

Task Force on Pediatrics

Report to the Board of Directors of The American Thoracic Society

May 2002

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I. INTRODUCTION

President Adam Wanner, M.D. formed the American Thoracic Society Task Force on Pediatrics in May 2001 in order to increase the focus on pediatric lung disease within the ATS. He did so with the recognition that many forms of adult lung disease start during childhood, and that interests of members of The Scientific Assembly on Pediatrics intersect with those of all other ATS Assemblies. Dr. Wanner felt it appropriate to promote the Assembly's activities during his presidency and beyond. Chaired by Julian Allen, M.D., past chair of the Assembly on Pediatrics, the Task Force members include Eduardo Bancalari, M.D., Robert G. Castile, M.D., Phyllis A. Dennerly, M.D., Gabriel G. Haddad, M.D. (Task Force co-Chair), Mary

Horn, R.N., Margaret W. Leigh, M.D. (Assembly Chair), Robert Lemanske, M.D., Albin Leong, M.D., Hugh M. O' Brodovich, M.D., Felix Sennhauser, M.D., Peter Sly, M.D., Renato Stein, M.D., Kurt R. Stenmark, M.D., Lynn M. Taussig, M.D., and William B. Wheeler, M.D. Several ad hoc members assisted the committee: Peter Lockett, MD (Critical care), Susan Kolb, CRNP, Eileen Hickey, CRNP and Laurie Miske, MSN (Nursing) and Clement Ren MD (Allergy/Immunology).

The work of the Task Force has the following goals:

- ? To increase the role and visibility of special interests within the Assembly on Pediatrics, -- clinicians, including neonatologists, critical care specialists, nurses, allergists and immunologists, and the international community.
- ? To support and enhance the contributions of the Scientific Assembly on Pediatrics within the ATS
- ? To promote pediatric advocacy outside the ATS in the areas of patient care, basic and clinical research, and training—specifically addressing ATS's role in promoting respiratory health in the areas of preventive respiratory medicine, technology dependent children, transition to adult care, physician and patient education, providing input into important pediatric research agendas and addressing fellowship training issues and academic career paths for young academic pediatric faculty.

The Task Force process involved a general conference call mapping the strategy of the proposed work. The Task Force then divided into 9 Working Groups:

- 1) Neonatology: Denery, Bancalari, Leigh
- 2) Nursing: Horn, Allen, Miske, Kolb, Hickey
- 3) Critical care: Wheeler, Stenmark, Leigh, Lockett
- 4) Allergy: Leong, Lemanske, Ren
- 5) Clinical: Wheeler, Castile, Taussig, Allen
- 6) International: Sly, Sennhauser, Stein
- 7) Basic research: Haddad, Stenmark, Leigh, O'Brodovich
- 8) Clinical research: Castile, Allen, Taussig, Sly
- 9) Training/Career: Haddad, Stenmark, Taussig, Castile

Each Working Group produced a report that was then reviewed by the entire Task Force. The Chair then synthesized these reports into the current Report to the ATS Board of Directors, which was again reviewed by the entire Task Force. The Board will note certain recurring themes common to many of the working groups:

- ? The ATS has a unique opportunity to act as a “fulcrum,” or coordinating body for other organizations regarding pediatric respiratory issues. Examples of such organizations include The Cystic Fibrosis Foundation (CFF), The American College of Chest Physicians (ACCP), The American Board of Pediatrics (ABP), and The American Academy of Pediatrics (AAP) for clinical issues, and The National Institutes of Health (NIH), The Pediatric Academic Societies (PAS), and the European Respiratory Society (ERS) for research issues.

- ? Interactions between The Scientific Assembly on Pediatric and the other ATS Assemblies can in many cases be enhanced by increased pediatric representation on the Planning and Program Committees of other Assemblies. The Task Force notes that the ATS has been very responsive to promoting important pediatric issues when those issues are raised by the Pediatric Assembly
- ? Support for trainees is key to the continued growth and vibrancy of the Pediatric Assembly. Continued travel support for trainees to the International Conference, and coordination of support for trainees in disciplines related to pediatric respiratory science between the ATS, American Society of Pediatric Department Chairs (AMSPDC), and NIH will be crucial.

This document represents the product of the 2001-2002 work. The Task Force recommends continued follow up of these issues in subsequent years, and proposes the continuation of its work in conjunction with the Assembly on Pediatrics Planning Committee.

II. CLINICAL ISSUES AND PATIENT ADVOCACY

A. THE ROLE OF THE PEDIATRIC ASSEMBLY

Clinical Working Group: Wheeler, Castile, Taussig, and Allen

The Clinical task force divided its charge into two components: 1) Raising the visibility and activity of the Assembly on Pediatrics within the ATS, and improving interactions and

initiating joint projects with other ATS assemblies, and 2) defining the missions relevant to pediatrics that the ATS should be promoting in its advocacy role.

1) Intra ATS:

Background:

The Assembly needs to reach out to various interest groups within the Assembly: Nursing, Allergy, Critical Care and Neonatology will be the initial interest groups developed and reports from each of these subcommittees will be included in the final report of this task force. The same is true for the Assembly's international membership, and a subcommittee of this task force will address issues relevant to this community as well. Allied health professionals (respiratory therapists, social workers, nutritionist, psychologists) should be included in such efforts as well.

The Assembly realizes that a large attracting force of the ATS is its international conference, and that the single most effective way it can attract members from beyond the ATS to the ATS is by promoting an excellent program at the International Conference by presenting symposia, workshops, Sunrise Seminars, Meet the Professor Seminars, and postgraduate courses. Since the number of symposia allotted to an assembly are determined by the number of abstracts submitted from that Assembly rather than the number of primary or secondary members, it behooves members of the Assembly to be as active as possible in addressing the scientific aims of the Assembly and submitting their work for presentation at the ATS International Conference.

Recommendations: Increased Pediatric visibility within the ATS can be achieved by several means:

? Since Program slots are limited, the Program Committee Chair should play an active role in interacting with other Assemblies to propose and jointly sponsor symposia and workshops of mutual interest to both the Pediatric Assembly membership and other ATS assemblies. There should be direct interaction between the Program Chairs of the Pediatric Assembly and the Assembly on Clinical Problems, especially in helping the International Conference Committee in the development of Meet the Professor and Sunrise Seminars. The development of Postgraduate courses of interest to pediatricians should be brought to the attention of the Education Committee.

? Consideration should be given to a “Pediatric Track” analogous to the current “Critical Care Track” as a way of highlighting presentations of interest to pediatricians, pediatric nurses and pediatric allied health care workers. The recently introduced “Program at a Glance” card in Pediatrics is a good start, as are the Pediatric Chest Rounds and Pediatric Clinical Year in Review.

? The Assembly should support efforts to assess the attractiveness of Pediatric Pulmonology as a subspecialty, and recommend ways to enhance recruitment to our field. The Assembly should partner with other organizations, e.g., the ABP, ACCP, to accomplish these goals. One example of such an effort currently underway is the Assembly sponsored and ATS funded

Assembly Project assessing attitudes toward Pediatric Pulmonology as a subspecialty
(Geoffrey Kurland, Chair).

The Assembly notes and approves of the mailing to non- ATS physicians, nurses and allied health professionals invitations to the International Conference as a way of broadening our interest base.

2) *Extra ATS:*

Background:

The Assembly should be a voice of advocacy for pediatric lung health. To be effective, the Assembly should concentrate on two or three issues of need rather than run the risk of being too diffuse, thereby being less effective. Preventive medicine, socio-economic factors, infections in the developing world, inner city asthma, and tobacco cessation were all topics discussed worthy of advocacy. Many other groups are already focused on these issues and the ATS Assembly on Pediatrics should lend its expertise wherever appropriate to organizations such as the AAP, ACCP, ABP, Federation of Pediatric Organizations, Pediatric Subspecialty For a, etc.

Recommendations:

? Two areas the committee identified as ones in which the Pediatric Assembly should be the standard bearer are:

- ? Physician education in asthma education. Despite the dramatic advances in understanding of asthma pathogenesis and therapy, asthma morbidity is on the rise. Poor physician and patient understanding of the illness and its management is a major contributing cause. Development of an “educating the educators” program would play to the strengths of the ATS’s expertise in pediatric lung health, allergy and immunology, and environmental and behavioral science.
- ? Transition of care for patients with pediatric lung diseases. The pediatric origins of chronic obstructive lung disease extend back to intrauterine and early childhood factors. Many children with pediatric respiratory illness are growing into adults with COPD, yet the process of transition of their care to adult Pulmonologists remains neglected. Certain centers have developed formal transition programs, most notably in the care of patients with cystic fibrosis. Similar programs should be developed for patients with asthma, neuromuscular disorders, bronchopulmonary dysplasia and chronic respiratory failure/ technology dependence. The development of such programs would employ the expertise of diverse assemblies within ATS, e.g., Nursing, Behavioral Science and Clinical Problems and the Section on Pulmonary Rehabilitation. Evidence based pathways for disease specific clinical care bridging the pediatric and adult populations would be a goal that could be realized with the Assemblies on Clinical Problems and Nursing. The other end of the spectrum, the transition of infants with chronic lung disease from neonatal intensive care to home care by parents, pediatric pulmonologists, nurse practitioners and allied personnel, needs to be coordinated as well.

? The development of pediatric specific drug indications and RFAs for multi center clinical research studies aimed at improving pediatric lung health is addressed in the document of the working group on clinical research. Outcomes research and clinical epidemiological studies are needed for a wide range of pediatric lung disorders.

? Interaction with other organizations outside the ATS, coordination of efforts; Planning Committee to continue with representatives from ABP, AAP, CFF, ERS, ASCCM, ACCP, SPR; “Pediatric Public Advisory Roundtable”

B. PEDIATRIC CRITICAL CARE INTERESTS

Critical care Working Group: Leigh, Wheeler, Lockett, and Stenmark.

Background: The Pediatric Assembly has many members involved in critical care medicine, both clinically and in a research capacity. Historically, the Pediatric Assembly has not provided as diverse a program or a forum for topics in critical care medicine as might be desired. There has been, however, an expressed interest on the part of members of the Pediatric Assembly to have more pediatric critical care exposure at the ATS International Conference.

Pediatric critical care physicians are often more clinically oriented than other members of the Pediatric Assembly. Therefore, the level of scientific merit of the abstracts is not as strong, and usually there are less abstracts in pediatric critical care than in other areas of

pediatric respiratory medicine. This poses a problem for the determination of how much time should be allotted at the meeting to pediatric critical care issues. The task force felt that there should be adequate time for pediatric critical care at the ATS meetings, and that this could be achieved in a number of ways.

Recommendations:

? Symposia directed at pediatric critical care topics should include both basic and clinical aspects of the problem and would be well received by more members in the Pediatric Assembly. We would suggest a symposium yearly in pediatric critical care topics that would include both basic science and clinical issues.

? We would recommend there be a Pediatric Assembly member on the critical care planning committee and an integrated approach to the critical care topics through the critical care assembly. This would include a pediatric perspective in most of the critical care symposia, i.e., mechanical ventilation in ARDS, hemodynamic monitoring, controversies in critical care, sedation during mechanical ventilation, etc.

? Develop a post-graduate course for pediatric critical care at the ATS meeting. This would include both basic and clinical topics that would be of general interest to the Pediatric Assembly, and particularly to clinicians who care for children with critical illness.

? Encourage the Pediatric Assembly membership and the Critical Care Assembly membership to submit more pediatric oriented abstracts, thereby supporting a yearly poster session in pediatric critical care.

? Develop a web-based questionnaire to obtain input from Assembly members regarding topics to include the yearly ATS International Conference.

C. NEONATOLOGY INTERESTS

Neonatology Working Group: Dennery, Leigh, Bancalari

Background:

? Lung immaturity and neonatal respiratory diseases contribute to the majority of neonatal morbidity.

? Neonatal lung diseases frequently give origin to problems that persist through child and adulthood.

? Many neonatologists have special interest in respiratory physiology and diseases but their participation in ATS activities is limited and mainly restricted to those involved in basic research.

? There is very little interaction between neonatologists, pediatric pulmonologists, and adult pulmonologists. This applies to clinical activities, training and to interdisciplinary research.

? Although a very large portion of the clinical activities in neonatology is related to respiratory care, many neonatal training programs provide only limited formal training in lung development and respiratory physiology.

? There is a small amount of clinical research activities dealing with neonatal respiratory problems in comparison to the frequency and importance of these problems.

Recommendations:

? ATS should encourage increased participation of neonatologists with both basic and clinical research interest in ATS activities. This can be accomplished by improving communication and dissemination of information and by increasing the number of activities dealing with lung development and neonatal respiratory problems in the annual meetings. Preferably these sessions should be concentrated in one or two days.

? Neonatal fellows should be encouraged to present data at the ATS meeting. Providing travel support could be a way of increasing their participation.

? The establishment of dedicated sessions on neonatal clinical research at the ATS meeting could draw more participation of clinical neonatologists.

? Another way of increasing the participation of pediatricians and neonatologists in the ATS meeting would be to have the Pediatric Academic Societies (PAS) and ATS meetings in the same city and overlap at least one day to have joint sessions dealing with lung development and

neonatal and pediatric respiratory problems. This is something that cannot be accomplished in the next few years but could be implemented in the future if planned with sufficient time.

? Neonatologists working in specific areas of respiratory research should be encouraged to integrate into the different assemblies dealing with those specific areas.

? ATS and NIH should be encouraged to increase funding for research dealing with lung development, neonatal lung diseases, and specially interdisciplinary research that explores the consequences of neonatal lung disease in later life.

? ATS should encourage cross training of neonatal, pediatric, and adult pulmonary fellows on lung development and the long-term consequences of neonatal lung diseases. This would help facilitate transition programs.

D. ALLERGY/IMMUNOLOGY INTERESTS

Background: Pediatric allergists are able to participate in the activities of both the Assembly on Allergy and Immunology and the Assembly on Pediatrics; this can at times lead to uncertainty as to the most appropriate venue for their activities. Greater communication between the two Assemblies is desirable, especially with regard to a mutual interest in asthma care, research and teaching. Several goals are suggested:

- ? To promote and foster a greater communication between the Pediatrics and Allergy assemblies. Increased communication between allergy and pediatric assembly members should result in cross-fertilization in ideas, research, educational meetings, and projects

- ? To promote greater communication and collaboration in the research, clinical care and understanding of pediatric allergic pulmonary diseases, primarily but not confined to asthma, especially in terms of molecular mechanisms, developmental biology and age-related phenomena, natural history, epidemiology, and relationship to adult pulmonary disease.

- ? To develop and foster leadership and collaboration in pediatric asthma research and care, including practice and care delivery models, education methodology for patients and providers, asthma guideline implementation, treatment, and outcomes research. To develop an ongoing agenda of identification and study of basic and clinical science issues in pediatric asthma. Other assemblies that should be considered in this effort (or possibly Task Force) might include Behavioral Science, Nursing, and Clinical Problems

Recommendations:

- ? Schedule Business meetings of the ATS Assembly on Allergy and Immunology and Assembly on Pediatrics at different times (enacted this year).

- ? Consider formal reporting or communication between the two groups. This would be best achieved by pediatric positions on the Program and Planning Committees of the Assembly on Allergy and Immunology

- ? Encourage development of joint symposia, abstract sessions, post-graduate courses.

E. NURSING INTERESTS

Background: As a group that often interfaces most directly and time intensively with patients, the nursing profession brings a unique patient- oriented focus, drawing attention to issues affecting patients very directly, e.g. quality of life, multi- disciplinary care (physical therapy, respiratory therapy, occupational therapy/speech pathology/swallowing function, nutrition, social work). Pediatric nurses, Nurse Practitioners and Clinical Nurse Specialists, are a minority within the Nursing Assembly, and, like Allergists and Intensivists, Pediatric Nurses have a confusing and sometimes limited choice of venues for where to channel their ATS activities. The cost of membership in ATS sometimes impedes access to this group; furthermore, the cost of registration at the International Conference is greater for ATS members without a PhD than for non- members.

Recommendations:

Intra ATS:

- ? Nursing Assembly to consider a dedicated slot on its Program and Planning Committees for a member of the Pediatric Assembly

- ? Increased participation by Nurses on Pediatric Assembly postgraduate courses, especially those addressing clinical topics, with emphasis on bringing at least one speaker to address issues of importance and interest to nurses, including those outlined above.

- ? Address the issues regarding costs for non- PhD members attending the International Conference. Reducing these fees, along with the cost of ATS membership, might enhance revenues by increasing participation in the ATS by Pediatric Nurses Practitioners and Clinical Nurse Specialists

Extra ATS:

- ? Promote agenda of importance to the pediatric nursing community. Examples:
 - Development of a Pediatric Nursing Curriculum for Pediatric Pulmonology, topics to include, e.g., home technology including mechanical ventilation, tracheostomy care, communication devices, case management, disease pathophysiology and management, multihandicapped children with special needs, effects of aerosolized drugs on care- givers.

 - Effects of nursing shortage on options for homecare

- Preventative medicine topics for the community, e.g., CPR, choking, feeding techniques to prevent aspiration
- ? Raising funds to research areas of interest to the pediatric respiratory nursing community, e.g., quality of life, transition to adult care

F. INTERNATIONAL INTERESTS

International Working Group: Sly, Sennhauser, Stein

Background: The ATS seeks to fill the roll of an International Society but does not really serve the international pediatric pulmonary community. There are several ways in which this could be improved:

Recommendations:

- ? Meaningful international representation of ATS committees to represent the needs of the international pediatric pulmonary community (appointed by invitation, not elected by assembly members)
- ? Broaden the focus of the assembly outside the US borders
- ? Increase Trans-Atlantic task forces (between ATS and ERS), using the very successful Infant Lung Function Task Force as a model, in order to further elaborate the development of Guidelines, international standardization and quality

requirements for research purposes, for diagnostic assessment and therapeutic protocols (e.g. for orphan diseases)

? ASM

- The majority of the international community come to the ASM for the research issues not clinical ones
- US can learn from the experience, often greater, of other parts of the world, e.g. asthma treatment, infectious diseases, etc
- Include an international perspective on the management of common conditions

? True international perspective on pediatric pulmonology

- Hold an international pediatric pulmonary meeting every 3-4 years, sponsored by ATS/ERS in different parts of the world, e.g. South America, Asia/Pacific, Africa, Europe, USA.
- Meeting held in conjunction with the relevant national society, who help with organization

? Financial support for Collaborative Research Projects

- ? Grants through either governmental or non-governmental agencies (ATS to lobby for the availability of such funds and be involved in the assessment of projects)

? Special grants from Pharma via ATS

? Training

Background:

Most countries are facing issues with attracting trainees into pediatric pulmonology. An international focus, in which trainees are actively encouraged to train in more than one center, preferably in more than one country could help improve this.

Recommendations:

- ? Standardization of training requirements for pediatric pulmonary, with a common core curriculum +/- country specific units
- ? Cross-recognition of training
- ? Central funding for trainees to travel/train in other countries
- ? Central funding for trainees to attend the International meetings (ATS, ERS)

A similar scheme could be developed for fully trained professionals (consultants, Professors, etc) along the lines of funded sabbatical programs, short-term research exchanges, etc.

III. PROMOTION OF PEDIATRIC RESPIRATORY RESEARCH

A. CLINICAL RESEARCH

Clinical research Working group: Castile, Taussig, Allen, Sly,

A major goal of the Assembly should be to decrease childhood morbidity and mortality from respiratory disorders through clinical research. Currently, there is sub-optimal progress in translational research on pediatric respiratory diseases. The obvious imperative is the “move from bench to bedside”. What do we need to do to facilitate this process?

Facilitate multi-disciplinary interactions. Background: The intense focus of both basic and clinical scientists on their specific disciplines necessitated by the need to stay current and win funding has left little time for developing interactions. Programs which foster basic and clinical scientists coming together to share data and ideas with the intent of defining the necessary steps leading to clinical trials need to be developed. These forums should also include, when appropriate, pharmaceutical manufacturers, experts in experimental design and statistics and clinicians involved in developing evidenced based clinical management programs. They probably will need to have a specific disease or therapeutic focus.

Recommendation: Advocate for ATS, ALA, NIH and industry support of focused, multi-disciplinary conferences in childhood respiratory disorders.

Facilitate multi-center collaborations. Background: In order to collect data in a timely manner many clinical trials will need to be multi-center in their scope. The development of multi-center clinical trial networks needs to be fostered. Once these groups are functioning, it

will be cost effective to maintain and use them repeatedly until they achieve their intended therapeutic end points. Again they will probably need to be focused and disease specific.

Recommendation: Advocate for NIH (NHLBI, NICHD, NIAID, NINR) RFAs and other funding programs targeting key childhood respiratory questions with a focus on collaborative, multidisciplinary projects involving or clearly leading to clinical applications and proposals dealing with the origins of childhood respiratory disorders. Advocate for ATS, ALA, NIH and industry support for the establishment of focused standing working groups with specific goals related to the development of therapeutic trials in children with respiratory disorders. Advocate for support for the establishment of regional multi-disciplinary centers or excellence to support design, implementation and analysis of multi-center collaborative clinical trials in pediatric respiratory diseases. Ideally these would be consortiums of many centers in a region. Some consideration should be given to advocating for the introduction of incentives that will begin to shift the model for medical research from one of competition to one of cooperation and collaboration.

Facilitate the development of better clinical outcome measures for children with respiratory disorders. **Background:** Uniform, safe, objective clinical outcome measures that can be used across centers are essential to the efficient conduct of multi-center clinical trials.

Recommendation: Advocate for ATS, ALA, NIH and industry support for funding programs targeting the development of objective outcome measures for childhood respiratory disorders.

Facilitate interactions with industry (pharmaceutical and device manufacturers).

Background: Pharmaceutical companies have out of financial necessity taken the lead in bringing basic and clinical science together in the development and testing of new drugs. They do not however remain focused on improved treatments, cures, or prevention of the major respiratory disorders of childhood. They need to be incorporated into and financially supportive of the development of focused pediatric respiratory clinical trial networks. The issue of how to deal with conflicts of interest and the potential for bias when participating in industry sponsored clinical trials was raised.

Recommendation: Advocate for a committee within the ATS (if one does not already exist) to interact with industry for the purpose of setting up and supporting mutually beneficial clinical trial networks focused upon testing new therapies and products for specific childhood respiratory disorders.

Additional Issues

Background: The immediate and long-term clinical research priorities of the Pediatric Assembly need to be defined. Some of the areas of focus discussed included: **Focus upon disease prevention** by facilitating investigations designed to provide insight into the pathophysiological origins of respiratory diseases in infancy and early childhood and development of methods to identify infants and children at high risk for chronic disease. **Focus upon providing the data needed to develop evidenced based management programs** for the respiratory disorders of childhood. Clinical researchers need to work with pulmonary clinicians involved in the development of disease specific clinical pathways to define the key management issues requiring experimental data. **Focus upon specific diseases and/or processes** (asthma, BPD, CF, RSV bronchiolitis, pneumonia, sleep disorders, “orphan” lung disorders, ILD...). Areas of clinical research focus could also be processes such as transition to adult care, smoking prevention or outcome assessment. Overall there was agreement that decisions need to be made regarding the focus or focuses of clinical research. The assembly should be proactive and united in efforts to guide future clinical research.

Recommendation: The Long Range Planning Committee of the Pediatric Assembly should develop a working document defining the key clinical research initiatives required to improve pediatric respiratory healthcare over the next 10 years. The document should not only specify which areas are of greatest importance to the assembly but also recommend mechanisms for implementation. This may require the creation of a sub-committee, drawing upon the expertise of clinicians and basic and clinical investigators. This document should be integrated into overall

Statement on ATS Research Priorities, emphasizing the pivotal role that early detection and treatment of respiratory disorders plays in preventing pulmonary morbidity in adults. This document should be shared with the full Pediatric Assembly with the intention of incorporating the thoughts and opinions of the membership prior to approval. The purpose of this statement will be to make clear the clinical research mission of the assembly and provide a written consensus opinion to be utilized to advocate within the ATS and with the NIH and other funding agencies. The current Pediatric Assembly representatives to the ATS Research Advisory Committee and the ATS Scientific Advisory Committee (Drs. Julian Allen and Gary Larsen, respectively) should play leading roles in the development of this initiative and should advocate for continuous Pediatric Assembly representation on these two ATS Committees.

Impact of Regulatory Issues on the Implementation of Pediatric Clinical Trials.

Background: Although the president has recently signed new legislation encouraging therapeutic trials in children (Best Pharmaceuticals for Children Act, 1-4-02), more stringent regulations on human experimentation, particularly in children, may further limit implementation of such trials. Tighter regulations may make it more difficult to conduct pediatric clinical trials with greater than minimal risk (where minimal risk is defined as presenting no increase in risk over those of daily life) and make trials requiring normal children as controls almost impossible to carry out. These changes in IRB regulations appear to be at odds with federal mandates for increased clinical trials in children. In addition, a clear distinction needs to be made between expert and evidence based clinical practice guidelines. Expert guidelines are frequently being used by IRBs to define minimal limits of therapy, thereby preventing the inclusion of

appropriate control groups in studies designed to test the validity of those same guidelines.

Excessive reliance on expert opinions should not impede the collection of the objective information required to transition from expert to evidence based guidelines. The complexities of and the lack of familiarity of investigators with FDA procedures may also impede the implementation of pediatric clinical trials.

Recommendation: The above issues are complex and represent potential impediments to rapid progress not only in the area of respiratory diseases but rather in all aspects of pediatric clinical research. The Pediatric Assembly should investigate these issues in conjunction with the APS and the SPR with the goal of developing national policies that both insure the safety of children participating in clinical trials and permit the timely collection of the information that will lead to improved clinical management of those children.

Training of more academic pediatric pulmonary clinician scientists. Background: This is a key issue but is being addressed by a separate subcommittee. Data needs to be acquired from all pediatric residents regarding why they have made the career choices that they have made. Why are some sub-specialties more popular than others? We might also, however, want to consider ways to enhance clinical research manpower by exploring ways to involve as many current clinicians (e.g., pediatricians as well as pulmonologists) as possible in trials. Limited numbers of clinicians can or want to organize and direct clinical trials but many clinicians want to contribute. Pharmaceutical companies and the CFF/TDN routinely design trials that incorporate the efforts of substantial numbers of our membership even though the “rewards” for participation have, for the most part, been less than optimal in many of these trials.

Recommendation: We agree that the assembly should collect pertinent data regarding career choices and advocate for additional support for the training of pediatric pulmonary clinician scientists. In addition efforts should be made to promote the design of multi-center clinical trials that facilitate participation by maximal numbers of current sub-specialists. Participation in clinical trials should be adequately compensated financially and/or academically. Definition by the assembly of clear immediate and long-term clinical research goals might serve to galvanize the efforts of the current membership and also help to attract new zealots to the cause.

B. BASIC RESEARCH

Working Group: Stenmark, Haadad, O’Brodivich, Leigh

Background:

A major problem in pediatric respiratory medicine is the lack of basic researchers who can compete at a national level and who can train a new generation in basic research. In the absence of such individuals, understanding the basic mechanisms of pediatric lung disease will lag behind. In order to make progress in understanding the many disorders that affect the lung and respiratory system of the developing child, it will be crucial to develop both basic science in pediatric pulmonology and the researchers who do the investigations.

Recommendations:

? The group felt that we can develop a strong rationale for ATS to cosponsor, a slot of the PSDP (Pediatric Scientist Development Program, sponsored by AMSPDC, American Society of Pediatric Department Chairs) every year for a first rate Pediatric Pulmonologist who wishes

to be a clinician/scientist and is at the transition between residency and fellowship. The rationale is based on 3 major issues: i) There has been only 2 individuals who have been on this Program since 1987. ii) There is a paucity of clinicians/scientists in this area. iii) There is an opportunity for such individuals to make a major impact on the care of children in general since there are many pediatric lung diseases that have not been well studied and whose underlying pathophysiology and basic science is not known. The Task Force realizes that for such an ATS cosponsorship to occur, funds will need to be raised , perhaps with the assistance of industry.

? To encourage the ATS to be an advocate for Pediatric lung diseases and for increased funding in this area at the NIH level. Since there are many pediatricians in several ATS assemblies (who are not necessarily in the Pediatric Assembly), it would be important for the pediatricians in these various assemblies to highlight the pediatric components in these assemblies and for the chair of the Pediatric Assembly to seek help from the chairs of other Assemblies to get the Pediatric agenda much more visibility to the ATS leadership.

? More representation and increase visibility on the ATS Scientific Advisory Committee.

? Make a case at the ATS level to increase funding for pediatric or developmental lung problems and diseases.

? Encourage at the NIH level institutional Training Grants that encompass both pediatric and adult pulmonary training programs to have cross-fertilization with adult colleagues as well as basic scientists.

? Encourage additional RFA or SCOR grants by the NIH on pediatric lung diseases.

IV. TRAINING AND CAREERS

Working Group: Haddad, Taussig, Stenmark,

Background: The group agreed that a major issue faced by the Pediatric Pulmonary Community (both in the United States and perhaps around the world) is the fact that there is a paucity of individuals who are choosing Pediatric Pulmonary Medicine as a subspecialty and further who are intending to focus on long term academic careers. The group agreed that a major focus of the ATS, as well as other academic pediatric societies, should be to develop strategies that will first generate an interest in Pediatric Pulmonology. Subsequently, we should develop better training programs that will teach individuals to ultimately assume the responsibility moving the field of Pediatric Pulmonology forward.

Recommendations:

? The group agreed that better information should be obtained regarding what medical students, and in particular, Pediatric Residents like and do not like about Pediatric Pulmonology. It was felt that the ATS could develop a survey that could be transmitted through Pediatric Pulmonary division heads at institutions throughout the United States to survey those students and residents rotating through Pediatric Pulmonology. This would help define what the critical issues for residents in training are. It was agreed that careful work

would have to go into designing this survey as well as ensuring its dissemination among Pediatric Pulmonary programs around the country.

? The group agreed that it would be a good idea to encourage an increase in the number of Institutional Training Grants. These institutional training grants can provide a visible focal point around which issues in Pediatric Pulmonary Medicine and developmental lung biology can be discussed. They can be used as models to stimulate and encourage the best medical students and residents to go into a subspecialty program where they know funding for basic and clinical sciences will exist.

? It was agreed that, whenever possible, the institutions which receive training grants make an additional commitment for a fourth year of training for fellows interested in an academic careers. This could be additional training in either the clinical or basic sciences. It was agreed that this year of training, perhaps with a level of pay which is greater than that which exists for the first three years, will encourage students to take the time to get the training that is necessary for a successful academic career.

? It was agreed that the Pediatric Pulmonary community needs to take a closer look at itself. Perhaps there needs to be a rethinking of the educational policies and programs that are utilized to train pediatric pulmonologists. It was agreed that there are some model programs that are being developed around the country, which all programs should be encouraged to look at. One, for example, is the Clinical Scholars Program that exists at the University of Colorado Health Sciences Center as well as in other institutions around the country. In programs such as

this, advanced degrees, either Masters or PhD's in a clinical sciences can be obtained during a fellowship. These programs appear well equipped to turn out individuals who would be very competitive for funding awards through the National Institutes of Health, either at the KO8 or K23 level.

? It was agreed that in all areas of Pediatric Pulmonary Medicine, that an eye toward investment in the future needs to be taken. One idea was to get the American Thoracic Society and the Cystic Fibrosis Foundation and perhaps other agencies to sponsor a trip to the annual American Thoracic Society Meeting for Pediatric Residents who are unsure of their future careers. This sponsorship would only occur if a mentor at the student or residents institution agreed to take and supervise them at the meeting. The idea would be to encourage or stimulate interest in Pediatric Pulmonology through seeing some of the new developments that are occurring in Pediatric Pulmonary Medicine and meeting some of the investigators responsible for these ideas.

V. EXECUTIVE SUMMARY OF TASK FORCE RECOMMENDATIONS

Priorities are assigned as follows:

Priority 1: Suggested immediate implementation

Priority 2: Longer time frame for implementation (over next year)

? Promote research advancing pediatric respiratory health

- The Planning Committee of the Pediatric Assembly should develop a working document within the next 6 months defining the key research initiatives required to improve pediatric respiratory healthcare over the next 10 years (Priority 1).

- ? ATS to initiate active fundraising campaign with ALA, and possibly with assistance of a “Pediatric Public Advisory Roundtable” to promote pediatric respiratory clinical research initiatives, as determined by Assembly Planning Committee (Priority 2).

- ATS to act as focal point by coordinating efforts of NHLBI and NICHD in developing SCOR grants for basic and translational research in pediatric respiratory medicine and RFAs for multicenter clinical trials. We suggest that ATS sponsor a multidisciplinary conference in March, 2003, including members of ATS, NHLBI and pharmaceutical industry to develop these mechanisms for increased funding for identified priority areas for pediatric respiratory medicine (Priority 1).

- ? Promote programs advancing pediatric respiratory health
 - “Educating the educators ” program for asthma education (Priority 2).
 - Programs for transition to adult care for patients with pediatric respiratory disease (Priority 2).

? Education and Training

- Promote international interactions in pediatric pulmonology by means of a Pediatric Pulmonary meeting every 3-4 years sponsored by ATS/ERS in different parts of the world, and by promoting international Fellowship Training opportunities (Priority 2).
- Cosponsor with AMSPDC a slot of the PSDP Program every year for a first rate Pediatric Pulmonologist who wishes to be a clinician/scientist and is at the transition between residency and fellowship (Priority 2).
- Encourage at the NIH level Institutional Training Grants by the T32 mechanism that encompass both pediatric and adult pulmonary training programs to have cross-fertilization with adult colleagues as well as basic scientists (Priority 1).
- Obtain, in conjunction with the American Board of Pediatrics, information on why residents do or do not choose pediatric pulmonology as a field, with ultimate goal to attract more trainees (Priority 1).

? Promote increased pediatric awareness within ATS and pediatric visibility at the International Conference

- Pediatric Assembly representative, (name to be suggested by Program Committee Chair), to sit on Program Committees of Assemblies on Clinical Problems, Allergy Immunology and Inflammation, Critical Care, Behavioural Science, Respiratory Neurobiology and Sleep and Nursing. (Priority 1)
- Pediatric Assembly representative (name to be suggested by Assembly Chair) on the Critical Care Assembly and Nursing Assembly Planning Committees (Priority 1)
- Pediatric Assembly member on Scientific Advisory Council and Research Advocacy Committee (Priority 1)
- “Pediatric Track,” including Neonatology and Pediatric Critical Care at International Conference (Priority 2)

VI. CONCLUSIONS

The Pediatric Assembly is at the threshold of an exciting time in its development. It has emerged as the premier national (and a major international) force for the coordination of efforts to improve pediatric respiratory health through excellence in patient care, patient education, physician training, and basic and clinical research. Within the ATS, the Assembly shares

interests all of the other ATS Assemblies through its interest in developmental aspects of respiratory health and disease, and through the realization that many of the precursors of adult respiratory disease start in childhood. Members of the Assembly are more often than not active members of other ATS Assemblies as well. External to the ATS, the Assembly is in a unique position to fulfill its mission of improving pediatric respiratory health by serving as a fulcrum, coordinating many of the efforts of other organizations, including the American Board of Pediatrics, the American Academy of Pediatrics, The Society for Pediatric Research, The Cystic Fibrosis Foundation, The American College of Chest Physicians, The Society for Critical Care Medicine, and The European Respiratory Society. Recognition and support of the key roles played by the Pediatric Assembly both outside the ATS, as well as in, will allow it to develop its mission to its fullest potential.