National Asthma Education and Prevention Program Task Force on the Cost Effectiveness, Quality of Care, and Financing of Asthma Care

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FOREWORD

The 1991 release of the National Asthma Education and Prevention Program's *Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma* marked a significant first step in the program's commitment to reducing asthma-related morbidity and mortality in the United States. With the wide dissemination and promotion of the guidelines, the NAEPP endeavored to improve clinicians' understanding of how to effectively manage asthma.

Recognizing that improved clinical knowledge alone is not sufficient to change asthma-related outcomes, the NAEPP has sought to identify and address other factors that may inhibit effective control of asthma. With this goal, the NAEPP established the Task Force on the Cost Effectiveness, Quality of Care, and Financing of Asthma Care in 1992.

Under the leadership of Kevin Weiss, M.D., M.P.H., the task force was charged with reviewing current knowledge of the economic factors that influence the delivery of asthma care and making recommendations to improve the quality of asthma care in this country. Three separate working groups explored and addressed issues relevant to specific topics.

The Working Group on the Cost Effectiveness of Asthma Care, chaired by John Eisenberg, M.D., sought to identify and characterize the role of cost-effectiveness analysis in selecting asthma management strategies. The Working Group on the Quality of Asthma Care, chaired by Mark Young, M.D., worked to develop an asthma quality improvement approach applicable to a variety of settings. The Working Group on the Financing of Asthma Care, chaired by Jinnet Fowles, Ph.D., made recommendations for the financing of health care that are likely to lead to improvements in asthma management.

Although each working group report was prepared with different audiences in mind, their recommendations are interrelated and are therefore presented here together. It is hoped that they will serve as a springboard for improvements in the delivery of asthma care in a variety of environments.

On behalf of the NAEPP Coordinating Committee and the National Heart, Lung, and Blood Institute, I would like to acknowledge the dedicated effort of the task force and, in particular, its chair. Dr. Weiss was the driving force behind this unprecedented report, and it is to his credit that the unique and valuable information in the report can now be made available.

Claude Lenfant, M.D.
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INTRODUCTION

In 1988, the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health recognized that data from the United States as well as from around the world showed increasing asthma prevalence, morbidity, and mortality despite the availability of effective treatment. The National Asthma Education Program (now known as the National Asthma Education and Prevention Program—NAEPP) was created in response to this public health concern.[1]

The NAEPP's overall goals are to decrease asthma morbidity and mortality and to optimize the quality of life for persons with asthma. One of the program's first major efforts was to develop and disseminate the "Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma."[2] The expert panel report, which provides clinicians with recommendations for optimal treatment of asthma, has been distributed to more than 300,000 health professionals. It is widely referenced and listed in most medical databases.

The NAEPP has broadened its focus beyond clinical and biomedical asthma management to the economics of asthma management. A clinician's ability to provide asthma care in accordance with guideline recommendations is largely influenced by the financial and organizational structures affecting both patient and provider. Thus if efforts to improve asthma care are to be successful, they must be placed in the context of comprehensive programs that reflect the complexities of the U.S. health care system.

In December 1992, the program established the Task Force on the Cost Effectiveness, Quality of Care, and Financing of Asthma Care. The purposes of the task force were to review and synthesize in a report the current knowledge of the economic factors that influence the delivery of asthma care and to provide recommendations to improve the quality of asthma care in the United States.

The task force, coordinated and chaired by Kevin M. Weiss, M.D., operated through three working groups: the Working Group on the Cost Effectiveness of Asthma Care, led by John Eisenberg, M.D.; the Working Group on the Quality of Asthma Care, led by Mark Young, M.D.; and the Working Group on the Financing of Asthma Care, led by Jinnet Fowles, Ph.D. Each group first defined its key issues in relation to what may be preventing clinicians from providing optimal care for patients with asthma. Each then addressed these issues using the best sources of information available.

- The **Working Group on the Cost Effectiveness of Asthma Care** explored such questions as What is cost-effective asthma management? What are the benefits of cost-effective approaches to asthma management? What needs to happen at the national, State, and local levels to effect the changes necessary to implement cost-effective measures for asthma care? The group reviewed the literature on the cost of the illness and on the cost benefit and cost effectiveness of asthma care, seeking to identify and then characterize the role of

cost-effectiveness analysis in selecting treatments for the management of asthma.

- The **Working Group on the Quality of Asthma Care** examined such questions as How does quality of care affect outcomes? What kinds of changes are necessary to improve quality of care? How do the current principles of quality improvement specifically apply to asthma care? This group sought to develop a framework and recommendation for asthma quality improvement and continuous care that could be implemented by various organizations and providers of care.
- The **Working Group on the Financing of Asthma Care** asked How does the financing of asthma care affect access to services? the treatment of asthma? potential health outcomes? This group thus investigated the myriad U.S. health care financing mechanisms, both public and private, to clarify their impact on asthma care.

Each working group reviewed, reported, and made recommendations from its own unique and useful perspective. The three reports—different in scope, intended audience, and recommendations—together form this task force report. The reports of the Working Group on the Cost Effectiveness of Asthma Care and the Working Group on the Quality of Asthma Care are based on literature reviews; the report of the Working Group on the Financing of Asthma Care is based on community meetings held throughout the United States.

The issues raised by the working groups are closely interrelated. Several important cross-cutting issues and insights emerged:

- The "Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma" provides a critically important benchmark for optimal clinical care of persons with asthma, but the quality of asthma care will increasingly be controlled by issues of financing and the health care industry's need for value, that is, for cost effectiveness.
- Solutions for improving the quality of asthma care must therefore extend beyond the individual patients and their clinicians. Efforts at improving quality of asthma care will require multidisciplinary teams that include health care providers, patients, and other representatives of health care organizations. Interorganizational or community-based involvement may also be required, particularly in light of the emerging trend toward managed care. Linking asthma-related health care financing decisions to studies of quality improvement and cost effectiveness is increasingly important. However, the existing literature does not provide a comprehensive understanding of the key issues either in quality of care or in the cost effectiveness of asthma care delivery.
- No public or privately funded programs have as yet taken responsibility for defining an asthma-related health services research agenda. This lack of a principal resource for defining and supporting research is a major impediment to achieving the goals set out in the "Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma."

Given these cross-cutting issues, this task force report provides an important perspective on the difficulties and possible next steps in best disseminating the knowledge gained from NHLBI-sponsored research and synthesized in the "Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma." The combined recommendations from the three working groups present an opportunity for significantly furthering the Healthy People 2000 goals for reductions in asthma morbidity.[3]

The recommendations of the Working Group on the Cost Effectiveness of Asthma Care build

on its literature review and urge the improvement and standardization of research studies so that meaningful comparisons on cost effectiveness can be made. The recommendations of the Working Group on the Quality of Asthma Care also build on its literature review and focus on "how to use" a continuous quality improvement model to ensure asthma care quality improvement. The recommendations of the Working Group on the Financing of Asthma Care are based on community meetings held throughout the United States and relate to ensuring adequate insurance to cover the costs of asthma care. These recommendations form the concluding sections of the cost effectiveness and quality of care reports, and the first section of the financing of asthma care report.

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National Asthma Education and Prevention Program Working Group Report on the Cost Effectiveness of Asthma Care

Recent reports of the economic burden on asthma on patients, their families, and society reflect a chronic disease that is costly to manage and disproportionately expensive for those with severe asthma. Given the variety of pharmaceuticals, education programs, and other management strategies, clinicians need to employ a rational approach to selecting and using appropriate medical technologies. The uncritical acceptance of medical innovation is not appropriate.[1] The evaluation of medical technologies should consider not only evidence on efficacy and safety but also costs and relative cost effectiveness of the alternatives.[2] Unfortunately, despite the obvious need for such information by clinical and health system decision makers, little evidence is available on the cost effectiveness of alternative asthma management strategies. Indeed, even the NAEPP therapeutic recommendations[3] lack an economic justification.

At this time, efficacy and safety profiles of the pharmacologic agents used most widely in the treatment of asthma are well described. Of the many management strategies available to clinicians, pharmacologic therapy predominates. There is also a fair amount known about the impact of asthma education programs on outcomes. The National Asthma Education and Prevention Program (NAEPP) of the National Heart, Lung, and Blood Institute (NHLBI) released management guidelines in an attempt to standardize the choice of therapies to optimize outcomes.[3]

Today, however, increasing medical costs, the emergence of managed care, and the burden of managing chronic disease have sensitized health care decision makers, public and private payers, and society to the problems of scarce resources and the need to make choices among multiple competing interventions. Within a world of finite health care resources, efficient allocation is important.

The goals of the NAEPP Working Group on the Cost Effectiveness of Asthma Care were to review the published literature on the economic burden of asthma; review the literature on the economic impact of organizational, therapeutic, and educational interventions; present and evaluate the published literature on the cost effectiveness of asthma management alternatives; describe the challenges facing asthma outcomes research, particularly cost-effectiveness studies; and advise the NHLBI on research priorities relative to asthma cost-effectiveness studies. This report makes clear that there is a great need for a focused and continuous program of research into the cost effectiveness of alternative asthma management strategies.

This report by the Working Group on the Cost Effectiveness of Asthma Care first briefly introduces the methods for the economic evaluation of medical technologies and then reviews the nature and usefulness of asthma-related outcome measures. The substantial economic costs of asthma to society are described next. Three types of asthma inter-

ventions are described, and the available economic literature on different asthma interventions is reviewed. The report concludes with a series of recommendations that the working group believes are critical to advancing the breadth and depth of understanding of the cost effectiveness of new and existing management strategies for persons with asthma.

METHODS FOR ECONOMIC EVALUATION OF MEDICAL TECHNOLOGIES

Medical technologies are "techniques, drugs, equipment, and procedures used by health care professionals in delivering medical care to individuals, and the systems within which such care is delivered."[4] Medical technology assessment is the generation and assessment of information about the costs, societal and ethical consequences, and clinical outcomes of medical technologies, whether intended or unintended.[5] Technology assessment can thus serve as a bridge between innovation and optimal application of medical interventions.

Among the methods and instruments that can be used for medical technology assessment are economic evaluations, technology life cycle and diffusion studies, and postmarketing surveillance. Conventional approaches to technology evaluation involve consideration of traditional measures of risks and benefits such as efficacy, effectiveness, safety, sensitivity, and specificity.

Decisions about which medical treatment or technology to employ often have been based primarily on evidence from controlled clinical trials regarding efficacy and safety. But efficacy is not synonymous with effectiveness. Efficacy is measured under tightly controlled research conditions, often on a highly selected patient population. Effectiveness refers to the impact of the intervention or technology under routine operating conditions when administered to a more generalized patient population. Further, clinical trials are not optimally designed for the assessment of economic impact. Clinical trials frequently involve blinded, placebo control groups or alternatives not widely used in clinical practice. More importantly, clinical trials are not powered for economic endpoints and often focus on physiologic rather than functional or health-related quality-of-life outcomes. Trial data may show that a therapy produces a small improvement in outcome but may not show that the improvement is achieved at a very high cost. Thus it is often difficult to determine which therapy or combination of therapies is most efficient at achieving a desired cost-related outcome.

In today's health care environment, however, this is changing as consumers and purchasers of medical technologies are becoming increasingly sensitive to the overall cost of care in relation to the health benefits the technologies confer. The implications of using inhaled or oral anti-inflammatory medications for prevention of asthma exacerbations, for example, extend well beyond the mere price and efficacy of the product. In addition, purchasers are demanding additional information on outcomes and cost consequences of therapies, and pharmaceutical companies are funding outcome studies that accompany their clinical trials. Purchasers, in particular, have become interested in total medical care resource requirements for managing illness as well as the potential benefits of new therapies in terms of work productivity, functional ability, and quality of life. With this attention comes the need to evaluate the relative efficiency of different approaches to achieving a desired medical outcome within the constraint of limited resources. Determining value for money is the goal of economic analysis.

Eisenberg and associates[6] have illustrated the three dimensions of economic analyses of medical technologies (figure 1). The horizontal axis depicts the different types of analytic frameworks or study designs: cost identification, cost effectiveness, and cost benefit. The vertical axis describes the four points of view that the analysis may consider: society, patient,

payer, and provider. The dimensional axis considers the scope of resources or economic outcomes that can be included in an economic study, including medical and nonmedical costs.

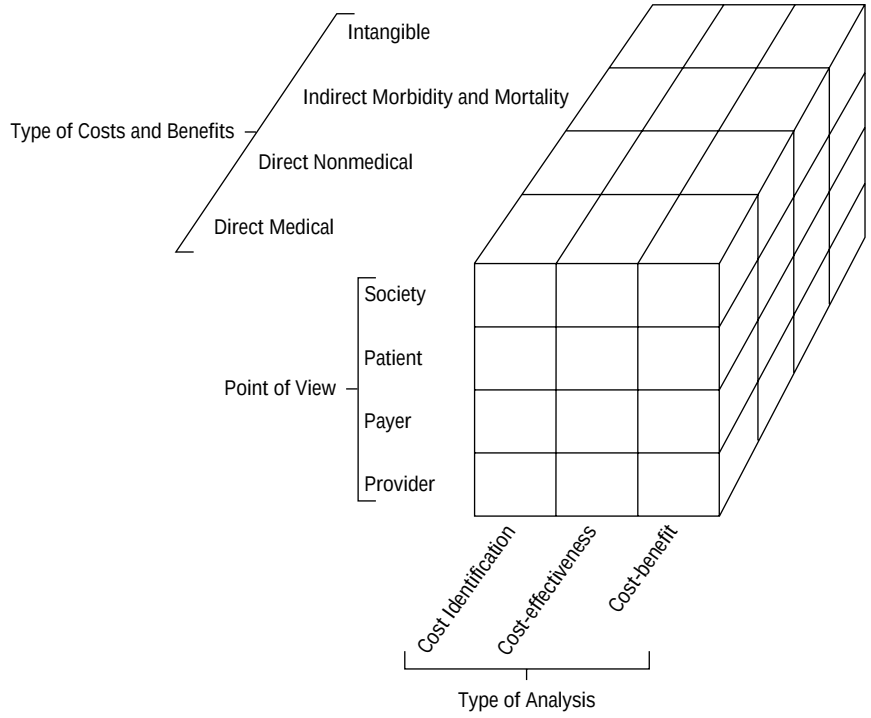
Cost-effectiveness and cost-benefit analyses compare the costs and consequences of alternative health care interventions to provide information on how to most efficiently allocate scarce resources. This report focuses on cost-effectiveness analysis partly because of its increased use in medical technology evaluations but primarily because of its potential for improving decision making in the treatment of asthma. Although cost-identification and cost-benefit methods appear in the asthma interventions literature, they are used less frequently and thus deserve only a general discussion.

Cost-Identification Analyses

The least complicated method of economic analysis is cost identification, which involves a comprehensive assessment of the costs of alterative treatment strategies. This technique is valid only when the health outcomes are so similar that a formal analysis would indicate no statistically significant difference. An example is a cost comparison of two asthma drug treatments that are considered to be equally effective, but one may be more expensive to deliver because of difficulty in titration or dose monitoring. In many cases, comparative cost-identification studies may not be appropriate; costs may differ because of differences in compliance or utilization of expensive health care resources associated with differences in patient preferences or adverse consequences.

Figure 1

THE THREE DIMENSIONS OF ECONOMIC EVALUATION OF CLINICAL CARE



Source: Eisenberg et al.[6]

Thus observed cost differences often are a subtle consequence of differences in treatment effectiveness.

Cost-Benefit Analyses

Cost-benefit analysis allows for the identification and comparison of the costs associated with the implementation or use of a medical program or technology and the benefits derived from its application.[7] Both costs and benefits are defined in monetary terms and adjusted to net present values and are usually reflective of a wider societal point of view. Thus the analysis considers both private and social costs and benefits. The ratio of monetary benefits to overall costs provides a way to determine whether the value produced by the technology is worth the cost: The intervention is said to be cost beneficial if the benefit-to-cost ratio exceeds 1.0. However, many technical, social, and ethical problems are associated with expressing all health outcomes in monetary terms. Difficulty arises when the benefits of the intervention are not amenable to economic valuation, such as years of life saved or improvements in psychosocial outcomes. Thus cost-benefit analyses tend to be used less widely.

Cost-Effectiveness Analyses

The most common economic evaluation technique is cost-effectiveness analysis. This analytic technique simultaneously considers the relative costs and outcomes of two or more alternative medical technologies when used to treat a similar condition.[8] Like cost-benefit analysis, the cost-effectiveness technique makes explicit the positive and negative costs and consequences of various medical technologies. However, cost-effectiveness analysis differs from cost-benefit analysis in that the health consequences of treatments are expressed in "natural" units such as symptom-free days or quality-adjusted years of life saved.

In cost-effectiveness analysis, as in other economic evaluation techniques, costs are comprehensively evaluated and not limited to measurement of cost of therapy. For example, if only the costs of medications are assessed in an evaluation of drug therapy for asthma, a number of important economic parameters will be disregarded. These may include the direct costs associated with the use of medical resources to treat significant adverse reactions to the drug or the savings that result from averted hospitalization and emergency department visits due to improved clinical outcome. Furthermore, important noneconomic factors, such as improvements in functional status and changes in quality of life, will also be ignored.

Cost-effectiveness analysis is grounded in the clinical effectiveness of health care interventions; thus the clinical effects of an intervention and its most likely alternatives must be clearly understood before cost-effectiveness hypotheses can be generated and tested. An important feature of cost-effectiveness analysis is its inherently comparative nature. One of the fundamental concepts underlying cost-effectiveness analysis is that of "opportunity costs," which states that the true economic cost of an intervention is the value of the alternative interventions that are foregone. This implies that choices must always be made among interventions and that an intervention can never be evaluated in isolation. At the very least, in a cost-effectiveness analysis the intervention should be compared to "no treatment."

Hence, fully informed resource allocation decisions require information about the clinical effectiveness of the intervention, its impact on the patient's functional status, and the full economic implications of its use. Inevitably, economic evaluations contain imperfect information, and the level and extent of uncertainty within the study necessitates further exploration; therefore, there is a need for simulations and sensitivity analyses that evaluate the impact of varying assumptions on the results of the study.

A cost-effectiveness evaluation requires estimation of two inputs: (1) a direct measure or proxy of absolute and comparative effectiveness and (2) an estimate of total and marginal costs. The next section considers outcome measures of asthma interventions that can be used to describe a technology's effectiveness; the following section describes the economic costs of asthma and the elements of medical care treatment costs.

METHODS FOR EVALUATING ASTHMA OUTCOMES

A variety of outcome measures can be used as a base for cost-effectiveness analysis. The choice of which outcome measure to select depends a great deal upon the intervention itself, the patient, and the nature of the medical care system. If the results of asthma cost-effectiveness analysis studies are to be useful to decision makers, the outcome measures must be measurable and relevant to the health system and the providers, and there must be some degree of standardization of outcome measures across studies so that interventions can be compared when resource allocation decisions are made.

A recent report of the NHLBI Workshop on Asthma Outcome Measures for Research Studies[9] provides a useful review of the myriad endpoints available to researchers who study asthma. The Working Group on the Quality of Asthma Care report further classifies these outcomes into patient- or family-centered outcome measures or organizationally based outcome measures (see figure 4 in that report; see also the report's appendix). These key outcomes are as follows:

- **Clinical and symptom measures.** Symptoms, clinical findings, and laboratory tests comprise one category of asthma outcome measures. Symptom data are the most frequently used outcome measure for asthma and correlate well with pulmonary function measures. These data are generally derived from questionnaires or direct interviews with the patient and include frequency, duration, and intensity of wheezing, dyspnea, coughing, chest tightness, sputum production, and nighttime awakenings. One outcome measure used in economic evaluation combines temporal measurements of several important symptoms into a multidimensional index.[10] This index is based on the concept of a symptom-free day, that is, a day with none of the just-mentioned symptoms. The symptom-free day index may provide a necessary standardized metric for comparing various economic evaluations of asthma management strategies.
- **Measures of lung function.** Lung function assessments of asthma interventions focus specifically on the extent of airflow obstruction. Objective pulmonary function measures include those derived in the clinic setting from spirometry (e.g., forced expiratory volume in 1 second [FEV_1], forced vital capacity [FVC]), airway responsiveness testing (e.g., histamine or methacholine provocation challenge), and peak expiratory flow (PEF). The latter can also be assessed by the patient at home using a manual or electronic hand-held device.
- **Measures of functional status and health-related quality of life.** Symptoms and pulmonary function measurements provide a unidimensional assessment of outcome, whereas functional status and health-related quality of life measures broaden the perspective. Functional status measurements typically include the degree of activity impairment of the affected individual. Health-related quality of life refers to the degree that disease impairment affects the social, physical, and mental well-being of the individual according to his or her own assessment. Important limitations on the use of these methods are the capacity of the instruments to discriminate among disease severities in patients and the ability to measure true within-patient change

in health status due to the intervention. Rothman and Revicki[11] have provided an excellent review of the issues in measurement of functional status and health-related quality of life in asthma research.

- **Outcomes of family and patient management.** The goal of most asthma education strategies is to affect behavioral change in the family or patient toward better awareness of exacerbation triggers and the role of various therapies in asthma management. Behavioral change is probably the most difficult medical outcome to achieve, sustain, and measure objectively.

  Medication adherence is an indicator of behavioral change because it represents the degree to which patients follow a prescribed regimen. A theoretically efficacious regimen that is so onerous to the patient that adherence is compromised may never be effective. Objective measures of adherence to asthma interventions are suspect, largely because of the lack of validated measurement tools. In the case where such tools are considered valid (i.e., drug blood levels), issues of feasibility arise.

- **Health services use and cost outcomes.** Health services utilization has been described as an important proxy measure of disease morbidity and as an independent measure of asthma outcome. The quantification of health services utilization includes the frequency and duration of use of various medical care services such as provider visits, inpatient care services, medications, devices, and other asthma-related services. It is assumed that well-controlled asthma will result in lower health care utilization, particularly expensive emergency and hospital care. However, health services utilization rates are fraught with measurement error when used as outcome measures for asthma treatments. It is frequently difficult to employ medication-use patterns, for example, to distinguish poorly controlled asthma from asthma of greater severity. Increasing patterns of bronchodilator use in one individual over time may be a marker for increasing severity or may be an indicator of declining use of inhaled corticosteroid.

THE ECONOMIC COSTS OF ASTHMA

Integrating costs and outcomes into one analysis is the goal of cost-effectiveness analysis. However, simply identifying the economic burden of asthma provides some insight into the extent and distribution of resources consumed by persons with asthma. In general, the economic consequences of asthma are substantial and can place a large burden on affected individuals, their families, the health care system, and society as a whole. Persons with asthma must cope with the immediate and long-term impact of the illness on their daily functioning and future plans. On days with symptoms, an individual's work productivity may be adversely affected. For the payer or provider operating within a limited budget, the scarcity of medical resources means that dollars must be reallocated from other uses to accommodate the need for new acute, chronic, and preventive treatments for asthma. For society, the impact of the disease on the work force participation and productivity of those directly or indirectly affected must be considered.

The cost-of-illness method of measuring a condition's economic burden is well defined, is relatively easy to understand and apply, and has been used extensively.[12,13] The cost-of-illness approach considers all costs resulting from illness and thus takes the perspective of society.

The cost-of-illness approach separates illness costs into those directly or indirectly associated with medical care treatments for the illness (direct costs) and those resulting from non-medical output losses as a consequence of the illness (indirect costs). Psychosocial costs, a third category of costs, are considered at least theoretically in the cost-of-illness approach but are difficult to estimate empirically. How can

the impact of chronic illness on scholastic achievement and career selection or the impact of premature mortality on the immediate family be valued in dollar terms? As a central component of cost-of-illness studies, direct and indirect illness costs are reported either as those occurring within 1 year for a population or cohort of asthma patients (prevalence costs) or those expected to occur over the lifetime of the illness for an individual (incidence costs).

A review of six asthma cost-of-illness studies suggested that, at least in developed countries, the average annual societal burden of asthma ranged from $326 to $1,315 per afflicted person. The primary data from these reports have been converted into 1990 U.S. dollars using country-specific price and labor compensation inflators for a more direct comparison. Table 1, adapted from a recent NHLBI report,[14] summarizes these data and indicates that, on average, approximately 40 to 50 percent of total asthma costs are directly attributable to asthma-related medical care treatments.

A close look at a prevalence-based study in the United States will provide further understanding of how these costs are distributed within the population of people with asthma. In 1990, according to Weiss and colleagues,[20] direct medical expenditures for asthma amounted to some $3.64 billion and indirect economic losses accounted for an additional $2.6 billion. Of the amount spent on medical care treatments, approximately 56 percent was for inpatient hospital stays ($1 billion), outpatient hospital visits ($129 million), and emergency department care ($200 million). Annual hospitalizations for asthma totaled 463,500 admissions (median length of stay was 5.0 days), of which 34.6 percent were for persons under 18 years of age. During the same period, there were an estimated 1.51 million visits to hospital outpatient departments and 1.81 million visits to emergency departments for asthma-related care. Physician-related services for asthma accounted for 14 percent of total expenditures and included 6.5 million ambulatory care visits at a cost of $193 million and an additional $81.3 million for inpatient physician services. Finally, 30 percent of direct medical costs ($713 million) were for the approximately 7.5 million prescriptions dispensed for asthma symptom management and prevention. These data highlight the significant cost of institutional care relative to more frequently used and less costly physician and pharmaceutical services.

The cost of nonmedical economic losses, such as days missed from work or school, caregiver expenditures, travel and waiting time, early retirement due to disability, and premature mortality, account for about 50 percent of total illness costs. Variability in the cost estimates from these studies can be attributed, in large part, to the extent to which indirect costs were measured and valued. For example, the U.S. study[20] provided an economic value for premature mortality from asthma, whereas no such estimate was made as part of the New South Wales study.[16] In short, the indirect effects of illness on individuals, health systems, and society are important and may represent a substantial proportion of the burden of illness, but they may not always be measured and valued in monetary terms.

Lack of primary data on illness costs by level of severity has prohibited all but a few analyses. In general, these studies document the significant and disproportionate use of medical care resources by patients with severe asthma. As the health status of individuals with asthma deteriorates, whether due to acute exacerbation or chronic decline, there is a concomitant (but not necessarily proportional) increase in the use of medical care. Average annual asthma illness costs in Canada were estimated to be $591 million.[17] People with severe asthma accounted for 10 percent of the population, roughly 51 percent of all direct medical care expenditures, and 54 percent of total asthma costs. People with mild asthma accounted for 70 percent of the population but only about

Table 1

COMPARISON OF DIRECT AND INDIRECT COSTS OF ASTHMA FROM SIX STUDIES, ADJUSTED TO 1990 U.S. DOLLARS

Country, year of data	Monetary conversion in 1990	Asthma prevalence in 1990	Direct medical costs	Indirect costs	Total costs	Costs per patient per year
Australia, 1991[15]	1.28A$/1$	8.5%	$250.0 million	$207.0 million	$457.0 million	$326
New South Wales, Australia, 1989[16]	1.28A$/1$	6.0%	$161.0 million	$48.0 million	$208.8 million	$769
Canada, 1989[17]	1.16C$/1$	2.5%	$355.0 million	$181.1 million	$536.1 million	$1,021
Sweden, 1975[18]	6SKr/1$	3.0%	$90.8 million	$257.5 million	$348.3 million	$1,315
U.K., 1988[19]	.562£/1$	3.0%	$722.5 million	$1.07 billion	$1.79 billion	$1,043
U.S., 1990[20]	1$/1$	4.0%	$3.6 billion	$2.6 billion	$6.4 billion	$640

Notes: Direct medical care costs were adjusted using the all-item price index, and indirect medical care costs were adjusted using the labor compensation index for each country code. The price and labor indices, monetary conversion factor, and population estimates were derived from volumes 1-4 of the *Australia Country Report* 1989-91, *Canada Country Report* 1989-91, *Sweden Country Report* 1985-91, and *United Kingdom Country Report* 1988-91. All were published and authored in London by the Economist Intelligence Unit.

Source: Adapted from National Heart, Lung, and Blood Institute.[14]

20 percent of the costs. A similar study of Australian adults with asthma confirms the association between disease severity and level of economic burden.[15] The average annual total costs of adult and childhood asthma were between $586 million and $718 million in 1991 Australian dollars. Although adults with severe and very severe asthma represented approximately 6 percent of the adult population, they consumed about 47 percent of the total annual adult costs of asthma. A similar result was obtained in a cost of asthma study in Transkei, South Africa,[14] in which 6 percent of asthma patients consumed 52 percent of total expenditures for asthma-related care.

The economic burden of asthma is large and disproportionately affects those with severe disease. The available cost-of-illness data suggest that an uneven share of costs relate

to nonscheduled acute or emergency care, indicating poor asthma management and suboptimal outcome. For a cost-effectiveness study in asthma, it is necessary to include estimates of the costs of medical care services most commonly used by people with asthma. Alternatively, the inclusion of indirect costs depends on the perspective of the analysis and the preference of the user of information. Health plans may elect a shortsighted approach and not consider the indirect impacts of disease on their members. From the individual, family, and employer perspective, indirect cost impacts may be tremendously important.

It is clear from these data that the relative cost effectiveness of new or existing asthma interventions depends a great deal on the underlying cost burden. For example, when a costly therapy is used for persons with less severe asthma and low cost of illness, the question of cost effectiveness focuses on the incremental costs of treatment relative to the incremental benefit achieved by the intervention. Specifically, in mild asthma where illness costs are low, a costly new intervention may not be as cost effective as in severe disease.

THE COST EFFECTIVENESS OF INTERVENTIONS

Economic evaluations depend upon evidence of safety and effectiveness, both absolute and relative to competing interventions. These interventions can be categorized into one of three types:

- **Primary prevention.** These strategies refer to those interventions that may prevent the initial expression of the illness and, as a result, reduce incidence of asthma. For example, minimizing exposure to environmental risk factors or conducting early medical interventions in healthy individuals at risk for disease are prevention strategies. There are few clinical studies assessing the effectiveness of primary interventions in asthma.[21]
- **Asthma management.** Interventions that target the treatment of active disease comprise asthma management and represent the most studied area of asthma care, particularly from the clinical outcomes perspective. These interventions are designed to reduce the severity and/or duration of morbidity associated with asthma, principally the prevention of symptoms and exacerbations. The most notable treatment options available to clinicians are the pharmacotherapeutic agents. Other examples include asthma management and education programs directed at physicians and patients, medical devices such as spacers and peak flow meters, changes in the delivery of medical care for people with asthma, and environmental programs aimed at reducing exposure to known risks such as house-dust mites, secondary smoke, or cat dander. The "Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma"[3] summarized most of the key clinical efficacy studies in the area of asthma management. The literature is dominated by placebo-controlled or comparative studies of medications. Little is known about behavioral modification, prevention, or other treatment strategies.
- **Emergency care.** These interventions often imply the need for immediate, advanced, high-cost medical care treatments. Patients requiring these interventions present with status asthmaticus, respiratory failure, progressive lung deterioration, or some other form of life-threatening severe disease. Typically, these patients are treated in emergency department or hospital settings where multiple technologies (e.g., mechanical ventilation, intensive care, drug therapy) are employed.

The few resources expended for technology assessment of asthma interventions have been in the area of medications or for asthma education/management programs. To the

working group's knowledge, no economic study has been conducted on primary prevention, and very few studies have been undertaken for emergency care strategies. Indeed, estimating the value of primary prevention strategies presents a unique challenge to researchers. The outcomes of prevention often require several years of observation and many patients. In addition, it is difficult to state with certainty that the poor health state was actually prevented. At the same time, the amount of resources required to implement large-scale prevention programs is considerable, especially in the first few years, but declines as efficiencies are gained.

In the working group's review of literature on economic evaluations of asthma interventions, only those studies in which all study participants had asthma either previously diagnosed or confirmed were selected. This eliminated studies with mixed populations, particularly those in which individuals with chronic obstructive pulmonary disease were mixed with patients with asthma. In addition, the working group selected only those studies published in English and for which clear measures of both costs and outcomes were described. Studies that evaluated only the impact of interventions on health services utilization endpoints without providing cost estimates or performing formal cost-effectiveness analyses were excluded.

Asthma Patient Education Programs

The economics of health education have been thoroughly assessed, and its economic benefits appear to be clear. The earliest study of an educational intervention for asthma included a discussion of the economic outcomes of the program.[22] In the last decade, a number of educational programs have been developed for asthma based on theories of behavior change.[23] The stated goals of asthma patient education programs are to reduce morbidity and mortality by (1) improving knowledge among patients with asthma and their caregivers to produce better self-management behavior, (2) increasing compliance with therapy, (3) improving relations and interaction with health care providers, and (4) increasing confidence among people with asthma in regard to controlling and managing symptoms.

Objective pulmonary function measures (such as FEV_1) have not been shown to be improved by health education programs. However, research has established that in some settings and in some populations, health education programs reduce other asthma-related morbidity. An extensive and critical review of asthma patient education programs has been undertaken by Boulet and colleagues.[23]

Asthma patient education programs have been targeted at both adults and children. Windsor and colleagues,[24] in a randomized cost-effectiveness trial of 267 adults with asthma, showed that inhaler, drug, and total medical adherence improved in the experimental group relative to the control group at an additional cost of $28 per person. No direct measures of health outcomes were attempted, and the costing protocol failed to account for potential economic benefits related to reductions in health services use.

A study by Muhlhauser and associates[25] reported on the efficacy of a 3-year structured asthma teaching and treatment program (ATTP) in Germany for adults with moderate-to-severe asthma. The program focused on better asthma control through self-monitoring and patient awareness and reported favorable effects on health services utilization and days missed from work. Trautner and colleagues[26] carried the analysis further by estimating the cost benefit of the ATTP program. From the perspective of the German health authorities, the program produced monetary benefits in excess of costs at a ratio of 2.7 to 1. When estimated from the perspective of society, the program appeared even more favorable, with a benefit-cost ratio of 5.0 to 1.

Bolton and associates[27] evaluated the cost effectiveness of a 12-month asthma self-management program in a sample of 241 adults who presented to an emergency department with asthma symptoms. When compared with the usual care control group, the intervention group had fewer emergency department visits (39 per 100 patients vs. 16 per 100 patients) and fewer days with activity limitations. Physician and hospital visits did not differ statistically between the two groups. The economic analysis showed that the $82 per person cost for the patient education program was offset by an estimated $628 per person reduction in emergency department visit charges.

In a mixed population of 62 adults and children with asthma, Sondergaard and colleagues[28] estimated the costs and benefits of a 6-month patient education program administered by a team of health professionals consisting of a physician, a nurse, and a pharmacist. The goal of the program was to improve disease awareness, medication compliance, and self-monitoring using peak flow meters. Among the economic evaluations in health education reviewed here, this study takes the most comprehensive approach to valuing costs and benefits, including program materials, personnel, and transportation costs. In addition, the study attributed monetary values to the benefits from reducing all health services utilization and work absenteeism. Changes from baseline in use of resources, work productivity, and health status were measured in both the experimental and usual care groups. The results suggest that experimental patients experienced more physician and drug costs and fewer emergency care visits and days missed from work. These results suggest predictable patterns of substitution of care—physician and drug services for emergency care. However, in this case, the overall the costs of the intervention (£6,546) exceeded the benefits (£4,528).

In children with asthma, there are three noteworthy economic evaluations of patient education programs. In the first, Fireman and associates[29] targeted a comprehensive health education program for both the affected child and the parent. When compared with a usual care group, the experimental group showed improvement in compliance and reductions in asthma exacerbations, lost school days due to asthma, and emergency and hospital visits. The cost-benefit analysis suggested that savings from health service utilization offset costs by about 2 to 1, or about $225 per affected child.

In the second, Lewis and colleagues[30] randomly assigned 76 children and their parents at the Los Angeles Kaiser Permanente facility to the Asthma Care Training program or usual care. Results indicated that disease knowledge improved equally in both groups. Medication adherence was greater and emergency department visits and days of hospitalization were fewer in the experimental group. Overall, the effect of the program on the experimental children represented a $180 savings per year per child when both program costs and benefits were accounted.

The third was a larger study by Clark and coworkers[31] on the costs and benefits of health education in low-income families with children with asthma (n=310). This evaluation study found no statistically significant difference in emergency department visits and hospitalizations. However, when the analysis was restricted to individuals with a recent history of hospitalization, the experimental group was found to have reduced frequency of health services utilization compared with the usual care group. The economic evaluation determined that, overall, benefits were less than costs by a ratio of 0.6 to 1. However, when considering only the subgroups of individuals with previous hospitalization, the benefits exceed costs by a ratio of 11.2 to 1, suggesting the obvious that targeting interventions to certain subgroups with greater baseline illness costs may elicit more favorable economic results.

These eight studies provide mixed evidence of the economic value of asthma education programs in both adults and children. More favorable results are reported when the program is targeted to high-risk or more costly patients. These high-risk patients include those who are more severely ill, young, from an ethnic minority, from a low-income family, and those who have frequent compliance problems. The ability to generalize from these studies is minimal because the patient education programs are not comparable in terms of goals and scope and the outcome measurements and followup periods vary across studies. More research is needed to understand the effectiveness and economic benefits of these programs in different high-risk populations. In addition, it would be important to determine which components of the asthma patient education programs are most cost effective. Based on present knowledge, it would be difficult for decision makers with limited resources to choose among these programs.

Pharmaceutical Interventions

Although relatively few economic evaluations of pharmaceuticals have been performed, there is increasing interest in this area, particularly by pharmaceutical manufacturers and health benefit payers. A major reason for this increased attention is the possible market advantage gained over a competitor if economic benefits are established.

Inhaled Corticosteroids

Evidence is overwhelming for the positive clinical effects of combining inhaled corticosteroids with bronchodilator therapy for the management of asthma.[32] The therapeutic management guidelines of the Expert Panel Report recommend as initial treatment such combination therapy for persons with moderate-to-severe asthma.[3] However, adding expensive, inhaled corticosteroid medications to an existing regimen of inhaled or oral bronchodilator therapy contributes significantly to the overall cost of treating asthma in these patients. An important, and as yet not fully explored, research question is Are inhaled corticosteroids in combination with bronchodilators cost effective compared with bronchodilator alone when used to treat persons with either mild-to-moderate or moderate-to-severe asthma?

At the time of this review, of the few published papers that investigated the economic consequences of using inhaled corticosteroids in patients with asthma, none was performed in U.S. populations. All of the studies were limited to assessment of either beclomethasone diproprionate or budesonide.

The first evidence of the cost beneficial effects of inhaled budesonide on health services outcomes was reported in a letter by Adelroth and Thompson.[33] The authors attempted to show the relationship between use of high-dose inhaled budesonide (800 μg per day) and asthma-related inpatient hospital days in 36 oral steroid-dependent patients with asthma over a 5-year period. The analysis employed a pre-post, quasi-experimental study design where patients served as their own controls. A dramatic reduction in inpatient admissions, days, and costs was observed in patients on budesonide when compared with the previous 2 years on oral steroid therapy. Cost per patient declined by over 55 percent per year for up to 3 years after the initiation of inhaled budesonide.

Gerdtham and colleagues[34] built on Adelroth and Thompson's initial work in Sweden by constructing a pooled, time-series model to investigate the association between greater use of inhaled corticosteroids and asthma-related hospital days in 14 counties over an 11-year period, using a nonexperimental methodology. More than 80 percent of inhaled corticosteroid use during this time was with budesonide. Although not a true cost-benefit analysis, the study did indicate a strong negative association between use of inhaled corticosteroids and hospital-bed-days for asthma. A cost-benefit

ratio was developed from the multivariate models suggestive of positive economic benefits in excess of costs on the order of between 1.5 to 1.0 and 2.8 to 1.0, depending on the analytic model.

The lack of experimental design in the study by Gerdtham and colleagues and the very small sample size of the Adelroth and Thompson study restrict the internal validity and conclusions of these two studies. However, these studies make use of an alternative evaluation strategy wherein the authors attempt to measure population effectiveness of the inhaled product in the absence of the constraints of a clinical study design.[35] The strength of the conclusions by Gerdtham and colleagues lies in the longitudinal and generalizable nature of the data.

The results from these two studies suggest a favorable economic impact of budesonide. Similar reductions in inpatient care have been associated with use of high-dose inhaled beclomethasone dipropionate, an inhaled corticosteroid available in the United States, in people with chronic asthma.[36] However, this study lacked any direct economic valuation.

Four recent economic studies have employed experimental research designs to investigate the cost effectiveness of inhaled corticosteroids. Campbell and coworkers[37] reported on the cost effectiveness of increasing the daily dose of inhaled budesonide from 400 to 800 μg after 6 weeks in patients with mild-to-moderate asthma. Data from a 12-week randomized trial of 556 patients ages 14 to 84 were used in the analysis. The efficacy of increasing the dose of inhaled budesonide in these patients was reported elsewhere[38] and indicated that 800 μg per day of budesonide failed to further improve lung function or reduce symptoms when compared with 400 μg per day. The total cost of treatment (medication only) was estimated to be £3,108 (about $4,660 U.S.) in the 400 μg/day group (12 weeks) compared with £4,662 (about $6,993 U.S.) in both the 400 μg/day (6 weeks) and 800 μg/day (6 weeks) groups. The authors concluded that increasing the dose of budesonide from 400 to 800 μg/day is not a cost-effective strategy in patients with mild-to-moderate asthma.

In a somewhat longer study, Connett and colleagues[39] studied the cost effectiveness of inhaled budesonide compared with placebo in a 6-month randomized trial of 40 children with asthma 1 to 3 years of age with persistent symptoms. The outcome results indicated that budesonide produced a favorable clinical response, increasing symptom-free days when compared with placebo (195 vs. 117 days). Direct medical costs (including the cost of budesonide) and indirect costs were tabulated for the numerator of the cost-effectiveness ratio. The results suggested that budesonide is a dominant therapy, that is, compared with placebo, budesonide increases overall effectiveness and reduces overall costs by £6.33 (about $9.45 U.S.) per symptom-free day gained.

Rutten-van Mölken and associates[40] reported on the cost effectiveness of adding inhaled corticosteroid to as-needed $beta_2$-agonist compared with as-needed $beta_2$-agonist alone in a 12-month randomized trial of 116 children with asthma 7 to 16 years of age. The investigators evaluated FEV_1 as the primary outcome. Frequency of symptom-free days and the number of school absences were included as secondary outcome measures. Patients randomized to inhaled corticosteroid plus as-needed $beta_2$-agonist experienced significantly increased lung function (FEV_1) and symptom-free days and reduced days missed from school relative to as-needed $beta_2$-agonist alone. Computation of the cost-effectiveness ratio indicated that, when compared with $beta_2$-agonist alone, $beta_2$-agonist plus inhaled corticosteroid increased FEV_1 by 10 percent at an additional total cost of about $83 U.S. Alternatively, the additional cost of $beta_2$-agonist plus inhaled corticosteroid was about $4.75 U.S. per symptom-free day gained. In this study, addition of inhaled corticosteroid

to a treatment regimen of inhaled $beta_2$-agonist was more effective than $beta_2$-agonist alone but at an additional cost, the value of which depended on whether the outcome was improved lung function (FEV_1) or better symptom control.

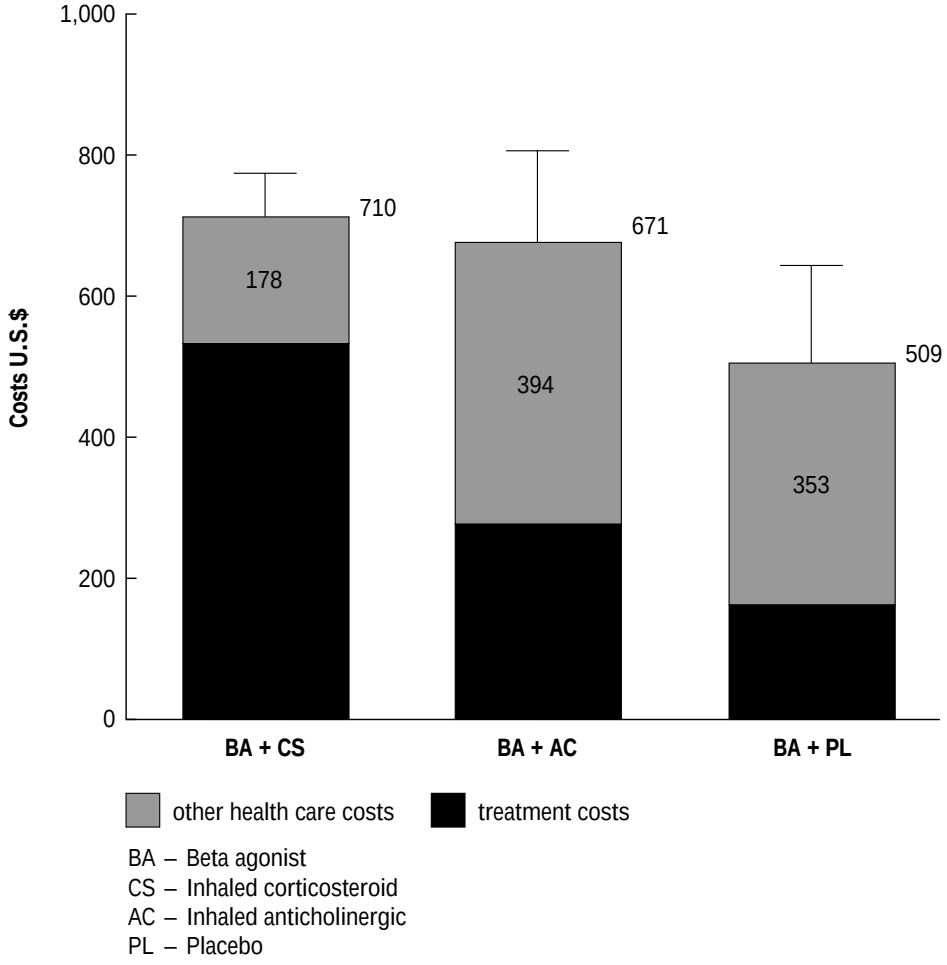
In the largest and most comprehensive study to date, Rutten-van Mölken and associates[41] analyzed data from a randomized trial of 274 adult participants (ages 18 to 60 years) in an effort to investigate the costs and effects of adding inhaled anti-inflammatory therapy to existing inhaled $beta_2$-agonist. Patients were selected for inclusion if they met the age criteria and had diagnosed moderately severe obstructive airway disease defined by pulmonary function criteria. The patients were of mixed diagnosis and could be enrolled if they had either asthma or chronic obstructive pulmonary disease. Patients were randomized to fixed-dose inhaled terbutaline plus inhaled placebo (BA+PL), inhaled terbutaline plus 800 μg of inhaled beclomethasone per day (BA+CS), or inhaled terbutaline plus inhaled ipratropium bromide 160 μg per day (BA+AC). Patients were followed for up to 2.5 years or until premature withdrawal.

The economic objective of this study was to determine if additional treatment costs of the combination therapies were outweighed or justified by additional clinical benefits and reduced utilization of other health care services. The clinical results suggested that addition of the inhaled corticosteroid to fixed-dose terbutaline led to a significant improvement in pulmonary function (FEV_1 and PC20) and symptom-free days, whereas addition of the inhaled ipratropium bromide to fixed-dose terbutaline produced no significant clinical benefits over placebo. The average annual monetary savings associated with the use of inhaled corticosteroid were not offset by the increase in costs from the average annual price of the inhaled product. Figure 2 shows the estimated average (and standard error) health care costs per patient year for each of the three treatment groups. The incremental cost-effectiveness ratio for inhaled corticosteroid was $201 per 10 percent improvement in FEV_1 and $5 per symptom-free day gained. It was not appropriate to evaluate the incremental cost effectiveness of ipratropium bromide because of the lack of clinical benefit relative to placebo. In many ways, this study represents a model for pharmaceutical cost-effectiveness analysis in asthma. The resource and cost estimates are clear and precise, the study period is sufficiently long, and the analytic techniques are appropriate. However, the mixed population of asthma and chronic obstructive pulmonary disease limits the utility of these data for decision making for asthma treatment.

Controlled clinical trials are necessary to investigate the efficacy and safety of pharmacotherapy. It is not clear whether such rigorous study designs are necessary for economic evaluation. Two of the economic studies just described show that inhaled corticosteroids reduced asthma-related morbidity in low doses (400 μg/day) and that the economic benefits either offset or add to overall treatment costs. The study by Campbell and coworkers[37] was brief in duration, measured only medication costs, and focused on clinical measures of pulmonary function, whereas most primary care clinicians and health plans are interested in symptoms. The studies by Connett and colleagues[39] and Rutten-van Mölken and associates[40,41] were somewhat longer in duration and evaluated symptom-free days as the primary outcome measure. All three studies determined that inhaled corticosteroids improved symptom-free days compared with the $beta_2$-agonist alone, but each arrived at a different economic conclusion. The study by Connett and colleagues[39] included an estimate of indirect costs, which increased the estimate of overall economic benefit. Both studies by Rutten-van Mölken and associates[40,41] valued only medical care costs and showed that adding inhaled corticosteroid to a regimen

Figure 2

ESTIMATED ADJUSTED MEAN HEALTH CARE COSTS PER PATIENT YEAR BY TREATMENT GROUP. ERROR BARS: UPPER LIMIT OF THE 95 PERCENT CONFIDENCE INTERVAL.



Source: Rutten-van Mölken et al.[41]

of inhaled beta$_2$-agonist improved clinical outcomes and increased the overall cost of care.

These studies highlight the need for standardization of study design, selection of comparator therapy, and standardization and valuation of economic and outcome measures. Without standardization, decision makers are likely to be confused by conflicting results.

Long-Acting Beta$_2$-Agonists

Long-acting bronchodilators such as formoterol and salmeterol represent a relatively new approach to prophylactic and symptomatic treatment for asthma. Only one published study has simultaneously evaluated the impact of a long-acting agent on clinical and economic outcomes for patients with asthma.[10] In this paper, the authors reported on a retrospective cost-effectiveness analysis of a clinical trial of 145 patients diagnosed with asthma and randomized to receive 12 weeks of maintenance therapy with either long-acting formoterol or short-acting albuterol. The primary clinical outcome measure was cumulative symptom-free

days over the 12-week period. The authors concluded that there were no statistically significant differences in symptom-free days between the two treatment groups. Because of these results, no incremental cost-effectiveness ratio was calculated. For illustrative purposes, the authors simulated a range of possible clinical benefits and cost-effectiveness ratios by respecifying the symptom-free composite score to include or not include adverse events.

Inhaled Cromolyn

Ross and coworkers[42] made use of patient and health services records in one large group practice to estimate the economic consequences of including cromolyn sodium in the treatment regimen of asthma patients. A total of 53 patients were retrospectively identified from medical records and categorized into two groups: those who received cromolyn sodium for at least 1 year (n=27) and those who received no cromolyn sodium as part of the treatment regimen (n=26). Patients receiving cromolyn sodium provided an average of 3.2 years of health service utilization data, and those in the comparison group provided 3.8 years of data. Medication costs for patients on cromolyn sodium were slightly higher ($27.90 per month) than for the control group ($25.20 per month). However, emergency department and hospital costs declined significantly for cromolyn sodium patients; after the change in medication, they experienced a 96 percent reduction in the rate of emergency department visits and a 92 percent reduction in the rate of hospital admissions. The authors made no direct measurement of outcomes of therapy and did not control for symptom severity or other baseline confounding that might partly explain differences in the results. Thus this study is not a true cost-effectiveness analysis; rather, it is a cost comparison of two retrospective cohorts of asthma patients.

Other Medications

The remaining economic studies of asthma medications identified in this review were not full cost-effectiveness evaluations. Tierce and colleagues[43] performed a retrospective cost-identification study comparing use of inhaled albuterol to inhaled metaproterenol in 1,463 Michigan Medicaid patients. Asthma-related medications, physician and emergency department visits, and hospital care were assessed and valued using Medicaid prices. The authors concluded that the overall cost of care was significantly lower in the albuterol group compared with the metaproterenol group. Because this study was not randomized, questions remain about baseline comparability of the two groups.

A modest number of papers exist on the impact of other beta$_2$-agonists on health services utilization,[44] methylprednisolone use in the emergency department,[45] or aerosolized versus metered-dose inhaler delivery of beta$_2$-agonists.[46,47] Three of the studies[44,45,47] were not included in this review because they did not attempt to value the intervention benefits in monetary terms; rather, these studies expressed outcomes in terms such as number of visits. Further, one[46] was not considered because of a mixed study sample that included patients without asthma among the evaluable patients.

Other Asthma Interventions

Alternative or adjunct interventions to health education and pharmacotherapy for management of asthma include the use of medical devices such as spacers, compliance-enhancing technologies, or peak flow meters; the use of specialists or other health care providers; psychosomatic therapy; acupuncture and other nontraditional approaches; desensitization programs; and exposure reduction programs. Little is known about the relative efficacy or effectiveness of most of these interventions, which makes cost-effectiveness or other economic evaluations difficult. A few reports are available, however. Although none have undertaken a full cost-benefit or cost-effectiveness analysis, they do suggest where further studies may be useful.

Deter[48] investigated the costs and benefits of providing psychosomatic therapy to 11 experimental and 11 control subjects. The program consisted of providing asthma patients with breathing and relaxation techniques and coping skills, and following the patients for up to 2.5 years. The authors concluded from this small study that the costs of the intervention were offset by the benefits (reduction in the cost of health services) of the program by a ratio of 1.8 to 1.

Two studies of the cost impact of providing enhanced emergency department care for asthma patients have been performed. McNamara and Kelly[49] evaluated the costs and outcomes of an emergency medicine residency program in an urban community hospital. The authors concluded that presence of the training program did not increase the overall cost of care for asthma patients presenting at the emergency department, but the study did not account for the additional training costs of the residents and instructors. Brillman and Tandberg[50] evaluated the cost impacts of introducing a clinical observation unit for asthma patients within the emergency department. The main outcome variables were hospitalization rates and charges evaluated both before and after initiation of the observation unit. Results indicated that hospitalization rates and charges failed to decline significantly after implementation of the observation unit.

Freund and associates[51] evaluated the outcomes and costs of asthma care provided by allergists, family physicians, and pediatricians for 378 individuals with asthma. Data were collected from the patient, the patient's medical record, and the medical provider. Patterns and costs of care varied widely across physician specialty. Assessment of patient outcomes revealed no significant differences across provider categories in health services utilization, work and school days lost, disease intrusiveness, and functioning among patients. However, allergists' patients incurred greater costs compared with other physicians' patients, primarily because of allergy shots and increased medications and visits.

Zeiger and coworkers,[52] although not valuing benefits in monetary terms, showed contrasting results when comparing allergists to generalists in a 309-person San Diego Kaiser Permanente asthma population randomly assigned after presenting for acute emergency department care. After completion of the 6-month study, researchers concluded that when compared with patients of generalists, patients of allergists had fewer emergency department relapses, greater use of inhaled anti-inflammatory agents, and improved health outcomes measured by decreased frequency of nighttime awakenings. The American College of Allergy, Asthma, and Immunology[53] has recently reviewed a number of studies examining the role of the allergist in the cost-effective treatment of asthma.

Several studies have reported on the positive impact of pharmacist intervention on the outcomes of care in patients with asthma.[54-56] Pauley and associates,[56] for example, studied the frequency and cost of emergency department visits in a cohort of persons with moderate-to-severe asthma 6 months before and 6 months after initiation of a comprehensive asthma education program delivered by a pharmacist/physician team. Taking the cost of providing the intervention into account, the program reduced the overall cost of care for these at-risk patients with asthma, demonstrating that asthma patient education can be provided in a cost-efficient manner by nonphysician health providers.

RECOMMENDATIONS

Asthma in some ways can be considered a model for other chronic conditions requiring continual care. Health care decision makers are interested in employing rational approaches to allocating resources among patients with chronic disease. Some policy makers may view cost-effectiveness analyses as a means to

justify rationing, but others embrace economic evaluation methods for improving decision making about, for example, limits on insurance coverage for specific interventions, formulary development, quality improvement programs, and appropriate utilization of services. However, before sound decisions can be made on appropriate selection and use of interventions, more comparative data on the economic value of the technologies are needed.

The working group's review has revealed many shortcomings in asthma economic data. There is no standard approach to evaluating the economic costs and benefits of medical technologies used to treat asthma or comparing the clinical and economic benefits of alternative treatments. Researchers conduct studies with varying lengths of followup, use different outcome measures, include different costs in the calculation of total cost, and evaluate different mixes of patients. These inconsistencies hinder efforts by decision makers to compare the clinical and economic benefits of alternative treatments for asthma.

Despite the many shortcomings, economic evaluations of asthma interventions need to be encouraged and nurtured. Substantial improvements and standardization are needed in the study design, study duration, sample size determination based on economic and health status endpoints, selection of appropriate comparison therapies, and selection and evaluation of costs and outcomes. The working group makes the following recommendations:

1. **Develop a standardized approach for economic evaluation study design.** Substantial improvements and standardization are needed in study design in such areas as the outcome measure, focus on effectiveness, intention-to-treat analysis, and study duration; age; socioeconomic status; and the incidence and distribution of asthma severity.

- **Outcome measure.** When there is no common asthma outcome measure, comparing studies is difficult. Some studies, for example, report on lung function parameters, others on symptom scores. Development of a standardized, universally accepted outcome measure for asthma intervention studies with economic evaluation components should greatly improve the usefulness of the data for decision makers. The working group proposes the concept of **symptom-free day** as the principal outcome measure for cost-effectiveness analysis of asthma interventions.
- **Focus on effectiveness.** Economic evaluations of asthma care should focus on the effectiveness of the intervention (the impact under average conditions) rather than upon efficacy (impact under ideal or optimal conditions).
- **Intention-to-treat analysis.** In order to account fully for the costs and effects of an intervention, using an intention-to-treat approach is critical, particularly when noncompliance or dropout from therapy is possible. In intention-to-treat analysis, results are reported for the entire sample of recruited patients—including those who drop out. Thus effectiveness rather than efficacy is assessed.
- **Study duration.** Asthma is a chronic condition, but most of the economic evaluations so far are short term, from 12 weeks to 6 months. Interventions aimed at improving asthma self-care require periodic reinforcement to maintain the desired behaviors. As in other chronic conditions requiring self-management and monitoring, the effects of asthma self-care interventions wear off after a short period of time. This

means that the followup period for a cost-effectiveness study should be long enough to allow assessment of long-term effectiveness and possible dropout from therapy. An intervention that has a lower initial effectiveness but a lower subsequent dropout rate may prove to be superior to an intervention with high initial effectiveness and a high dropout rate. Evaluations of the cost effectiveness of treatments need to involve longer term studies for providing cost and outcome data on which to base resource allocation decisions.

- **Age.** What works in one age cohort may be different from what works in another. According to Freund and associates,[51] pediatric and adult patients are different in terms of age of onset of asthma, insurance coverage, and other important demographic characteristics and as a result have very different patterns and costs of care. Thus pediatric and adolescent patients may be better studied separately from adults. However, there is no unanimity in defining pediatric and adolescent patients relative to adults. Are pediatric and adolescent patients less than 12 years of age? Less than 15 years of age? Less than 18 years of age? Further, targeting interventions at pediatric or adolescent patients requires involving caregivers, and educating both caregivers and patients requires significant resources.
- **Socioeconomic status.** Assuming that economic results from the use of certain asthma interventions will be the same in both nonindigent and indigent populations in the United States is not reasonable. Socioeconomic status is a major determinant of asthma morbidity and health care use. In addition, because emergency department use, hospital care, and mortality affect disadvantaged populations disproportionately, interventions may yield the greatest improvement in health and economic outcomes in these populations.
- **Asthma severity of subjects.** Severity needs to be considered directly in cost-effectiveness analysis studies. Those whose baseline use of health care resources and overall socioeconomic burden are greatest have the greatest potential for improvement in symptoms, use of resources, and impact on functional status. Thus targeting interventions on patients with severe asthma, low-income patients with significant morbidity, and patients with previous high use of medical resources (for example, those hospitalized during the previous year for an asthma exacerbation) should reveal greater economic benefits.

2. **Convene a workshop for the purpose of developing consensus on economic evaluation standards for asthma interventions.**

Too few studies as yet adequately characterize the economic impact of the large number of interventions currently being used to manage asthma. Therefore, the working group makes the following recommendations:

3. **Encourage and fund the inclusion of economic evaluation components within all National Institutes of Health, Agency for Health Care Policy and Research, and Health Care Financing Administration studies and demonstration projects involving new or existing asthma-related health care interventions.** Randomized clinical trials are not the optimal study design for economic evaluation studies. However, the incremental cost of adding an economic evaluation component to most clinical trials will be small in the context of an overall study budget.

4. **Compare new therapies to existing alternative therapies to provide useful and clinically relevant information to decision makers.** Most asthma-related economic evaluation literature pertains to pharmaceuticals because of the marketplace incentive for pharmaceutical manufacturers. However, most of this literature compares active therapy to placebo, and these placebo-controlled economic studies offer little practical knowledge to clinicians and health system decision makers who need to make comparative resource allocation decisions. New therapies should instead be compared with existing and multiple alternative therapies. An example is the 5-year, randomized, multiple intervention Childhood Asthma Management Program study funded by the NHLBI, which could be a model for conducting an economic evaluation as part of a clinical trial.

5. **Conduct economic studies that focus on nonpharmacologic interventions for the prevention and treatment of asthma.** Many important and frequently used asthma interventions have been inadequately evaluated from an economic perspective. There are, for example, no published data on the cost effectiveness of medical devices and diagnostics such as hand-held peak flow meters, spirometry, compliance aids, home air filters, or spacers; on preventive maneuvers such as immunotherapy, dust mite removal, and the use of mattress covers; on disease and case management programs; and on the application of asthma guidelines. Further, there is currently no formal mechanism for setting research priorities for economic studies.

6. **Examine the economic benefits of patient education programs.** A better understanding of these programs is necessary. What specific aspects are most cost beneficial and in which risk group? How long do the beneficial effects of a patient education program last? When is repeated intervention necessary?

7. **Determine how to identify high-risk individuals in order to better target interventions.** The literature reveals that not all interventions are cost effective, particularly when higher cost technologies are used in individuals with minimal morbidity or economic burden. Clinicians and decision makers need to be able to identify high-risk patients in order to target cost-effective interventions.

Finally, in order to promote the appropriate role of cost effectiveness in asthma care, the working group makes the following recommendation:

8. **Establish a focused and continuous asthma economics research program within one or more Federal agencies with an interest in asthma.** The program would support research on the cost effectiveness of alternative asthma management strategies and other areas of economic evaluation, as well as the dissemination of the results of such research. The program would do the following:

   - **Develop priorities for asthma-related evaluations.** Investigating the cost effectiveness of adopting the Guidelines for the Diagnosis and Management of Asthma is a high priority. Another is investigating the economic impact of nonpharmacologic interventions.
   - **Serve as a clearinghouse.** Clinicians and patients need to have access to information on studies of the cost effectiveness of asthma interventions. Setting up an online retrieval service for better public access to information may be a service provided.

- **Support programs to educate consumers, providers, managed care organizations, and the general public about the role of costs and cost effectiveness in clinical decisions.**
- **Convene a conference on standardization of outcome and cost measures for cost-effectiveness studies of asthma interventions.** The NAEPP could serve as a catalyst for such a conference.
- **Foster the use of economic evaluation data for making coverage and payment decision among health care payers.**

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National Asthma Education and Prevention Program Working Group Report on the Quality of Asthma Care

Over the past few years, the epidemiological literature on asthma has identified important findings that suggest a notable increase in morbidity and mortality[1,2] as well as large geographic variation in disease outcomes.[3,4] The geographic variation in asthma outcomes is found among States,[4] among counties within States,[5] among cities,[3] and even among neighborhoods within cities.[6] For example, Carr and colleagues[6] described nearly tenfold differences in asthma hospitalization and mortality rates among New York City neighborhoods. Similar findings were seen in an analysis of asthma mortality in Chicago.[7]

These studies of trends and geographic variations in asthma outcomes raise important questions as to the role that quality of health care plays in contributing to these epidemiological patterns.[8] Community-based studies of asthma mortality from several countries suggest that nearly 50 percent of all asthma mortality is preventable and that asthma mortality is often associated with inadequate or poor quality of care.[9,10] At least one U.S. study of near-fatal asthma suggests similar findings.[11]

Given this enhanced understanding of the link between quality of care and poor clinical outcomes for persons with asthma, it is essential that mechanisms and strategies be developed that strive to improve the quality of asthma care.

The charge to the Working Group on the Quality of Asthma Care, as part of the NAEPP's Task Force on Cost Effectiveness, Quality of Care, and Financing of Asthma Care, was to explore past and current efforts to understand and improve the quality of care for persons with asthma and to present a framework for asthma quality improvement that could be implemented by various organizations and providers of care. This report first describes two approaches to quality improvement that are combined in the continuous quality improvement model. A four-step framework for asthma quality improvement efforts is then presented in detail. How to use the framework in both medical and nonmedical environments is explored through case studies. Finally, recommendations are made for further developing and disseminating the model.

Introduction to Continuous Quality Improvement

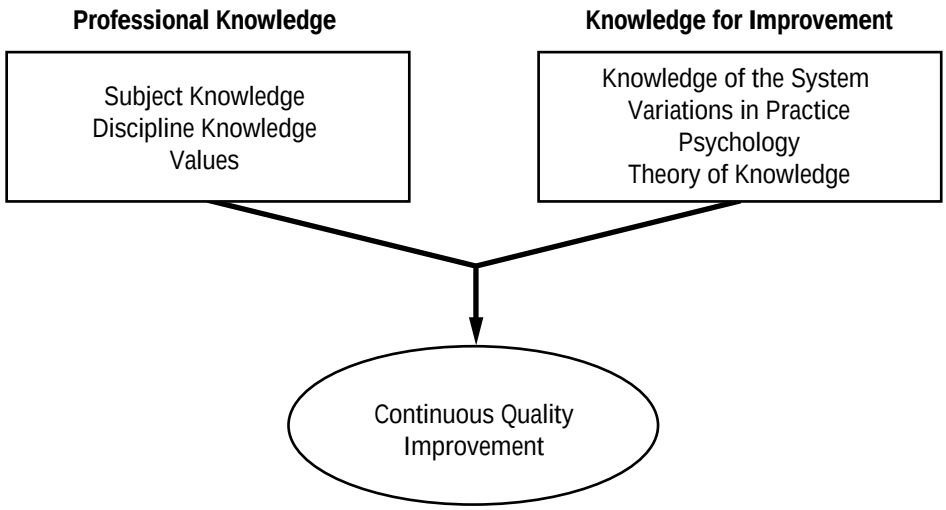
Although there are many ways to approach improving the quality of health care, most quality improvement efforts fall into two general areas:

- Professional knowledge—those efforts related to diagnosis and treatment; and
- Knowledge for improvement—those efforts examining the design and delivery of care.

The professional knowledge approach, which has been used traditionally to judge quality, is currently changing to incorporate the applied discipline inherent in the knowledge for improvement model. Figure 1 illustrates how professional knowledge and knowledge for improvement are conceptually combined in

Figure 1

CONTINUOUS QUALITY IMPROVEMENT MODEL IN HEALTH CARE: FOCUSING ON THE NEEDS OF THOSE BEING SERVED



Source: Adapted from Batalden and Nolan, 1994, with permission.[12]

the continuous quality improvement model.[12,13] The purpose of this section is to explain these two approaches and construct a model for continual improvement of *asthma* care.

Professional Knowledge

The professional knowledge approach reflects a traditional medical model of care. It requires the clinician not only to understand and keep up with knowledge regarding the pathophysiology, diagnosis, and treatment of disease but also to practice in concert with that knowledge. Professional knowledge consists of three components: subject knowledge, which includes basic science, such as biochemistry and physiology; discipline knowledge, which takes basic science and applies it to the practice of medicine; and values, which encompass the professional ethics and attitudes important to the relationship between patient and provider.

Current professional knowledge, as presented in the "Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma,"[14] helps to define key aspects of asthma care. These include:

- Pharmacotherapeutic treatment based on an understanding of the chronic inflammatory nature of asthma
- Intervention directed toward controlling the environment to minimize exposure to allergens and irritants
- Measurement of outcomes including symptom reports and objective measures of lung function
- Development of a patient-provider partnership through patient education.

The first two aspects rely on the clinician's subject knowledge and discipline knowledge. An understanding of the natural history of asthma—and of the latest scientific advances—provides clinicians with a basis for prescribing effective therapies. Outcomes assessment, the third aspect, may employ a variety of tools to measure quality of care and quality improvement. Asthma-specific outcome measures, which include functional status and quality of life, patient symptoms, measures of lung function, patient satisfaction, and costs of care,

are discussed in the next section and the appendix to this report (as well as in the Working Group on the Cost Effectiveness of Asthma Care report). The fourth aspect, developing a patient and provider partnership, is at the core of quality care. The clinician's guide "Teach Your Patients About Asthma"[15] describes components of this partnership, including open communication between patient and provider, joint development of a treatment plan acceptable to both the patient and the provider, and encouragement of family involvement to improve the prevention and treatment of asthma symptoms. Note that this proposed partnership is not limited to the individual patient or providers; it includes the family and community as well as the medical care system.

Knowledge for Improvement

The knowledge for improvement approach to quality improvement focuses on the design and delivery of care. This approach uses organizational theory, psychology, statistics, and small-scale experiments to understand and improve the *process* of care.[12]

The knowledge for improvement approach has four major elements:

- **Knowledge of the system** refers to everything related to the functioning of the system—the purposes, motivations, and desired outcomes; the processes to achieve these; and ways the system might be improved.
- **Variations in practice** refers to the way processes fluctuate. Variation can be a source of unnecessary waste and repetition.[16] In health care, unintended variation erodes quality and reliability.
- **Psychology** refers to the premise that most people begin a job intrinsically motivated to do their best but may be prevented from doing so by poorly functioning processes at work.
- **Theory of knowledge** refers to gaining new knowledge by conducting small experiments to test efforts to improve. Every decision is data driven, including the choice of an intervention, the measurement of its results, and the decision to keep the change in place or try an alternative.

Knowledge for improvement, when combined with professional knowledge, creates a useful model for continuous quality improvement (CQI).

Continuous Quality Improvement

The terms "quality assurance" and "quality improvement" are often confusing. In some settings, the terms refer to specific measurement and feedback activities. In other situations they describe a conceptual framework of all activities designed to maintain and improve the quality of care. In either case, evaluations of quality usually document the structure, process, and outcomes of health care, based on the paradigm developed by Donabedian,[17] and point to areas where improvements can be made.

In the Donabedian paradigm, structure refers to examining the resources available in the delivery of care; process looks at what was done, that is, how care was delivered; and outcomes examine the results of the process. In the past, much of the health profession's concern over quality focused on the structure and process components of the paradigm. Outcomes, if examined at all, were usually organizational measures of utilization such as hospital length of stay. Today, the operational means of studying quality has shifted. New emphasis on quality improvement in health care settings stresses the importance of identifying and evaluating appropriate and useful outcome measures in addition to mapping out the structure and process.

While the measurement and feedback activities of many quality improvement programs are

important and necessary, they may not be sufficient.[18-20] It is one thing to know that improvement is needed; it is another to understand *how* it can be achieved. If the goal is to improve asthma care for everyone, a greater knowledge of how the process of care links with outcomes is needed.[21-23] A strategy to improve care, not just measure it, is needed, especially if improvements are to be achieved within the context of the patient-provider partnership.

Continuous quality improvement, also known as total quality management (TQM), is based on the premise that most problems in quality result from problems in processes rather than problems with people.[16,24,25] Four central tenets are the basis for the quality improvement process[26]:

- The success of any endeavor depends on meeting the needs of those being served.
- Most people care about the quality of their work and want to do a good job.
- Unintended variations in processes may lead to undesirable variations in the outcomes.
- Ongoing data collection and simple statistical methods can identify the causes of these variations, pointing the way toward improvement.

Applications of Continuous Quality Improvement in Health Care

Applications of continuous quality improvement/total quality management in health care initially focused on the support services of patient care processes. For example, the Park Nicollet Medical Center in Minneapolis needed to address the issue of patient dissatisfaction with telephone access. Using continuous quality improvement, Park Nicollet reduced the average time for the medical information nurse to answer an incoming telephone call from an average of 3.5 minutes to 1.7 minutes.[27] In another example, Rush-Presbyterian-St. Luke's Medical Center in Chicago decreased laboratory turnaround time for routine laboratory tests by 25 percent.[28] In yet another example, Parkview Episcopal Medical Center in Pueblo, Colorado, reduced late starts in the operating room from 48 to 8 percent.[29] A byproduct of CQI/TQM has been substantial cost savings. For a further example, the University of Michigan Medical Center estimates that their TQM projects generated a 4-year total savings of $17.7 million.[30]

Applications of continuous quality improvement to processes involving direct patient care, as opposed to administrative processes, are just now beginning to appear in the literature.[31] For example, McEachern and colleagues[32] reported the work of a team at West Paces Ferry Hospital in Atlanta. Interventions based on their study of the process of cesarean section resulted in a significant drop in the rate of cesarean sections, from 22.3 to 17.8 percent of all deliveries. For another example, in Twin Falls, Idaho, public health workers, hospital executives, local physicians, and others used continuous quality improvement methods to improve prenatal care. As a result, the number of drop-in deliveries (women who presented for delivery without a primary care obstetrics physician) decreased from 20 to 5 per month in 3 years. The annual number of drop-in births that resulted in admissions to the neonatal intensive care unit dropped from 22 to 2.[33]

Applications of Continuous Quality Improvement in Asthma Care

Evidence of the use of continuous quality improvement in asthma care is also just beginning to emerge. For example, Headrick and colleagues[34] used quality improvement concepts in a project to teach medical students at Case Western Reserve University in Cleveland, Ohio, about quality and cost in asthma care. The students wrote case reports describing the care of patients with asthma in primary care settings across the community, reported considerable practice variation, sometimes among physicians at the same site, and

analyzed the links between process and outcomes for each individual patient. In the 1991-92 academic year, 123 students at the university worked together to analyze 78 asthma cases. Disease severity was the major determinant of asthma care outcomes, but it was the most important factor in only 21 percent of cases. Treatment effects accounted for another 15 percent. For nearly 66 percent of the patients with asthma seen by the medical students, other factors, particularly patient adherence, exposure to extrinsic triggers, and patient education, were more important.[35] Based on these observations and hypotheses, the students generated a number of recommendations for improved care.[36]

The case studies presented in the next section of this report are adapted from actual examples of applications of continuous quality improvement principles in a number of health care settings.

THE FRAMEWORK FOR ASTHMA QUALITY IMPROVEMENT

The knowledge gained from quality improvement efforts can be combined with the professional knowledge from the "Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma"[14] to achieve continuous quality improvement in asthma care. Figure 2 illustrates the basic four-step framework that can guide asthma quality improvement efforts in any setting.

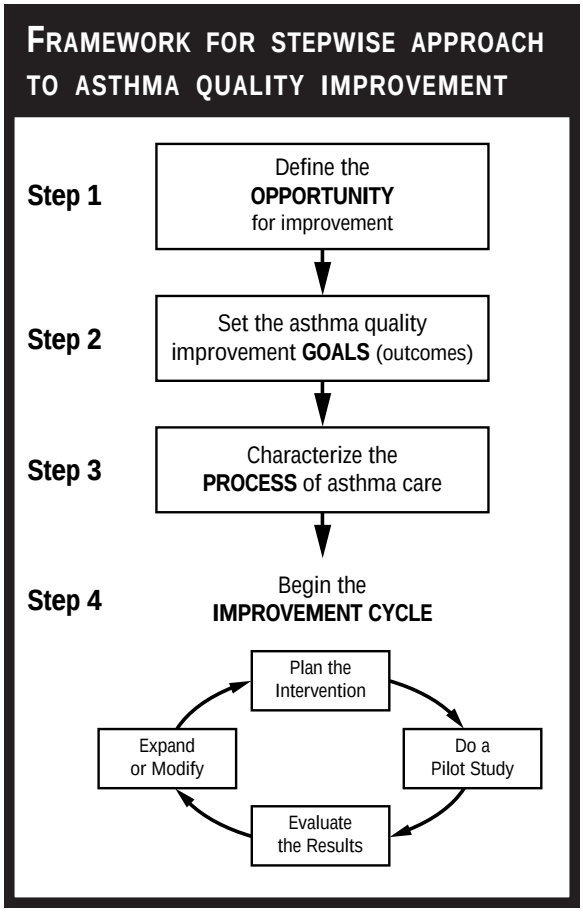
Each of the steps is described in detail in this section. A case study example of asthma quality improvement in a large health maintenance organization (HMO) follows each step. Additional case studies that complement the descriptions and illustrate how the framework can be used in various settings, including an emergency department, a hospital, a school system, and a community, as well as by an individual provider, are in the next section.

Step 1—Define the Opportunity for Improvement

This step identifies the opportunity for improvement in asthma care by requiring participants to define the reason for the proposed effort. Three actions are basic.

- **Identify what is driving the concern about asthma care in your health setting.** That is, what has made asthma care a priority for quality improvement? Was it a particular patient-related event, such as a recent asthma death or a high rate of asthma hospitalizations, or was it concerns about patient satisfaction or access to care? In most settings, the concern about asthma care is the result of suboptimal health outcomes, such as a patient's inability to maintain normal activity levels or to prevent recurrent exacerbations; or suboptimal

Figure 2



STEP 1 CASE STUDY: PEDIATRIC ASTHMA TEAM IN A LARGE HMO

This case describes how the pediatrics department of an Arizona health maintenance organization used continuous quality improvement to improve the care of children with asthma. The case will be presented in several parts, each following the general description of the four steps of the asthma quality improvement model. Each case segment concludes with a "perspective" commentary, comparing the actual events to the ideal process.

Step 1—Define the Opportunity for Improvement

- *Identify what is driving the concern about asthma in your health care setting.* The chair and senior leaders of the pediatrics department in the HMO perceived that their hospitalization rates for children with asthma were higher than they should be, 6.5 to 6.8 per 1,000 pediatric patients in 1987-88. They also suspected that there were too many exacerbations of asthma within their population as well as increasing costs for asthma care within the HMO.

  These leaders wrote an opportunity statement identifying the medical management of pediatric patients with asthma as a place where improvements could be made. They thought that suboptimal home and office management of asthma were likely contributors to increasing hospitalizations, high rates of exacerbations, and increasing costs. They decided that this was a high priority for the organization.

- *Determine your place in the patients' system of asthma care.* The HMO serves 40,000 children (infants to age 15) in a large metropolitan area in Arizona. This staff-model HMO provides complete health care to its members—including primary care, specialty care, emergency services, and hospitalization—and offers a pharmacy and certain durable medical equipment.

- *Choose the right opportunity.* Because the HMO provides complete services, the leaders decided to address the entire process of asthma care, beginning when the patient is diagnosed with asthma and ending when the patient's asthma is managed appropriately in a cost-effective manner.

Getting started and documenting progress. The chair of the pediatrics department recruited a team that included a pediatrician from the outpatient department as the team leader, a nurse educator, an allergist, a pulmonary specialist, the medical director of utilization management, and another nurse. The team members kept careful records and decided to publish an asthma newsletter to keep other members of the HMO informed of their activities. In addition, they instituted an inservice and continuing medical education program to educate staff at all levels.

Step 1 perspective. This team does a good job in developing the first step; however, two comments are noteworthy. First, the team chose the entire process of care as the starting place. But it is not possible to improve the entire process at once. The team later focused on specific issues within the care process. Second, because the team eventually identified opportunities for improving home equipment procurement and telephone triage, the team might have benefited by including individuals involved with these activities as members of the team. It is not uncommon that a team needs to add members as it begins to understand the care process.

health care processes, such as the lack of needed drugs on the formulary or of patient access to 24-hour telephone advice; or a combination of both suboptimal outcomes and processes.

- **Determine your place in the patients' system of asthma care.** Each patient with asthma interacts with a system of care—that is, with a network of interdependent components that work together to accomplish a goal.

But connections among system components are not always apparent. Individuals working in a system may simply work in their own component and give little thought to the system as a whole. Before planning an inter-vention, it is important to consider its potential impact on all system components. Figure 3 contains a useful series of questions that providers can ask themselves to clarify their role in the patients' system of asthma care.

- **Choose the right opportunity.** That is, identify the right place to start your asthma quality improvement effort. Alignment of goals within the health care environment is essential for success. To select the best focus, consider:
  - — **The mission of your organization.** Organizational support is more likely if the asthma quality improvement effort is a good match with the overall goals of the organization.
  - — **The size of the project.** Involving a limited number of people, a discrete part of the overall process of asthma care, helps to ensure manageability.
  - — **Evidence that certain practices are more likely to produce better outcomes.** Choosing an improvement opportunity supported by the best current knowledge—such as in the "Guidelines for the Diagnosis and Management of Asthma"[14]—is a good place to start.
  - — **The expected benefits exceed the costs.** The asthma quality improvement effort should be considered worth the investment of resources (i.e., persons, time, money).

Figure 3

THE PROVIDER'S ROLE IN THE PATIENT'S SYSTEM OF ASTHMA CARE

Where am I in my patient's system of asthma care?

We all operate within a variety of environments that often affect health care directly or indirectly. Learning to ask questions that help to clarify our place in the patient's system of asthma care allows us to create a process that is not only appropriate but more likely to be workable. Some examples:

- What is my role within the medical care system? For example, is my focus on primary care, specialty care, or emergency department care? Do I primarily see patients on an inpatient or an outpatient basis? What perspective do I hold (such as health insurer, pharmacist)?

How do other systems affect my patient with asthma?

- *Home:* How does my patient's illness affect family members? Is the family willing to be an active part of the treatment process? How do the circumstances of the other family members affect the patient (e.g., family members who smoke, history of family violence)? How does the burden of health care costs affect my patient and his or her family?
- *School:* Does my patient need to take asthma medicine while at school? Does the school allow for this? Is someone there to monitor and evaluate medication administration? How does the health system in which I work interact with my patient's school?
- *Workplace:* Does my patient have to take asthma medications or treatments at work? Does the work setting allow for this? Does my patient's illness prevent opportunities for job growth and advancement? How does the health system in which I work interact with my patient's place of work?

Getting Started

With the opportunity for asthma quality improvement defined, it is time to get the effort under way. Nearly all quality improvement efforts require a team. Two categories of team members are critical for asthma quality improvement: those who have an overview of the entire health care process, such as clinical staff and managers; and those who have expertise in the day-to-day care of persons with asthma. Many asthma quality improvement teams also include patient representatives.

A realistic timeline should be established for the asthma quality improvement project. In addition, it is critical to establish an overall goal, together with short-term goals that can act as mileposts (see step 2). For example, plan to have a pilot intervention in place within 2 months, results in 6 weeks, and the next pilot shortly thereafter.

Documenting Progress

Try to keep a record of all discussions, the people involved, the data that support the decision-making process, and the results of pilot interventions. It is also helpful to keep those who have a stake in the effort informed of progress and results. The need for adequate documentation is often overlooked, and there is a tendency to move directly to outcome measures without documenting not only that the intervention took place but also how it took place. But documenting the effort is important, for example, if the successful pilot is to be expanded to the rest of the organization. Documenting the effort also helps improve the efficiency and effectiveness of the asthma quality improvement process.

Step 2—Set the Asthma Quality Improvement Goals (Outcomes)

This step sets the goals of the improvement effort and requires team members to identify the most appropriate outcome measures.

- **Choose an outcome.** To recognize improvements in the quality of asthma care, defining the outcomes of interest is necessary. Choose those outcome measures most relevant to and useful in your health care setting. The following criteria may be useful for selecting outcomes and outcome measures:
  - — The measures of the health outcomes selected should be observable for all patients in the population studied.
  - — The measures of outcome should not be dependent on expensive tests or technology.
  - — The outcomes should be measurable in several ways or at differing levels of precision without losing their usefulness. For example, exercise tolerance can be evaluated with a few questions in a clinician's office or with an exercise challenge test performed with objective measures of airflow obstruction.

An excellent way to maximize outcomes is through benchmarking, that is, through identifying organizations that have achieved best results and learning from them.

Asthma outcome measures for quality improvement fall into two major categories: patient- and family-centered outcomes, and organizationally based outcomes. Figure 4 provides brief descriptions of the types within these categories. (For greater detail, see the appendix.)

- **Identify sources of outcome data.** Outcome data that are most relevant for asthma quality improvement may in some cases not be readily available and may need to be collected. Thus before deciding to use a particular outcome, considering the effort required to gather the data is critical. Collection of new data is time consuming and often expensive. In other cases, data may already be available, but their quality

STEP 2 CASE STUDY: PEDIATRIC ASTHMA TEAM IN A LARGE HMO

Step 2—Set the Asthma Quality Improvement Goals (Outcomes)

We revisit the HMO case study to illustrate step 2 of the asthma quality improvement model.

- *Choose an outcome.* The HMO pediatric team identified the following outcomes to mark their progress: school attendance, as a measure of functional status (patient- and family-centered outcome measure), and resource utilization (organizational outcome measure). The specific utilization measures of concern were office visits, emergency department visit rates, hospitalization rates, and costs (e.g., pharmacy, equipment, emergency department, hospitalization, office visit, laboratory tests).
- *Identify sources of outcome data.* The HMO team surveyed patients who participated in the intervention to compare each child's rate of office visits and school days lost before the intervention and 12 months afterwards. The team also took advantage of existing data. The HMO's utilization management system provided information on emergency department visits, hospitalizations, and costs.
- *Measure the outcome.* The patient survey was limited; only 62 of 330 families responded. The team realized that the poor survey response rate limited the generalizability and noted this when reporting the results to others. The team planned to repeat the survey, with new strategies to improve the response rate.

  The resource data were gathered routinely by the organization for some time and were felt to be reliable and valid.
- *Consider how the outcome data will be analyzed.* The team planned to examine the outcome measures annually to identify trends.

Step 2 perspective. This segment of the case study illustrates several important points about outcome measurement. The team chose both patient-centered and organizationally based outcomes data. Team members relied principally on data already collected by their organization. However, they sought new data for patient and family outcomes. Their efforts in conducting the patient survey illustrate how difficult it is to collect primary data. Appropriately, they recognized the limitations of their results.

may not be adequate. Making an effort to improve routine asthma-related outcome data collection before deciding to collect new data may be the best course of action.

- **Measure the outcome.** The validity of measures, their reliability and statistical significance, and sources of bias in measurement must be considered in measuring the outcomes selected as the basis for asthma quality improvement efforts. Asking the following questions is helpful:
  - — **Do the selected measures really measure your conceptual outcome?** For example, level of medication use is sometimes used as a proxy measure for severity of asthma; but this measure could reflect access to care or to financial resources to pay for medications, or practice patterns of individual clinicians, or severity. Perfect measures for all outcomes of interest are rarely found. Thinking about what available data actually represent will help your asthma quality improvement process.
  - — **Are the findings statistically significant, that is, unlikely to have occurred by chance or random variability?** This is important to assess even in small studies conducted without large resources.

Figure 4

USEFUL OUTCOME MEASURES FOR ASTHMA QUALITY IMPROVEMENT EFFORTS

Patient- and Family-Centered Outcome Measures

- **Symptoms of asthma.** These measures reflect an effort to set goals for control of airway irritability or hyperresponsiveness.
- **Functional status and quality of life.** These measures evaluate the degree to which the patient and family can live without significant physical, social, or psychologic limitations.
- **Physiologic measures of airflow obstruction.** Tests of pulmonary function provide a wide array of measures of lung function that are useful in diagnosing asthma and in assessing response to preventive therapy over time.
- **Patient satisfaction with care.** This is an important, independent dimension of quality of care. Satisfaction with care may or may not correlate with the technical quality of care—the appropriateness of diagnosis and treatment—and should not be treated as a proxy measure of those aspects of care. Rather, satisfaction with care is related to important aspects of the relationship between patient and provider and to the institutional arrangements for obtaining health care.
- **Costs of care.** These include measures of both direct costs (such as out-of-pocket expenditures on health insurance premiums and copayments) and indirect costs (such as lost income or extra expenses for travel and child care).

Organizationally Based Outcome Measures

- **Resource utilization.** These measures for asthma care can be classified broadly into measures of acute use of the health care system (such as hospitalizations and emergency department visits) and comprehensive measures of routine care (such as office visits or prescription patterns).
- **Organizational costs of care—direct medical expenditures.** Cost outcomes from the organizational perspective are measured principally in terms of direct medical expenditures in relation to covered benefits.
- **Population-based indices of quality of life and health status.** These serve both as measures of patient- and family-centered outcomes and as important organizational measures of optimal care for the patient population as a whole.

Carefully evaluated results are far more likely to be convincing to others, and seeking the help of someone with statistical expertise is very useful. Even if a small study does not have a statistically significant result the first time it is performed, confidence that the results observed are real will increase if the changes observed are consistent over time.

— **Are there measurement errors in the data?** There are no perfect measurement instruments for asthma care. Each time an outcome measure is made, there is always a risk of error. Even data usually considered objective may in fact be subject to measurement error and bias. For example, a peak flow meter may not be appropriately calibrated and thus provide readings that are consistently too high—a systematic error that can lead to inaccurate results. In addition, if the meter is used to assess patients receiving an intervention to improve care, but a differently calibrated meter is used to assess the control group in the study, the intervention may seem more effective than it really is.

Measurement error is also possible in health care utilization records. For example, a hospital computer system may be designed to code discharges to provide optimal reimbursement for diagnosis-related group (DRG) payments. Because of this DRG orientation, the hospital discharge coding of asthma may either over-recognize or underrecognize asthma as a first-listed discharge diagnosis.

Measurement error and bias are not uncommon in self-reported data. If these data are used, the following precautions might be taken:

– Duration of symptom recall information should be limited to no more than 2 weeks in order to reduce recall bias.

– Peak flow diary information requires frequent re-instruction on instrument use.

– Long-term daily diary maintenance is hampered by adherence problems and should be used with caution in quality improvement projects involving large populations.

Although there are problems with self-reported data, these data should not be disregarded, for they are often the only, and perhaps the most appropriate, data for many important outcomes.

- **Consider how the outcome data will be analyzed.** Before undertaking any data collection, it is critical to consider how the data will be used. Planning ahead saves time and resources. Ask, for example, who is the most important audience for these results? Get the needed data; don't waste effort and resources on data that will not be used. It is likely that only a small number of data elements will be needed to observe changes in quality of asthma care. Consider the exercise of creating empty graphs and tables to display the data to be collected. Such an exercise, when completed early in the asthma quality improvement effort, may help clarify what is really needed and reduce the collection of unnecessary data. (For development of a plan to analyze the data, see step 4.)

Step 3—Characterize the Process of Asthma Care

This step characterizes the existing process of care and helps team members observe what happens as patients interact with the system of health care. This step identifies barriers within the context of the entire process, and thus identifies where improvements can be made.

- **Define the process of asthma care; develop a flowchart.** A flowchart explicitly maps the steps of the asthma care process. A flowchart is reminiscent of an algorithm (or guideline), but the subject here is the process of care, not the content. See figure 5 for the standard symbols used in flowcharting. Developing a flowchart of the part of the asthma care process in your environment that is of interest to the team will provide a clearer focus on any problem of concern—and can be done quickly:

  — Gather the team together and have each team member write down the steps he or she knows, with each step written on an index card.

  — As a team, arrange (and rearrange) the steps on a large sheet of paper until consensus is reached that the resulting chart represents the process as it usually occurs.

  — If the team is unclear about a particular step, recognize that the input of a key person who is not yet on the team may be missing. Further, in 24-hour settings, such as hospitals, make sure to consider including team members from various shifts.

Brassard[37] described the best way to use flowcharts:

— **Draw a flowchart of the steps that the process actually follows** in your environment.

— **Draw a second flowchart of the steps that the process should follow** if everything worked right.

— **Compare the two flowcharts.** Figure 6 demonstrates the documentation of the steps for ordering a spacer device for a child whose insurer requires prior authorization—first in a flowchart of the process as it should be and then in a flowchart of the process as it was actually operating.

- **Explore the process; evaluate the flowchart.** Circulate the flowchart developed by the team to others involved in the process for review. Agree on a final version that depicts the best process—that is, the process as it should work. Use the flowchart to identify where an intervention is likely to have the greatest impact on the outcomes of interest. One of the following scenarios is likely to emerge:

  — The current process is so complex and appears so dysfunctional that major restructuring must be planned, piloted, and evaluated. There is enough information to move on to step 4's improvement cycle.

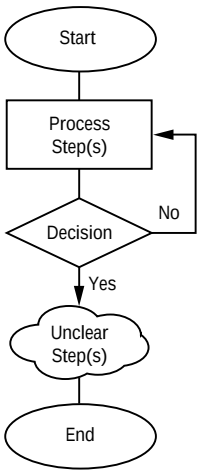
  — The current process appears good—except for one or two steps that are in obvious need of modification. There is enough information to move on to step 4's improvement cycle.

  — The current process appears good; the reasons for suboptimal outcomes remain unclear. When this happens—which is often—day-to-day events may not be occurring exactly as represented, and there may be variation in certain steps of the care process. As noted in the discussion of the models of quality improvement, unintended variations in process can lead to unreliable outcomes and poor quality.[38]

- **Identify the factors that contribute to unwanted variations in the process of asthma care.** To identify these factors, a more detailed analysis of key asthma care process steps is required. For example, a small, focused patient survey might reveal the most common reasons for going to the emergency department instead of calling the telephone advice system. A provider survey might identify barriers in obtaining urgent treatment for asthma exacerbations in the office. Time studies of office staff might reveal the causes of long telephone waiting times. Other commonly used data

Figure 5

SYMBOLS USED IN FLOWCHARTING

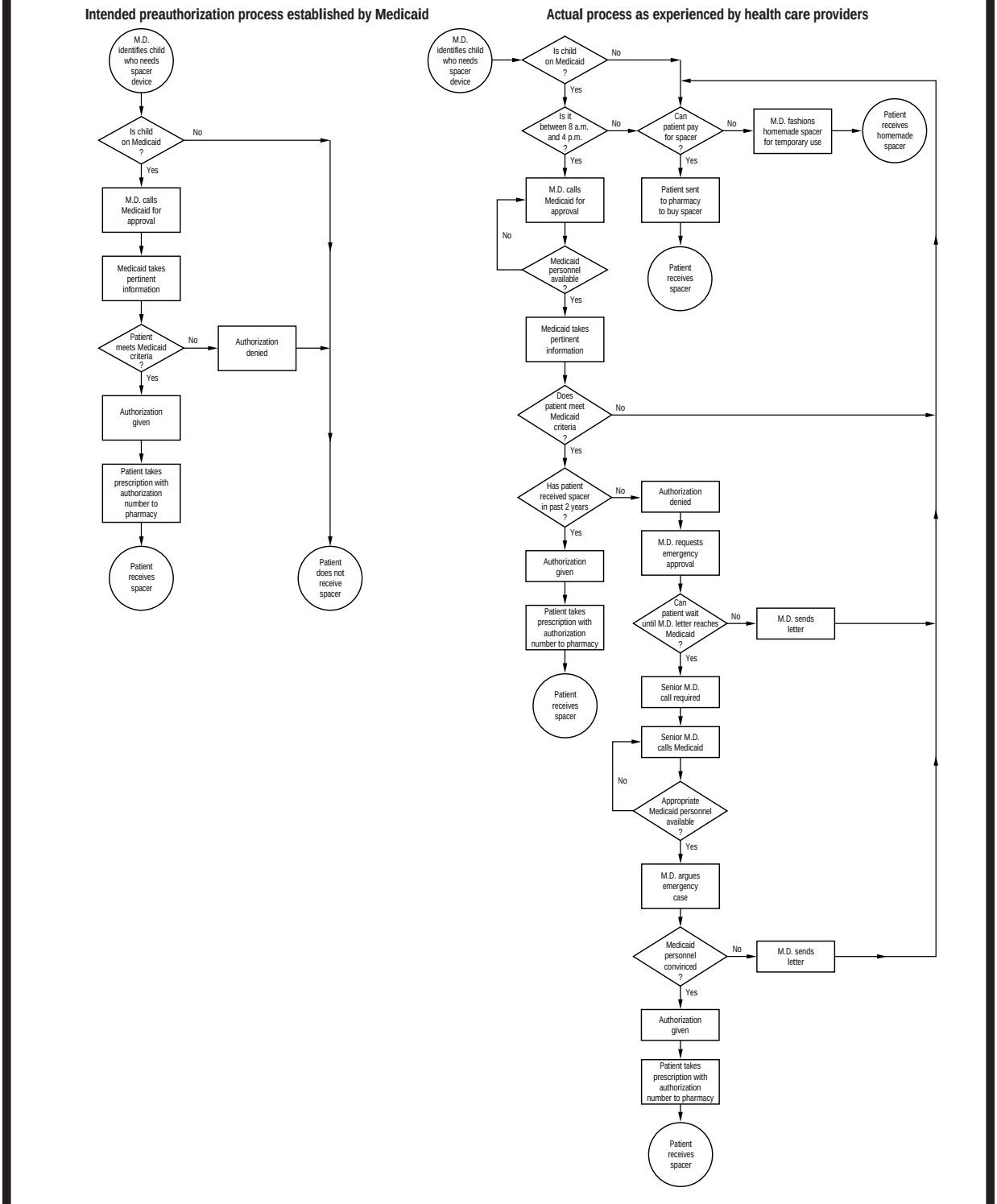


Although there may be ways to describe the process of care, a flowchart is likely to be a key step in clarifying problems. This figure demonstrates some of the basic symbols used in flowcharting. The oval is used at the beginning and end of the process. Rectangles are used to identify each step in the process. A diamond is used to describe a decision point. The cloud identifies one or more steps in the process of care that are uncertain and usually indicates that a key person involved in the care is missing from the team that constructed the flowchart.

Source: Brassard, 1985.[37] Used with permission from GOAL/QPC 1985. Reproduction without permission is prohibited.

Figure 6

USING FLOWCHARTS TO COMPARE AND DEFINE PROCESS: MEDICAID PREAUTHORIZATION FOR A SPACER



STEP 3 CASE STUDY: PEDIATRIC ASTHMA TEAM IN A LARGE HMO

Step 3—Characterize the Process of Asthma Care

We revisit the HMO case study to illustrate step 3 of the asthma quality improvement model.

- *Define the process of asthma care; develop a flowchart.* The HMO pediatric asthma team used flowcharting to understand the acute care process for asthma exacerbations. See figure 8.

  Input from all team members is needed to map out the process of care. The flowchart begins when the patient calls the emergency assistance telephone system. A home management protocol is initiated; if successful, an appointment is scheduled for the patient to be seen in the office the next day. If the home management protocol is not successful, the patient is referred to the emergency department or the urgent care center.

  The flowchart also maps out the process of care in the office, emergency department, or the urgent care center. If the patient responds to treatment, a followup appointment is scheduled. If the patient does not respond to treatment, he or she is admitted to the hospital.

- *Explore the process; evaluate the flowchart.* The team members agreed that the flowchart represented the process as it should happen. They talked with their coworkers and used their own experience to identify where the actual process varied; that is, where the process of care often did not go as planned. They used that information in the next step.

- *Identify the factors that contribute to unwanted variations in the process of asthma care.* The team brainstormed to generate many ideas quickly about where unwanted variations occurred in the process of asthma care at the HMO. The results are displayed on a cause-and-effect diagram (see figure 7). The desired or optimal effect is "asthma well managed," the rectangle on the right. The causes of variation are displayed in four categories on the arms of the figure, "people," "procedures," "methods," and "materials." For example, important procedures that affect "asthma well managed" are the "complex referral system to asthma education classes," "poor communication at time of discharge from hospital," and "no followup or feedback after education class."

  Ultimately, the team identified four areas that team members believed had the greatest impact on the outcomes of interest (see step 2), each contributing unwanted variation in the process of pediatric asthma care: problems with the diagnosis of asthma; inconsistent management of asthma by providers; availability of equipment for patients with asthma; and patient, family, and support staff knowledge regarding asthma.

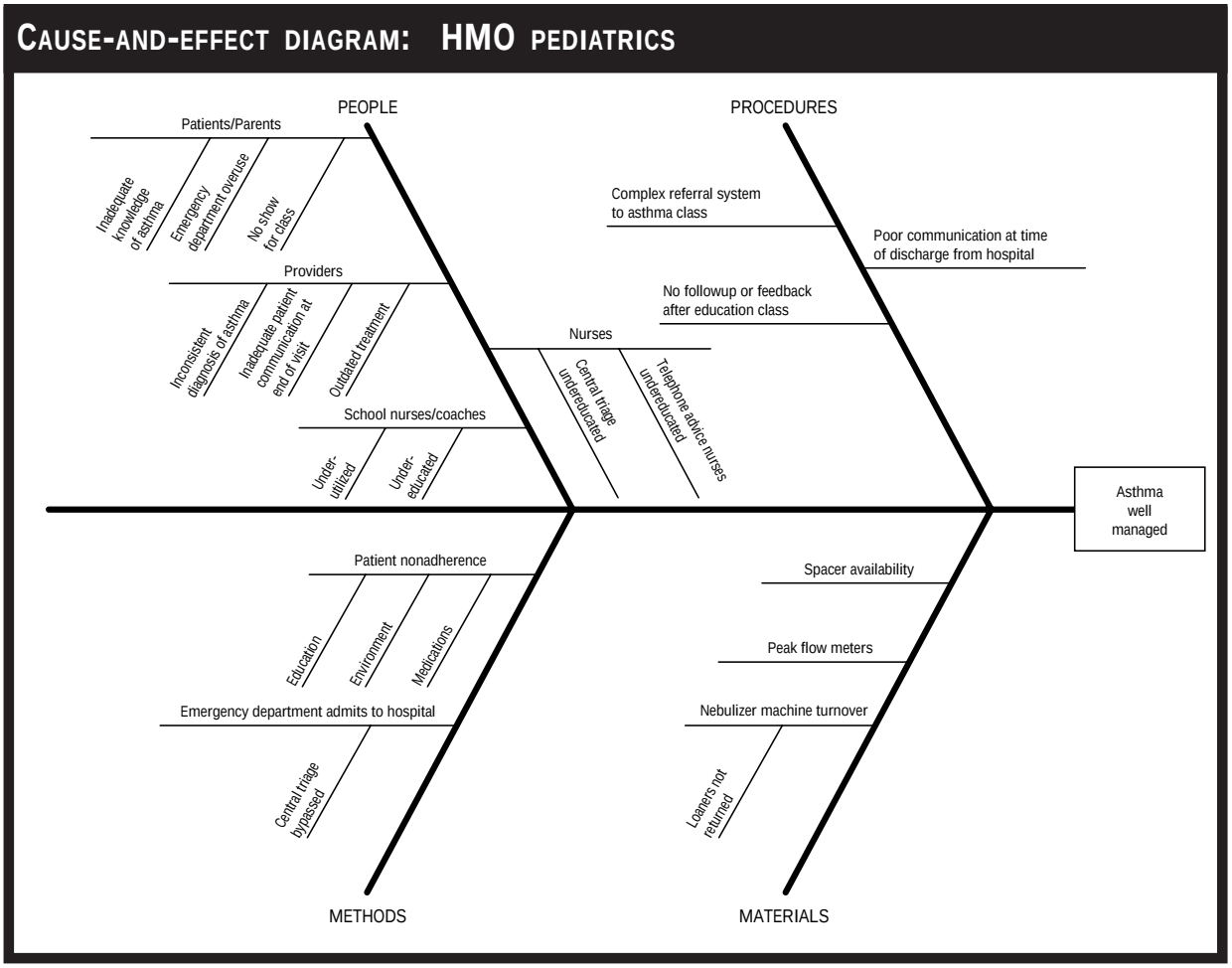
Step 3 perspective. The team used several tools that give information about processes: flowcharting, brainstorming, and the cause-and-effect diagram. It was not obvious how the team chose the four areas of intervention. Sometimes intuition and direct experience are adequate. In other situations, small-scale studies of the process of care may provide data to help determine which factors are the greatest source of undesired variation.

collection strategies for such analyses include chart reviews and focus groups. Results of your analysis can be summarized graphically and communicated to others with a cause-and-effect diagram, as illustrated in figure 7 (which is based on the case study for step 3).

Choosing an Intervention

Once the process of care is characterized, team members have a clear understanding of how the process of asthma care should work, how often and whether it works as planned, and the most common reasons for irregularities. Based on these data, the team is now ready to choose

Figure 7

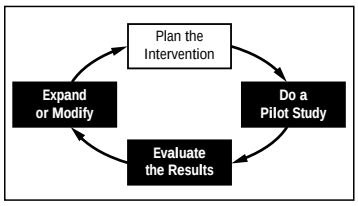


an intervention. Although several areas in the asthma care process are likely to benefit from improvement, do not try to change everything at once. Focus the first intervention on the area most amenable to change with the highest chance of benefit to the chosen outcome. Other areas needing improvement can be addressed in future interventions in step 4's improvement cycles. The goal is steady, incremental change to ensure continuous quality improvement.

Step 4—Begin the Improvement Cycle

This step takes the intervention through the continuous loop of planning, testing, evaluating, and revising, thus setting up the improvement cycle.

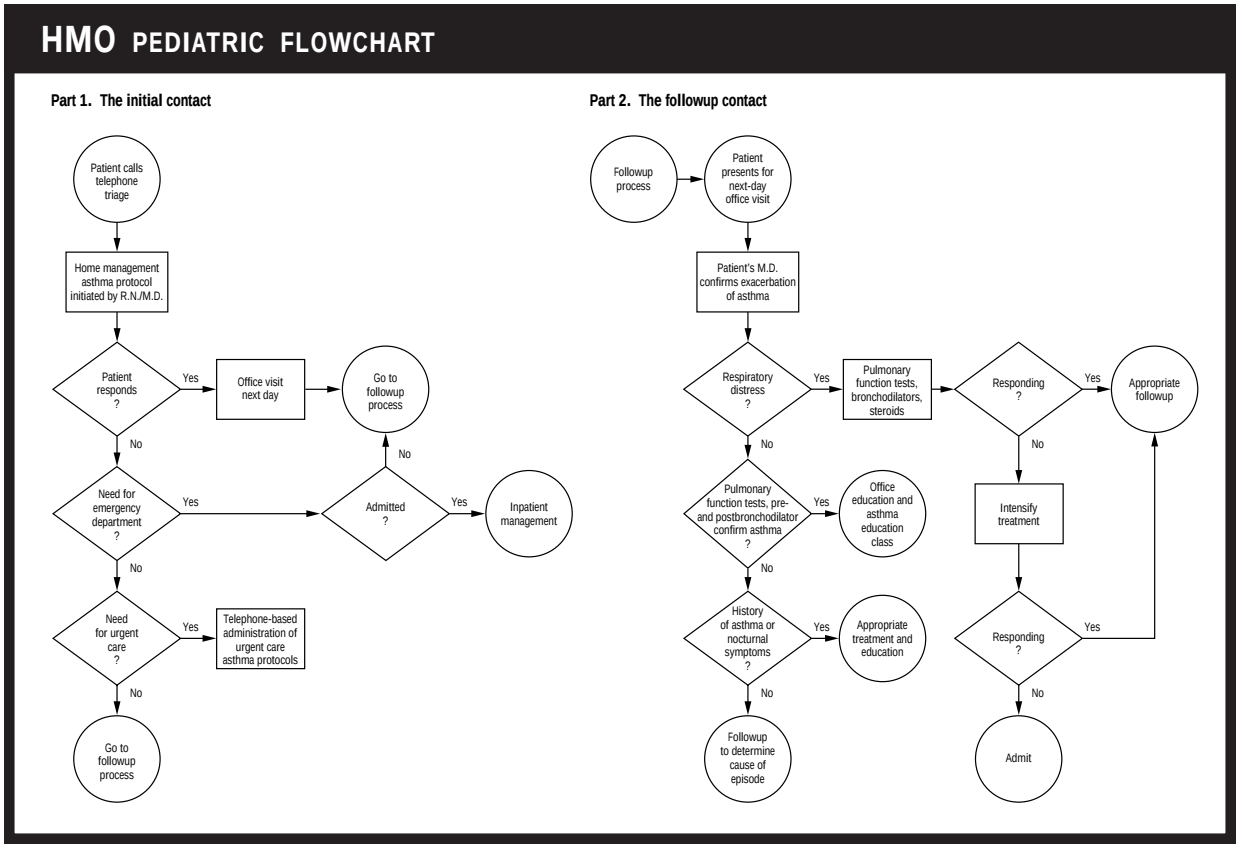
- **Plan the intervention based on what the team learned in step 3.**



Careful work here is essential to ensure being able to interpret results. The efforts invested now will make the next steps relatively easy.

— Make sure that it is clear who is responsible for overseeing the intervention and that other tasks are clearly assigned to team members.

Figure 8



— Establish a timeframe for the intervention. For example, let the intervention work for 2 to 4 weeks and then have team members evaluate the results.

— Enlist the support and cooperation of those individuals whose work will be directly affected by the intervention.

— Identify a few key data elements that can indicate whether the intervention has produced improvement in care. Select no more than one or two outcome measures and one or two process measures for the area the intervention is targeting.

— Develop a mechanism for data collection. Keep it simple. Easiest is integrating data collection into routine work activities. Simple check sheets are often sufficient.

— Plan the data analysis. Again, keep it simple. Unless your intervention is part of a formal research project, with a goal of generalizability and national peer review, simple analysis is enough. Following the rate of key outcomes of interest over time, before and after the intervention, may be all that is needed. A particular outcome can be followed with a run chart or a control chart—graphical displays of data that are easy to compile and that simplify statistical interpretation. However, before selecting a run-chart format, consider the potential frequency of the outcome variable. Mortality and hospitalizations, for example, may be too infrequent to demonstrate results within the timeframe of the quality improvement cycle. (To find out more about these methods, see Brassard, 1985, or Wheeler, 1993.[37,39])

STEP 4 CASE STUDY: PEDIATRIC ASTHMA TEAM IN A LARGE HMO

Step 4—Begin the Improvement Cycle

Based on the work in steps 1 through 3, the HMO team was ready for step 4, the improvement cycle. Team members chose several improvements they wished to initiate, each driven by the most important variations in the process of asthma care identified in step 3.

- *Plan the intervention.* Ideally, one might wish to initiate interventions as a series of small experiments to determine which has the greatest impact. In this case, however, the team decided to proceed with several at once.
- *Do the pilot study—*

Intervention 1: Guidelines for asthma diagnosis and treatment. The HMO's staff initiated work on its guidelines for asthma diagnosis and treatment before the "Guidelines for the Diagnosis and Management of Asthma" were published in 1991; the national guidelines were incorporated when they became available. The department initiated a process through which all providers could contribute to the creation of the guidelines. Through this method, they agreed on procedures for outpatient treatment of acute exacerbations, maintenance therapy for persons with chronic asthma, and inpatient management. These were discussed at continuing education conferences for physicians, inservice programs for other staff members, and in an asthma newsletter circulated throughout the organization. Office procedures were changed to support the implementation of the guidelines, including the creation of an asthma education team, with an identified asthma educator on the staff of each outpatient pediatrics office.

Intervention 2: Availability of equipment for asthma patients. Procedures for obtaining spacing devices and peak flow meters were simplified to encourage their use at home, in the office, and in the urgent care center. The HMO also made small-volume nebulizers easier to obtain, when deemed appropriate by the provider.

Intervention 3: Asthma education. Asthma education for physicians and other HMO staff members was tied to the dissemination of asthma guidelines, as already mentioned. Education for patients with asthma was improved in several ways:

— A "No Wheeze Please" class replaced an earlier, poorly attended asthma class. Previously, a physician referral was required to attend the class; that extra step proved to be an unnecessary barrier to patients interested in attending. Also, the previous classes were scheduled at a time that turned out to be difficult for families with young children. Patients could attend the new class whenever they chose, without waiting for a referral from their physician. Patients received a "No Wheeze Please" fanny pack with a peak flow meter and educational materials. The goal was to make the class convenient for families and fun to attend.

— A nurse in each pediatrics office was identified as the "asthma nurse." He or she received special training and was given responsibility for office-based education for patients with asthma.

— The team initiated home-based education for patients who could not attend the asthma class. An educational video was available at the office for loan to patients and their families. Patients who returned the video and completed a questionnaire assessing their asthma knowledge received a coupon for a free office visit, without the usual $15 copayment.

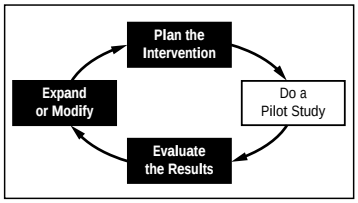
Intervention 4: Emergency assistance telephone line. Anecdotally, the team leader reported that the patient education efforts were so successful that the nurses on the HMO's emergency telephone triage line had to receive additional asthma education because the patients calling in knew more than they did. Patients were encouraged to call that number to receive advice and instructions rather than to go directly to the emergency department.

STEP 4 CASE STUDY (CONTINUED): PEDIATRIC ASTHMA TEAM IN A LARGE HMO

- *Evaluate the results.* The survey of patients attending the "No Wheeze Please" class was limited, as noted in step 2. However, the results were promising. The patients responding indicated a 49 percent decrease in office visits per year per child (4.7 to 2.4 percent) and a 33 percent decrease in school days lost per year per school-aged child (4.6 to 3.0 percent). Emergency department visits were tracked from 1991 to 1993. Figure 12a shows the improvement—from 9.2 to 4.8 asthma visits per 1,000 pediatric patients. This improvement occurred despite steadily rising numbers of pediatric patients served through the HMO. Hospitalizations also decreased, measured as asthma admissions per 1,000 pediatric patients, as shown in figure 12b. The length of stay increased because only the sicker patients were admitted. Finally, cost savings were estimated at more than $400,000 per year, largely through decreased visits to the emergency department and decreased hospitalizations.
- *Expand or modify.* The team continues to work, with activities designed to hold the gain and expand the effects of their interventions. These include:
  - — Ongoing provider and support staff education through continuing medical education, the asthma newsletter, peer review of charts, and updating of guidelines to reflect new therapies regarding asthma
  - — Continual modification of the "No Wheeze Please" asthma education program to meet future demands
  - — Continued impact monitoring of hospital and emergency department utilization and tracking office and urgent care visits for asthma.

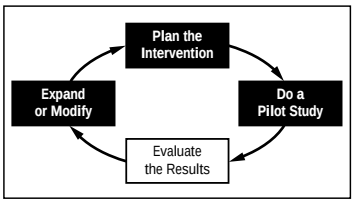
Step 4 perspective. There are several aspects of this asthma quality improvement pilot implementation that are worth noting. First, in addition to collecting survey data, the team also took advantage of data already available in the system. Although it is generally not recommended that teams take on several quality improvement activities simultaneously, this group focused its interventions on the parts of the process it found to be the most important causes of variation in "asthma well managed." The team attended to the need to educate staff, patients, and families about the interventions. The team kept working even after improvement was demonstrated in order to maintain progress. This is important because it is easy for an organization to slip back into old ways of doing things if efforts toward change are not sustained. However, as a cautionary note, it is uncertain to what degree any of the specific results mentioned can be directly attributed to the asthma quality improvement interventions.

- **Do a pilot study.**



  - — Conduct any training needed to implement the intervention, including training on the data-collecting mechanism.
  - — Begin collecting the data—and make sure the collection mechanism works before the intervention starts.
  - — Define a few days as a lead-in period to be sure the intervention is working smoothly.
  - — Let the intervention work for the allotted time.
  - — Keep notes on unexpected events, reactions of staff and patients, and other effects. They may be important for interpreting the data and revising the intervention.
  - — Evaluate the results after the allotted time, as planned.

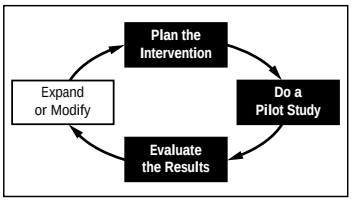
- **Evaluate the results.**



  — Summarize the data according to the analysis plan. Visual display is often the best way for the team to look at the data together. Types of visual data displays include pre and post flowcharts, histograms, run charts, and scatter diagrams, as illustrated in figure 9.[37] Figures 10 and 11 provide examples of an asthma-specific histogram and run chart prepared by the New York City Health and Hospitals Corporation as part of a continuous quality improvement effort.

  — Based on your analysis of the data (and of any unexpected events), decide whether the pilot study of the intervention has resulted in any asthma care quality improvement.

- **Expand or modify.**

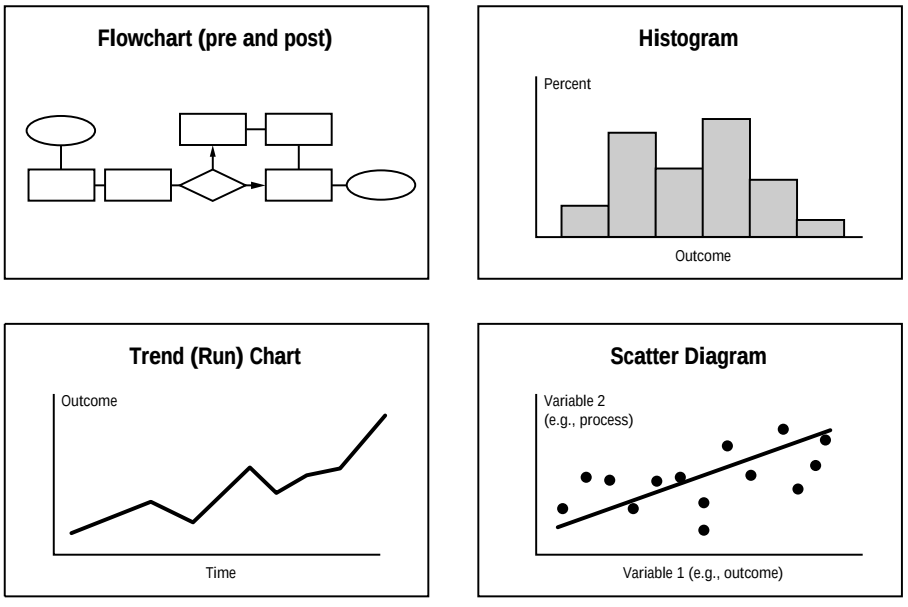


Intervention results—and expansion or modification activities—can be placed in the following categories:

  — **The asthma care process changed, and outcomes improved.** But was the improvement as much as the team wanted? Will a modification of the intervention lead to more improvement? Should this intervention now be expanded to other areas of your health care environment?

Figure 9

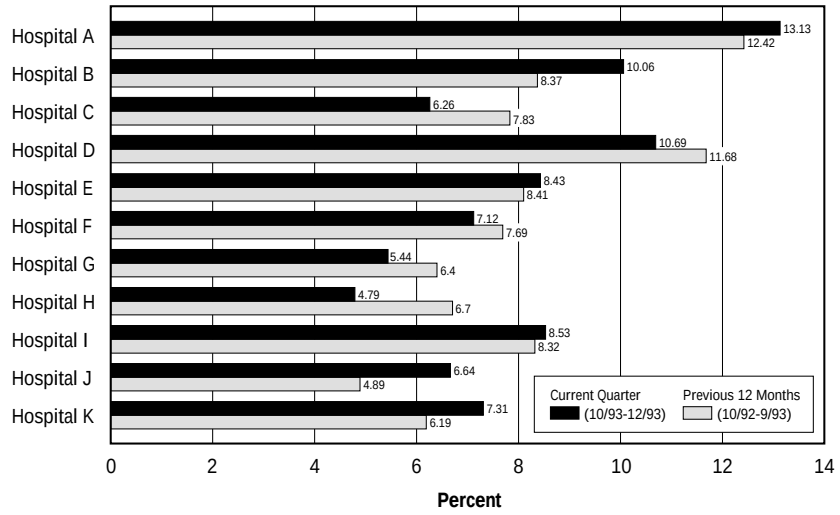
CHART TYPES USED IN MEASURING SUCCESS



Source: Brassard, 1985.[37] Adapted and used with permission from GOAL/QPC 1985. Reproduction without permission is prohibited.

Figure 10

EXAMPLE OF A HISTOGRAM: ASTHMA-SPECIFIC VISITS TO THE EMERGENCY DEPARTMENT: CHILDREN

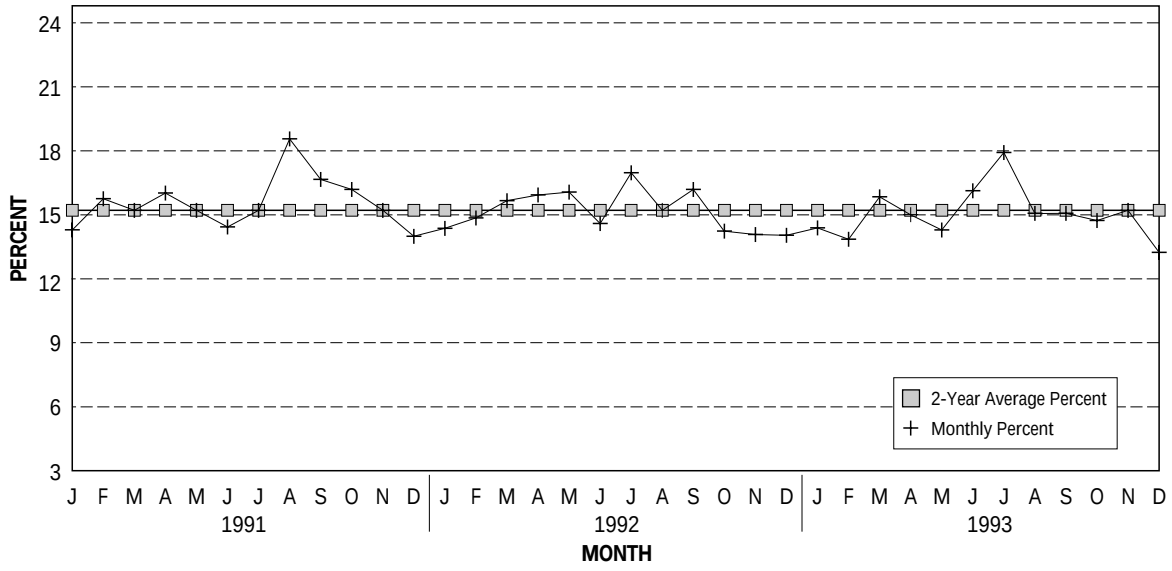


Percent of Visits With a Revisit Within 7 Days

Source: New York City Health and Hospitals Corporation.
Corporate Clinical Quality Improvement Demonstration Project.

Figure 11

EXAMPLE OF A RUN CHART: ASTHMA-SPECIFIC VISITS TO THE EMERGENCY DEPARTMENT: ADULTS

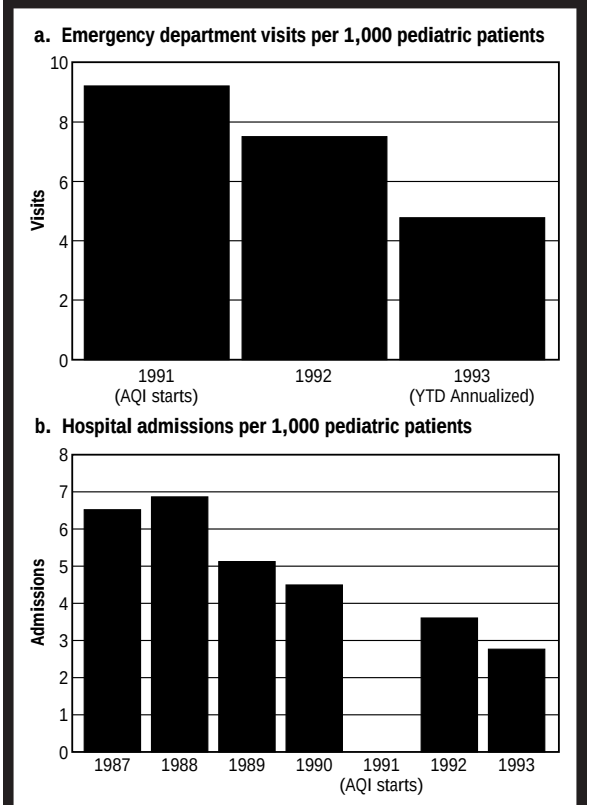


Percent of Visits With a Revisit Within 7 Days
Average for 1991 and 1992

Source: New York City Health and Hospitals Corporation.
Corporate Clinical Quality Improvement Demonstration Project.

Figure 12

TRENDS IN PEDIATRIC ASTHMA IN A LARGE HMO THAT INITIATED ASTHMA CQI IN LATE 1991



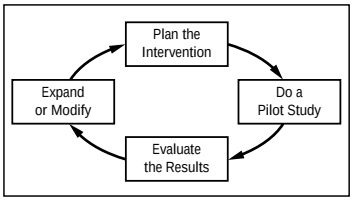
Note: Change in information system resulted in loss of data for part of 1991.

— **The asthma care process changed, but outcomes did not improve.** From what was learned, can the pilot intervention be modified to try again? Or should a completely new intervention be implemented?

— **The asthma care process did not change as planned, but outcomes improved.** What happened here? Did an important change go unmeasured? The answer may lie in the notes kept by the team on unexpected events, reactions, and effects. A new and potentially successful pilot intervention may emerge. However, it may be the classic Hawthorne effect that is operating here (when the subject's performance changes simply because he or she is being studied), and the improvement will drift away if nothing further is done. (Study designs often include a control—with or without placebo intervention—to measure the impact of this potential bias.)

— **Nothing changed.** Why? Was training insufficient? Were key materials missing? Were there barriers to the improvement that must be addressed next?

Starting the Cycle Again



The improvement cycle can be repeated many times. New interventions, based on what was learned from the preceding interventions, can be tried. The result will be, over time, a continuous quality improvement of asthma care.

USING THE FRAMEWORK FOR ASTHMA QUALITY IMPROVEMENT: ADDITIONAL CASE STUDIES

This section includes five case studies in using the four-step framework for asthma quality improvement. Three are in a medical environment (emergency department, hospital, individual provider), two in a nonmedical environment (school, community).

The improvements demonstrated in the case studies are encouraging. Nevertheless, the results should be interpreted with caution. It is important to consider the possibility that variables other than the planned intervention may have influenced the outcome. Quality improvement projects are primarily study designs without a control group. Therefore, it is difficult, if not impossible, to determine

how most quality improvement efforts contribute to improved health care outcomes. Although this type of uncertainty is inherent in quality improvement activities, a multidimensional approach will strengthen interpretation of results.

Including more than one outcome measure has distinct advantages. For example, a health care organization that targets an asthma quality improvement goal of reducing hospital utilization may inadvertently achieve that goal at the expense of lowering patient functional status and satisfaction with care.

Note that measurements of patient- or family-centered outcomes—such as functional status and quality of life, patient satisfaction, costs of care—often prove to be extremely useful in assessing quality improvement activities. Interventions focusing on organizational outcomes should be modified to include at least one of these measurements.

Improving the Quality of Asthma Care in the Medical Environment

In reviewing the three case studies in medical environments, it is helpful to consider the initial model for continuous quality improvement described in the first section of this report. The cases illustrate how professional knowledge, such as the "Guidelines for the Diagnosis and Management of Asthma,"[14] forms a basis for defining appropriate asthma care. Yet as seen in the case studies, many organizational factors beyond professional knowledge are necessary to provide good quality asthma care. For example, in the case of emergency care, it is the organizational relationship and responsibilities between the emergency department and respiratory therapy, and not the lack of professional knowledge, that have created the critical barriers to optimal care.

Combining the knowledge for improvement model with the professional knowledge model can, as noted earlier, lead to improved outcomes. Knowledge for improvement examines four components: the systems of care, variations in process or outcomes, the psychology of the system and the motivation of the individuals involved in the process, and the theory of knowledge. Specifically, the case studies help to illustrate the importance of mapping out the system of care in order to begin to understand the interrelationships and interdependencies of its parts. The teams in each of the cases also seek to decrease an identified source of variation. As the spectrum of cases illustrates, variation can exist throughout the processes of care (use of medications, measurements such as peak flow meters), causing variation in the outcomes (rates of hospitalization, lost school days). The cases also illustrate the importance of the psychological and motivational factors. In each situation, there is no attempt to blame either patients or clinicians. Rather, the desire to improve is assumed, and efforts are focused on improving the system.

These asthma quality improvement examples are intended to illustrate how learning occurs through testing a change. Quality improvement efforts not only provide data based on experimentation but also allow learning to occur at the actual site of care. Although this type of learning does not replace the professional knowledge gained from more traditionally accepted methods such as randomized clinical trials, it does provide a "real-time" mechanism to apply traditional study results to actual care of patients.

Examining asthma from a quality improvement perspective highlights the complex interactions among individual patients, their families, and the actual components of the health care system. Thus this model of asthma quality improvement suggests a template for those individuals and organizations that are attempting to improve care for persons affected by this chronic condition.

CASE STUDY 1: PEDIATRIC EMERGENCY DEPARTMENT PHYSICIANS

This case describes the experience of a pediatric emergency department in an inner-city hospital. At this pediatric emergency department, the percentage of total visits for asthma was rising steadily. In addition, several childhood deaths from asthma had been reported in the community, and the county served by the hospital had been shown to have the highest hospitalization and death rates from asthma in the United States.

Step 1—Define the Opportunity for Improvement

- *Identify what is driving the concern about asthma care in your health care setting.* The physicians in the hospital's pediatric emergency department expressed concern over the increase in the number of asthma cases presenting to the pediatric emergency department and the excessively high rates of hospitalization and mortality due to asthma in their community. In all but the most severe cases, asthma, if managed in a timely fashion with adequate outpatient care, should not advance to the point where hospitalization is required. Asthma deaths can be prevented.
- *Determine your place in the patients' system of care.* A group of individual physicians was trying to optimize the care of children with asthma who present in the pediatric emergency department. The doctors worked in a complex setting in which the individuals responsible for allocating hospital resources were far removed from those providing patient care. In addition, the hospital was located in a poor urban environment. Families living in the surrounding community had to face many obstacles that accompany a life of poverty, including inadequate housing, food, and transportation. For many of these families, the emergency department was their primary source of health care. This often resulted in overcrowding, especially after normal office hours and on weekends.
- *Choose the right opportunity.* This situation included many problems at many different levels. The physicians realized that they could not concentrate effectively on all areas at once. Instead, they decided to narrow their focus to the actual process of care that took place within the walls of the emergency department. This decision had the advantage of limiting the scope of initial improvement efforts to aspects of care for which the physicians were more likely to have direct responsibility and the ability to change means of delivering care.

Step 2—Set the Asthma Quality Improvement Goals (Outcomes)

- *Choose an outcome.* The outcome of interest was the proportion of children who were seen in the emergency department who required admission to the hospital.
- *Identify sources of outcome data.* Data were easily available from the standard emergency department records that were kept on a routine basis. No new data collection was necessary.
- *Measure the outcome.* This was a straightforward measurement of the decision to admit to the hospital or to discharge the child from the emergency department.
- *Consider how the data will be analyzed.* The physicians were interested in identifying any aspect of care delivered in the emergency department—such as the administration of steroids, the timing of the delivery of $beta_2$-agonist therapy, or the type of personnel caring for the patient—that was associated with the percentage of children who required admission for asthma.

Continued on page 52

CASE STUDY 1: PEDIATRIC EMERGENCY DEPARTMENT PHYSICIANS (CONTINUED)

Step 3—Characterize the Process of Care

- *Define the process of asthma care; develop a flowchart.* The physicians constructed a flowchart outlining all the possible steps in their care of a child with asthma—from the patient's initial presentation at the emergency department to the time of transfer or discharge. Upon examining the flowchart, the physicians noted that all the key interventions required the use of respiratory equipment, including nebulizer treatments and peak flow monitoring, and that a respiratory therapist gave most of the treatments during daytime hours.
- *Explore the process; evaluate the flowchart.* The physicians noted that the ability to evaluate the patient's status quickly and deliver the necessary medications varied with the availability of a respiratory therapist. However, a respiratory therapist was assigned to cover the pediatric emergency service only 12 hours per day and was not available during the busy evening hours.

Step 4—Begin the Improvement Cycle

- *Plan the intervention based on what the team learned in step 3.* The physicians believed that assigning a full-time respiratory therapist to the pediatric emergency department would improve the care of children with asthma.
- *Do a pilot study.* The physicians wanted to see if the presence of the respiratory therapist made a difference in the number of patients presenting with asthma in the emergency department who were subsequently admitted to the hospital. The team conducted a pilot study to examine the rates of admission during the 12 hours per day that the therapist was present compared with the 12 hours per day that there was no therapist.
- *Evaluate the results.* The rates of hospital admission for children with asthma after arriving at the emergency department were examined over a 5-week period, and the results were impressive. The review indicated there was a 50 percent lower rate of hospital admissions of children with asthma during the time when a respiratory therapist was available in the emergency department compared with the 12-hour period when there was no therapist.
- *Expand or modify.* Ironically, the decline in hospital admissions had a negative financial effect on the hospital. The hospital was not able to identify resources to expand the respiratory therapist coverage to the night shift.

Improving the Quality of Asthma Care in the School, Workplace, and Community

Thus far, both in this section and in the report, the focus has been on the development of asthma quality improvement in the medical setting. Asthma quality improvement has been applied primarily to the patient-provider partnership and the systems that immediately surround this relationship. In the case studies so far, these systems of care include the patients, their families, physicians, and other clinical staff members. However, patients also participate in other social systems with unique goals, some of which may conflict with the asthma care goals that patients share with health care providers and which may provide barriers to achieving quality asthma care.

Incorporating asthma outcomes as valued objectives in nonmedical environments such as the school, the workplace, and the community is therefore an important task. The social and economic costs in terms of asthma-related absenteeism, work days lost, and other indirect costs of asthma in these environments are substantial.[40] Health care providers and others

CASE STUDY 2: TEACHING HOSPITAL-BASED PHYSICIANS

This case illustrates how asthma quality improvement may be applied in an inpatient setting. Some of the physicians associated with a large teaching hospital expressed concern over the use of medications for patients hospitalized for asthma. In managing the acute episode, intravenous aminophylline was routinely prescribed by many physicians, especially the residents. However, newer medications and therapeutic treatments for asthma, such as inhaled corticosteroids, were not being introduced in a timely fashion prior to the patient's discharge, leading to possible delays in discharge and inadequate treatment of airway inflammation.

Step 1—Define the Opportunity for Improvement

- *Identify what is driving the concern about asthma care in your health care setting.* Several pulmonary specialists were concerned that the medications routinely prescribed for patients hospitalized with asthma were effective but did nothing to facilitate the transition from inpatient care to outpatient management of this condition. These physicians believed that there was clear scientific evidence to support the use of inhaled corticosteroids in the day-to-day management of persons with asthma, but overall, the attending physicians and residents delayed adding inhaled corticosteroids to the intravenous medications of hospitalized patients. They were concerned that the residents at this teaching hospital were adopting suboptimal prescribing patterns. Therefore, they saw an opportunity for improving both the quality of medical care and patient outcomes.
- *Determine your place in the patients' system of care.* The physicians comprising this asthma quality improvement team were part of the teaching faculty and were responsible for both the education of resident physicians and the appropriate management of hospitalized patients with asthma under the care of the residents.
- *Choose the right opportunity.* The underlying concern was how to teach residents to adopt a new set of asthma treatment options, specifically encouraging appropriate use of inhaled corticosteroids early in the care of an acute episode. The asthma quality improvement team sought a way to impress on the residents the benefits of using newer pharmacotherapeutic methods in the management of asthma.

Step 2—Set the Asthma Quality Improvement Goals (Outcomes)

- *Choose an outcome.* Ideally, the outcome would be a directly measurable item related to the opportunity for improvement, such as readmission to hospital, that could demonstrate improved patient outcomes as a result of maintenance on inhaled corticosteroids. However, the team did not have the resources to develop a method for extracting such data from the hospital billing system. Therefore, as a first step, the physicians decided to focus on changing the prescribing patterns of the residents based on the support of scientific evidence and national guidelines. The immediate outcome of interest to the asthma quality improvement team was the average length of time patients were kept on intravenous medications before adding inhaled corticosteroids.
- *Identify sources of outcome data.* Because all inpatient and discharge medications require a physician order, the physician prescribing patterns could be determined by examining the hospital pharmacy records.
- *Measure the outcome.* The physicians tracked data for a period of 3 months.
- *Consider how the data will be analyzed.* The team decided to analyze the average number of days hospitalized patients were kept on intravenous medications before they were prescribed inhaled corticosteroids.

Continued on page 54

CASE STUDY 2: TEACHING HOSPITAL-BASED PHYSICIANS (CONTINUED)

Step 3—Characterize the Process of Care

- *Define the process of asthma care; develop a flowchart.* In this case, the team did not use a formal flowchart. However, the physicians did examine the interactions within their system of care. Because it was the behavior of the residents the team wished to influence, the physicians took a closer look at the process of resident education within the hospital. The team was particularly interested in the delivery of information to residents. Upon analysis, the physicians discovered many barriers within the traditional forms of education, especially those involving group assembly. Lectures often were poorly attended. Even when the residents were able to make it to lectures, there were frequent interruptions for patient care needs. This situation proved frustrating for the faculty as well.
- *Explore the process; evaluate the flowchart.* The team decided that they needed to approach the residents on an individual basis, focus on a specific issue, and develop a means to reinforce the message.

Step 4—Begin the Improvement Cycle

- *Plan the intervention based on what the team learned in step 3.* The physician team decided to focus on a single message: When treating hospitalized patients with asthma, encourage the timely initiation of inhaled corticosteroids prior to discharge.

  The team members decided to approach the residents on an individual basis, whenever possible, timing it so that the residents were not in the middle of patient care activities. The nurses also were brought into the team and asked to reinforce the preferred drug therapies. The faculty emphasized to the residents that the nurses were colleagues in this educational effort.
- *Do a pilot study.* The asthma quality improvement team continued the practice of delivering individualized asthma pharmacotherapy education to the residents for a 3-month period.
- *Evaluate the results.* By the end of the 3-month period, there was a noticeable difference in the desired prescribing behaviors. Before the asthma quality improvement intervention, asthma inpatients spent an average of 2.4 days on intravenous medications before being started on inhaled corticosteroids; after the asthma quality improvement intervention, the switchover time dropped to an average of 1.8 days.
- *Expand or modify.* The team considered the pilot to be a great success and well worth the time and effort required by the individualized approach. The pilot was expanded to determine the effect of changing prescribing behavior on patient outcomes. The hospital faculty also expressed interest in using this educational model to promote other aspects of asthma care.

concerned with improving asthma care can provide data to institutions to enable them to see how asthma morbidity affects their organization's ability to achieve their goals. Once institutions—such as schools, workplaces, and communities—find opportunities for asthma care quality improvement, the asthma quality improvement model can be applied.

Implementing School-Based Efforts

More than 4 percent of U.S. children are affected by asthma. "Managing Asthma: A Guide for Schools" delineates the link between asthma and absenteeism, a critical outcome for school administrators.[41] The guide assists school staff members in developing an asthma management program, including:

CASE STUDY 3: INDIVIDUAL PATIENT AND PROVIDER

This case illustrates how practitioners can help individual patients to implement the asthma quality improvement process. In this situation, a woman experienced the onset of severe asthma at the age of 24. Her asthma was severe at diagnosis, and she often experienced sudden, serious exacerbations. Her quality of life had deteriorated markedly. The patient felt that she had no control over her asthma or her life.

Step 1—Define the Opportunity for Improvement

- *Identify what is driving the concern about asthma care in your health care setting.* For this previously healthy person, asthma presented a major obstacle to leading a normal life. She felt she always needed to be within 30 minutes of emergency services because of her sudden, severe exacerbations. She was limited in a number of activities important to her, including exercise (she is a runner) and travel (professional and recreational). Her life suddenly revolved around her asthma. Unpredictable exacerbations made her afraid even to make plans with her friends.
- *Determine your place in the patients' system of care.* Although this patient was at the center of the system of care and responsible for her own asthma management outside the hospital, she felt poorly equipped for the task. Her education about asthma was self-initiated because she had failed to get all the information she needed from her providers. She remembered being so confused about asthma on her first hospitalization that she thought the intravenous line contained the key to her recovery. She was afraid her severe shortness of breath would return if the line were disconnected; she was extremely anxious when it was removed.
- *Choose the right opportunity.* The patient's top concern was to learn about her asthma and be able to manage exacerbations at home if possible. For this patient with asthma, the key was identifying a physician who recognized her concerns, shared her goals for independence and self-management, and could provide continuity of care for her asthma. Together, they formed a team.

Step 2—Set the Asthma Quality Improvement Goals (Outcomes)

- *Choose an outcome.* The patient's major goal was to minimize the number of urgent visits to the office, the emergency department, and the hospital. Counting those visits provided an easy outcome measure. Other measures might have included routine peak flow measurements, the number of days she was able to run, or the number of appointments or plans broken because of asthma symptoms.
- *Identify sources of outcome data.* The patient could simply keep track of the number of emergency visits, as defined above.
- *Measure the outcome.* The patient maintained a written record of her urgent and emergency visits.
- *Consider how the data will be analyzed.* From her written record, the patient could note increases or decreases in frequency of her urgent and emergency visits over time.

Step 3—Characterize the Process of Care

- *Define the asthma care process; develop a flowchart.* The patient couldn't make a formal flowchart; when she tried, she discovered she had no process for home management of exacerbations. In the future, a flowchart could be very useful in evaluating and modifying the intervention.

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CASE STUDY 3: INDIVIDUAL PATIENT AND PROVIDER (CONTINUED)

- *Explore the process; evaluate the flowchart.* In this case, the task was to work with her physician to plan, pilot, and evaluate a process for home management.

Step 4—Begin the Improvement Cycle

- *Plan the intervention based on what the team learned in step 3.* The patient and her physician identified a home treatment plan. She was able to initiate the treatment plan whenever she noticed decreased exercise tolerance. If her peak flow measurements reached a critical level, the plan called for a more intense therapy regimen. The patient and her physician agreed that if she did not improve, she would call an emergency number for help.
- *Do a pilot study.* The patient implemented the home management regimen as planned. She followed her urgent visits, recording them over time.
- *Evaluate the results.* Figure 13 shows the improvement in exacerbation-related visits over time. Initially, urgent office visits increased, replacing visits to the emergency department.
- *Expand or modify.* Although the patient noted improvement as a result of the pilot test, she had yet to reach her goal of no urgent visits. Therefore, the patient and her physician together modified her home management plan, preparing to test the new regimen in another improvement cycle.

  Serial asthma quality improvement experiments led to a home management regimen that worked well for the patient. As shown in figure 13, she has had no emergency department visits or hospitalizations for more than 10 years. Future improvement cycles most likely will require more rigorous measures of success, such as the number of days she is able to exercise normally.

- School policies and procedures for administering medications
- Specific actions for staff members to perform in the asthma management program
- An action plan for asthma episodes

Many opportunities exist for improving asthma care in schools. Case study 4 provides an example of how such an opportunity for improvement was identified, developed, and implemented. Although asthma quality improvement was not implemented explicitly during this effort, nearly all its key steps can be identified.

Implementing Workplace Efforts

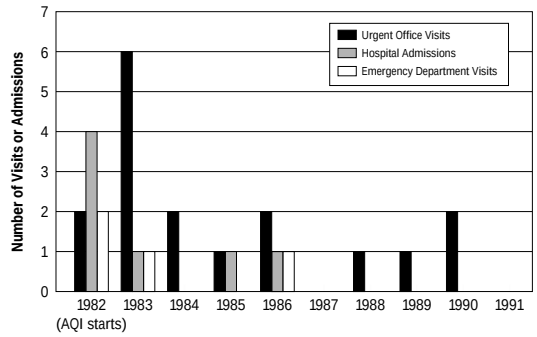
Many corporations already have realized the role of exercise and smoking reduction in improving employee performance and job satisfaction. Efforts to improve the quality of asthma care in the workplace should capitalize on this thinking and use it to enhance asthma management. Further, workplace medical care providers should evaluate the working environment of the employees to check for potential exposures to respiratory irritants. For employees with asthma, modification of work practices, improved ventilation, or the use of respiratory protection devices may improve the control of asthma symptoms. If companies are aware of the costs due to worker absenteeism from asthma,[42] they may act to reduce barriers to asthma care. They may, for example, provide health insurance or drug reimbursement plans or simply change policy to allow workers to obtain preventive care for asthma without using vacation days or to change worksites if they experience symptoms.

Implementing Community Efforts

Efforts to persuade people to change their risk behaviors and to get individuals or public or

Figure 13

URGENT OFFICE VISITS FOR AN INDIVIDUAL PATIENT FOLLOWING ASTHMA QUALITY IMPROVEMENT (AQI) INTERVENTION IN 1982



Source: Neuhauser et al., 1992[36]

private agencies (including employers) to adopt new health practices sometimes have been disappointing. It is much easier to work one on one with a patient or apply asthma quality improvement within a single organization to accomplish improvements in health. Once a provider steps out of these environments and tries to reduce barriers to improved asthma care in other institutions or other systems, it may be much harder to effect real change.

Communities can use asthma quality improvement to improve asthma outcomes through health policy efforts. Legislative efforts can be more effective at improving health than efforts to persuade individual institutions or agencies to change their practices. Legislation sets standards for building codes and air quality that may affect asthma in the workplace[43] as well as in schools. Yet legislation does not necessarily have to mandate in order to support the local initiatives of individuals, public agencies, or private corporations. As previously noted, enabling legislation has been particularly effective in encouraging local school boards to allow asthma medications to be administered in schools by removing the fear of liability. Case study 5 describes how local community initiatives resulted in the creation of a staff education program to improve asthma care.

Also related to community-based asthma quality improvement are public health initiatives. For example, professional knowledge suggests that allergens and irritants are important triggers for asthma exacerbations. In this light, a community-based opportunity for improvement might be the distribution of mattress covers and instructions for home environment control for parents of children with moderate and severe asthma. The outcome of concern may be community-based rates of emergency department use or school days missed due to asthma. Establishing a process to implement this type of program and conduct a feasibility study could be next steps in an asthma quality improvement process.

Although likely to provide large-scale improvement, public health-based improvement efforts are often the most difficult to accomplish because they require that political groups with very different goals be convinced to invest already limited public health resources in efforts to reduce asthma morbidity.

RECOMMENDATIONS

In viewing the complex issue of asthma care, many of the interventions, including asthma prevention and control strategies, reflect complex interorganizational partnerships among health care providers, health care systems, schools, workplaces, and communities. Each of these individuals and institutions (e.g., health provider, health care system, insurance company, patient, school board or administrator, employer, political body) makes its own decisions for care delivery based on a limited understanding of cost-effective care strategies. Collaborative efforts by physicians, nonphysician care providers, health care administrators, behavioral scientists, environmentalists, and epidemiologists are needed to maximize opportunities for quality improvement of asthma care. It is only through this collaborative approach to asthma quality

CASE STUDY 4: SCHOOL HEALTH SERVICES

Step 1—Define the Opportunity for Improvement

Members of the New Jersey School Boards Association recognized that one of the critical issues of school health services was the administration of medication in public schools. Traditionally, only school nurses or parents/guardians are permitted to administer medication. Many schools, however, did not have a school nurse onsite on a daily basis, and working parents/guardians are often unable to leave their jobs. The schools faced liability issues if unauthorized persons administered medications, yet children with chronic conditions needed medication on a regular basis.

Step 2—Set the Asthma Quality Improvement Goals (Outcomes)

The immediate goal was to change the board of education policies to better facilitate administration of medication in the school setting. The long-range goals (outcomes) for the schools were to decrease asthma morbidity of the children and perhaps to reduce asthma-related school days missed as well as to decrease the amount of time lost from work by parents/guardians of the affected children.

Step 3—Characterize the Process of Care

The sponsoring boards reviewed the current New Jersey State Department of Education guidelines. These guidelines indicated that the certified school nurse and the parent/guardian are the only persons permitted to administer medications in the schools. A change in the policies and legislation was needed, specifically addressing the issue of liability.

Step 4—Begin the Improvement Cycle

The Marlboro Township Board of Education drafted and submitted a resolution petitioning the New Jersey State Department of Education or State legislature to allow students to self-medicate or to allow a responsible person not on staff to be designated by the parent/legal guardian to administer medication in the case of known potential life-threatening situations, provided the physician and parent/guardian approve, in writing, and that the parent/guardian releases the school district from any liability. As a result of successful lobbying efforts, this petition was approved, and a bill (S. 1506) was introduced. This bill was signed into law (A. 2600) on December 23, 1993.

improvement that individuals and institutions can work together as a system and design the optimal intervention strategies needed to improve asthma care and outcomes.

The asthma quality improvement model can serve as a framework for health care providers working in health care systems as well as for individuals working in other types of systems, such as schools and workplaces, where asthma is identified as a problem. Therefore, the Working Group on Quality of Asthma Care recommends disseminating the asthma quality improvement process to a broad range of primary and specialty providers of asthma care in the United States. Specifically, the working group makes the following recommendations:

- Develop and implement an active dissemination process designed to facilitate the teaching of asthma care quality improvement techniques in different environments such as hospitals, managed-care organizations, emergency departments, and public health departments. Dissemination efforts should also target asthma support groups and advocacy groups to raise individual awareness of opportunities for asthma care quality improvement.
- Develop resource workbooks to enhance the asthma care quality improvement learning process within various environments.

- Establish and support a clearinghouse for asthma care quality improvement activities occurring in various environments across the United States. To accomplish this, the task force encourages the development of partnerships among appropriate stakeholders such as members of the NAEPP coordinating committee and members of professional organizations such as the Institute for Healthcare Improvement, the National Committee on Quality Assurance, and the Group Health Association of America.
- Support research to explore further the effectiveness and cost effectiveness of the clinical quality improvement approach to asthma care (as compared with traditional quality assurance). A number of Government organizations—such as the National Heart, Lung, and Blood Institute and the Agency for Health Care Policy and Research—are in a position to put forth a request for applications to facilitate research of this nature.
- Encourage the incorporation of asthma care quality improvement indicators into the formal monitoring and evaluation efforts of organizations such as the National Committee on Quality Assurance and the Joint Commission on Accreditation of Healthcare Organizations. The working group suggests that hospitals be expected to monitor patient outcomes in all clinical areas and to relate changes in process to these outcomes.
- Provide support for the incorporation of asthma quality improvement into all aspects of patients' systems of care, including workplaces and schools.

CASE STUDY 5: COMMUNITY TRAINING PROGRAM

Step 1—Define the Opportunity for Improvement

Within the Chicago Head Start Program disability category, health impairment is the third largest category, and within health impairment, severe asthma is the number one diagnosis. There are also many Head Start children with mild-to-moderate asthma in addition to those who qualify for disability. Yet the Head Start teachers and staff were ill equipped to manage the children with asthma in their classrooms. The Head Start Policy Council recognized a need to train its staff for a better understanding of asthma identification, prevention, and control. The council members began by examining the resources and processes currently in place.

Step 2—Set the Asthma Quality Improvement Goals

The patient-centered outcome sought was to improve the management and control of children with asthma in Head Start settings in order to maintain normal, desired activity levels for each child.

Step 3—Characterize the Process of Care

The Head Start Policy Council examined its current practices and realized that there was no formal process to orient and educate staff about managing children with asthma and no one within the Head Start program to provide such expertise.

Step 4—Begin the Improvement Cycle

Chicago Head Start teamed up with staff from Children's Memorial Hospital in Chicago to sponsor three conferences on asthma and to design a training program to educate staff about how to identify and manage children with asthma in Head Start settings.

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APPENDIX
ASTHMA-RELATED OUTCOME MEASURES

At first, the task of selecting appropriate outcome measures for a specific asthma quality improvement (AQI) project may seem overwhelming, given the variety of possible outcomes and the need to consider carefully the dimensions and analysis of each measurement. Therefore, the purpose of this appendix is to provide a detailed introduction to asthma-related outcome measures for use in AQI projects.

A recent report from the National Heart, Lung, and Blood Institute (NHLBI), "Workshop on Asthma Outcome Measures for Research Studies"[1] needs to be highlighted. This workshop report provides a highly useful, state-of-the-art review of these measures. Although the workshop primarily focused on clinical research, many of the same issues are also relevant to the measurement of outcomes for quality improvement activities.

As mentioned in the report on quality of asthma care, the study of asthma outcome measures may be approached from two perspectives: patient- and family-centered or organizationally based (see figure 4). Patient- and family-centered outcomes examine areas such as patient symptoms, functional status, physiologic function, satisfaction with care, and individual or family out-of-pocket medical expenditures. Organizationally based measures examine outcomes from the perspective of the health care site or delivery system. Examples of these types of measures include resource utilization (e.g., hospitalizations, emergency department visits, physician prescribing patterns), asthma-related costs (to the organization), and population-based measures of health status. Patient satisfaction is an outcome measure of interest to both the organization and the individual.

The following two sections explore in greater detail the patient-centered and organizational outcomes for asthma.

PATIENT- AND FAMILY-CENTERED OUTCOME MEASURES

When assessing quality of care, it is important to ask how the patient and family are doing. What can a patient whose asthma is well controlled expect to experience? Patient-specific outcomes include measures of the symptoms of asthma, measures of health status and quality of life, and physiologic measures of airflow obstruction. In addition, as the report on the financing of asthma care demonstrates, it is important to examine the out-of-pocket costs to the individual because asthma-related expenses frequently influence patients' decisions to seek and comply with health care recommendations.

Symptoms of Asthma

As highlighted in the NHLBI asthma outcome measures workshop report,[1] the most distinctive characteristic of asthma is a pattern of airway irritability that increases over time when the disease is active and that decreases in response to appropriate therapy. Yet the most distinctive clinical measure from the patient/family perspective of this disease process is the

presence of symptoms. Questions to help the provider characterize a set of patient goals for symptom control include the following. Please note that these goals reflect ideal control: some patients with more severe asthma may have difficulty achieving the levels of symptom control listed, even with optimal therapy.

- **Does the patient awaken more than once or twice a month with coughing or shortness of breath?** Night wakening is a disruptive, anxiety-provoking problem that reflects significant bronchial reactivity. It can be measured easily by asking the patient to recall the approximate number of nighttime disruptions due to asthma.
- **How frequently do asthma symptoms occur?** According to the "Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma,"[2] mild asthma is characterized by *infrequent symptoms*, minimal effect on work and school, good exercise tolerance, and generally normal peak flow rates with easily reversible airflow obstruction. Except for those with very severe asthma, most patients' asthma can be controlled to the level where symptoms occur no more than once or twice a week with a duration of less than 1 hour.

Over the past few years, research groups have developed standardized tools for measuring asthma symptom control. As outlined in a publication by O'Connor and Weiss,[3] the most recent instruments for symptom measurement in adult populations include the Denver Asthma Symptom Checklist,[4] the University of Alabama at Birmingham Comprehensive Asthma Program Scales,[5] the St. George's Hospital questionnaire,[6,7] the American Institute for Research adult asthma questionnaire,[8,9] and the University of Cincinnati disease severity score and airway reactivity score.[10] For children, the current standardized tools for assessing symptoms include the Usherwood et al.[11] questionnaire and the American Institute for Research "Wee Wheezers" questionnaire.[12]

One of the most current approaches to symptom measurement involves the concept of symptom-free days or episode-free days.[13] This concept includes a global measure of the number of days for which the patient has had *no* symptoms (including cough, wheeze, shortness of breath, or nighttime awakening). In general, patients should not be asked to recall more than a 2-week time period; beyond this the accuracy of the information begins to diminish significantly. Although information on the performance of the symptom-free day measure remains imperfect, the unidimensional nature of this measure might make symptoms outcome measurement a very attractive alternative for any quality improvement effort. The report on the cost-effectiveness of asthma care also recommends measures of symptom-free days in the conduct of cost-effectiveness studies for persons with asthma.

Functional Status and Quality of Life

Like all persons with chronic disease, patients with asthma want to feel normal, or as close to normal as possible.[14] To find out whether the patient and his or her family can live without significant physical, social, or psychological limitations, as well as to discover the functional goals of the patient, helpful questions to ask include the following:

- **Can the patient maintain his or her normal or desired activity levels? Does the patient perceive any limitation in his or her physical or social activity because of asthma?** Some patients may have adjusted their expectations downward in response to asthma symptoms. The Asthma Quality of Life Questionnaire developed at McMasters University[15,16] and the Living With Asthma Questionnaire[17] are both examples of research instruments that measure various aspects of the patient's activity level.
- **Can the patient exercise vigorously without coughing or shortness of breath?** Although not all patients exercise, this is a valid

measure of the impact of asthma on physical activity. Exercise intolerance can be assessed by questioning the patient about daily activities that increase exertion (e.g., climbing stairs) or by administering an exercise challenge with observation of symptoms and reduction in maximum airflow rates. Note that some patients with severe asthma will never be able to exercise vigorously without displaying some symptoms.

- **Does the patient or family report significant social or psychological stress as a consequence of asthma or asthma therapy?** Common psychological stress, which may occur even when asthma symptoms are well controlled, often includes issues such as guilt, anger, lowered self-esteem, and fear of death during an attack. Common social stress includes family conflict about the causes and treatment of asthma as well as the impact of asthma on family activities.

Most of the functional status and quality-of-life instruments mentioned throughout this section can be used to formally measure some of the psychological aspects of asthma. On a less formal note, this area may also be assessed by asking simple, open-ended questions about the patient's or family's fears or concerns. Although responses to open-ended questions are difficult to analyze from a quality improvement perspective, they usually provide the clinician with valuable insight into the patient's and family's coping mechanisms and may serve to strengthen the patient-provider relationship. If the psychological stressors appear to be high, the clinician may choose to refer the patient and his or her family to a mental health professional, who may adopt more rigorous methods of psychosocial evaluation and intervention.

- **Do the patient and family have the knowledge, skill, and confidence to control asthma?** Readiness to face future challenges usually is not considered an indicator of functional status or quality of life. However, anyone who has ever taken an important test without feeling prepared can understand easily how feeling able to meet upcoming challenges improves quality of life. Both patients and their families often report being overwhelmed and frightened by the difficulty of managing asthma, particularly when asthma is new to them. Research in health psychology shows that when patients feel they can control their condition, they report increased well-being, reduced pain and discomfort, and increased motivation to adhere to the treatment plan.[18] The NHLBI asthma outcome measures report[1] reviews numerous tools designed to measure patient and family knowledge, skill, and behavior regarding asthma management. Several measures of self-efficacy to control asthma also have been developed.[16,19]

Functional status measures include loss of work or school days. Data from the National Health Interview Survey indicate that of the estimated 6 million adults with asthma who are employed, approximately 3 million work days are lost annually due to asthma.[20] The average loss of work for the whole asthma population is 0.5 days per person per year.[21]

National data also indicate that approximately 10 million school days are lost annually by the estimated 3.5 million children ages 5 to 17 who have asthma; on average, these children miss 3 to 5 days of school per year because of their asthma.[21,22]

Although there are many generic quality-of-life and functional status measures, few instruments have been specifically designed for evaluating persons with asthma. Most of the generic measures are well tested in various populations, but they have not proven to be very useful in evaluating persons with asthma. *Therefore, when undertaking an AQI project, it is best to use one of the tested asthma-specific measures.* Several research groups have developed instruments that address adults with asthma: these include the previously mentioned Asthma Quality of Life Questionnaire[15] and

the Living With Asthma Questionnaire[17] as well as instruments developed by the American Institutes for Research/Kaiser Permanente,[23] the Ohio University group,[24] the University of Alabama at Birmingham,[5] and Dr. Woolcock's group in Australia.[25] Many of these groups are in the process of designing asthma-specific measures for children. However, at this time there are no validated measures in published or referenced reports.

Cautions to keep in mind when incorporating quality-of-life or functional status measures into any asthma quality improvement project include the following:

1. Current instruments are designed to measure *populations* and are not designed to measure *individual* patient outcomes accurately. The reliability and validity of these measures have been proven only when they are used to compare groups of persons. The measurement error intrinsic to these instruments makes the accuracy of interpreting change for individual patients extremely tentative at best.
2. Current instruments have been tested only on small, select populations of persons with moderate-to-severe asthma and primarily high-end socioeconomic status. The use of these measures in populations with mild asthma and/or groups of lower socioeconomic status is largely untested and may not be appropriate.
3. When choosing any of these data collection instruments for use in an AQI project, it is important to include estimates of error when reporting results (i.e., include standard errors).
4. These instruments do not provide a summary (global) measure of quality of life or functional status; rather, they provide estimates of selected aspects (domains) of these asthma-specific patient outcomes.

Physiologic Measures of Airflow Obstruction

Measures of lung function or spirometry are used primarily to determine the degree of lung obstruction affecting the individual. Yet the information obtained from these tests does not necessarily correlate with the patient's perception of the severity of his or her condition.[3] Spirometry or peak flow measurements often detect airflow obstruction in patients who may not even be aware of symptoms. Unfortunately, spirometry is not widely available to all patients and is expensive in relation to the overall cost of medical care for most persons with asthma. As a result, the focus here is on how peak flow monitoring might be used as an outcome measure for quality improvement activities. When assessing peak flow, helpful questions include the following:

- **Is peak flow reduced by at least 20 percent from predicted or personal best at any point?** This is the definition of minimal airflow obstruction that the "Guidelines for the Diagnosis and Management of Asthma" recommend as the signal to initiate bronchodilator therapy.[2] However, all patients experience this at one time or another, and health status can be assessed only by determining the frequency of this level of airflow obstruction.
- **Is peak flow reduced by 15 percent after 6 minutes of vigorous exercise?** This measure was used by Tsanakas et al.[26] to diagnose asthma in school children and is comparable to inability to exercise vigorously without coughing or shortness of breath. The peak flow measure should be performed 5 to 10 minutes after exercise ceases. However, some patients with severe asthma will never be able to exercise vigorously without reductions in peak flow, despite preventive therapy.
- **Is morning-to-evening peak flow variability greater than 20 percent?** A ratio of evening peak flow divided by early morning peak

flow of greater than 1.2:1 indicates increased airway irritability or hyperreactivity and is comparable to waking at night more often than once or twice a month. Again, some patients with severe asthma may not be able to achieve this goal even with aggressive therapy.

It remains uncertain whether these measures of lung function will continue to be useful or practical within the context of quality improvement activities over time. Although peak flow monitoring may be a useful clinical tool for persons with moderate-to-severe asthma, there is concern about the practicality of peak flow monitoring as an outcome measure for studying quality improvement, especially for the vast majority of persons with mild asthma.

Patient Satisfaction With Care

Patient satisfaction with care is an important, independent dimension of quality of care. The absence of satisfaction with care not only is disturbing to patients, provoking both anger and anxiety, but also is associated with reduced adherence to the treatment plan.[27] When patients are not satisfied with care, the causes of dissatisfaction should be investigated.

Satisfaction with care may or may not correlate with the technical quality of care—the appropriateness of diagnosis and treatment—and should not be treated as a proxy measure of these aspects of care. Rather, it is complimentary to other measures of quality. In particular, satisfaction with care is related to important aspects of the relationship between patient and provider and to the institutional arrangements for obtaining health care.

Research shows that patient satisfaction is strongly related to several very specific behaviors and communication skills of providers. Satisfaction is increased when (1) providers are perceived as friendly and accepting; (2) providers offer to share with the patients the information gathered during the history, physical examination, and testing; (3) patients' expectations for the visit are met; and (4) patients feel that providers really listen to their concerns.[27,28] Korsch and Negrete[29] found that patient satisfaction with care was not related to the length of the visit but with the patient's perception of the provider's communication skills and with discussion of the patient's major concern or fear early in the visit. Satisfaction with care also is related to organizational factors such as cost, waiting time, continuity of care, and time required to make an appointment. Patients may not feel free to express dissatisfaction with their care. Therefore, patient satisfaction measures are most valid when obtained by individuals not providing care to the patients.

Although working group members are not aware of any current, published measures of satisfaction with care specific to asthma, the Rand Patient Care Satisfaction Scale is a widely used measure that can be applied to asthma care.[30,31] In addition, Kaiser Permanente of Northern California has recently developed and piloted a quality improvement instrument that includes asthma-specific satisfaction items (personal communication, Steve Black, M.D., Regional Director of Quality Assessment, Northern California Kaiser Permanente Medical Care Program).

Costs of Care

For the individual and/or family, direct costs of care such as out-of-pocket fees for health insurance premiums, copayments, deductibles, and nonreimbursable services can be quite substantial (see the working group report on financing of asthma care). Indirect costs such as lost income or extra expenses for travel and child care can also have a significant impact on persons with asthma and their families. In addition to monetary expenses, costs may also be attributed to areas such as lost opportunities for the family to engage in other activities. Collection of this information is commonly achieved via patient diaries.

ORGANIZATIONALLY BASED OUTCOME MEASURES

Health care organizations often view quality from a different perspective, primarily in terms of resource utilization and its related costs. There is also a recent trend among health care purchasers to include indices of population health status as an important measure of health care quality.

Resource Utilization

From the organization's perspective, the most commonly employed outcome measures are those that examine resource utilization. From a quality improvement perspective, the interest in examining asthma-related health care utilization stems in part from a desire to understand the large geographic variations in events such as hospitalizations and emergency visits. Although the exact linkage between resource utilization and quality has not been fully elucidated, an emerging body of literature suggests that fatal and near-fatal asthma is often attributed to inadequate or inappropriate outpatient care.[32-35]

Utilization measures for asthma care fall into two broad classifications: measures of acute (crisis) use of the health care system and comprehensive measures of routine care.

Crisis Use of Health Care Services

Crisis management of asthma exacerbations is a useful outcome for organizations to measure. If patients have adequate access to high-quality primary care, including patient education and appropriate preventive and rescue therapy, the use of emergency health care services and related hospitalizations for asthma should be almost completely avoidable. The use of urgent or emergency services also may reflect various problems in the management of asthma care, such as limited access to continuous care, inadequate self-management by the patient, suboptimal care by the clinician, or in the case of patients with severe asthma, occasional exacerbations that cannot be controlled at home. Data show the use of emergency services is more frequent in children under 5 years of age, perhaps because the treatment plan may not be well developed and understood by the child, the family, and their health care system.

The three basic measures of crisis health care management for asthma care are as follows:

1. **Hospitalization rates** are one measure of poorly controlled asthma. Admissions usually follow efforts to improve lung function in the emergency department. Current rates of admission vary sharply by race and income level, with low-income minority groups having rates up to three times higher than the national average. Asthma has been characterized as a condition that is sensitive to ambulatory care, which means that hospitalizations rise in the absence of continuing, preventive care.[36] The National Committee on Quality Assurance (NCQA) has developed a report card for health maintenance organizations[37] in which they are judged according to their quality of care. Asthma hospitalization rates are one of the measures included in the NCQA report card.

   To date, there is no optimal hospitalization rate identified in the literature. Local organizations may choose to benchmark their own hospitalization rates according to the U.S. rate (18.3 per 10,000; see table 1). Alternatively, recent historical rates within the local organization might be a more relevant benchmark, making it easier to adjust for such factors as age, sex, race, and socioeconomic status. At present, there is no generally accepted method to adjust for asthma severity. However, hospitalizations associated with respiratory failure and/or intubation are a logical adjustment.

   There are many explanations for fluctuations in hospitalization rates that

Table 1

HOSPITAL DISCHARGES* AND AVERAGE LENGTH OF STAY FOR PATIENTS WITH ASTHMA AS FIRST-LISTED DIAGNOSIS AND ICD-9-CM CODE† (UNITED STATES, 1993)

Age groups	Number of patient discharges (x 1,000)	Rate of discharge (per 10,000 pop.)	Average length of stay (days)
All ages	458	18.3	4.4
Under 15 years	159	28.0	3.4
15-44 years	128	10.9	3.5
45-64 years	94	19.0	5.4
65 years and over	87	26.5	6.7

* Discharges from non-Federal hospitals, excludes newborn infants.

† Diagnostic groupings and code number inclusions are based on the International Classification of Diseases, 9th revision, Clinical Modification (ICD-9-CM).

Source: Centers for Disease Control and Prevention, National Center for Health Statistics, hospital discharge data, unpublished, 1993.

conceivably are independent of the quality of care. Perhaps the most important of these explanations relates to variations in hospital emergency departments' policies and procedures for admission and observation of persons requiring asthma treatment.

2. **Emergency department utilization rates** are perhaps just as important an indicator of health status as hospitalization rates. In 1990, approximately 15 percent of persons with asthma made visits to the emergency department for exacerbations of their condition.[21] A national survey of emergency department care for pediatric asthma suggests that 16.9 ($\pm$9) percent of emergency department visits for asthma will end in hospitalization.[38] It is important to note that emergency department utilization rates may be affected by clinicians' decisions to manage asthma episodes in the office versus the emergency department. This is especially true in areas where hospitals are a great distance away. In these areas, it may be more appropriate to measure urgent, unscheduled ambulatory visits to the office.

3. **Asthma mortality** is also a measure that may reflect inadequate health care. However, some persons with asthma suffer from life-threatening asthma even with the best of care. Asthma mortality is an extremely infrequent event, usually measured in deaths per 100,000 population. Due to the infrequent nature of asthma mortality, it is not possible for most health care organizations to calculate stable rates or accurately assess changes in asthma mortality rates. Rather, asthma mortality should be viewed as a rare event worthy of detailed evaluation. Each death due to asthma should be individually reviewed for problems in the process of care.[39]

Indices Detailing Comprehensive Health Care Utilization for Asthma Care

Although routine use of ambulatory care could be considered an outcome measure, it has yet to gain widespread acceptance. Some of the more promising indices of asthma health care utilization attempt to include measures of both acute (crisis use) and routine ambulatory care. Examples of these measures are the ratio of

hospitalization to ambulatory care and the concept of episodes of care.

Because hospitalizations are correlated with lower levels of access to continuing, primary care for asthma,[36] a low ratio of outpatient visits to hospitalizations may serve as an indicator of poor quality of care or inadequate access to care. National data estimate an average of 17 outpatient visits (exclusive of emergency department visits) for each asthma hospitalization.[21] Any organization that provides comprehensive care to patients with asthma should be monitoring this ratio of primary care visits to hospitalizations. Although it is not possible to establish an absolute standard in this area, ratios that increase over time may be a reflection of improved care.

A more novel approach to conceptualizing chronic care is to view care in the context of multiple encounters over time—often referred to as "episodes of care." Recent work by Vollmer and colleagues[40] suggests that this type of measure reflects morbidity due to asthma more accurately than individual visit encounters.

Organizational Costs of Care: Direct Medical Expenditures

The total direct medical expenditures for asthma is a critical outcome for health care organizations. Although the health care provider/system and the individual are both concerned with issues of cost, they each offer a different perspective.

From the organizational perspective, cost outcomes are measured principally in terms of direct medical expenditures in relation to covered benefits.

When using direct costs as an outcome measure of quality, the evaluation of the quality improvement activity should consider whether costs are being measured from the individual or the organizational perspective. As mentioned in the section on patient-centered outcomes, the individual patient is more concerned with the medical expenses *not* covered by insurance (e.g., health insurance premiums, copayments). The impact of direct medical expenditures that are not covered by insurance has not been clearly defined in the current literature on health economics. In addition to direct costs, individuals with asthma also are affected by indirect costs such as loss of income due to illness and the costs of caregiving provided by family members.

Population-Based Indices of Quality of Life and Health Status

Ideally, asthma should have only minimal impact on the individuals with this condition and their families. Although functional status and quality-of-life measures were described as patient- and family-centered outcomes, the survey instruments were actually designed to evaluate populations. In fact, these instruments also serve as important organizational tools to measure optimal care. Optimal asthma health status can serve as the goal for quality improvement projects at all levels of care from insurers to physician practices, health maintenance organizations, emergency departments, or hospitals.

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National Asthma Education and Prevention Program Working Group Report on the Financing of Asthma Care

The Working Group on the Financing of Asthma Care is a component of the NAEPP Task Force on the Cost Effectiveness, Quality of Care, and Financing of Asthma Care. The working group sought to examine the issues of health care financing as they relate to quality care for persons with asthma. This group had the fortune, or perhaps the misfortune, of exploring these issues during the most dynamic period in health care policy reform within the United States since the inception of Medicare and Medicaid. The working group first searched the literature on medical and health care financing for information that addresses the effects of health care financing on asthma outcomes, but the data were nearly nonexistent. In light of such scant literature, the working group broadened the search to include literature reflecting the financing of treatment for chronic conditions in general. However, this literature did little to elucidate the issues of financing that most directly affect persons with asthma and their families.

Given the near absence of published data, the working group conducted a series of public hearings throughout the country to elicit first-hand the experiences of those dealing with asthma on a daily basis.

Four hearings were conducted in San Francisco, Chicago, Miami, and Portland, Maine. At each hearing, the working group heard testimony from a panel of individuals representing a wide range of areas that affect the financing of asthma care (e.g., insurers, managed-care organizations, public and private clinical settings, personal perspectives). The main purpose of the hearings was to explore issues of financing in terms of access and barriers to care. The public hearing format was chosen in an attempt to achieve a better understanding of how the consequences of financing play out in the lives and work of all people in the community involved with asthma. The various perspectives represented public and private hospitals, community health centers, school health, migrant health, Head Start, managed care, private insurers, occupational health, pharmacies, and individuals.

In addition to the hearings, the working group conducted an in-depth analysis of Medicaid coverage for asthma care in the State of Maryland. The group also examined the results of a pilot survey of public and private insurance plans conducted by the American Lung Association (ALA) and the George Washington University Medical Center. The ALA survey was designed to determine the variations in the coverage benefits important to persons with asthma.

After a year of research, surveys, hearings, and other investigations, the working group developed 12 recommendations to improve the financing of asthma care. Those recommendations are presented and explained briefly in the first section of this report. The second and third sections provide a summary of the background information collected and describe highlights of the literature review, survey efforts, and public hearings as they relate to and explain the recommendations further.

RECOMMENDATIONS TO IMPROVE ASTHMA CARE FINANCING

The following recommendations are the result of literature reviews, public hearings, surveys, and other analyses that the working group completed over the course of a year in an effort to improve the financing of asthma care. The recommendations are targeted to health insurers, both public and private; public health officials at the Federal, State, and local levels; and health researchers.

Recommendations Related to Insurance

- **Make asthma care affordable and accessible by keeping out-of-pocket expenditures to a minimum.** Chronic conditions such as asthma represent an ongoing financial burden that is above and beyond the cost of the routine health needs of most families. Total health expenditures for families with incomes over 200 percent of the poverty level should be no more than 5 percent of the families' incomes. Those with incomes below two times the poverty level should pay nothing or nominally for their health care. These proposed limits on cost-sharing include health care expenditures for all family members.
- **Eliminate barriers to coverage such as limitations on insurance coverage for pre-existing conditions and other exclusionary clauses.** For persons with chronic illnesses such as asthma, potentially high health care expenditures often make it impossible to obtain adequate insurance coverage, limit job mobility, and have other dramatic effects on family well-being. It is essential that these exclusionary practices be eliminated.
- **Eliminate deductibles and limit the amount of copayments for inpatient and ambulatory care. Adequate coverage for asthma should include a minimum of four maintenance visits annually without copayment.** A choice of health plans that includes options with no deductibles and limits on copayments is an essential component of any health insurance reform measure—especially if it is to meet the needs of persons with chronic conditions. General health maintenance for persons with asthma requires periodic health visits. Access to an adequate base of primary care and subspecialty clinicians also is essential.
- **Eliminate or minimize the impact of copayments and overly restrictive controls on the utilization of drug benefits.** For persons with asthma, health insurance that excludes pharmaceutical benefits represents inadequate and inappropriate coverage. In addition, copayments for prescription medications are often a critical barrier for many persons with modest-to-low incomes. Two or three prescription copayments every month quickly add up and are compounded for families in which more than one member suffers from a chronic condition. Also, pharmacy controls on utilization (e.g., limiting coverage for prescriptions to 30-day supplies, requiring monthly copayments) interfere with the care of persons with chronic conditions. For persons with asthma, these restrictions should be eliminated.
- **Ensure coverage of durable medical equipment without lengthy prior authorizations.** Insurance carriers vary dramatically in their policy coverage of durable medical equipment (DME), even though several types of equipment (e.g., spacers, home nebulizers) may be critical to the care of persons with asthma. Insurance plans that exclude these items from coverage contribute to the problem of inadequate or inappropriate asthma care. Preauthorization procedures required to obtain many of these items are often lengthy and should be viewed as an inappropriate barrier to quality asthma care. Within

individual health plans, durable medical equipment needs to be broadly defined to cover disposable items necessary to operate the equipment.

- **Offer free or low-cost formal asthma patient education programs through health plans.** In developing ways to reduce unnecessary utilization of expensive services, many health care organizations have turned to patient education programs, such as on smoking cessation or diabetes, to promote health maintenance. Asthma is another condition that is amenable to patient education models. Most health plans can afford to offer formal asthma education programs either without copayment or at a substantial discount to participants. Health insurance without this benefit is inadequate for asthma care.
- **Support research efforts focused on evaluating the cost-effectiveness of clinical case management.** There is some evidence that clinical case management may improve health outcomes for some persons with severe asthma. However, more research is needed to evaluate the cost effectiveness of these programs.
- **Maintain uninterrupted health coverage for all individuals involved in workers' compensation claims throughout the duration of the workers' compensation proceedings. Increase primary care providers' awareness of the potential for occupational causation of asthma. Hold employers financially responsible for occupational disease.** Any future restructuring of workers' compensation must ensure that employers remain at financial risk for asthma-related occupational disease. Otherwise, they have no incentive to clean up occupational hazards. In addition, many State workers' compensation programs are not structured to compensate persons with work-related asthma adequately.

Recommendations Related to Public Health and Unrelated to Insurance

- **Support community asthma education programs.** State and local public grants should be awarded for the design and implementation of community-based asthma patient education programs. Public funding helps to ensure access to asthma education for persons with marginal incomes and those living in poverty.
- **Promote early identification and intervention for populations at high risk for asthma morbidity.** Federal resources in the form of categorical grant funding should be used to promote the early identification of children with asthma. Programs are needed to train public health professionals in the early recognition of asthma. Federally sponsored programs such as Head Start and the Early Periodic Screening, Detection, and Treatment program provide an ideal opportunity for early identification and disease control for children at highest risk for asthma morbidity. Federal agencies that sponsor research and demonstration granting programs—such as the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Health Care Policy and Research, and the Health Care Financing Administration—are ideally positioned to provide necessary support to Medicaid programs. Together, these agencies could develop programs to promote early intervention.
- **Support asthma case management efforts that provide (nonclinical) enabling services.** Persons living in poverty usually require the help of social services to obtain the minimum medical care necessary to control a chronic illness such as asthma. Health systems that care for these populations also need to provide the necessary enabling services; otherwise, adequate asthma care is unlikely to be achieved. Research and demonstration projects are needed to

explore the efficacy and cost effectiveness of interventions using this strategy.

Recommendation Related to Individual Financial Responsibility

- **Ensure that the individual's financial responsibility for asthma care does not present a barrier to obtaining optimal care.** Given the current state of the U.S. health system, it is likely that some level of cost sharing will continue to fall on the individual. The working group strongly recommends that copayments be eliminated or reduced to a minimum so as not to discourage access to asthma care.

PERSPECTIVES: A VIEW FROM ACROSS THE COUNTRY

In the absence of universal coverage, access to health care in the United States remains subject to the abilities of each individual to identify a mechanism to pay for his or her own health care. Nearly 64 percent of the U.S. population achieves some degree of financial coverage via private health insurance, 22 percent secure public financing, and 14 percent have no source of payment other than personal or family resources.[1] Yet even for those with private health insurance, the scope of benefits varies greatly among the thousands of current health plans. Furthermore, private insurance typically does not cover all costs of care.

A 1987 survey found that even persons with insurance averaged $476 per year in out-of-pocket health care expenditures (e.g., deductibles, copayments, uncovered health needs).[2] In addition, most individuals—even those with employer-based health coverage—have to pay at least some portion of their health insurance premium. The complex and often incomplete mechanisms of U.S. health care financing directly influence the health care options available to individuals and families.

Very little published information addresses the effect of health care financing on preventive and chronic care for the estimated 12 million persons with asthma. One of the few published studies of the financial impact of asthma costs on family income[3] found that asthma care expenditures accounted for an average of 6.4 percent of the family's yearly gross income. For one family in this study, the cost of asthma care was nearly 33 percent of its annual income. This study suggests that the burden associated with the costs of care can become high enough to have a negative influence on important health care decisions such as when to seek care and whether to purchase appropriate medications. Although this study is informative, it is also based on information collected between 1977 and 1980 on only a small number of families. Unfortunately, no more recent studies in the medical literature have examined the specific issues of asthma costs and the individual.

The literature does suggest a correlation between the source of health care financing (private versus public) and clinical outcomes for asthma. Asthma hospitalization rates are much higher for persons receiving public assistance (Medicaid) than for those with private health insurance.[4,5] Although the literature clearly identifies a correlation between clinical outcomes and source of health care financing, the reasons behind this effect are unclear. High on the list of possible risk factors contributing to increased hospitalizations are lack of access, affordability of services, and differences in quality of care.

Although few published studies have examined the relationship between health care financing and clinical outcomes for persons with asthma, the information that is available strongly suggests the need to explore this issue further.

The economic impact of a chronic health condition such as asthma can be viewed from three basic perspectives:

- The perspective of society
- The perspective of service providers (including hospitals, health care centers, and health professionals)
- The perspective of consumers and purchasers (including public and private insurers, employers, and individuals).

Society

Asthma is a chronic condition affecting 9 to 12 million persons in the United States.[4] The prevalence and incidence are highest in children and young adults.[6] Asthma currently affects at least 4 percent of U.S. children, and the prevalence appears to be rising.[7] Throughout the 1980's, asthma hospitalizations of persons of all ages increased 6 percent, with a 24-percent increase in hospitalizations of persons under 20 years of age.[8] Socioeconomic status, particularly poverty, appears to be an important contributing factor to asthma morbidity and mortality.[5,9] Asthma disproportionately affects minorities and the poor. In the United States, asthma prevalence rates for nonwhites are only slightly higher than those for whites; however, asthma hospitalization and mortality rates for nonwhites are more than twice those for whites.[10]

As a chronic condition, asthma creates a substantial burden of illness for the affected individuals, their families, and society. The 1990 total cost of illness related to asthma was estimated to be more than $6 billion based on projections from 1985 data.[11] Hospital expenditures for asthma were estimated to exceed $1.5 billion. In 1985, asthma accounted for an estimated 463,000 hospitalizations, nearly 2 million emergency department visits, and more than 6.5 million ambulatory care visits.[11] A recent study conducted by the Massachusetts Rate Setting Commission identified asthma as the most common diagnosis for preventable hospitalizations in that State.[12]

Service Providers

The focus narrows as we move from the societal perspective to the view of persons and organizations directly involved in the delivery of care.

Testimony from representatives of hospitals and managed-care organizations at each of the public hearings sponsored by the NAEPP working group supported the fact that asthma hospitalizations continue to remain a significant source of health care expenditures. At Children's Memorial Hospital in Chicago—the fourth largest children's hospital in the Nation—asthma is the number one diagnosis for hospitalizations. This hospital also has noticed a marked increase in the number of asthma admissions to the intensive care unit over the last few years. Wyler Hospital and LaRabida Hospital, both also in Chicago, admit four to six children with asthma per week to their intensive care units.

These statistics are especially significant in terms of hospital costs. In 1992, at Children's Memorial Hospital, the average cost per day for a hospital stay was $1,490, with a charge of $2,700 per day for the intensive care unit. That year, the total cost of asthma care at Children's Memorial Hospital amounted to approximately $6.5 million.

At Maine Medical Center, from 1989 to 1992, admissions for children with a primary diagnosis of asthma increased by 33 percent. The number of pediatric asthma cases seen in the emergency department doubled during the same time period.

The experience described by representatives of Miami Children's Hospital is similar, with asthma and asthma-related conditions accounting for the largest portion of the hospital patient census and the largest increase in the census from 1989 to 1992. In 1991, the Miami Children's Hospital inpatient charges attributed to asthma, based on patient discharge

records, totaled more than $2 million. The combined asthma inpatient charges for all hospitals in Dade County, Florida, were more than $7.8 million.

From the perspective of public health care providers, asthma is significant not only in terms of admissions but also in terms of emergency department utilization. Like the experiences shared by many private hospitals, asthma represents the single most frequent diagnosis for pediatric hospitalizations at San Francisco General Hospital.

The indigent population served by public hospitals is also much more likely to use the emergency department as the primary source of care, primarily because of lack of access to a primary care provider. At Chicago's Cook County General Hospital, the adult emergency department sees approximately 11,000 patients for asthma each year, and the pediatric emergency department sees about 3,000. Many of those visits were thought to be due to a lack of access to primary care. Together, these two emergency departments see more patients for asthma than all their outpatient clinics combined. Although these bills remain largely uncollected, the emergency department visits are billed at an estimated rate of more than $2.5 million per year.

The managed-care providers who testified at the public hearings also identified organizational issues affecting asthma care, despite managed care's potential lack of the traditional barriers to care. Northern Kaiser Permanente Medical Group (PMG) of California has examined discharge rates for asthma and other respiratory conditions at 15 of its medical centers. In 1992, PMG's hospital discharge rates for pediatric asthma ranged from 1 to 7.5 per 1,000 children with a regional average of 2.6 per 1,000. PMG indicated that a variety of factors may affect the wide range in discharge rates, including differences in air quality and socioeconomic demographics. However, PMG also attributed some of the differences in discharge rates to variations in the practice patterns of the primary care physicians.

PMG took a closer look at the three medical centers with the lowest discharge rates for pediatric asthma. They discovered that these centers used a variety of cost-effective approaches to supplement the physician encounter. The pediatrics departments at these medical centers had established a number of collaborative efforts among the staff members. Physicians, health educators, nurses, respiratory therapists, pharmacists, and other health care providers had all adopted a vigorous asthma management crusade. Most important, the cost of financing the reduction of hospitalizations for asthma was essentially zero. Once the physicians and other providers were aware of the magnitude and wasted cost of large variations in facility discharge rates, there were both altruistic and financial incentives to implement practice guidelines in order to reduce unnecessary expenditures for hospitalizations for asthma.

Several of the managed-care representatives who testified at the hearings noted that although managed-care programs provided optimal access to most services, copayments and partial coverage of durable medical equipment often create financial barriers for patients.

Constraints on the amount of time physicians can spend with a patient during a visit were mentioned as a barrier to care, especially in managed-care settings using a traditional staff model, where time limits are often strictly enforced.

Representatives of the public sector who attended the hearings also identified many barriers related to the overall financing of health care. Public programs share the chronic problem of inadequate resources, especially in terms of human resources. They

often lack nurses, social workers, and midlevel providers to help educate patients and guide them through the complex process of coordinating public health services.

A community needs assessment performed by one of the Chicago Head Start programs reported that the number of medical providers in its community has decreased by roughly one-half over the last several years. San Francisco General Hospital and Jackson Memorial Public Hospital expressed similar concerns. Insufficient numbers of primary care providers often result in waiting times of 4 to 6 weeks for an appointment at one of the outpatient clinics. This in turn translates into a high degree of repeat visits to the emergency department, especially for persons with asthma, who often cannot maintain control for the length of time it may take to get a regular appointment.

Consumers and Purchasers

Representatives of public assistance and Medicaid from each of the States in which the hearings took place presented testimony on asthma-related expenditures and initiatives within their programs. California's MediCal program obtained asthma expenditure data from a 5 percent sample of fee-for-service claims over a 6-month period in 1992. The figures were then extrapolated to represent the entire MediCal system of approximately 5 million participants. The results indicated that the 6-month reimbursement for inpatient hospital stays totalled $62.6 million for 17,520 patients. The average length of stay was 3.75 days, and the estimated cost per beneficiary was $3,666. In contrast, the reimbursement for medical and outpatient claims totalled only $3 million.

The Illinois Department of Public Aid also presented data on Medicaid expenditures. In 1992, the claims for inpatient asthma expenditures totaled slightly more than $30.5 million for 9,228 admissions. These expenditures alone represent 8 to 9 percent of the total Medicaid budget for the State of Illinois. In contrast, the outpatient and physician asthma claims amounted to just under $1 million.

In Florida, the Medicaid asthma expenditures were not quite as dramatically disproportionate. They revealed an inpatient-to-outpatient ratio of 3 to 1 in expenditures over a 6-month period in 1992.

The ratio of inpatient-to-outpatient expenditures for asthma care was even lower within the Maine Medicaid program. Asthma data for 1992 reflect a ratio of nearly 1 to 1.

Table 1 provides a summary of asthma-related utilization and expenditures for each of these public assistance programs. All the Medicaid data were obtained at the request of the working group. None of the States had reported an examination of asthma-related expenditures prior to this request.

The disparities in these inpatient-to-outpatient ratios for asthma expenditures do not appear to be related to differences in the scope of benefits. In general, the State Medicaid programs have a broad scope of benefits, incorporating a majority of optional benefits in addition to those that are mandated.

Within the private sector, Blue Cross and Blue Shield of Maine (BCBSME) presented limited data on its asthma expenditures, specifically those related to inpatient costs. In general, BCBSME inpatient costs for asthma care were low at $850,000 for fiscal year 1992. Data on outpatient costs were not presented. Despite its relatively low costs of asthma care, BCBSME expressed an interest in improving the quality of care. Under the current arrangement, member interactions with the plan's administration are fragmented, and member questions are usually addressed out of the context of the patient's overall treatment needs.

Additional information on public and private coverage of asthma care was acquired from the American Lung Association study, which

Table 1

ESTIMATED ASTHMA-RELATED MEDICAID UTILIZATION AND EXPENDITURES IN FOUR STATES*

	California	Florida	Illinois	Maine
Inpatient Care				
Percent with age <18 years	63	64	58	58
Number of admissions	17,520	n/a	9,228	n/a
Number of recipients admitted	n/a	8,700	7,041	367
Number of days of care	n/a	45,234	37,084	n/a
Average length of stay	3.65	n/a	4.02	n/a
Average inpatient expenditures per admission	$3,770	$3,555	$3,320	$4,138
Ambulatory Care				
Percent with age <18 years	63	37	n/a	58
Number of ambulatory visits for asthma	308,680	266,232	n/a	n/a
Number of recipients with any asthma visit	n/a	78,944	n/a	8,009
Average outpatient care expenditures	$99	$149	n/a	$166

* All estimates were derived from data provided by the State programs to the working group for the public hearing in that State. These data are presented as estimates; each State was not asked to provide any further detailed analysis beyond the data presented at the public hearings.

California data from the Department of Health Services. A 5-percent sample was extrapolated to provide an estimate of the MediCal population. Data were from a 6-month period (1/1/92-7/1/92) and were annualized to provide a 1-year estimate of 1992 utilization and expenditures.

Florida data from the Medicaid Management Information System. Based on 6-month data (1/1/92-7/1/92) and annualized to provide a 1-year estimate of 1992 utilization and expenditures.

Illinois data from the Department of Public Aid are for the fiscal year 1992.

Maine data from the Maine Department of Human Services, Bureau of Medical Services, Reimbursement and Financial Services. Estimated data based on 1-year data (7/1/91-6/30/92).

surveyed a selected group of 13 private insurers (including 5 Blue Cross and Blue Shield programs) and 10 State Medicaid programs to learn more about coverage of outpatient asthma care. The private insurance plans offered fairly comprehensive benefits with the exception of no coverage for patient education. However, many of the private insurance products attached significant copayments and deductibles. Both the public and private insurers demonstrated some degree of variation in asthma care coverage.

Persons with asthma and their families are the ultimate consumers of asthma care. Unlike the perspectives of insurers and employers, an individual's health care affects not only his or her bank account but also his or her health status and quality of life. Since the 1980s, several important studies of the effect of health insurance policies on health outcomes have been conducted; perhaps the most notable are the health insurance studies conducted by the Rand Corporation. The Rand experiments demonstrated that even small changes in the amount of individual cost sharing clearly affected health care utilization and health outcomes.[13,14] Studies of State changes in Medicaid programs that limited eligibility also

have demonstrated a significant decline in access to care as well as health outcomes.[15,16]

Although these studies of the effects of insurance coverage on health outcomes provide a broad policy perspective, they do little to address the many subtle issues directly relevant to asthma care. For asthma-specific information, the working group once again benefited from the testimony of the individuals attending the public hearings. The concerns expressed by persons with asthma and their families are incorporated throughout this report.

Major Employers and Managed-Care Organizations

It is important to note that this working group sought to examine issues of health care financing in what is recognized as a rapidly changing environment. The public hearings of 1993 attempted to solicit the input of large employers as purchasers of care, but no representatives from large employers were present at any of the hearings. Although employers were beginning to respond to pressures of overall rising health care costs, few had studied and therefore understood the impact of a particular illness (or even the impact of chronic versus acute conditions) as it translates into specific health care costs for their employed populations. Since the conclusion of the hearings, however, several examples of emerging employer involvement have been brought to the working group's attention.

At least one major midwestern manufacturing company has taken the initiative to study its expenditures for asthma and chronic obstructive pulmonary disease (COPD) in order to develop better management strategies for the health care of its employees and their dependents (see case study 1).

In addition, managed-care organizations, insurers, and employers are beginning to take a leadership role in more appropriately managing the use of existing health care resources. In a recent study,[17] 13 major U.S. employers and 16 managed-care organizations collaborated to examine how variations in asthma practices affect the lives and productivity of their patients/employees (see case study 2). Their goal is to improve the quality of care. The concept of quality improvement is an approach to health care that moves beyond the solely reactive treatment-of-illness approach to one that examines problems within the context of the surrounding system. Quality improvement in health care introduces accountability at all levels of care—for health plans, providers, and patients—and attempts to create incentives aimed at prevention and management of disease while monitoring costs. These efforts represent the vanguard of how business interest in health care quality will, in the future, direct changes in health care spending both globally and for specific health conditions such as asthma.

BACKGROUND FOR RECOMMENDATIONS

The debate over health care reform and the continuing discussions about health insurance reform help to illuminate the tremendous opportunity for the creation of financial incentives aimed at effective delivery of high-quality health care. Yet as encouraging as the emerging trends in managed health care may be, the majority of current financing structures are replete with gaps and disincentives. These barriers are the focus of the final section of this report and form the basis for the task force's recommendations. The working group discusses these issues in three contexts:

- Insurance-related financing issues—those aspects of care that require health insurance changes or reform
- Public health noninsurance-related financing issues—those aspects of care that require financing resources other than those based on health insurance

CASE STUDY 1: EMPLOYER EXPENDITURES FOR ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE

A major midwestern manufacturing company engaged the assistance of the Mayo Clinic in Rochester, Minnesota, to help develop management strategies for the health care of its employees and their dependents. The overall objective was to develop management strategies for asthma and COPD that would maximize quality and control costs. The initial step toward development of these strategies was to gather data on the corporation's expenditures for asthma and COPD in 1990 and 1991.

All health care records of the corporation's employees and dependents are stored in a computerized master database. The researchers searched the database to obtain 1990-91 data on the number of patients with asthma or COPD, physician visits and hospitalizations, emergency department visits, and prescription drug use for asthma or COPD. The data were further characterized by severity of asthma or COPD. Of the 73,165 individuals in the database, 13,742 (19.1 percent) carried the primary diagnosis of asthma or COPD. Of the total health care cost of $334 million, $16.2 million, or 4.9 percent, was attributed to asthma or COPD. Sixty-one percent of the asthma or COPD costs were inpatient related, 23 percent were outpatient related, and 16 percent were for medications.

From 1990 to 1991, there was an 8.3 percent increase in costs for asthma or COPD, primarily in outatient services and medications. Similarly, 80 percent of asthma costs were concentrated in 30 percent of asthma patients. Five percent of patients hospitalized for asthma stayed in the hospital for longer than 10 days. Twenty percent of emergency department visits for asthma resulted in hospital admissions. The three most commonly used drugs for asthma were albuterol, theophylline, and amoxicillin.

This study demonstrated that expenditures for asthma and COPD consume a significant proportion of health care resources and that the costs are concentrated in a small number of patients, primarily for inpatient-related services. The company plans to use these data to develop management strategies for asthma and COPD.

[Adapted with permission from Li, J. Expenditures for asthma and chronic obstructive pulmonary disease in a major manufacturing company. American Journal of Respiratory and Critical Care Medicine 1994;149(4 pt 2):573.[18]]

- Individual financial responsibility—those aspects of care that remain the financial burden of persons with asthma and their families.

Insurance-Related Financing Issues

Health care in the United States is currently financed through a complex collection of private and public insurance mechanisms. Coverage is typically provided via three financing options: private health insurance; public assistance such as Medicaid; and self-payment, meaning either out-of-pocket expenditures or indigent care supplied by health care providers and organizations.

Private insurance is, and is likely to remain, the primary means of financing health care in the United States. As insurers and employers have responded to rising health care costs, several trends have emerged within the private insurance industry. The concept of cost sharing is now common, with individuals increasingly responsible for contributions in the form of premiums, deductibles, and coinsurance.

CASE STUDY 2: THE MANAGED HEALTH CARE ASSOCIATION OUTCOMES MANAGEMENT SYSTEM PROJECT

This project represents a unique collaboration among 13 major U.S. employers and 16 managed-care organizations to learn about differences in asthma care practices, to evaluate the impact of those practices on patients' lives, and to improve the quality of asthma care through application of this knowledge.

Employers want to know how the care provided by managed-care organizations is affecting the daily lives of their employees. Using functional status measures and other patient reports, the asthma project will provide data to be used in provider-based continuous quality improvement activities. The context of managed care provides an opportunity for systematic data collection and large-scale quality improvement activities. Employer participants believe that managed-care participants can take big steps toward realizing the potential of managed-care arrangements through this kind of outcomes management process.

The objectives of the asthma project revolve around testing the usefulness of patient outcomes information in managed-care environments. Usefulness is being examined in several ways, including:

- Collecting data on recommended medical practices (process measures), comparing these across provider organization types, benchmarking, and collaborating to promote practice improvement
- Evaluating the feasibility, quality, and cost effectiveness of data collection and analysis on a large-scale basis involving multiple organizations and organizational types
- Investigating the utility of generic measures of health-related quality of life as measures of health care outcomes.

Initial baseline data collected on 6,612 adult patients with asthma in 16 managed-care organizations nationally provided information on current treatment, asthma severity, health status, patient knowledge, and patient satisfaction with care. Generic and disease-specific health status measures demonstrated the significant impact that asthma had on the lives and work of the patients (see table 2). The health status of people with asthma was significantly lower than that of the general population, and the extent of work loss was apparent. Half of patients reported missing at least a day of their usual role activity in the past month due to their health. Roughly one-third (32 percent) of patients with severe asthma reported canceling or rearranging activities in the past month due to asthma. The percentage was 24 percent among people with severe asthma who were employed full time or part time. Among those working full time or part time, 50 percent with severe asthma and 43 percent with moderate asthma reported missing at least 1 day of work during the past month due to illness of any kind.

The trend for children is toward reduced coverage. According to newly released data from the Bureau of the Census, only 57 percent of children under age 18 were covered by employment-based insurance for at least 1 month in 1993. This represents a drop in employment-based coverage of more than 1 percent from 1992.[19] Not surprisingly, the number of uninsured children climbed by more than 850,000 between 1992 and 1993.

The testimony from the public hearings illustrates the many restrictions health plans have placed on benefit coverage. At the same time, insurers are increasingly placing limitations on coverage for pre-existing conditions

Table 2

PERCENTAGE WITH CHANGE IN ACTIVITIES BY SEVERITY AND RANGE AMONG MANAGED-CARE ORGANIZATIONS

	Total	Severe	Moderate	Mild
Canceled or rearranged activities because of asthma in past month	17.1	32.0	8.3	0.5
Persons working full time or part time				
Cancelled or rearranged activities activities because of asthma in past month	12.6	24.3	7.0	0.3
Missed 1 or more days work in past month due to any illness or injury	43.1	50.1	42.9	24.9

Comparisons of adjusted rates of performance showed that although there was substantial variation across managed-care organizations, there was also little consistency within organizations for all of the quality indicators examined in the study. Different patterns of practice suggest interventions that target physician prescribing patterns, patient education and self-management training, and organizational changes within practices and organizations.

Source: Excerpted with permission from Steinwachs DM, Wu A, Skinner EA, Campbell D, and the Managed Health Care Association's Outcomes Management System Project Consortium. Asthma patient outcomes study: baseline survey summary report. Bloomington, MN: The Health Outcomes Institute, 1995.[17]

to protect themselves against high-cost illnesses. In an attempt to control rising health care costs, insurers, including managed-care providers, are placing utilization controls on covered services such as limits on the number of outpatient visits or inpatient days, dispensing limits on prescription medications, the practice of requiring prior authorizations to obtain medical services, and gatekeeper designs, in which each patient is assigned a single medical provider who delivers primary care services and coordinates and authorizes the management of outside specialty services.

In our present multipayer health care system, many individuals experience problems maintaining coverage during periods of transition. This is particularly true for certain groups such as persons unable to change jobs due to a pre-existing medical condition, students, persons pursuing claims for workers' compensation, and persons passing in and out of welfare.

Although the majority of persons with asthma have some type of health care coverage, the types of benefits, as well as the number of potential barriers to obtaining asthma care services, vary widely. Following is a detailed discussion of the problems that underlie the working group's recommendations for addressing these insurance-related issues.

Recommendation: Make asthma care affordable and accessible by keeping out-of-pocket expenditures to a minimum. Given the increasing number of uninsured and underinsured persons in the United States today, the cost and availability of health insurance is perhaps the single most important financing issue affecting

the care of persons with asthma. For many persons or families with asthma, the burden of asthma care directly affects the family budget. Whether fully insured, partially insured, or uninsured, persons who testified before the working group emphasized the disproportionately high share of their family income that went toward asthma care. Health care cost sharing creates a burden that affects a family's key decisions regarding personal spending, even for basics such as food, clothing, and shelter.

Health insurance arrangements for persons with chronic illnesses such as asthma should include caps on the family's percentage of total out-of-pocket expenditures (including premiums and coinsurance payments), so that medical expenditures do not create an unreasonable burden to the family income. The total cost of health expenditures per family should be limited to no more than 5 percent of the gross family income for those above 200 percent of the poverty level and should be none or nominal for those below 200 percent of the poverty level. In addition, the scope of benefits needs to be broad and comprehensive enough to be appropriate for quality care. The majority of health insurance plans ensure catastrophic coverage for situations such as hospitalizations. Yet these plans often provide very poor coverage with excessive cost sharing for the routine ambulatory care services that are critical for day-to-day asthma management.

Recommendation: Eliminate barriers to coverage such as limitations on insurance coverage for pre-existing conditions and other exclusionary clauses. For many individuals, exclusionary clauses create tremendous gaps in health care coverage. The common insurance practices of limiting coverage for pre-existing conditions and assessing high premiums for those determined to be at actuarial risk pose the greatest barriers to persons with chronic conditions. In general, these practices effectively deny coverage to those who need it most. Pre-existing condition limitations and exclusionary clauses are used to protect the insurer from high-cost illnesses. They typically deny medical care coverage for a specified period of time for illnesses diagnosed prior to the health insurance application and often force applicants to wait 6 months to several years.

For many persons with asthma, this presents an impossible situation because they need access to quality health care on a continuous basis. It is particularly problematic for those who are self-employed or who work for small businesses. Families often are forced to make some very difficult choices, as exemplified in the following excerpts of public testimony.

> *I am from a self-employed family, and right now we don't have any health coverage. Part of the reason is because our son has asthma and he can't get coverage. My husband and I can't afford to pay for health insurance for ourselves and cover his asthma expenses as well. So we choose to pay out of pocket for our son's expenses in the hopes that we won't have anything catastrophic happen to us.*—Public Hearing, Portland, Maine, August 1993

> *I consider the financing of my asthma to be one of the most difficult and controlling factors in the care I receive. I am now insured for the first time in 12 years. But my current insurance company—which was the only one out of 15 who would take me with less than a 2 1/2-year wait—is going out of business. So I'm about to become uninsured again.*—Public Hearing, San Francisco, May 1993

> *When we went from a group plan to private insurance, we were unable to get our son covered. The only insurance company that would even consider our family would do so only if our son was not on inhaled steroids. If he could stay off of inhaled steroids for 1 year, they would consider him, with a $2,500 deductible.*—Public Hearing, Portland, Maine, August 1993

There are other gaps in the current patchwork system of health insurance. Health plans often

terminate coverage for dependent children once they reach the age of 18 or 21. This is of particular concern for young adults with chronic illnesses such as asthma who cannot afford to purchase individual coverage. These young adults usually end up using the emergency department and incurring a debt that may take them years to resolve.

The transition out of public assistance poses another potential gap in health insurance coverage. Many families struggle during the interim period between leaving welfare and getting a job with full insurance coverage. For families or persons with asthma in this situation, giving up the security of public assistance to face an uncertain, albeit potentially better, employment situation becomes a difficult choice.

For persons with chronic illnesses such as asthma, it is essential that health coverage be guaranteed and continue without interruption, regardless of whether they lose or change jobs, move from one area of the country to another, or become seriously ill. Although some States now have laws against limitations on insurance coverage for pre-existing conditions and other exclusionary clauses, it has yet to become a uniform or national policy.

Recommendation: Eliminate deductibles and limit the amount of copayments for inpatient and ambulatory care. Adequate coverage for asthma should include a minimum of four maintenance visits annually without copayment. There is wide variation in the inpatient and outpatient coverage offered by the numerous insurance plans currently available to consumers. Employee cost sharing has become popular due to increasing pressure to control health care expenditures. Some plans keep premiums low by offering only minimum benefits and requiring substantial cost sharing. Cost-sharing practices are intended to encourage individuals to seek less expensive care and control unnecessary utilization. Yet in general, they effectively discourage primary and preventive care. For persons with chronic illnesses, adequate health maintenance requires routine primary care visits. However, because of the utilization controls and cost-sharing policies of many health plans, persons with asthma may delay seeking or ignore the preventive care necessary to manage their disease adequately. These cost-control measures in many ways help to perpetuate a delivery system that remains focused on acute episodic care.

For persons with asthma and their families, the seemingly small amounts associated with copayments quickly add up.

> *If you have an asthma episode, it means multiple visits. You have to consider the cost of that. I know that from the health maintenance organization's point of view, I only have to cover the copayments, but it filters into our family's budget. So I say to myself, maybe I shouldn't go to the doctor because I'm going to have to pay for the visit, and then for the medicines, and then for the return visits—it just goes on and on.*—Public Hearing, San Francisco, May 1993

> *Followup visits are the first things to go, even though I know I really need that checkup. . . . I think that pulmonary function testing has made a huge change in my life, but I struggle with questions such as Do I have the money this morning to make a visit?*—Public Hearing, San Francisco, May 1993

Many health plans currently operate a gatekeeper model of managed care in which each patient is assigned a single medical provider who delivers primary care services and coordinates and authorizes the management of outside and specialty services. In concept, both the patient and the health plan benefit. The patient receives continuity of care while the gatekeepers help to deter utilization of expensive services. However, limited access to specialists could pose significant problems for persons with moderate-to-severe asthma. Many children with asthma are seen repeatedly

by their primary care physician without achieving control of their chronic disease. There are also occasions when patients are not referred either because the specialists are not available within the health care plan or because referrals to specialists outside the plan would result in loss of revenue for the program. Smaller managed care plans may be at particular risk for limited access to subspecialists.

> *Our child had to go through two hospitalizations before we got a specialist referral, and that specialist referral was to a child psychologist to see if there were stress-related problems triggering his attacks. . . . We went through our son's first 2 years of life with a modest estimate of 10 emergency room visits and 6 hospitalizations. . . . Finally we were given a referral to a pulmonologist, and he point blank told us that our child definitely had asthma. . . . We've now been 18 months without any hospitalizations.*—Public Hearing, San Francisco, May 1993

There are also barriers to access within the public sector. The majority of Medicaid programs suffer from an inadequate provider base, largely stemming from limited reimbursement. A pilot study[20] of the Maryland Medical Assistance Program revealed that for an established patient (as opposed to a new patient), the reimbursement for an office visit could be as low as $10. Many public assistance programs do not reimburse for services provided by nurse practitioners, physician assistants, social workers, and psychologists.

> *At La Clinica [La Clinica de la Raza, a community health center in California], we've never had the funding to allow the nurses in our setting to bring groups of kids together to talk about their asthma. We have the right environment, we know the kids, and we know the language—we just don't have the staffing. Until very recently, we didn't have nurses at all.*—Public Hearing, San Francisco, May 1993

Insufficient numbers of primary care providers often increase waiting times for a clinic appointment and lead to repeat visits to the emergency department.

Health plans with no deductibles and limits on copayments are essential for persons with chronic conditions. Unlike other types of illnesses or health situations, chronic illnesses by definition require regular contact with health professionals. Conditions such as asthma are extremely sensitive to intervention. That is, intervention can improve asthma outcomes in a relatively short period of time. For individuals with asthma, preventive services are absolutely necessary for health maintenance and may influence greatly the number of acute exacerbations that in turn lead to emergency department visits and hospitalizations.

Health insurers need to recognize the importance of health maintenance for chronic conditions. One option in support of health maintenance for persons diagnosed with chronic conditions could be to expand the health plan's definition of preventive services to include a minimum of four scheduled ambulatory visits per year without copayment. This recommendation is based on the average number of visits required by a person with mild-to-moderate asthma.

Access to an adequate base of providers is also essential. For many persons with asthma, midlevel providers, psychologists, and counselors are important sources of primary care. Health insurers should be encouraged to expand access to care by recognizing and reimbursing services delivered by nonphysicians.

Health plans also need to be cognizant of access to specialists. Although greater emphasis on access to primary care helps to eliminate overutilization of unnecessary, expensive services, the system must be monitored carefully to avoid situations where the practice of penalizing physicians who frequently refer patients to subspecialists creates an incentive to

Table 3

MEDICAID DISPENSING PRACTICES

State	Maximum allowable amount
Colorado	30-day supply
Hawaii	30-day supply or 100 units
Idaho	34-day supply
Kansas	100-day supply
Kentucky	No limit
Maine	No more than 6-month supply*
Minnesota	3-month supply
Ohio	11 refills or 1-year supply
South Dakota	"Whatever the doctor writes"
Texas	180-day supply

*Maine is considering establishing a dispensing limit of a 30-day supply.

Source: American Lung Association survey, 1992-93 (unpublished).

retain complex cases. This practice could potentially increase the cost of care as a result of unnecessary visits and avoidable emergencies.

Recommendation: Eliminate or minimize the impact of copayments and overly restrictive controls on the utilization of drug benefits. Pharmaceutical benefits are critical to quality asthma care. At present, insurance coverage of pharmaceuticals is highly variable. The American Lung Association study examined variations in public and private benefit coverage of asthma medications. In general, the study found that most insurers have extensive formularies covering nearly all pharmaceuticals approved by the Food and Drug Administration. The variations in the insurance packages appeared in the form of deductibles, copayments, and dispensing policies (see tables 3 and 4). The amount of deductible ranged from none to $2,500. One of the surveyed plans required a separate deductible of $1,000 for prescription drugs before paying 80 percent of charges.

> *Even a small amount of copay . . . adds up. . . . Those who are lucky enough to be in an HMO where the copay is $3 or $5 are better off than families who may not have that . . . where [instead] it is $15 or $20 a month. We [Rush-Anchor] now see copays as high as $15 for medication. Fifteen dollars a month on a limited budget is a significant amount of money. I have many, many patients who, although they have their health insurance paid for, are the working poor—and don't have those dollars to get their medications.*—Public Hearing, Chicago, July 1993

Dispensing practices vary among health plans, ranging from a 30-day limited supply to unrestricted quantities of medications.

The variations in dispensing policies are of greatest concern at both extremes. In addition to needing medication for acute exacerbations, persons with chronic illnesses such as asthma commonly need to take medication on a daily basis to maintain a controlled health state. Placing a 30-day dispensing limitation on chronic medications imposes an unnecessary burden. When considering trips to the pharmacy, many individuals also have to factor in the cost of transportation as well as copayments. Individuals with low income face the additional obstacle of finding a pharmacy that

accepts Medicaid. In some cases, the extra steps required to refill medication on a monthly basis may deter many individuals from following a course of optimal care.

At the other extreme is the practice of dispensing unlimited quantities of medications. The concern here is the potential for individuals to abuse their prescription drugs unintentionally. Some inhaled asthma medications are intended for use on an as-needed basis, yet extended overuse could cause harm. In some cases, individuals ordering their prescriptions in bulk from mail-order pharmacy warehouses receive a 6- to 12-month supply all at once. These programs have no regulatory mechanisms to educate and monitor the frequency of drug use.

> *In many DME [durable medical equipment] companies and pharmacies, the unit dosing is dispensed by some external laboratory, and it is impossible to stop those prescriptions. I may write one prescription, but they automatically renew by mail every single month. I have patients who bring me boxes of extra medication to give to somebody else who might be able to use them.*— Public Hearing, Miami, September 1993

Even if pharmaceutical benefits are available, health insurance policies vary considerably in the types and amounts of copayments and deductibles for this benefit. Persons with asthma have a chronic illness and therefore are almost certain to require prescriptions on a regular basis. If a pharmaceutical benefit is offered, most health plans have extensive formularies and will include nearly any approved asthma medicine. However, the copayments for pharmaceutical benefits remain a cause for concern, particularly for insurance plans that mandate 30-day maximum dispensing limits.

Persons with asthma frequently have to take several medications. Children may require extra reserves, such as keeping an inhaler at school and another at the babysitter in addition to the medication at home. Two or three prescription copayments every month quickly

Table 4

PRIVATE INSURER DISPENSING PRACTICES

Insurer	Maximum allowable amount
Blue Cross and Blue Shield A	90-day supply
Blue Cross and Blue Shield B	30-day supply
Blue Cross and Blue Shield C	34-day supply
Blue Cross and Blue Shield D	90-day supply
Blue Cross and Blue Shield E	Limited to what is "medically necessary"*
Private insurer A	34-day supply or 100 units, whichever is greater
Private insurer B	Limited to what is "medically necessary"
Private insurer C	As billed
Private insurer D	1 month, unless more would be cost effective†
Private insurer E	1- to 3-month supply
Private insurer F	30-day supply retail pharmacy, 90-day supply mail order
Private insurer G	30-day supply
Private insurer H	30-day supply

*Note that there are no controls in the system to identify abuse.

†"Cost effective" for the insurer, not the patient.

Source: American Lung Association survey, 1992-93 (unpublished).

add up and are certainly compounded for families where more than one member suffers from a chronic condition such as asthma. Health plan policies should protect individuals with chronic diseases from unnecessary financial burden. Persons requiring medications on a long-term, daily basis should not have prescription copayments. Also, 60- to 90-day supplies should be the standard dispensing practice for chronic maintenance medications, subject to physician discretion.

Recommendation: Ensure coverage of durable medical equipment without lengthy prior authorizations. Optimal management of asthma often incorporates the use of one or more items of durable medical equipment. Spacer devices help to ensure accurate dosing of inhaled medications. Home nebulizers and peak flow meters allow many individuals to intervene at the early stages of an asthma episode, possibly preventing exacerbation and the need for urgent care. Environmental controls such as mattress pads may be of some benefit in reducing the allergen load that may provoke symptoms.

The American Lung Association survey of public and private benefit coverage revealed a wide variation among insurance plans with respect to coverage of durable medical equipment. In addition, those items that are covered usually require prior authorization. The issue of coverage or copayment for durable medical equipment was emphasized on numerous occasions throughout the public hearings. Testimony revealed that sometimes an insurer will pay for a nebulizer but not for the items that are necessary to operate the equipment properly, such as disposable tubing.

> *The kids needed a [home] nebulizer. The HMO paid for part of that, but I had to pay for half. . . . They will pay for the medicines sometimes . . . but the actual tubing that attaches to the machine—the HMO won't pay for that. We have to pay for that ourselves, and the kids need new tubing sets every few weeks.*—Public Hearing, Chicago, July 1993

Hospitals, particularly those serving low socioeconomic groups, face similar hidden costs.

> *. . . [T]he normal or half-strength saline that is used to nebulize the medication costs around $24 per box of 100 vials. We dispensed 1,450 boxes of normal saline at LaRabida Hospital last year . . . a cost of about $35,000, which is totally unreimbursed.*—Public Hearing, Chicago, July 1993

The American Lung Association survey revealed that most insurers have no set policy with regard to coverage of disposable nebulizer tubing or replacement of lost or broken equipment. Most of these requests trigger case-by-case decisions based on utilization review. The requirement for prior authorizations contributes to lengthy delays in obtaining equipment.

Coverage of durable medical equipment depends on the specificity of the health insurance policy and is highly sensitive to the type of language used to define the requested item and its uses. Spacer devices and home nebulizers improve functional abilities and are therefore fairly easy to justify. However, requests for peak flow meters and nebulizer replacement tubing may require an additional explanation to the insurer at the time of the request. Within individual health plans the definition of durable medical equipment should be broadened to include coverage for related disposable items. All health plans for persons with asthma should guarantee coverage of spacers, peak flow meters, home nebulizers, and tubing without copayment.

Prior authorizations continue to pose barriers, especially for low-income individuals. Persons living in poverty face daily obstacles in their efforts to meet the basic needs of food, clothing, and shelter. The extra steps of prior approval could easily discourage these indi-

viduals from adopting a treatment regimen of optimal care. Health plans should monitor the requests for certain devices such as peak flow meters. If the number of requests remains fairly moderate, health plans should eliminate the restriction.

Environmental controls such as mattress covers, air filters, and vacuum cleaners are rarely included in health plan definitions of durable medical equipment. However, through bulk purchase agreements, individual health plans could be in a position to offer these items to their members at a large discount. This practice would help to promote quality improvement measures within the plan in addition to providing a small amount of financial benefit to plan participants.

Recommendation: Offer free or low-cost formal asthma patient education programs through health plans. Optimal management of a chronic illness such as asthma requires the creation of a partnership between patient (family) and provider. Health maintenance is largely dependent on the individual. Persons with asthma need to be educated and encouraged to practice preventive measures such as avoidance of environmental triggers. The need for patient education was emphasized repeatedly throughout the public hearings. Patients testified as to the difference asthma education has made in their ability to manage their lives. They emphasized how asthma education improved their ability to communicate with physicians and schools and how it provided access to the support of other families in similar circumstances. Providers also advocated for patient education as a means of strengthening their ability to aid patients in the comanagement of asthma. With education, patients often will access their provider or initiate intervention at the earlier stages of an asthma episode, thereby preventing many avoidable emergency visits.

> *[Asthma] education allowed me to speak for myself and work for myself. . . . It gave me a common language. A peak flow meter gave me a common vocabulary with my doctor so that we could better utilize our visits.*—Public Hearing, San Francisco, May 1993

> *I just reached out wherever I could, to gather what I could. . . . I watch my daughter very carefully to see what brings it [asthma] on. . . . I just watch and then I learn . . . but I see other parents out there who don't know where to begin . . . and they need to know because if the parents are better educated, they can work with the physician, and this will help the child so that maybe they won't need the emergency room.*—Public Hearing, San Francisco, May 1993

> *. . . [W]e educate them [asthma patients] on a one-to-one basis. . . . All of the patients receive very aggressive management, and we are also very aggressive in management by phone. . . . We do not have to admit them, and very few of our patients have to go to the emergency room—we can handle most of those patients in the home.*—Public Hearing, Miami, September 1993

In general, asthma patient education remains a service that insurers will not reimburse. However, the public hearings did uncover a few exceptions to this general rule. The Maine Medicaid program is the only Medicaid program in the country to provide coverage for educational programs in asthma self-management. The American Lung Association survey revealed that Minnesota Medicaid also will cover patient education as a general service, although it does not specifically designate coverage for asthma self-management. Blue Cross and Blue Shield of Maine also has announced plans for coverage of formal asthma education programs. Although these examples are encouraging, they still represent a small minority.

Recommendation: Support research efforts focused on evaluating the cost-effectiveness of clinical case management. In many health plans, clinical case management is an increasingly popular feature. The concept of case

management involves providing individual attention aimed at coordinating a variety of cost-effective health care services for a particular beneficiary. It is typically reserved for costly, severe cases involving complex, lengthy, or chronic illnesses. The San Francisco public hearing included testimony from a managed-care company that is in the process of implementing a multidisciplinary case management model for chronic, disabling asthma. The model's activities include early intervention with referral to a hospital specializing in the treatment of respiratory disease, coordination of asthma-related health care services, monitoring of the patient's treatment and progress, and outcome measurement. However, despite the growing popularity of clinical case management, little empirical evidence is presently available to support its effectiveness. The preliminary evidence is encouraging for some groups of high-risk individuals. Nevertheless, strong research designs focused on explicit outcome measurements are needed to evaluate the true effectiveness of these programs.

Recommendations: Maintain uninterrupted health coverage for all individuals involved in workers' compensation claims throughout the duration of the workers' compensation proceedings. Increase primary care providers' awareness of the potential for occupational causation of asthma. Hold employers financially responsible for occupational disease. The Chicago public hearing held a special panel to address the issues surrounding occupationally acquired asthma and workers' compensation. Two case scenarios were presented to illustrate the barriers encountered by patients who develop a chronic disease such as asthma due to exposure in the workplace.

The first scenario described a situation in which an individual may develop asthma as a result of his or her work environment, but the disease goes undiagnosed by the patient's physician until after the statute of limitations for workers' compensation has expired. This scenario emphasizes the need for increased provider awareness of the occupational or environmental component of many diseases.

The second scenario described the typical obstacles encountered by an individual who attempts to prove a workers' compensation case. Under typical workers' compensation laws, a worker who acquires asthma—either caused or aggravated by exposure in the workplace—is eligible to receive certain benefits. These benefits include compensation for temporary and permanent disability as well as the medical and hospital rehabilitation services necessary to cure or relieve the effects of the disease. They are lifetime benefits without limitations. However, these benefits are not paid automatically. In a majority of cases, the employer disputes the claim, leaving the burden of proof on the worker. Meanwhile, as soon as a claim is filed, the third-party payer stops paying disability and health care benefits. The case can take up to a year to wind its way to the Illinois Industrial Commission. The worker is then sent for examination by a physician representing the insurance company, who is most likely to conclude that the asthma was not work related. At this point, the worker is typically confronted with the choice of accepting a settlement that does little more than cover his or her current expenses or pursuing a hearing with the Industrial Commission—which could take up to 3 additional years to resolve. A majority of individuals in these circumstances take the settlement and forego the benefits they truly deserve.

As mentioned above, several recommendations evolved out of analysis of the testimony presented at the Chicago public hearing. The first recommendation concerns continuity of health care coverage. Health plan arrangements need to ensure uninterrupted health coverage throughout the duration of workers' compensation proceedings. The second recommendation is for a campaign to increase the primary

care provider's awareness of occupational causation of disease. Early recognition will enable many more individuals to obtain the benefits they truly deserve. The third recommendation involves employer accountability. Employers must remain at financial risk for occupational disease. Otherwise, the employers have no incentive to clean up occupational hazards.

Public Health Noninsurance-Related Financing Issues

Ensuring the health of a community raises the issue of the role of the public health system in the financing of asthma care. It is the role of the public health system to protect citizens against preventable communicable diseases and poor quality health care, to identify and control outbreaks of disease, and to inform and educate consumers and providers about their roles in preventing and controlling disease.

In examining the issues specific to asthma care financing, public health initiatives could make a significant impact in three major areas: community health education, early identification of illness, and support for enabling services.

Recommendation: Support community asthma education programs. As previously discussed, asthma patient education is rarely covered by health insurance. Yet asthma education promotes an awareness of self and the environment that is essential for optimal control of the disease. Many organizations, providers, and patient support groups have responded to the need for patient education by designing demonstration projects and programs of various types. Nevertheless, the quality of educational offerings continues to vary greatly, and there are concerns regarding access to such activities by low-income populations.

At the State and local levels, public grants could be awarded for the design and implementation of community-based asthma education programs. Public funding will help to ensure access to health education for persons near or below poverty incomes.

Recommendation: Promote early identification and intervention for populations at high risk for asthma morbidity. Many children with asthma who are from low-income families are not identified until they present at the emergency department in a state of distress. At this point, the opportunities for prevention and early intervention have already been lost. Further, emergency departments generally are not the ideal environment in which to conduct patient education because the emotions and efforts of both parent and provider are primarily concentrated on managing the acute attack.

Federal resources, in the form of categorical grant funding, could be used in several ways to promote the early identification of children with asthma. Grants could be awarded to public health programs to educate and train public health professionals in the early recognition of asthma. Grant funding also could be used to establish asthma identification training programs in nontraditional health care settings such as Head Start programs, schools, and school-based clinics.

Asthma affects young children, minorities, and the poor at a disproportionately high rate. Federally sponsored programs such as Head Start provide an ideal opportunity for early identification of young children with asthma. These programs are also in an excellent position to provide the necessary links to Medicaid that could help to promote early intervention.

Recommendation: Support asthma case management efforts that provide (nonclinical) enabling services. Transportation, child care, and language barriers often pose enormous obstacles for persons living in poverty and can deter access to primary and preventive health services. Testimony at the public hearings

revealed that patients with asthma often missed their clinic appointments for lack of a caregiver to watch their children and that obtaining public assistance for transportation to health services often sets off a vicious cycle.

> *You can get the money for transportation costs—but you have to spend $3.60 to get to the public aid office, to get the $3.60 to go to the doctor's office.*—Public Hearing, Chicago, July 1993

Persons living in poverty often lack the coping skills necessary to negotiate simultaneously problems in obtaining food, shelter, clothing, and health care. For many impoverished individuals, a focus on any one of these basic issues is enough to paralyze progress in all other directions. There is a tremendous need for nonclinical asthma case management to coordinate the various services available through public assistance programs.

In an extension of the recommendations for early identification, grants also could be used to fund demonstration projects aimed at developing links between the various existing block grants and early entry into Medicaid programs. Many block grant models are already established to provide enabling services. For example, the Head Start programs provide case management services for the entire family. Given their inner-city populations, educational settings, and connections to health and social services, Head Start programs are in an ideal position to form partnerships with other publicly financed programs. There is an opportunity to create formal and informal bridges between these independent financing streams.

Individual Financial Responsibility

Although universal health coverage must be the ultimate goal for our population, at present, most U.S. health plans fall far short of this goal, to the extent that some level of cost sharing rests with nearly every individual or family. The working group strongly recommends that the individual or family contribution to asthma care financing be kept to a minimum so as not to create a burden that interferes with the ability to maintain optimal asthma outcomes that are consistent with the national goals outlined in "Healthy People 2000: National Health Promotion and Disease Prevention Objectives."[21]

Recommendation: Ensure that the individual's financial responsibility for asthma care does not present a barrier to obtaining optimal care. The working group recommends that an employed individual's contribution, including premiums and cost sharing, should not exceed more than 5 percent of the family's total income for those 200 percent above the poverty level. The working group recommends significantly less than 5 percent of a family's income (or total elimination) for those who are unemployed or living at or below 200 percent of poverty level. The working group recognizes that there is little empiric evidence on which to base this recommendation. As a result, the recommendation of a 5 percent cap on personal expenditures was based on a review of the literature and analysis of the burdens faced by the various individuals and families who testified during the public hearings.

Ideally, health insurance arrangements should incorporate carefully designed mechanisms that will limit the financial burden on individuals and families. This concept prompted the working group to raise a number of questions, such as How should insurance plans be packaged to ensure total personal expenditures of less than 5 percent for families with one or family members with chronic illness? Should the total personal expenditure of 5 percent be collected up front in the form of premiums and deductibles or at point of service in the form of copayments?

Tables 5 and 6 illustrate the impact of various financing options on out-of-pocket expenditures. Both examples are based on a single-working-parent family with two dependent

children, one of which has asthma. The tables depict the annual cost-sharing burden associated with asthma care for this family under a range of income levels and health insurance options. Specifically, the tables compare the out-of-pocket expenditures for a self-insured family versus the high and low cost-sharing options offered in the original Health Security Act. In table 5, the child has moderate asthma. He or she requires four outpatient visits to the pediatrician and monthly prescriptions for a bronchodilator and inhaled corticosteroid. In table 6, the child has severe asthma. In addition to the same outpatient care and prescriptions described in the moderate case, the child requires one visit to the emergency department and one 3-day hospitalization stay. These examples focus only on the health care of the child with asthma and do not take into consideration the health expenditures of other members of the family.

The working group strongly recommends that copayments be eliminated or reduced to a minimum so as not to discourage access to care. Studies of the effects of point-of-service consumer costs on access to health care clearly demonstrate that requiring these types of payments may contribute to critical delays and other failures in the delivery of care.

CONCLUSIONS

Asthma morbidity is nationally recognized as a major public health problem, with goals for improvement outlined in the Healthy People 2000 initiative. The "Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma"[22] provides a benchmark for the actual elements of care, but these guidelines cannot be operationalized in a health care financing environment that creates barriers to their use. The literature on the direct impact

Table 5

COST SHARING FOR FAMILY OF THREE WITH ONE CHILD WITH MODERATE ASTHMA*

		Low cost-sharing option		High cost-sharing option		Self-payment	
% Poverty†	Income‡ ($)	Family pays ($)	% Income	Family pays ($)	% Income	Family pays ($)	% Income
100	11,980	160	1.3	511	4.3	862	7.2
130	15,574	160	1.0	511	3.3	862	5.5
150	17,970	160	0.9	511	2.8	862	4.8
180	21,564	160	0.7	511	2.4	862	4.0
200	23,960	160	0.7	511	2.1	862	3.6
250	29,950	160	0.5	511	1.7	862	2.9
300	35,940	160	0.4	511	1.4	862	2.4
400	47,920	160	0.3	511	1.1	862	1.8

Based on copayments and deductibles for family of three with full-time working mother and two dependent children and not receiving Aid to Families With Dependent Children (AFDC) or Social Security Insurance (SSI).

* Moderate-income working families under self-insurance versus high and low options of the Health Security Act.

† According to Federal poverty guidelines for 1993.

‡ Income refers to adjusted gross income.

Table 6

COST SHARING FOR FAMILY OF THREE WITH ONE CHILD WITH SEVERE ASTHMA*

		Low cost-sharing option		High cost-sharing option		Self-payment	
% Poverty†	Income‡ ($)	Family pays ($)	% Income	Family pays ($)	% Income	Family pays ($)	% Income
100	11,980	160	1.3	1,166	9.7	3,228	26.9
130	15,574	160	1.0	1,166	7.5	3,228	20.7
150	17,970	160	0.9	1,166	6.5	3,228	18.0
180	21,564	160	0.7	1,166	5.4	3,228	15.0
200	23,960	160	0.7	1,166	4.9	3,228	13.5
250	29,950	160	0.5	1,166	3.9	3,228	10.8
300	35,940	160	0.4	1,166	3.2	3,228	9.0
400	47,920	160	0.3	1,166	2.4	3,228	6.7

Based on copayments and deductibles for family of three with full-time working mother and two dependent children and not receiving AFDC or SSI.

* Moderate-income working families under self-insurance versus high and low options of the Health Security Act.

† According to Federal poverty guidelines for 1993.

‡ Income refers to adjusted gross income.

of health care financing on asthma care and related outcomes is scarce. In the absence of such data, the working group sought out the direct experiences of persons with asthma, their families, health care organizations, and providers. The recommendations in this report are the culmination of this effort to improve the financing of asthma care. Some of these elements can and should be addressed without delay by both private and public health insurers. Other recommendations reflect issues that extend into the realm of Federal health care reform or research efforts. As long as the financial barriers identified in the recommendations and this report continue, it will be difficult, if not impossible, to achieve the national (as well as many local) goals for the improvement of asthma care in the United States.

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