF	Teacher Report Form
WPAI	Work Productivity and Activity Impairment Questionnaire

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TABLE I

Recommendations for classifying outcome measures for asthma healthcare utilization and costs for NIH-initiated clinical research: adult and children populations

	Characterization of study population for prospective clinical trials (ie, baseline information)	**Prospective clinical trial efficacy/ effectiveness outcomes**	**Observational study outcomes***
Core outcomes	History of: **1** Asthma-specific hospital admissions **2** Asthma-specific ED visits **3** Asthma-specific outpatient visits **4** Asthma-specific medication use	**1** Asthma-specific hospital admissions **2** Asthma-specific ED visits **3** Asthma-specific outpatient visits **4** Asthma-specific detailed medication use (name, dose, duration) **5** Resource use related to the intervention (eg, personnel time, mite eradication, equipment)	**1** Asthma-specific hospital admissions **2** Asthma-specific ED visits **3** Asthma-specific outpatient visits **4** Asthma-specific detailed medication use (name, dose, duration) **5** Resource use related to the intervention (eg, personnel time, mite eradication, equipment)
		Measurements of outcomes and resource use should be collected in a detailed, standardized manner, to allow subsequent valuation within and across studies†	
Supplemental outcomes	**1** Categorization of asthma-specific outpatient visits: **a.** Primary care **i.** Scheduled **ii.** Unscheduled **b.** Specialty care **i.** Scheduled **ii.** Unscheduled **2** Respiratory healthcare use (pneumonia, bronchitis, etc) **3** Asthma school absences **4** Asthma work absences	**1** Categorization of asthma-specific outpatient visits: **a.** Primary care **i.** Scheduled **ii.** Unscheduled **b.** Specialty care **i.** Scheduled **ii.** Unscheduled **2** Respiratory healthcare use **3** Asthma school absences **4** Asthma work presenteeism and absenteeism (WPAI instrument) **5** Cost analysis and cost-effectiveness analysis	**1** Categorization of asthma-specific outpatient visits: **a.** Primary care **i.** Scheduled **ii.** Unscheduled **b.** Specialty care **i.** Scheduled **ii.** Unscheduled **2** Respiratory healthcare use **3** Asthma school absences **4** Asthma work presenteeism and absenteeism (WPAI instrument) **5** Cost analysis and cost-effectiveness analysis
Emerging outcomes	**1** Remote visits‡ **2** Teacher rating of student achievement **3** Academic standardized test results	**1** Remote visits‡ **2** Teacher rating of student achievement **3** Academic standardized test results	**1** Remote visits‡ **2** Teacher rating of student achievement **3** Academic standardized test results

ED, emergency department; *NIH*, National Institutes of Health; *WPAI*, Work Productivity and Activity Impairment Questionnaire.

*Observational study designs include cohort, case control, cross sectional, retrospective reviews, and genome-wide association studies (GWAS), and secondary analysis of existing data. Some measures may not be available in studies using previously collected data.

†The intent of the core measures is to provide sufficient detail to allow for estimation of asthma-related costs. It is not expected that each study will conduct cost calculations; rather, we recommend that the specific information on resource use and outcomes needed to calculate direct costs should be included.

[‡]Remote visits include patient-initiated telephone or e-mail contact.

TABLE II

Methods for measuring and reporting core and supplemental outcome measures for healthcare utilization and costs

Outcome	Measure/report method
All healthcare events	Preferred method for prospective studies is structured clinical encounter forms, patient or family-reported data (2-week recall period for low-impact events such as office visit, ≤6 month recall for major events such as hospitalization) Report as: • Count each healthcare event as an independent contribution (in contrast to an episode of care, which may include multiple events). • For ≥12-month studies, report as annual counts and/or rates. Extrapolation in studies of shorter duration is not recommended. • Rates of healthcare events should use an appropriate denominator (eg, the population at risk for the outcome) and a common denominator when rates are compared. • Report: ○ Mean, median, and interquartile range ○ Optional additional measure: proportion of the group with none versus any number of events
Asthma-specific healthcare events and resource utilization • Hospital admission (asthma related) • Hospital admission (respiratory related, in patients who have asthma) • ED visits	• Hospital-asthma admission preferred method: Length of stay and ICU days. Alternative: Average length of stay for study population. If administrative data, ≥24 hour stay required, describe how admission, readmission, and transfer are defined. • Report ≤23 hour asthma observation stays separately. • Hospital/ED visit costs: ○ Preferred: study- or institution-specific payments, if available. Alternative: use standard sources of cost estimation (eg, hospital cost-to-charge ratio). ○ Disclose unit costs wherever possible.
• Outpatient visits ○ Scheduled (preventive) ○ Unscheduled ○ Subspecialist care ○ Remote care	• Outpatient visits: ○ Scheduled: Count comprehensive scheduled health visits for asthma patients, asthma-specific preventive visits, and visits scheduled at least 72 hours in advance. ○ Unscheduled: Count patient-initiated visits resulting from worsening symptoms. ○ Subspecialty: Count separately, and categorize as scheduled and unscheduled visits. ○ Remote visits: e-mail, telephone, consults. Costs: No standardized method; if rates are not established, use mean or median paid amounts per call for nurse triage service as estimate; or costs estimate of clinical/staff time to handle email/telephone consult.
• Outpatient costs	• Outpatient costs ○ In administrative data, use CPT codes; use E/M codes to identify level of service (eg, spirometry, inhalation therapy, pulse oximetry, and where reported, patient education/counseling). ○ If actual paid amounts not available, use Medicare adjusted allowable limits associated with these CPT codes.
Respiratory outpatient and ED visits and hospitalizations	Respiratory visit and admission diagnostic categories—for example, ICD-9CM codes 422,427–428, 460–466, 470–474,480–487, and 490–519.

Outcome	Measure/report method
Intervention-related resources • Medication • Supplies • Patient costs • Personnel time	Measure resource use that may not be captured in healthcare claims and encounter data. Research costs (design, implementation, evaluation) should not be included). • Report medication name, dose duration. Report utilization by class of medication per person per year. • Report purchase cost. • Report time invested for treatment and travel. • Methods include time-and-motion studies and work sampling. Report as personnel cost per study participant per year.
Other asthma-related events • Absenteeism ○ School ○ Work	• Count days missed from school (preferably days missed due to asthma). Report rates for 12-month periods, as mean, median, and interquartile range. • Use WPAI (http://www.reillyassociates.net/WPAI_General.html) to count work absence days. Report as total counts, mean number of days, rates, and the proportion of study participants with at least 1 absence day. Summary reports include mean, median, and interquartile range with 12-month rates and appropriate denominators (eg, those employed). • May also use WPAI measure of percentage of missed work time due to asthma symptoms.
• Presenteeism ○ School ○ Work	• Use Teacher Report Form of Child Behavior Checklist (http://www.aseba.org/products/forms.html) or standardized test scores. • WPAI can be used to collect a school impairment measure for older children. • WPAI instrument measures reduced effectiveness while working.
Cost-effectiveness analysis	• See Section II: Cost and Cost-Effectiveness Analysis.

CPT, current procedural terminology; *ED*, emergency department; *E/M*, evaluation and management; *ICU*, intensive care unit; *ICD-9CM*, International Classification of Diseases, Ninth Revision, Clinical Modification; *WPAI*, Work Productivity and Activity Impairment Questionnaire.

TABLE III

Key points and recommendations for Section I

1	*Perspective of the analysis*. The study perspective (patient, clinician, payer, society) should be specified and used to guide data collection and measurement of outcomes. Study perspective also provides the context for interpreting published study results.
2	*Defining healthcare utilization*. For the purposes of measuring healthcare utilization and cost, each healthcare event should be considered as independently contributing to healthcare utilization and costs; this is an important distinction from defining an asthma exacerbation or episode of care, where healthcare events may be combined. Another aspect that distinguishes measurement of healthcare utilization from measurement of exacerbations is that the former provides adequate information to allow for cost assignment transparency or subsequent valuation.
3	*Study timeframe*. Because asthma healthcare utilization and other events may be seasonal or rare, we highly recommend a 12-month follow-up period for healthcare utilization. For studies of 12-month duration or longer, outcomes should be reported as annual counts and/or rates. We do not recommend extrapolating outcomes collected in studies of shorter duration than 12 months.
4	*Differentiating types of healthcare utilization*. Where possible, unscheduled healthcare visits, which are considered indicators of worsening asthma, should be distinguished from scheduled (preventive) visits, which are appropriate for ongoing assessment of asthma control and management.
5	*Resource utilization data collection*. Resource use related to the specific intervention should be collected with as much detail as possible. For example, a drug intervention trial would collect medication name, dose, frequency and duration of use, and medication refills. This level of detail for asthma medications should be collected. Personnel time in administering interventions should be measured to help evaluate required resources and cost. The method for measuring personnel time should be clearly justified and the limitations acknowledged. Resource use and personnel time related strictly to research activities should not be included as intervention related.
6	*Measures of productivity loss*. Measures of work or school productivity losses should include absenteeism and also presenteeism, a measure of productivity loss while at work or school, to account for a broader range of impact of asthma morbidity and interventions.

TABLE IV

Key points and recommendations for Section II

Valuing health care events and resources and cost-effectiveness analysis:

1 *Cost reporting*. Report costs per category (eg, total, hospital, medications) per study participant per 12 months.

2 *Unit costs*. Costs may be estimated using average unit cost for the type of healthcare visit (eg, cost per visit, cost per hospital stay, cost per medication). The subcommittee strongly recommends using paid amounts (including patient copayments) rather than charges, because paid amounts are closer approximations of actual transaction cost. If unit costs are used as proxy for paid amounts, disclosure of unit cost values and sources is necessary (eg, institution-specific payments received or costs from a standard source, such as the Medicare Physician Fee Schedule) and must be in line with the stated analytic perspective. The presentation of cost estimates should include a table of the individual unit costs.

3 *Measurement of intervention-related resources*. In some asthma interventions, measuring intervention-related resources (labor costs, home modifications, etc) not typically captured in administrative data is an important part of establishing the cost and cost-effectiveness of the intervention. For example, in measuring personnel time, the measurement approach should be justified and the limitations acknowledged. Whenever possible, the impact of the chosen method on the cost and cost-effectiveness estimates should be evaluated.

4 *How to handle research costs*. Research costs (design, implementation, evaluation) should not be included in estimating the cost of the intervention.

5 *Reporting recommendations*. Transparency and clarity of presentation are critical when reporting cost-effectiveness analysis. Detailed tables and figures describing the inputs, unit cost of input, outcomes, and cost consequences of the intervention(s) should be provided.

TABLE V

Healthcare utilization survey items on national/international health surveys

The following table presents examples of survey questions used to gather self- or proxy-reported data on asthma healthcare utilization. The data sources and acronyms appear at the end of the table.

Hospitalizations	"During the past 12 months, [have you/has your child] stayed overnight in a hospital because of asthma? Do not include an overnight stay in the emergency room." Question used in: • BRFSS Asthma Call-back Survey, 2005-present • NHIS sample adult and sample child core questionnaire, 1997-present • NSCH 2003 questionnaire • SLAITS National Asthma Survey 2003 "During the past 12 months, how many different times did [you/your child] stay in any hospital overnight or longer because of [your/his/her] asthma?" Question used in: • BRFSS Asthma Call-back Survey, 2005-present • SLAITS National Asthma Survey 2003 "In the past 12 months, how many times has your child been admitted to hospital because of wheezing or asthma?" Question used in: • ISAAC Phase II module — "How many nights did (PERSON) stay in (PROVIDER)?" — "Did this hospital stay begin with a visit to an emergency room?" — "Was this hospital stay related to any specific health condition or were any conditions discovered during this hospital stay?" — "What conditions were discovered or led (PERSON) to enter the hospital?" — "Tell me which category best describes the reason (PERSON) entered (PROVIDER) on (ADMIT DATE): operation, treatment, diagnostic tests, delivery, pregnancy-related complications, other." — "At the time (PERSON) (were/was) discharged, were any medicines prescribed for (PERSON)? Please do not include medications received while (PERSON) (were/was) a patient in the hospital." — "Please tell me the names of the prescribed medicines from this stay that were filled." Questions used in: • MEPS Hospital Stay Questionnaire
ED visits	"During the PAST 12 MONTHS, [have you/has your child] had to visit an emergency room or urgent care center because of asthma?" Question used in: • NHIS sample adult and sample child core questionnaire, 1997-present • NHANES core questionnaire, 1999-present • BRFSS Asthma Call-back Survey, 2005-present • SLAITS National Asthma Survey 2003 "During the past 12 months, how many times did [you/your child] visit an emergency room or urgent care center because of [your/his/her] asthma?" Question used in: • BRFSS adult asthma module 2001-present • BRFSS Asthma Call-back Survey, 2005-present • SLAITS National Asthma Survey 2003 — "Did (PERSON) see a medical doctor during this particular visit?"

	— "Tell me which category best describes the care (PERSON) received during the visit to (PROVIDER) emergency room on (VISIT DATE): diagnosis or treatment, emergency room, psychotherapy, follow-up, immunization, pregnancy-related, other." — "Was this visit related to any specific health condition or were any conditions discovered during this visit? — "What conditions were discovered or led (PERSON) to make this visit?" — "During this visit, were any medicines prescribed for (PERSON)? Please include only prescriptions which were filled." — "Please tell me the names of the prescriptions from this visit that were filled." Questions used in: • MEPS Emergency Room Questionnaire
Scheduled visits	"During the past 12 months, how many times did [you/your child] see a doctor or other health professional for a routine checkup for [your/his/her] asthma? Question used in: • BRFSS adult asthma module 2001-present • BRFSS Asthma Call-back Survey, 2005-present • SLAITS National Asthma Survey 2003
Unscheduled visits	"Besides those emergency room or urgent care center visits, during the past 12 months, how many times did [you/your child] see a doctor, nurse or other health professional for urgent treatment of worsening asthma symptoms?" ["or an asthma episode or attack?"—BRFSS Call-back Survey extra wording] Question used in: • BRFSS adult asthma module 2003-present • BRFSS Asthma Call-back Survey, 2005-present • SLAITS National Asthma Survey 2003
All outpatient visit types and remote visits	"In the past 12 months, how many visits has your child made to any of the following health professionals for wheezing or asthma: — for a regular 'check-up' for asthma?" [health worker, nurse, doctor, hospital emergency department] — for a wheezy episode?" [health worker, nurse, doctor, hospital emergency department] Questions used in: • ISAAC Phase II module "During the past 12 months, how many times did your child see a doctor or other healthcare provider because of [his/her] asthma?" Question used in: • NSCH 2007 questionnaire **If outpatient department:** — "Did (PERSON) visit the outpatient department at (PROVIDER) on (VISIT DATE) in person or was this a telephone call?" **If medical provider:** — "Did (PERSON) visit (PROVIDER) on (VISIT DATE) in person or was this a telephone call?" — "What kind of place is that—a managed care plan center or HMO, a clinic, a doctor's office, or some other place?" **Then all respondents receive these questions:** — "Did (PERSON) see a medical doctor during this particular visit?/Was this telephone call about (PERSON)'s health with a medical doctor?" **IF MEDICAL DOCTOR:** "What was the doctor's specialty?" **IF NOT MEDICAL DOCTOR:** "What type of medical person did (PERSON) talk to on (VISITDATE)?" — "Tell me which category best describes the care (PERSON) received during the visit to the outpatient department at (PROVIDER) on (VISIT DATE): general checkup, diagnosis or treatment, emergency, psychotherapy, follow-up, immunization, vision exam, pregnancy related, well child exam, other."

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<td>

— “Was this [visit/telephone call] related to any specific health condition or were any conditions discovered during this [visit/telephone call]?”
— “What conditions were discovered or led (PERSON) to make this [visit/telephone call]?”
— “Which of these treatments, if any, did (PERSON) receive during this visit: physical therapy, occupational therapy, speech therapy, chemotherapy, radiation, dialysis, iv therapy, drug or alcohol treatment, allergy shot, psychotherapy, immunizations, no treatments?”
— “Which of these services, if any, did (PERSON) have during this visit: laboratory test, ultrasound, x-rays, mammogram, MRI, CAT scan, EKG, EEG, vaccination, anesthesia, other diagnostic test, throat swab, no serviced received?”
— “During this [visit/telephone call], were any medicines prescribed for (PERSON)? Please include only prescriptions which were filled.”
— “Please tell me the names of the prescriptions from this [visit/telephone call] that were filled.”

Questions used in:

MEPS Medical Provider Visits Questionnaire
MEPS Outpatient Department Questionnaire

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<tr>
<td>Medication use, by class (short- or long-term control)</td>
<td>
“Have you ever used a PRESCRIPTION inhaler?” [Y/N] IF YES:
“DURING THE PAST 3 MONTHS, [have you/has your child] used the kind of PRESCRIPTION inhaler THAT YOU BREATHE IN THROUGH YOUR MOUTH, that gives QUICK relief from asthma symptoms?”
Question used in:

NHIS sample and sample child asthma supplement questionnaire, 2003, 2008

“During the past 30 days, how often did you use a prescription asthma inhaler DURING AN ASTHMA ATTACK to stop it?”
Question used in:

BRFSS adult asthma module 2005-present

“[Have you/has your child] EVER taken the preventive kind of ASTHMA medicine used every day to protect your lungs and keep you from having attacks? Include both oral medicine and inhalers. This is different from inhalers used for quick relief.” IF YES:
“Are you NOW taking this medication (that protects your lungs) daily or almost daily?”
Questions used in:

NHIS sample and sample child asthma supplement questionnaire, 2003, 2008

“During the past 30 days, how many days did you take a prescription asthma medication to PREVENT an asthma attack from occurring?”
Question used in:

BRFSS adult asthma module 2005-present

“In the past 3 months, [have you/your child] taken prescription asthma medicine using an inhaler?” IF YES:
In the past 3 months, what medications did [you/your child] take by inhaler? [MARK ALL THAT APPLY. PROBE: Any other medications?]
<table>
<tr><th>Brand name</th></tr>
<tr><td>Advair</td></tr>
<tr><td>Aerobid</td></tr>
<tr><td>Albuterol</td></tr>
<tr><td>Alupent</td></tr>
<tr><td>Atrovent</td></tr>
<tr><td>Azmacort</td></tr>
<tr><td>Beclomethasone dipropionate</td></tr>
<tr><td>Beclovent</td></tr>
<tr><td>Bitolterol</td></tr>
<tr><td>Brethaire</td></tr>
<tr><td>Budesonide</td></tr>
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Brand name
Combivent
Cromolyn
Flovent
Flovent Rotadisk
Flunisolide
Fluticasone
Foradil
Formoterol
Intal
Ipratropium bromide
Levalbuterol tartrate
Maxair
Metaproteronol
Nedocromil
Pirbuterol
Proventil
Pulmicort Turbuhaler
QVAR
Salbutamol
Salmeterol
Serevent
Symbicort
Terbutaline
Tilade
Tornalate
Triamcinolone acetonide
Vanceril
Ventolin
Xopenex HFA
Other, Please Specify

Question used in:

- BRFSS Asthma Call-back Survey, 2005-present
- SLAITS National Asthma Survey 2003
  - — “During this [visit/telephone call], were any medicines prescribed for (PERSON)? Please include only prescriptions which were filled.”
  - — “Please tell me the names of the prescriptions from this [visit/telephone call] that were filled.”

Questions used in:

- MEPS Outpatient Department Questionnaire
- See also MEPS Prescribed Medicines Questionnaire

BRFSS, Behavioral Risk Factor Surveillance Survey; *ISAAC*, International Study of Asthma and Allergies in Childhood; *MEPS*, Medical Expenditure Panel Survey; *NHANES*, National Health and Nutrition Examination Survey; *NHIS*, National Health Interview Survey; *NSCH*, National Survey of Children's Health; *SLAITS*, State and Local Area Integrated Telephone Survey.

For more information:

BRFSS: Administered by the Centers for Disease Control and Prevention, disproportionate stratified random sampling telephone survey. See http://www.cdc.gov/brfss/questionnaires/questionnaires.htm.

BRFSS Asthma Call-Back Survey: Continuation of the SLAITS National Asthma Survey, administered by the Centers for Disease Control and Prevention, random digit dial telephone survey. See http://www.cdc.gov/asthma/survey/brfss.html.

ISAAC: See http://isaac.auckland.ac.nz/phases/phases.html.

MEPS: Administered by the Agency for Healthcare Research and Quality, face-to-face household interview. See http://www.meps.ahrq.gov/mepsweb/survey_comp/survey.jsp#Questionnaires.

NHANES: Administered by the Centers for Disease Control and Prevention, face-to-face household interview. See http://www.cdc.gov/asthma/pdfs/NHANESquestions.pdf.

NHIS: Administered by the Centers for Disease Control and Prevention, face-to-face household interview. See http://www.cdc.gov/nchs/nhis.htm.

NSCH: Administered by the Centers for Disease Control and Prevention, random digit dial telephone survey. See http://www.cdc.gov/nchs/slaits/nsch.htm.

SLAITS 2003 National Asthma Survey: State and Local Area Integrated Telephone Survey, administered by the Centers for Disease Control and Prevention, random digit dial telephone survey. See http://www.cdc.gov/nchs/slaits/nas.htm.