

Review Article

National Asthma Education and Prevention Program: Expert Panel Report 2. Guidelines for the diagnosis and management of asthma: Translating research for clinicians and patients

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ABSTRACT

Asthma is a chronic, inflammatory disease of the airways that exacts a large burden of illness among patients, their families, and the health-care system. Yet advances in research have generated the means for addressing this public health problem. The challenge is to bridge the gap between excessive asthma morbidity and the science that holds the promise of reducing it; that is, to translate the scientific advances into meaningful recommendations for clinical care and to promote adoption of the recommendations. This paper will demonstrate how national asthma education programs, founded on science-based clinical practice guidelines, meet this challenge and help reduce illness and improve the quality of life for people with asthma.

Key words: asthma, clinical practice guidelines, guidelines, national asthma program.

INTRODUCTION

The burden of asthma

In the United States, asthma affects 15 million people, and is the most common chronic disease of childhood.

In 1995, there were over 1 million hospitalizations with asthma listed as the first or secondary diagnosis. As shown in Fig. 1, age-adjusted hospitalization rates for asthma, as a first-listed diagnosis, have remained fairly constant since 1980. But it is of concern that the rate among blacks is three and a half times that among whites, and the rate among young children has increased. More than 5000 people die of asthma annually. It is troubling that the mortality rates have increased steadily over the last 15 years following a 10-year decline, and that the mortality rate among blacks is nearly twice that of whites.¹ The reasons for the disparity are not entirely clear, but it is likely that factors related to income and access to appropriate medical care contribute.

The burden of disease is also measured by quality of life. Children with asthma miss an average of twice as many school days as other children; 21% of children with asthma miss over 2 weeks of school a year due to asthma.² Twenty-one percent of people of all ages with asthma restrict their daily activities due to asthma (Centers for Disease Control, National Center for Health Statistics, National Health Interview Survey 1996). The estimated direct and indirect monetary costs for asthma totaled US\$11.3 billion in 1998.³

Accentuating our concern over these rates of serious illness due to asthma is the awareness that asthma prevalence rates for people of all ages doubled in the last 15 years (Fig. 2). The prevalence increased 160% among children aged 0–4 and 74% among children aged 5–14 years.¹

It is imperative, then, that measures be implemented to address this serious and growing public health problem. Fortunately, the tools are at hand to do so.

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Received 1 May 1999.

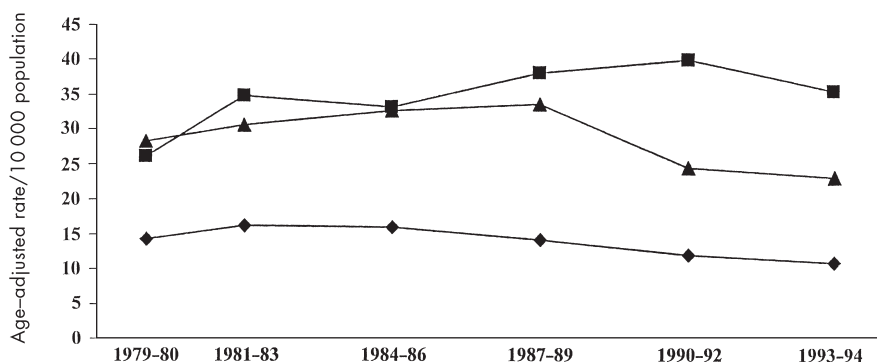


Fig. 1 Trends in asthma hospitalizations by race. (◆), white; (■), black; (▲), other. Ages are adjusted to the 1970 USA resident population. Data are from the National Hospital Discharge Survey, National Center for Health Statistics.²³

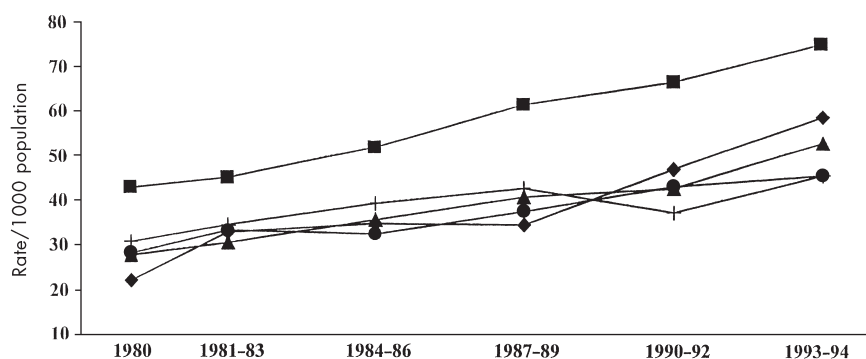


Fig. 2 Trends in asthma prevalence by age. (◆), 0-4; (■), 5-14; (▲), 15-34; (●), 35-64; (+), 65 years of age and older. Data are from the National Health Interview Survey, National Center for Health Statistics.²⁴

The role of national asthma education programs and clinical practice guidelines

Advances in scientific research have improved our understanding of the pathophysiology of asthma, and the molecular and cellular events that contribute to it.⁴ Such research revealed the central role of inflammation in asthma, helped identify appropriate targets for medical intervention, and led to the development of new treatments. If treated appropriately, most people with asthma can now expect to live physically active and productive lives with minimal disruption due to their asthma.

The National Heart, Lung, and Blood Institute (NHLBI), as an agency of the US government's Department of Health and Human Services, is a scientific organization supporting basic, clinical and health education research on all heart, lung, and blood diseases. But the role of the NHLBI is not only to support research in academic institutions around the country. It is also to evaluate results from the scientific literature and translate the research results to positively impact on public health. An effective means to implement this mandate is through national education programs. The NHLBI sponsors several separate programs, for example, on high blood pressure and cholesterol, that have led to substantial reductions in heart disease

over the last 15 years. A National Asthma Education and Prevention Program (NAEPP) was created in 1989 with the goals of raising awareness among patients, health professionals and the public that asthma is a serious chronic lung disease, and to develop programs for effective control and prevention of asthma. The NAEPP Coordinating Committee, which provides overall direction to the national program, is composed of representatives from more than 30 medical, professional and voluntary health organizations, patient groups, and government agencies (Table 1). This representation ensures that groups and individuals who have major responsibility in the US health-care system for educating professionals and the public about asthma are directly involved in planning the very programs they will be asked to implement. By working together, consistent messages about asthma and its care are developed, duplication of effort is prevented, and partnerships are created among organizations at both the national and local level to enhance dissemination programs.

The initial task of the NAEPP was to develop clinical practice guidelines for asthma to serve as the foundation for all NAEPP education programs. Clinical practice guidelines are systematically developed statements that assist practitioners in making decisions about appropriate

Table 1 National Asthma Education and Prevention Program Coordinating Committee Member Organizations

Public Organizations

- Allergy and Asthma Network/Mothers of Asthmatics
- American Academy of Allergy, Asthma, and Immunology
- American Academy of Family Physicians
- American Academy of Pediatrics
- American Academy of Physician Assistants
- American Association for Respiratory Care
- American Association of Occupational Health Nurses
- American College of Allergy, Asthma, and Immunology
- American College of Chest Physicians
- American College of Emergency Physicians
- American Lung Association
- American Medical Association
- American Nurses' Association
- American Pharmaceutical Association
- American Public Health Association
- American School Health Association
- American Society of Health-System Pharmacists
- American Thoracic Society
- Association of State and Territorial Directors of Public Health Education
- Asthma and Allergy Foundation of America
- National Association of School Nurses
- National Black Nurses' Association
- NHLBI Ad Hoc Committee on Minority Populations
- National Medical Association
- Society for Public Health Education

Federal Agencies

- Agency for Health Care Policy and Research
- Centers for Disease Control and Prevention
- National Center for Environmental Health
- National Center for Health Statistics
- National Heart, Lung, and Blood Institute
- National Institute for Occupational Safety and Health
- National Institute of Allergy and Infectious Diseases
- National Institute of Environmental Health Sciences
- US Environmental Protection Agency
- US Food and Drug Administration
- US Public Health Service

Additional Representatives to the NAEPP School Asthma Education Subcommittee

- American Alliance for Health, Physical Education, Recreation, and Dance
- National Association of Elementary School Principals
- National Education Association Health Information Network
- National School Boards Association

NHLBI, National Heart, Lung and Blood Institute; NAEPP, National Asthma Education and Prevention Program.

health care for specific clinical conditions.⁵ As such, guidelines offer physicians, other health-care professionals, and patients a synthesis of the most up-to-date management

strategies and a common reference point for communicating with each other.

In 1991, the NAEPP published the first *Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma*,⁶ that emphasized four essential components of asthma management: objective measures of lung function to assess asthma severity and guide selection of medications; a stepwise approach to pharmacologic therapy that promotes adjusting the amount or number of medications according to asthma severity and emphasizes the importance of anti-inflammatory therapy for persistent asthma; environmental control measures to avoid exposure to those factors ('triggers') in the environment that worsen asthma; and patient education to teach patients asthma-management skills and promote a partnership between the patient, his or her family, and the clinician for managing asthma together.

THE DEVELOPMENT OF NATIONAL ASTHMA EDUCATION AND PREVENTION PROGRAM CLINICAL PRACTICE GUIDELINES

The NAEPP strives to assure the scientific validity, credibility and practical utility of its guidelines through several mechanisms. As a federal government activity, the NAEPP is independent of any single medical specialty or pharmaceutical interest, and the wide membership of its panels of experts and the Coordinating Committee provides the capacity for consensus building and extended peer review that are deemed critical in producing credible guidelines. For example, the members of the panels are selected for their research and clinical expertise in different areas of asthma and its management so that individual panels are composed of pulmonologists, allergists, nurses, family physicians, pediatricians, emergency medicine specialists, behavioral scientists, and health educators. Further, each NAEPP Coordinating Committee member and his or her organization participates in the review and endorsement of the guidelines, resulting in the involvement of over 140 individuals from 40 public and private organizations.

Expert Panel Report, 1991

There is a spectrum of models for organizing the development of clinical practice guidelines.⁵ On one end of the spectrum is the model that requires a formal and extensive analysis of the literature, using quantitative methodology such as meta-analyses, along with expert judgment. This model frequently takes several years work,

is very expensive, and has been most successfully used to answer specific questions that have a limited scope. On the other end of the spectrum is the consensus workshop model, which brings together a small group of experts who listen to scientific presentations for one day and spend a second day preparing a written statement. For a complicated disease like asthma, neither approach was deemed appropriate. Accordingly, the NAEPP used a combination of methods to create a process for reviewing the literature and developing recommendations for clinical care. The overriding principle of the development process of the guidelines was to base recommendations on the best available science. The members of the panels divided responsibility for reviewing the literature individually and their group meetings generated consensus on either interpreting the science or articulating the members' expert opinion. Although sometimes open to controversy, consensus opinions are valuable to further scientific and clinical understanding of a condition, particularly when data are inconclusive or lacking.

Expert Panel Report 2, 1997

No sooner had the 1991 guidelines been published than new literature became available. Over the next few years, the complexity of asthma became increasingly apparent, and the options for care had expanded rapidly. Accordingly, in 1994 the NAEPP formed a Science-Based Committee to examine all relevant research since 1991, through MEDLINE searches. After review of over 6500 abstracts, the committee recommended that a total revision of the Expert Panel Report, 1991 was not warranted because much of the new literature substantiated the recommendations the panel had originally made without having numerous studies available. However, the Committee identified selected areas for which an update would be appropriate. For example, new medications were available and there was more evidence about the effectiveness and side effects of asthma therapies; a significant upsurge of information about quality of life measures as well as symptom and peak-flow monitoring techniques merited consideration; there were new studies about asthma in young children; and there was new evidence regarding the role of allergy control measures in asthma management.

An update to the Expert Panel Report, 1991 was recommended in 1995. It was agreed at the outset that recommendations in the 1991 guidelines would not be changed unless there was compelling evidence to do so.

This was essential to minimize confusion about a revision and to reinforce the key messages about asthma management as much as the science allowed.

A more systematic, iterative process for reviewing the literature was used by the second expert panel, in part to accommodate the explosive increase in the number of studies about asthma therapies. Subcommittees for each of the four major areas in the Expert Panel Report, 1991 conducted a general review of research pertinent to recommendations in its section. Although a formal ranking system was not used to weight the evidence, the panel agreed that its recommendations would be documented as much as possible by research published in peer-reviewed journals; randomized clinical trials had preference, but case studies and review articles also were included. Where sufficient studies were not available, the panel used its expert opinions based on theory and clinical experience. Clearly, some recommendations were more thoroughly supportable than others; it is important to remember that many questions regarding the clinical management of asthma have not yet been subjects of empiric research. The panel selected several issues for which controversy or a significant body of new literature existed for in-depth review. For example, in the monitoring section, all the literature on peak-flow monitoring was ranked and reviewed according to its research design and methods; in the pharmacology section special safety issues regarding inhaled corticosteroids and inhaled beta agonists were reviewed in detail, and a dosage chart was created to give estimated comparative daily dosages for inhaled corticosteroids since studies revealed that inhaled corticosteroid preparations are not equivalent on a per-puff or per-microgram basis.

Once the subcommittee reports were drafted, the full panel critically reviewed the evidence and rationale for each recommendation, and discussed revision, reaching final agreement on each recommendation through a voting process. The panel then forwarded its draft report to all members of the NAEPP Coordinating Committee for review. Revisions to the draft were made to incorporate as many suggestions made by the Coordinating Committee as possible, in light of the scientific review and consensus of the panel. This review cycle was essential because it helped assure that representatives from key affected audiences were a part of the report's development. This enhanced the credibility and, importantly, the feasibility of the recommendations. The Expert Panel Report 2 was published in 1997.⁷

Refinements in the format of the report were made in

order to make the guidelines easier for busy clinicians to use. For example, all recommendations appeared in boldfaced text to separate the specific recommendation from the text explaining its rationale. Recommendations were accompanied by either a specific citation of studies that supported the recommendation or by an indication that the recommendation was based on the opinion of the panel. Each chapter was prefaced with a list highlighting the significant changes from the first report. Summary charts geared to primary care physicians and sample patient education materials were presented as integral to the guidelines. A practical guide was prepared to summarize key recommendations. Laminated cards were created to present the recommendations for stepwise therapy, essentially distilling asthma-management strategies onto two cards. Such summaries meet the perceived need among primary care clinicians for easy-to-use reference charts. However, there was some concern that charts may oversimplify information and inadequately reflect the differing levels of certainty and scientific support that accompany different recommendations within the chart. Thus, it was felt that it was important to remind clinicians that the guidelines are not intended to be inflexible prescriptions for care, but rather to provide general guidance, based on the best available scientific evidence, to improve clinical decision-making.

Future updates

Developing guidelines is a dynamic process: as research continues, so too does the need to translate the findings into useful public information. Therefore, publication of the Expert Panel Report 2 marked the beginning of a new round of discussions for the Science-Based Committee to continue to monitor the scientific literature for advances that may signal a need to update the guidelines yet again. The NHLBI has searched for ways to monitor the literature on an ongoing basis rather than at 3–5 year intervals, and to update relevant sections of the report in a more timely way. Working with the National Library of Medicine, the NHLBI is building an evidence-based computer model for scientific review and clinical practice guidelines revision. This computer-accessed model, called the Asthma Management Model System, sorts and stores scientific literature in categories of asthma management and research analogous to the four components of therapy that comprise the organizational framework for the Expert Panel Reports. Researchers and clinicians can ask search questions through the computer

program that will link newly published evidence of specified therapies to designated patient outcomes. The searcher can also be linked to ongoing research supported by the National Institutes of Health (NIH). Emerging trends can be readily identified and the Science-Based Committee can recommend brief reviews for selected topics. The position papers can then be labeled 'new updates' and integrated into the guidelines that are stored in the Asthma Management Model System.

DISSEMINATING AND IMPLEMENTING THE GUIDELINES

Dissemination activities

Preparation of the guidelines is just the first step in the research translation process. A wide range of activities is necessary to disseminate the guidelines and promote their adoption. Through its member organizations, the NAEPP has mailed over 500 000 copies of its reports and distributed them widely at national professional society meetings. An important additional dissemination strategy has been to incorporate the guidelines into documents tailored to special audiences, such as the different specialities in the medical profession, as well as patients and the public. For example, the NAEPP has worked with nurses, emergency department physicians, pharmacists, and consumer groups to prepare special editions of the guidelines. Because asthma is a prominent problem among school children and frequently disrupts school activities, the NAEPP has targeted information directly at school teachers, staff and families, in order to promote adequate management of asthma in the school environment and to encourage children to participate fully in all school activities, including physical education and sport. Patient booklets have also been developed (*Your Asthma Can Be Controlled*, *Expect Nothing Less*, and *Facts about Controlling your Asthma*), and patient advocacy groups within the NAEPP sponsor bimonthly patient newsletters. Public information campaigns, through radio announcements and billboard advertisements, have alerted the public to the importance of recognizing asthma as a serious disease, and identifying its symptoms and seeking medical advice.

Educational programs to promote implementation

Simple dissemination of guidelines and information is certainly a necessary foundation for improving the quality

of asthma care, but it is seldom sufficient to create lasting changes in physician and patient behavior. A recent survey reminds us of this principle. In a national telephone survey of 2000 people in the USA with asthma and 512 physicians, a comparison was made between patients' reports about their disease and the goals for asthma management stated in the Expert Panel Report 2. The survey revealed that 49% of children with asthma and 25% of adults missed school or work due to asthma, whereas the goal is to have no absences. And 41% of persons with asthma had required urgent medical care in a doctor's office or emergency department, whereas the goal is to have minimal need for emergency department visits. Significantly, only 35% of asthma patients in the survey reported having had a lung-function test in the past year, and only 27% of the patients said they had been given a written action plan for managing their asthma, and yet objective measures of assessment and written treatment plans are strongly recommended in the guidelines. The survey also revealed that patients had a tendency to underestimate the severity of their disease, and to settle for levels of asthma control that were clearly short of the expectations for care promulgated by the guidelines (Press Release: Ogilvy Public Relations Worldwide, October 6, 1998).

While surveys have inherent methodologic drawbacks, the overall message is clear: there is still much work to do to improve asthma management and the quality of life for people with asthma. The message from this survey is not that guidelines do not work; the message is a reminder that educational strategies must not stop at mere transfer of information. Indeed, research studies have demonstrated that clinical outcomes have improved through good guidelines-implementation programs;⁸ for example, decreased anticoagulant-related bleeding,⁹ lower cesarian section rates,¹⁰ improved health for patients with diabetes,¹¹ and shortened stays in the hospital.¹² A review of 59 rigorous evaluations of clinical practice guidelines for a variety of medical conditions concluded that guidelines improve clinical practice and achieve health gains for patients, but they are most likely to be effective when they are scientifically valid, when they are introduced in the context of an interactive education and evaluation program, and when they help integrate the recommendations into the patient's care routines.¹³ Examples of effective implementation strategies include interactive training programs using academic opinion leaders,¹⁴ computer-generated prompts in patient-encounter forms that remind the clinician to ask specific questions or

perform certain tests,^{13,15} and embedding protocols from guidelines into medical records (e.g., emergency-department treatment and discharge checklists that conform to the guidelines). Computer-based audits and feedback comparing a physician's patient-care practices with national guidelines are also effective.¹⁶

Although there are few studies evaluating how effective clinical-practice guidelines for asthma have been in changing clinician behavior, the conclusions in five reports¹⁷⁻²¹ were similar: guidelines influenced behavior change among clinicians, but only with targeted, and fairly intensive, educational programs. One study in a primary care setting emphasized the need to include all members of the clinic staff, not just the physicians, in the implementation program to reinforce behaviors among the staff, and to provide consistent messages and reinforcement directly to the patients.¹⁷ All the studies indicated the need for multiple educational strategies, repetition of key messages, and reinforcement for implementing the guidelines.

The NAEPP encourages use of these principles of implementation in its educational efforts. For example, a recent partnership project with the Academy of Allergy, Asthma and Immunology is focused on promoting best clinical practices among clinicians who care for children with asthma. A special guide has been prepared that extracts the information on treating asthma in children from the Expert Panel Report 2 and provides additional information about community resources for improving asthma health-care systems for children. The guide will be disseminated through regional workshops around the USA, using interactive, problem-based medical learning techniques. The NAEPP programs targeted at school audiences include strategies to stimulate action. The NAEPP works with organizations that govern schools to foster appropriate school-wide policies; for example, adoption of school record forms that include written asthma treatment plans for each student with asthma, and rules allowing students to carry their inhalers with them during school hours. A NAEPP checklist, 'How Asthma Friendly is Your School?', serves as an assessment tool for teachers, administrators and parents to evaluate how well the school follows recommended asthma management strategies that enable a child with asthma to participate fully in school activities. A further example of implementation programs oriented towards creating changes in clinician behavior is the 1998 NAEPP conference of clinicians, administrators and educators working in managed-care settings. Participants facilitated

the design of quality assurance programs and strategies in order to implement them once they returned to their medical centers, and made recommendations for the development of nationwide performance indicators to enhance implementation of guidelines in various managed-care settings.

Actual change in clinical practice and patient behavior, however, must be accomplished at the local level: where clinicians practice and patients live. It is unrealistic to educate patients about asthma self-management skills if they are not prescribed appropriate medications. A superb treatment plan is useless if a patient cannot afford the medication, a family cannot get to a pharmacy before it closes, a child cannot easily get to his medication during school hours, or a person works in a building where smoking is permitted. Programs are needed that encourage system-wide approaches to asthma management at the local community level.

A new NAEPP education and outreach effort focuses on developing networks of community-based groups at the local level. These groups, which are often called Community Asthma Coalitions, are defined as broad-based, multi-organizational, community partnerships that bring together the public, private, and non-profit sectors for a prolonged period in an effort to reduce asthma morbidity and mortality, and improve quality of life for asthma patients and their families. Local asthma coalitions develop goals and objectives that meet the needs of their own communities. The coalitions are typically composed of members from local public health departments, hospital/medical centers, community clinics, schools, community recreation centers, church groups, pharmacies, concerned patient groups, local chapters of voluntary allergy or lung associations, city and county government officials, and local media. One of the earliest coalitions demonstrates a successful community intervention model. The group started with a small federal grant and conducted professional and patient education programs at work sites, schools, hospitals and clinics. Now, 3 years later, through the support of local foundations and private businesses, the group is self-sustaining.²² A more recently formed coalition in a large USA city with particularly high asthma morbidity and mortality rates has organized over 50 organizations to share information through newsletters and a specially designed resource directory, and to influence change in community systems. For example, the coalition's efforts changed school policies on asthma medications, and it is now working with pharmaceutical companies and

pharmacists to improve the accessibility and availability of medications to patients.

The NAEPP held a conference in 1998 called 'Strengthening asthma coalitions: Thinking globally, acting locally', which brought together over 50 coalitions from across the country to exchange information and define ways the NAEPP could help the local groups do their work effectively. At the conference, the coalitions demonstrated the value of building their programs on standardized messages of the NAEPP. Ideas were generated to help them learn how to implement key information from the guidelines in practical, concise learning aides (such as algorithms) for primary care clinicians in their locality, and suggestions were shared on making patient education materials sensitive to the needs and interests of different cultural and ethnic groups in the respective communities. The coalitions expressed a desire for an information clearinghouse, and for help adapting national media campaigns to local city campaigns. The NAEPP will work with the coalitions to address these needs. As an initial response to the conference, the NAEPP has created an Asthma Coalition Exchange page contained within the NAEPP Asthma Management Model System website mentioned earlier. Through this site, coalitions can learn about each other, communicate through discussion forums, and join a coalition internet mailing list.

The Asthma Management Model System (AMMS) embodies the entire spectrum of NHLBI asthma research and research translation, and education activities. The site, launched on World Asthma Day in December 1998, can be accessed through the NHLBI home page at <<http://www.nhlbi.nih.gov>>. The site brings together three high-technology functions within one integrated system to help health-care professionals, researchers, public health planners, and patients reduce the burden of asthma. Through the research function, the interactive AMMS lets users quickly formulate research questions and access key databases. The user can formulate, for example, questions about what effects a selected treatment will have on a selected patient for whom selected conditions are known. The system then retrieves relevant information from such major scientific databases as MEDLINE, CRISP and CORDIS, as well as documents from the Food and Drug Administration and Centers for Disease Control. Hyperlinks send the user to the relevant section of the NAEPP guidelines and the Global Initiative for Asthma (GINA). The education function allows the site user to retrieve the latest treatment guidelines,

browse and download materials for professional and patient education, and engage in interactive educational programs for university-certified continuing medical education credits.

This up-to-date informatics technology allows for more rapid translation of research findings into clinical practice. It also helps to monitor the literature to identify gaps in the science and set priorities for future research.

The dynamic nature of the guidelines process (namely, the translation of research to improve clinical care, and the continuing cycle of transforming clinical questions into new research initiatives) is perhaps its most important value. When we celebrated the 50th Anniversary of the NHLBI in 1998, we were able to announce that effective control of asthma was a *possibility* for most patients. With the national guidelines and education programs in place and supported by state-of-the-art information technology, and with the continued support of research, we can look forward to announcing within the next 50 years that effective control of asthma is a *reality* for all patients, and that the opportunity for preventing the onset of the disease is at hand.

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