RESPIRATORY SYNCYTIAL VIRUS AND AFRICAN AMERICANS

A Peer-Reviewed Consensus Panel Paper

National Medical Association

THE NATIONAL MEDICAL ASSOCIATION RSV CONSENSUS PANEL

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EXECUTIVE SUMMARY

Introduction and Overview

Respiratory Syncytial Virus (RSV) is a member of the paramyxovirus family.[28] This is the same family of viruses that includes other childhood illnesses for which effective vaccines have been developed. Respiratory Syncytial Virus is a member of the subfamily pneumovirinae. Respiratory Syncytial Virus's name is derived from the fact that when grown in a cell culture, it is manifested as a syncytia, a multi-nucleated mass of cytoplasm that is not separated into individual cells.

Background and Epidemiology

While several viruses may be associated with respiratory infections, respiratory syncytial virus, also known as RSV, distinguishes itself by being singularly responsible for the annual hospitalization of up to 125,000[7 8] infants and roughly 177,000 persons age 65 and over.[9] RSV also leads to an estimated 14,000 annual deaths in the United States alone.[10] Worldwide, RSV-related deaths are even greater. Indeed, Zlateva et al. (2005)[11] describe HRSV (human respiratory syncytial virus) as "…the most important cause of acute respiratory disease in infants." Moreover, Bourgeois et al. (2009)[12], in a study of the prevalence and impact of human respiratory syncytial viruses, found that while the public is most familiar with influenza as an acute health problem, RSV actually impacts human health more than influenza infections. Analyzing data for the winters of 2003, 2004, and 2005, these investigators discovered that RSV generated 21.5 visits to the emergency departments (ED) of hospitals per 1,000 children relative to only 10.2 visits per 1,000 children for influenza. Thus, RSV led to 110 percent more ED visits than were attributed to influenza. For children in the age group 0 to 23 months, the rate of ED visits for RSV was even higher— 64.4 visits per 1,000 children.

The aggregate impact of RSV relative to influenza is also observable through other data cited in this study. Specifically, RSV resulted in 8.5 hospitalizations per 1,000 children during this time period. In contrast, the national hospitalization rate for influenza was 1.4 per 1,000 children. Such data suggests that a child was 507.14 percent more likely to have been hospitalized for RSV than for influenza. Similarly, the researchers found that parents and/or other caregivers of young children in the study missed 716,404 days of work as a result of caring for children infected with RSV. Yet, only 246,965 days of work were missed due to influenza-related care. Thus, RSV led to 190 percent more missed workdays by caregivers than did influenza.

Given such findings, it is highly significant that many parents and some primary care physicians are unfamiliar with RSV infections and, as a result, may be unable to properly prevent, diagnose, and/or treat this disease. Thus, National Medical Association (NMA) and the National Black Nurses Association (NBNA) convened a Consensus Panel to define the key needs in the area of RSV on May 20, 2010 in Washington, DC.

Causatively associated with factors such as premature birth[14], congenital lung disease or heart disease[15], low birthweight[16], higher density living conditions that include the presence of older brother and sisters[17], attendance in day care[18], a family history of asthma[19], the presence of tobacco smoke[20], and multiple births[21], some evidence suggests that African Americans and other minorities may be at greater risk for contracting RSV infections. Moreover, if such disparities do exist, they may be aggravated by recent changes in the 2009 American Academy of Pediatrics, Red Book 2009 Report of the Committee on Infectious Diseases. Despite the FDA-approved treatment of five dosages of immunoprophylaxis for all premature babies, this document reduced the recommended dosages of this preventive measure to three doses for certain less-than-term infants. Such a recommendation may have the unintended consequence of increasing health disparities in the African American community.

The NMA and its partner, the NBNA, convened a Consensus Panel to review the issue of RSV with respect to the impact on African Americans and other minorities. This group of experts addressed several key queries:

- What is the prevalence and incidence of RSV among African Americans and other minorities and what are the needs in this area?
- What key epidemiological issues surround RSV and African Americans and other minorities?
- Are there unique approaches to preventing and/or treating RSV among African Americans and other minorities?
- What evidence supports the reduction in immunoprophlyaxis from five (5) to three (3) dosages for certain categories of premature infants?

Findings and Recommendations

The RSV Consensus Panel included twenty experts who provided knowledge and expertise on various research and policy issues related to RSV. This panel has provided a scientific and comprehensive paper that makes policy recommendations to the NMA Board of Trustees regarding RSV. Key findings from this report are described below.

FINDING #1: While researchers have argued that RSV is a more prevalent viral infection than influenza, accurate and well-defined data on the prevalence of RSV are unavailable.

The United States Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), tracks the prevalence of RSV through the National Respiratory and Enteric Virus Surveillance System (NREVSS). However, the data are far from complete. This is because the universe for NREVSS data collection is limited to laboratories that perform RSV testings and also participate in NREVSS tracking. Data gathered through NREVSS may possibly under-represent the incidence of RSV for several reasons:

- First, not all laboratories report RSV data.
- Second, data reported are only for detection that occurred in laboratories. Many physicians, however, do not screen for RSV unless patients are hospitalized.
- Third, even within the subgroup of laboratories that participate in surveillance, only screenings that occurred utilizing antigen detection tests at these labs are reported. The CDC, Morbidity and Mortality Weekly Report of March 5, 2010, states that, "For consistency, only antigen detection tests, which were used by 97 percent of participating laboratories during 2008-2009, were included in the analysis."
- Fourth, the data collected are not used to track health disparities.

FINDING #2: The RSV season has the greatest duration – 23 days – in Region 4 – an area that includes disproportionately high percentages of African Americans in the population.

The length of the RSV season is a risk factor. Utilizing data from the Centers for Disease Control and Prevention NREVSS database, the Consensus Panel noted that African Americans are heavily concentrated in those states which have the longest RSV seasons. These states include: Alabama, Georgia, Mississippi, North Carolina and South Carolina.

FINDING #3: There is a need for physicians to ensure early detection of RSV so that appropriate management can be instituted.

Defined as a contagious acute infection of the respiratory tract, RSV is the etiologic agent for bronchiolitis as well as pneumonia in infants, children, the elderly, and persons with selected chronic diseases. In addition to airway inflammation, observable symptoms in infants generally include wheeze and cough. However, in seeking to detect RSV, it is important to remember that RSV is not the only virus that can cause bronchiolitis.

When RSV infection results in bronchiolitis, it can be diagnosed in several ways. When x-rays are used, for example, RSV presents as a diffuse inflation pattern throughout the lungs with areas of consolidation. While chest x-rays can reveal some signs, particularly when bronchiolitis is present, radiographic screenings for RSV may reveal findings that resemble pneumonia and/or which are, indeed, symptoms of pneumonia.

FINDING #4: Physicians are unable to utilize clinical findings alone as a basis for the differentiation of the etiology of viral respiratory tract infections.

Viral culture, an approach that will generally not provide results until after the illness symptoms have abated because results occur over three to seven days, remains the gold standard for diagnosis. The shell vial method, which involves centrifugation of the specimen onto a cell monolayer in a vial in order to decrease the time to a positive culture result, has also been used. This method requires one to three days for a positive result. However, rapid diagnostic procedures can also be used to detect viral antigens. These detection processes utilize nasal and/or other respiratory secretions. Rapid RSV tests are important since reports based on tissue culture will be generated too late to impact treatment. A broad range of laboratory tests are now available that can definitively diagnose RSV with a sensitivity of approximately 80 to 90 percent and a specificity that averages 90 to 95 percent.

FINDING #5: In the absence of an RSV vaccine, however, RSV prevention primarily involves several steps: 1) Tracking the duration of the season when RSV infections occur most frequently; 2) Avoiding contact with individuals suspected or confirmed as having RSV infection; and 3) Reducing the spread of the illness by educating parents regarding the importance of sanitizing hands through regular hand-washing and/or by utilizing antiseptic cleansing agents. Finally, for children who are already hospitalized, isolation is required to prevent nosocomial transmission of the virus.

Research also indicates that hospitalizations as a result of RSV bronchiolitis can be reduced. One highly critical strategy involves the administration of palivizumab over a period during the RSV season to protect at-risk infants. Importantly, this agent must be used before the RSV season activity begins.

FINDING #6: Palivizumab is considered as an effective prophylaxis because its clinical trials resulted in an overall reduction in hospitalization by 43 percent in the intervention group.

The IMpact RSV trial subsequently demonstrated a 39 percent reduction in the hospitalization of preterm infants with chronic lung disease (CLD) and a 78 percent reduction in hospitalization among those without CLD.[37] In infants born between 32 and 35 weeks, there was an 80 percent reduction overall in RSV-related hospitalization.[38] Equally impressive, premature infants without chronic lung disease experienced an 82 percent decrease in hospitalization rates. This finding revealed that not only babies who have chronic lung disease, but even healthy preterm babies, can benefit from this prophylaxis.

Palivizumab was first made available commercially in 1998. The American Academy of Pediatrics Committee of Infectious Disease (AAP/COID) first made recommendations regarding its use in 1997. The 2003 Red Book made only minor changes as revealed by a comparison of the two sets of guidelines.[39] The community of pediatricians and neonatologists accepted these recommendations as evidence-based guidelines. The 2009 Committee on Infectious Disease Guidelines departed significantly from previous recommendations. These guidelines incorporated changes that reduced the recommended administration of palivizumab from five (5) months to as few as one (1) month for certain at-risk babies. For very preterm infants, the guidelines remained relatively the same. Recommended dosing, however, was limited to three or fewer months as opposed to the traditional FDA-approved five-month period for palivizumab use for certain categories of preterm babies. The traditional five-month period was the Food and Drug Administration (FDA)-approved guideline for palivizumab use.

In addition to the change in dosing, the 2009 Red Book Guidelines introduced a change in language that may affect treatment outcomes. Input from pediatric groups and parents indicated that use of the term “near term” for those infants with a gestational age of 32 to 35-6/7 weeks in the 2009 Red Book Guidelines can also affect how they are treated for RSV under the new guidelines.

Both parents and the pediatric community have questioned the alterations in the 2009 Red Book Guidelines[40] for RSV based on the fact that no supportive research is provided for these changes. Indeed, the National Perinatal Association recently concluded that the recommendation regarding a reduced dosage is inconsistent with current evidence. Thus, implementation of these guidelines may result in inadequate protection for at-risk infants.

Other areas of change in the 2009 Redbook Guidelines have also raised questions. For example, as currently written, the new guidelines may only allow some babies to receive one dose of palivizuma before the start of the season. Such children would not, have adequate prophylaxis throughout the duration of that RSV season. Yet, in patients with chronic lung disease or BPD and premature infants born at less than 36 weeks gestational age, prophylaxis decreased hospitalization rates by 55 percent. In the subgroup of patients born between 32 and 35 weeks gestation, hospitalization rates decreased by 80 percent.

The efficacy of this prophylaxis is actually greater in well preterm babies as measured by decreased RSV hospitalization rates. The 2009 Guidelines are less reliant upon palivizumab as an agent of prevention in high-risk infants and children. However, because of the absence of an evidence base for the alteration in dosage levels, the Consensus Panel recommends that these guidelines be revised.

FINDING #7: Multiple factors appear to place children worldwide at risk of RSV.

Many of the factors that place children at risk of RSV are disproportionately present in African American communities. Therefore, African Americans may be disparately affected by the change in RSV treatment guidelines.

- **PREMATURE BIRTH AND LOW BIRTHWEIGHT**

  Premature birth and low birthweight are risk factors for RSV. Data from the National Center for Health Statistics reveals that African American babies are over-represented among preterm and low birthweight babies.

  For example, the State of Florida has the longest RSV season in the United States (30 weeks). Yet, within the State of Florida, African American premature infants are at greatest risk of RSV because of an earlier gestational age at birth. Based upon such disparities, the 2009 Red Book modifications regarding recommended dosages may have a disproportionate impact upon African American infants. Several factors support the formulation of such an hypothesis.

- **BREASTFEEDING**

  Bulkow et al. (2002)[69], in an analysis of RSV risk factors, found that breastfeeding reduced the risks of RSV hospitalization among Alaska Native infants. Both the U.S. Department of Health and Human Services[70] and the American Academy of Pediatrics[71] recommend breastfeeding as a protective factor among children and youth in the United States. Yet, data on breastfeeding behaviors suggest that African American women are less likely to breastfeed their newborns and infants.[72] Even when they do breastfeed, African American women do so for shorter periods of time.

- **OVERCROWDING**

  Bulkow et al. (2002)[69]also identified household crowding as a risk factor for RSV-related hospitalizations. Survey data from 2005 that was analyzed by ICF International reveal that overcrowding is more probable in African American households than among their Caucasian counterparts.

- **ASTHMA**

  While findings regarding the relationship between asthma and RSV are not definitive, some research suggests a correlation. For example, Lee et al. (2007)[75] sought to clarify the relationship between RSV and asthma by analyzing data from 455 infants with a parent and/or sibling who had asthma. Children with RSV as well as other respiratory infections were more likely to experience wheezing and other symptoms that signaled the presence of asthma.

- **ENVIRONMENTAL FACTORS**

  Research by Karr et al. (2009)[81] also reveals that air pollutants are causally related to bronchiolitis, a condition which can lead to hospitalization for RSV. Thus, the disproportionately poor air quality in many African American communities also suggests that African American infants and children may be at greater risk of hospitalization for RSV.

- **OTHER FACTORS**

  Other factors may also affect the odds of African American children contracting RSV. Among these factors are: enrollment in day care of the child and/or a sibling; tobacco smoke; a compromised immune systems and/or the existence of HIV/AIDS in the child.

Priority Recommendations

Based upon the previous referenced findings, the following Priority Recommendations were made by the Consensus Panel.

PRIORITY RECOMMENDATION 1: The Consensus Panel recommends that evidence be provided by AAP/COID regarding the change in clinical guidelines regarding dosage. The Consensus Panel also proposed that additional research and/or empirical evidence be established and disseminated to support the current clinical recommendations regarding the number of doses of immunoprophylaxis that should be given.

The Consensus Panel specifically recommends that more research is needed to confirm when fewer doses will achieve the same effect as a full season of prophylaxis. The research should also more explicitly provide evidence regarding the point at which eligibility can be best ended. This evidence must conclusively demonstrate the terms that should determine when immuno-prophylaxis should or should not be used.

PRIORITY RECOMMENDATION 2: In order to improve the accuracy of RSV prevalence data, the Consensus Panel recommends that the Centers for Disease Control and Prevention make RSV a reportable disease.

As is known, reportable disease status confers a number of advantages in addressing key issues. A reportable disease is defined as a condition or disease that is usually contagious and/or serious that must be reported to federal, state, or local health entities in order to track patterns of progression. National notifiable or reportable diseases identified by the CDC for 2010 include: active tuberculosis, viral hepatitis, syphilis, gonorrhea, AIDS/HIV, cholera, influenza-associated pediatric mortality, malaria, measles, pertussis, rubella, small pox, tetanus, yellow fever and many others. National non-contagious diseases are also reported. For 2010, the CDC has identified cancer, elevated blood lead levels, pesticide-related illness, silicosis and waterborne disease as reportable diseases.

RSV does not currently have reportable disease status. Each state's list of reportable diseases differs since the reporting of these diseases is mandated by state laws or regulations. Ultimately, the CDC and the Council of State and Territorial Epidemiologists (CSTE) will determine which diseases are listed and which may be removed due to a decline in incidence. The state public health departments also work with the CDC to identify national reportable diseases.

The Consensus Panel recommends that state health departments be made aware of the seriousness of RSV and add it to the notifiable disease state lists. The Consensus Panel also suggests that State Public Health Departments be included as partners in urging the CDC to monitor the prevalence and incidence of RSV for inclusion on the national registry of reportable diseases.

PRIORITY RECOMMENDATION 3: The Consensus Panel recommends that research be completed to assess the role that "tiers of care" may play in reducing access to this highly critical immunoprophylaxis on a state-by-state basis.

One of the problems with the current RSV prophylaxis guidelines is that they create tiers of care. These tiers of care vary depending upon the individual health maintenance organizations and health insurance entities in general, as well as public and private insurers. Moreover, in some states, practice guidelines regarding RSV prophylaxis differ among private and public insurers. In this regard, a state-by-state analysis of current guidelines is needed to determine which guidelines can create disparities in the provision of RSV care.

These two-tier systems do not merely apply to the insured and the uninsured. Even within the insured population, a dichotomous effect is observable. The Consensus Panel recommends that a case study be completed regarding the introduction and institutionalization of polyclonal pneumococcal vaccine. The case study will identify groups that were excluded based on financial decisions. The information can then be used to ensure that such exclusions are not replicated in terms of the RSV prophylaxis in any state.

PRIORITY RECOMMENDATION 4: The Consensus Panel recommends that persons knowledgeable about RSV participate in the current ICD-10 coding discussions in order to minimize the risk of RSV miscoding.

Even with the use of the physician training on RSV recommended by the Consensus Panel, coding problems may emerge. ICD-9 coding is woefully inadequate in terms of actually identifying that an RSV diagnosis has been made. Indeed, many newer therapies have not been included in ICD-9 because it utilizes an historical basis for code assignment. However, the revised coding ICD-10 is currently being completed. The committee charged with this task is seeking to identify some of the more common constraints of ICD-9. Thus, the Committee will welcome input regarding RSV. Incorrect coding will, of course, obscure the severity of the problem.

Summary

In addition to the four priority recommendations above, the RSV Consensus Panel made an additional twenty recommendations. These recommendations encompassed the areas of RSV detection and surveillance, research, prevention and treatment, education and training, and advocacy.

A continuing theme throughout the multiple recommendations is that RSV threatens the health of premature infants and that clinical guidelines should reflect the appropriate FDA-approved immunoprophylaxis treatment for premature babies during the RSV season.

The National Medical Association supports all of the Consensus Panel's recommendations as requirements to identify and remediate RSV-related disparities.

RESPIRATORY SYNCYTIAL VIRUS AND AFRICAN AMERICANS

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Introduction and Overview

A multiplicity of antigenically distinct viruses is associated with infections of the upper and lower respiratory tracts. Collectively, the illnesses that result from these viruses result in the greatest numbers of absences from work, school, and/or other productive activities than any other acute medical condition. Known by a variety of genus names - picornaviruses, myxoviruses, para-influenza viruses — the so-called "common cold" and other localized mucous membrane infections are the result of viral respiratory infections.

Research by the National Institute of Allergy and Infectious Diseases indicates that people in the United States contract approximately one (1) billion common colds per year.[1] Adults suffer from approximately two to four common colds per year and children have six to ten colds per year. [2] It is estimated that the common cold is the reason for 22 million missed school days in the country.[3] However, individuals can also suffer from high fevers, coughs and other symptoms as a result of influenza virus infection. Others may suffer from temporary incapacitation as a result of lower respiratory disease, exudative and nonexudative pharyngitis, and other symptoms due to infection by other viruses.

The economic costs associated with communicable respiratory infections were approximately $13 billion for the year 2008.[4] For some segments of Americans, however, the costs of such infections extended beyond the realm of the financial. In 2009, the Centers for Disease Control and Prevention (CDC) re-estimated annual deaths from influenza in the United States and determined that approximately 36,171 persons lost their lives due to this acute condition.[5] In 2006, the last year for which data are available, approximately 55,000 persons died as a result of viral pneumonia. Deaths also resulted from other non-influenza acute respiratory diseases.[6] While all Americans are at risk, infants and young children, and adults made frail by age or intercurrent disease, are at higher risk of severe illness and/or death from viral infections that result in lower respiratory tract diseases.

While several viruses may be associated with respiratory infections, respiratory syncytial virus, also known as RSV, distinguishes itself by being singularly responsible for the annual hospitalization of up to 125,000 infants[7] [8] and roughly 177,000 persons age 65 and over.[9] RSV also led to an estimated 14,000 annual deaths in the United States alone.[10] Worldwide, RSV-related deaths are even greater. Indeed, Zlateva et al. (2005)[11] describe HRSV (human respiratory syncytial virus) as "…the most important cause of acute respiratory disease in infants."

Moreover, Bourgeois et al. (2009)[12], in a study of the prevalence and impact of human respiratory syncytial viruses, found that while the public is most familiar with influenza as an acute health problem, RSV actually impacts human health more than influenza infections. Analyzing data for the winters in 2003, 2004, and 2005, these investigators discovered that RSV generated 21.5 visits to the emergency departments (ED) of hospitals per 1,000 children relative to only 10.2 visits per 1,000 children for influenza. Thus, RSV led to 110 percent more ED visits than were attributed to influenza. For children in the age group 0 to 23 months, the rate of ED visits was 64.4 visits per 1,000 children.

The aggregate impact of RSV relative to influenza is also observable through other data cited in this study. Specifically, RSV resulted in 8.5 hospitalizations per 1,000 children during this time period. In contrast, the national hospitalization rate for influenza was 1.4 per 1,000 children. Such data suggest that a child was 507.14 percent more likely to have been hospitalized for RSV than for influenza. Similarly, the researchers found that parents and/or other caregivers of young children in the study missed 716,404 days of work as a result of caring for children infected with RSV. Yet, only 246,965 days of work were missed due to influenza-related care. Thus, RSV led to 190 percent more missed workdays by caregivers than did influenza. A poster abstract report by Forbes et al.[13] estimated that the mean cost of RSV hospitalizations equals $9,014 for full-term infants (n = 1,983), $13,876 for infants born at less than 33 weeks gestational age (n = 46), and $18,403 for infants born at 33 to 36 weeks gestational age (n = 149).

Given such findings, it is highly significant that many parents and some primary care physicians are unfamiliar with RSV infections and, as a result, may be unable to properly prevent, diagnose, and/or treat this disease. Causatively associated with factors such as premature birth[14], congenital lung disease or heart disease[15], low birthweight[16], higher density living conditions that include the presence of older brother and sisters[17], attendance in day care[18], a family history of asthma[19], the presence of tobacco smoke[20], and multiple births[21], some evidence suggests that African Americans and other minorities may be at greater risk for contracting RSV infections. Related disparities may include associated co-morbidities as well as an adverse economic impact.

Moreover, if such disparities do exist, they may be aggravated by recent changes in the American Academy of Pediatrics, Red Book 2009: Report of the Committee on Infectious Diseases. The 2009 Red Book, despite the FDA-approved treatment of five dosages of immunoprophylaxis for all premature babies, reduced the recommended dosages of this preventive measure to three doses for certain less-than-term infants. Such a recommendation may have the unintended consequence of increasing health disparities in the African American community. In this regard, the National Medical Association and its partner, the National Black Nurses Association, convened a Consensus Panel to review the issue of RSV with respect to the impact on African Americans and other minorities. This group of experts addressed several key queries:

- What is the prevalence and incidence of RSV among African Americans and other minorities and what are the needs in this area?
- What key epidemiological issues surround RSV and African Americans and other minorities?
- Are there unique approaches to preventing and/or treating RSV among African Americans and other minorities?
- What evidence supports the reduction in immunoprophlyaxis from five (5) to three (3) dosages for certain categories of preterm babies?

Preliminary to reviewing the findings and recommendations of the RSV Consensus Panel, it is necessary to introduce the National Medical Association (NMA) and its partner, the National Black Nurses Association (NBNA).

Introducing...The National Medical Association

The National Medical Association is the oldest and largest non-profit professional , educational national organization in the world that represents African American physicians and the patients they serve. The NMA, on behalf of its members, is seeking to develop a comprehensive Respiratory Syncytial Virus (RSV) Policy Panel and Advocacy Plan with our partner, the National Black Nurses Association. Together, the NMA and NBNA will implement strategies to elevate public awareness of RSV; educate African American parents and caregivers regarding RSV prevention and recognition; improve the quality of training offered to minority physicians and allied health professionals on RSV detection, prevention and treatment; and enhance education and advocacy among lawmakers/policymakers regarding RSV in minority communities.

The National Medical Association, a 501(c)3 organization, headquartered in Silver Spring, Maryland, is comprised of 130 local, state, and regional NMA affiliates/chapters located in 46 states. Member physicians practice in 24 specialty areas. The organization is committed to improving the health status and outcomes of minority and disadvantaged people through its membership, professional development, community health education, advocacy, and research efforts in partnership with federal and private agencies and corporations.

The membership of the National Medical Association represents predominantly African American physicians. The NMA is comprised of physicians in the primary care specialties, as well as all other medical and surgical sub-specialties, academic medicine, military medicine and medical administration. NMA members serve a disproportionately high number of patients who are African American and/or members of other minority groups. Poor, uninsured, underinsured, and/or patients who are beneficiaries of Medicaid or Medicare are also overrepresented among the patients served by NMA's membership.

The NMA has an extensive national, regional, and local infrastructure for its advocacy, health promotion and disease prevention, treatment, and research initiatives. NMA's 130 state and local affiliated societies across the country are organized into six regions. This provides an optimum structure for the implementation of programs that have national impact.

NMA members are available to provide specialty expertise for scientific review, evaluation, and validation of project proposals and efforts through 24 scientific sections. These sections include: (1) Aerospace and Military Medicine, (2) Allergy, Immunology and Asthma, (3) Anesthesiology, (4) Basic Science, (5) Community Medicine and Public Health, (6) Dermatology, (7) Emergency Medicine, (8) Family Medicine, (9) Internal Medicine, (10) Medical Neurosurgery, (11) Medical Administrators, (12) Obstetrics and Gynecology, (13) Ophthalmology, (14) Orthopedic, (15) Otolaryngology, (16) Pathology, (17) Pediatrics, (18) Physical Medicine and Rehabilitation, (19) Plastic and Reconstructive Surgery, (20) Psychiatry and Behavioral Sciences, (21) Radiology, (22) Surgery, (23) Urology, and (24) Women In Medicine. Within each of the twenty-four sections, there is an enormous capacity and interest to support and conduct a variety of community disease prevention and educational outreach projects including the improved prevention and treatment of RSV.

Inherent to the National Medical Association's mission is an implicit intent and concerted effort to eliminate health disparities among minority populations with a particular focus upon African Americans. Some evidence exists that past mainstream education and training efforts to introduce physicians and health care providers to culturally sensitive and competent approaches to health care have lacked comprehensiveness. Yet, comprehensive training is needed in order to realize substantial gains in parity relative to health outcomes, service, access, and cost-effective care for minority populations. Some evidence exists that past mainstream education and training efforts to introduce physicians and health care providers to culturally sensitive and competent approaches to health care have lacked comprehensiveness.

Yet, comprehensive training is needed in order to realize substantial gains in parity relative to health outcomes, service, access, and cost-effective care for minority populations.

The organizational structure of the NMA provides an established framework of collaborative linkages within which physicians as NMA's principal group of health professionals can be mobilized. Through this infrastructure, physicians can address major health issues and implement national health program initiatives associated with RSV and other illnesses. These physicians, and the health institutions with which they are affiliated, are a "natural" structure and medical home for addressing concerns that disproportionately impact African Americans and other underserved populations.

Introducing...The National Black Nurses Association

The National Black Nurses Association was organized in 1971 under the leadership of Dr. Lauranne Sams, former Dean and Professor of Nursing, School of Nursing, Tuskegee University, Tuskegee, Alabama. NBNA is a non-profit organization incorporated on September 2, 1972, in the State of Ohio. NBNA, a worldwide organization, represents 150,000 African American registered nurses, licensed vocational/practical nurses, nursing students and retired nurses from the United States, Eastern Caribbean, and Africa. It has 72 chartered chapters in 35 states.

The National Black Nurses Association's mission is to provide a forum for collective action by black nurses to investigate, define, and advocate for the health care needs of persons of African descent. NBNA also implements strategies that ensure access to health care, equal to, or above the health care standards of the larger society. Its goals include: 1) support for the development of a cadre of ethnic nurses reflecting the nation's diversity; 2) advocacy for culturally competent, accessible, and affordable health care; 3) promotion of the professional and educational advancement of ethnic nurses; 4) education of consumers, health care professionals, and policymakers on health issues implicit to ethnic minority populations; 5) development of ethnic minority nurse leaders in the areas of health policy, practice, education and research; and 6) the endorsement of best practice models of nursing practice, education, and research for minority populations. With a rich legacy of advocacy in health care and education, NBNA is uniquely positioned as the voice of the African American nursing community.

The National Black Nurses Association also serves as a national collaborative for minority nurses and is one of the five founding organizations of the National Coalition of Ethnic Minority Nurse Associations (NCEMNA). Other founding organizations include the Asian American/Pacific Islander Nurses Association, Inc.; National Alaska Native American Indian Nurses Association, Inc.; National Association of Hispanic Nurses, Inc.; and the Philippine Nurses Association of America, Inc. This collaboration gives voice to 350,000 minority nurses.

The current president is Debra A. Toney, PhD, RN, FAAN, and the current Executive Director is Millicent Gorham, MBA. NBNA, a 501(c)(3) organization, is based in Silver Spring, MD

The Consensus Panel as a Methodology for Understanding RSV and the Needs of African Americans

The National Medical Association and its partner use consensus panels to achieve the goal of developing strategic plans for improving health outcomes in a number of health areas including RSV. The operational structure for the NMA/NBNA's Respiratory Syncytial Virus Consensus Panel involved assembling a body of physicians, nurses, and other leaders who have extensive knowledge and experience in the area of RSV as well as a commitment to patient and provider education. The clinical and academic concerns of practicing physicians and nurses were represented, as well as the needs and concerns of African American patients. The RSV Consensus Panel included 20 experts who provided knowledge and expertise on various research and policy issues related to RSV. This panel has provided a scientific and comprehensive paper that makes policy recommendations to the NMA Board of Trustees regarding RSV. Individuals for these various roles were recruited from among the NMA/NBNA memberships and other organizations and agencies. These roles have been described in the subsections that follow:

EXPERT PHYSICIANS AND NURSES: The selected physicians and nurses had knowledge and expertise in RSV and related diseases and were engaged to serve on the panel in various roles to support and analyze data and to represent the practitioner perspective in the panel deliberations.

FACULTY: Selected expert faculty complemented the RSV panel deliberations and offered the perspectives of industry, government, and academia, etc.

PANEL CHAIR: The panel chair was given the task of assuring that all RSV panel goals and objectives were met. In addition, the Chair served as the lead spokesperson for all RSV media contact and presentations related to the panel.

FACILITATOR: The Facilitator assisted in the panel deliberations, served as the intermediary and did not express any vested interest in the outcome of the panel deliberations. The Facilitator focused only on providing feedback and managing the group process.

INTERNAL STAFF: The day-to-day management and implementation of this project was conducted by NMA and NBNA internal staff with the support of a consensus panel team. As part of the overall consensus panel process, sound health policy can be developed that stems from the recommendations made regarding RSV tracking, prevention, detection and treatment.

Consensus Panel Policy Development

The NMA and the NBNA utilized the consensus panel process for the development of a comprehensive consensus paper that can broadly impact both public health and/or the science/practice of medicine around the issue of RSV. This was a multiple stage process which involved several steps.

- **BRIEFING PAPER**

  NMA/NBNA's health policy staff, with the assistance of a team of professional health communications writers/researchers, developed a background briefing paper that provided an extensive overview of the issues, including epidemiological considerations, potential disparities, and the potential of the 2009 Red Book Committee on Infectious Diseases Guidelines to adversely impact existing disparities.

- **CONSENSUS PANEL DELIBERATION**

  A group of 20 leading experts on RSV were selected from among the NMA/NBNA memberships and other organizations or agencies to deliberate on the issues based on the background briefing paper and their own professional expertise. The panel was convened in a variety of modes including face-to-face deliberations; conference calls; and through electronic communication to expound on key issues and propose specific RSV policy recommendations.

- **CONSENSUS PAPER-FINALIZED**

  This final RSV consensus paper represents the product of the panel deliberations. The consensus paper underwent extensive revision and editing by the Panel prior to finalization.

- **CONSENSUS PAPER POLICY ADOPTION**

  The RSV consensus paper, with supporting recommendations, has been forwarded to the NMA Board of Trustees and NBNA's Board for adoption as official policy.

- **CONSENSUS PAPER DISSEMINATION**

  The contents of the RSV consensus paper, policy recommendations, and officially adopted policies will be disseminated widely, internally and externally, to NMA and NBNA's members, health advocates, other health care providers, policymakers and the media in our effort to maximize public awareness.

- **NMA/NBNA SPOKESPERSONS**

  Dissemination will include the formal education of NMA/NBNA leaders on RSV including Officers, Regional Chairs and State Association Presidents during the Annual Convention in Washington, D.C., National Colloquium on African American Health. During the Colloquium, NMA leaders will be trained to serve as spokespersons on salient RSV issues contained within the consensus paper and the recommendations. Faculty for the Colloquium will consist of two members of the RSV Consensus Panel. The physicians and nurses trained will then share their expertise with their patient/ consumer populations.

- **PHYSICIANS AND NURSES**

  The consensus paper will be reproduced for dissemination to the NMA and NBNA memberships. The dissemination mechanisms will include a printed document that is a supplement to the Journal of the National Medical Association. The issue will also be presented by NMA and NBNA spokespersons at local NMA and NBNA meetings. Depending on the medium, both physicians and nurses may receive continuing medical education credit for their educational experiences related to these efforts. Thus, NMA and NBNA will utilize the consensus panel format to directly move from research to praxis. More concretely, the information included in the Consensus Panel can be directly integrated into the day-to-day RSV prevention, diagnosis, and treatment practices of physicians and nurses.

BACKGROUND

RSV: Estimating Its Prevalence

Despite the absence of familiarity with RSV-related diseases by the general public, it is a highly prevalent medical condition. Current data suggest that approximately 60 percent of all infants are infected during the first RSV season. Moreover, nearly all children become infected with the virus by age two.[22] Indeed, without prophylaxis for RSV, two to three percent of all RSV infected children will develop bronchiolitis of significant severity as to require hospitalization.[23] An understanding of the incidence and prevalence of RSV infection is confounded by the fact that natural immunity from RSV does not confer lasting immunity. As a result, tracking the incidence and prevalence of RSV requires care. Since infants can become infected more than once during the same RSV season[24], reinfection is common. For example, researchers Glezen et al. (1986)[25], using data from the Houston Family Study, found that by the age of two years, all infants in the study had been infected with RSV and 50 percent of those infants experienced reinfection within the same timeframe.

This is not to say that natural infection with RSV does not induce a protective immunity. Whether seeking to assess the magnitude of RSV Type A or Type B infection, it is important to note that immunity wanes over time. Specifically, an infant with documented RSV infection will develop an immunity which may last for fewer than two, three or four years, depending on the child.

While researchers have argued that RSV is a more prevalent viral infection than influenza, accurate and well-defined data on the prevalence of RSV are unavailable. The United States Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), tracks the prevalence of RSV through the National Respiratory and Enteric Virus Surveillance System (NREVSS).

However, the data is far from complete. This is because the universe for NREVSS data collection is limited to laboratories that perform RSV testings and also participate in NREVSS tracking. Data gathered through NREVSS may possibly under-represent the incidence of RSV for several reasons. First, not all laboratories report RSV data. Second, data reported are only for detection that occurred in laboratories. Many physicians do not screen for RSV unless patients are hospitalized. Third, even within the subgroup of laboratories that participate in surveillance, only screening that occurred utilizing antigen detection tests at these labs are reported.[26] The CDC, Morbidity and Mortality Weekly Report for March 5, 2010[27], states that, “For consistency, only antigen detection tests, which were used by 97 percent of participating laboratories during 2008-2009, were included in the analysis.” Fourth, the data collected is not used to track health disparities. For example, the CDC’s, March 5, 2010, Morbidity and Mortality Weekly Report primarily focuses on the season onset and variations rather than the demographic and/or clinical characteristics of the populations from whom laboratory samples were taken. Thus, the most respected existing dataset fails to provide information that is sufficiently comprehensive as to be used to identify the prevalence and incidence of RSV across the population in general and across key subpopulations in particular. This dataset is also insufficient for identifying the co-occurrence and interaction effects of RSV infections across the key high risk populations. Table 1 reproduces data from the CDC NREVSS database. (Race/ethnicity of the states has been added by NMA/NBNA).

Table 1: Reported RSV Onset by Laboratories in All States

HHS Region or state/area	States	% of total	No. of	Onset week ending	Offset week ending	Season duration (wks) in General	No. of	Onset week ending
			2008-2009				2009-2010 (onset only)	
National	All contributing states and DC	12.8	238	11/1	3/21	20	634	11/14
Florida	FL	15.9	20	7/12	2/7	30	35	7/18
Region 4 (Atlanta)	AL GA KY MS NC SC TN	26.4 30.0 7.7 37.2 21.6 28.5 16.8	28	10/11	3/21	23	85	10/24
Region 10 (Seattle)	AK ID OR WA	4.3 .9 2.0 3.7	12	11/22	4/4	19	32	12/26
Region 5 (Chicago)	IL IN MI MN OH WI	14.9 9.1 14.2 4.6 12.0 6.1	34	11/29	4/4	18	109	12/5
Region 6 (Dallas)	AR LA NM OK TX	15.8 32.0 3.0 8.0 11.9	29	10/25	2/14	16	78	11/14
Region 1 (Boston)	CT ME MA NH RI VT	10.3 1.0 7.0 1.2 6.4 .9	8	11/29	3/21	16	31	12/5
Region 7 (Kansas City)	IA KS MO NE	2.7 6.2 11.5 4.5	15	11/29	3/21	16	33	12/26

Table 1: Reported RSV Onset by Laboratories in All States—*Cont'd*								
HHS Region or state/area	**States**	**% of total population that is African American**	**No. of laboratories reporting**	**Onset week ending**	**Offset week ending**	**Season duration (wks) in General**	**No. of Laboratories reporting**	**Onset week ending**
			2008-2009				**2009-2010 (onset only)**	
Region 2 (New York)	NJ NY	14.5 17.3	23	11/15	2/28	15	62	11/7
Region 9 (San Francisco)	AZ CA HI NV	4.2 6.7 3.1 8.1	31	11/29	3/14	15	71	12/26
Region 8 (Denver)	CO MT ND SD UT WY	4.3 .7 1.1 1.1 1.3 1.3	10	11/29	4/11	15	25	12/19
Region 3 (Philadelphia)	DE DC MD PA VA WV	20.9 54.4 29.4 10.8 19.9 3.6	28	11/22	2/28	14	70	11/21

As Table 1 indicates, many of the states with higher percentages of African Americans have a longer RSV season and, as a result, may have a greater RSV risk. Overall, the review of literature reveals an urgent need for more accurate demographic data on RSV prevalence. One factor that can benefit RSV tracking is making RSV a reportable disease for both general and ethnic subpopulations, especially with respect to African Americans.

RSV: Its Origins and Manifestations

RSV is a member of the paramyxo-virus family.[28] This is the same family of viruses that includes other childhood illnesses for which effective vaccines have been developed. RSV is also a member of the subfamily *pneumovirinae*. RSV's name is derived from the fact that when grown in a cell culture, it is manifested as a syncytia, a multi-nucleated mass of cytoplasm that is not separated into individual cells. It is the F protein on the surface of the virus which causes the cell membranes of nearby cells to merge and form these syncytial elements.

The genomic structure of RSV consists of 10 single-stranded genes. These genes encode for 11 different proteins. The complexity of this structure has made finding immunologic solutions to RSV prophylaxis far more difficult than was the case with measles and mumps, two other childhood diseases that are a part of the RSV family. RSV includes the proteins NS1 and NS2. Researchers have found that these two proteins inhibit type one interferon activity. As is known, interferons are glycoproteins that are highly responsive to the presence of pathogens, including viruses. Like some other viruses, RSV's viability is closely associated with the M protein (matrix). However, RSV also functions through viral coat proteins. The viral coat is comprised of a host cell membrane that has been modified by the addition of the viral proteins or other agents. These proteins are important for viral entry into the cells. Additionally, such proteins are important because these are oftentimes the immuno-targets of vaccines or, immunotherapy.

No active immunization has yet been developed for RSV. One barrier to the development of such a vaccine is the fact that it is not currently possible to target the key elements without adverse events. However, there is evidence of an antibody response. Infants, children, and adults produce antibodies in response to these particular proteins. These antibodies determine, in part, the severity of an RSV infection.

As mentioned, M2 is also a key element in the biological structure of RSV. M2 is the second matrix protein which is required for transcription. M2 is comprised of an elongation factor and a transcription regulation factor, known as M2-1 and M2-2, respectively. These structures may become key potential targets in the development of an RSV virus vaccine at some point in the future. It is primarily through the ultimate development of a vaccine that the prevalence and incidence of RSV infection may be reduced.

RSV Detection

Defined as a contagious acute infection of the respiratory tract, RSV is the etiologic agent for bronchiolitis as well as pneumonia in infants, children, the elderly, and persons with selected chronic diseases. In addition to airway inflammation, observable symptoms in infants generally include wheeze and cough. However, in seeking to detect RSV, it is important to remember that RSV is not the only virus that can cause bronchiolitis. When RSV infection results in bronchiolitis, it can be diagnosed in several ways. When x-rays are used, for example, RSV presents as a diffuse inflation pattern throughout the lungs with areas of consolidation. While chest x-rays can reveal some signs, particularly when bronchiolitis is present, radiographic screenings for RSV may reveal findings that resemble pneumonia and/or which are, indeed, symptoms of pneumonia. There is a need for physicians to ensure early detection of RSV so that appropriate management can be instituted.

The CDC considers RSV to be the most common cause of bronchiolitis in children under one year of age. For some infants, RSV leads to bronchiolitis requiring hospitalization and, occasionally, leading to death. Thus, its detection is important.

Some investigators believe that recurrent wheezing and asthma are more common among infants who suffered from severe RSV infection during the first few months of life relative to control patients. These long-term effects have been observable throughout the neonatal period and across all babies rather than only those who were pre-term. The true impact of RSV infection may be underestimated because the long-term effects are not always reflected in an endpoint such as hospitalization. Some investigators have proposed that RSV infections may lead to recurrent wheezing.[29] For those predisposed to asthma, some evidence exists that they become more severely ill with RSV. [30]

As a consequence of its status as the most common cause of lower respiratory infections in young children, an extensive body of research now exists regarding risk factors for the acquisition of RSV, and its manifestation and progression in at-risk populations not only in the United States, but worldwide. For example, Venter et al. (2002)[31] compared viral isolates from young children with severe lower respiratory tract infections in evaluated hospital sites in both South Africa and Mozambique. While some differences were identified in the isolates from one community, the incidence of the virus was not significantly different across community and hospital sites in the alternate locations.

However, one important finding associated with this study was that homologous RSV genotypes were associated with upper and lower respiratory tract infections, as well as with infant-based RSV disease of great severity. Such findings suggest that more research is needed so that pediatricians and primary care physicians can more accurately predict when RSV in younger infants and children will progress in its severity. The absence of such predictive data confounds the development of specific treatment.

As is known, physicians are unable to utilize clinical findings alone as a basis for the differentiation of the etiology of viral respiratory tract infections. Viral culture, an approach that will generally not provide results until after the illness symptoms have abated because results occur over three to seven days, remains the gold standard for diagnosis. The shell vial method, a process that involves the centrifugation of the specimen onto a cell monolayer in a vial in order to decrease the time to a positive culture result, has also been used but still requires one to three days for a positive result. Rapid diagnostic procedures are used to detect viral antigens from nasal and/or other respiratory secretions. Reports based on tissue culture will be generated too late to impact treatment. A broad range of laboratory tests are now available that can definitively diagnose RSV with a sensitivity of approximately 80 to 90 percent and a specificity that averages 90 to 95 percent.

Indeed, this problem – the need for rapid detection in the diagnosis of an acute illness such as RSV - has led to considerable attention being directed to detection issues. For example, Hadziyannis et al. (1999)[32] compared the outcomes of a more rapid RSV screening tool – Vitek Immuno Diagnostic Assay System by Biomerieux, Inc. (VIDAS RSV) - with immune-fluorescence. An analysis based upon 238 tested samples revealed that results were concordant in 92 percent of the cases. As a result, these researchers recommended VIDAS as an appropriate method for the rapid detection of RSV that is less costly than immune-fluorescence.

Deiman et al. (2007)[33] tested another methodology by Biomerieux, an RSV assay that utilized Nucleic Acid Sequence Based Amplification (NASBA) technology. This analysis confirmed that results could be very rapidly obtained with a high rate of reliability. Whiley et al. (2002)[34] tested the Light Cycles rapid RT-PCR assay for RSV. This detection method yielded extremely acceptable results. RSV was identified in 41 percent of the 140 samples used relative to 39 percent of the specimens using alternative methods.

RSV Prevention and Treatment

RSV in the respiratory secretions of infected individuals can remain viable for up to thirteen minutes on the hands and/or other parts of the human body, and even longer on hard surfaces and/or in an aerosol. The prevention of RSV must rely on measures to modify social conditions and behaviors in order to decrease transmission since no vaccine exists for this condition. DeSwart et al. (2002)[35] report that clinical trials associated with attempts to develop an RSV vaccine in the decade of the 1960s led to increased severity of the RSV infection in immunized infants. This inactivated vaccine, for unknown reasons, produced more severe disease in those who were vaccinated than among controls.

Yang et al. (2007)[36] highlight one factor that has hindered the development of an RSV vaccine: the lack of a standard human reference serum enabling normalizaation of the results generated within and between laboratories that evaluate the immune response to candidate RSV vaccine. Specifically, these authors argue that the results of RSV vaccine clinical trials are processed by multiple laboratories utilizing nonstandardized processes. To address this issue, these investigators utilized samples from approximately 400 persons to develop what they characterized as a "human reference serum" for the A2 strain of RSV. These researchers suggest that this reference serum can be used to improve quality control as efforts move forward to create a vaccine.

In the absence of an RSV vaccine, however, RSV prevention primarily involves several steps: 1) Tracking the duration of the season when RSV infections occur most frequently; 2) Avoiding contact with individuals suspected or confirmed as having RSV infection; and 3) Reducing the spread of the illness by educating parents regarding the importance of sanitizing hands through regular hand-washing and/or by utilizing antiseptic cleansing agents. Finally, for children who are already hospitalized, isolation is required to prevent nosocomial transmission of RSV.

Research also indicates that hospitalizations as a result of RSV bronchiolitis can be reduced. One highly critical strategy involves the administration of palivizumab over a period during the RSV season to protect at-risk infants. Importantly, this agent must be used before the RSV season activity begins.

Palivizumab is a monoclonal antibody directed against the RSV F protein, the fusion protein, which the virus uses to gain entry into the cell and to form the syncytial elements in tissue culture. It has replaced earlier methods of prophylaxis such as the administration of RSV IVIG which is no longer available. Palivizumab is given by way of monthly injections which are typically begun just prior to the RSV season and are continued during the peak infectivity period.

Palivizumab is considered as an effective prophylaxis because its clinical trials resulted in an overall reduction in hospitalization of 55 percent in the intervention group versus the control group. The IMpact RSV trial subsequently demonstrated a 39 percent reduction in the hospitalization of infants with chronic lung disease (CLD) and a 78 percent reduction in preterm infants without CLD.[37] In infants born between 32 and 35 weeks, there was an 80 percent reduction overall in RSV-related hospitalization.[38] Equally impressive, pre-mature infants (born between 32 and 35 weeks) without chronic lung disease experienced an 82 percent decrease in hospitalization rates. This finding revealed that not only babies who have chronic lung disease, but even healthy preterm babies can benefit from this prophylaxis.

Palivizumab was first made available commercially in 1998. The American Academy of Pediatrics Committee of Infectious Disease (AAP/COID) first made recommendations regarding its use in 1997. The 2003 Red Book made only minor changes as revealed by a comparison of the two sets of guidelines.[39] The community of pediatricians and neonatologists accepted these recommendations as evidence-based guidelines.

The 2009 Committee on Infectious Disease Guidelines departed significantly from previous recommendations. These guidelines incorporated changes that reduced the recommended administration of palivizumab from five (5) months to as few as one (1) month for certain at-risk babies. For very pre-term infants, the guidelines remained relatively the same. Recommended dosing, however, was limited to three or fewer months as opposed to the traditional FDA-approved five-month period for palivizumab use for premature infants (with a gestational age of 32 weeks and zero days to 34 weeks and six days) with at least one risk factor and born three months or more before, or during the RSV season. Input from pediatric groups and parents indicated that use of the term “near term” for those infants with a gestational age of 32 to 35-6/7 weeks in the 2009 Red Book Guidelines was another factor that could affect how this group of babies are treated for RSV.

Both parents and the pediatric community have questioned the alterations in some of the 2009 Red Book Guidelines[40] for RSV based on the fact that no supportive research is provided for these changes. For example, the National Perinatal Association also recently concluded that the recommendations regarding the decrease in dosage are inconsistent with current evidence.

Thus, implementation of the 2009 Red Book Guidelines may result in inadequate protection for at-risk infants. For example, a baby that is born at one of these late preterm gestations and who is discharged from a neonatal intensive care unit (NICU) directly before the start of the RSV season may be eligible for only one dose of palivizumab before losing eligibility. As currently written, the new guidelines may only allow that baby to receive one dose before the start of the season. This child would not have adequate prophylaxis through the duration of that RSV season at all. Yet, in patients with chronic lung disease or BPD and premature infants born at less than 36 weeks gestational age, prophylaxis decreased hospitalization rates by 55 percent. In the subgroup of patients born between 32 and 35 weeks gestation, hospitalization rates decreased by 80 percent.

The efficacy of this prophylaxis is actually greater in well preterm babies as measured by decreased RSV hospitalization rates. The Consensus Panel therefore recommends that not only babies with chronic lung disease, but that all preterm infants in the at-risk gestation be provided access to full palivizumab prophylaxis when they leave the hospital. The Consensus Panel also recommends that the American Academy of Pediatrics Committee on Infectious Diseases demonstrate that an evidence-based cost model was used to justify a reduction in the number of dosages for specific subgroups as well as provide the clinical data that support its current dosing recommendations. It also recommends that the evidence-based model that was used to officially introduce palivizumab serve as the basis for palivizumab dosing until the evidence can be shown to suggest that another model of dosing will give the same or improved results.[41]

In addition, the Consensus Panel recommends that strategies to identify certain higher-risk populations be applied. Relying on a “need to treat” of 15 to 16 infants to prevent one hospitalization appears to have initiated a large-scale, informal experiment. More specifically, in order to save costs, it appears that a testing process is underway to determine whether reducing the number of doses of palivizumab RSV prophylaxis can be achieved while minimizing the erosion of clinical quality. Particular at-risk population groups appear to be the subjects of this informal experiment.

If such a presumption has merit, the current and emerging patterns of use of palivizumab may embody racial/ethnic disparities. If risks are stratified according to the number of preterm births, costs, and by demographic and socioeconomic groups, the higher birth rates and elevated rates of prematurity in African-American and other minority groups[42] places these infants in multiple jeopardy. Moreover, the economic models used to determine those subgroups that should have access to palivizumab are flawed. The need-to-treat/need-to-prevent-hospitalization approach that is currently used ignores the increased costs of care as an outpatient that can accompany RSV infection in a child. If RSV and its sequelae do cause exacerbated asthma (an issue that remains unsettled based upon current research), the need for bronchodilator therapies and frequent visits to the pediatrician and the emergency room may cause current cost/benefit models to severely underestimate the costs associated with RSV. Thus, the Consensus Panel recommends the initiation and completion of new research using more realistic endpoints so that more accurate cost projections are estimated.

This model should also consider the economic impact to families outside of the health care system. For example, the provision of care to an infected or affected infant may require a parent or guardian to drop out of the workforce to attend to the frequent needs of the infant if long-term health problems do occur as a result of RSV. This outcome can exacerbate the cycle of poverty in certain socioeconomic groups. Only new research can provide evidence-based answers to these pressing questions.

As mentioned, prophylaxis is available as an intramuscular monoclonal antibody preparation, palivizumab. Since this monoclonal preparation does not induce a lasting immunity, its administration is required monthly in order to continue to protect the infant from RSV. As also mentioned, RSV infection is not benign in infants. It is responsible for significant hospitalizations, morbidity and mortality in infants less than 24 months of age who have chronic lung disease, bronchopulmonary dysplasia (BPD), congenital heart disease, and/or com-promised respiratory immune systems. Therefore, candidates for RSV prophylaxis and decisions regarding the appropriate RSV prophylaxis must be individualized.

Infants or children with chronic lung disease or bronchopulmonary dysplasia who are less than 24 months of age at the start of RSV season, and who have required intervention or maintenance therapy for their chronic lung disease or BPD within six months of the start of the RSV season, will benefit from RSV prophylaxis. Other interventions for chronic lung disease or BPD may include the ongoing use of corticosteroid preparations, methylxanthine, supplemental oxygen, and bronchodilators or diuretics. However, costs of prevention are considered high based upon the assumption that one must treat 15 infants to prevent one hospitalization. This assumption must be modified to include issues related to disparities, and the possible ongoing costs to society of outpatient care.

Relative to treatment, physicians are restricted to the use of measures to decrease symptomatology such as fever, headache, and other effects. Because viral infections are not impacted by the use of antibiotics, they are not required, except when RSV is accompanied by a secondary bacterial infection such as pneumonia, otitis media or sinusitis.

The 2009 Guidelines are less reliant upon palivizumab as an agent of prevention in high-risk infants and children. However, because of the absence of an evidence base for the alteration in dosage levels, the Consensus Panel recommends that these guidelines be revised.

Epidemiology

Multiple factors appear to place children worldwide at risk of RSV. Queiroz et al. (2002)[43] sought to assess the degree to which Brazilian infants less than and/or older than three months were able to develop an immune response when infected with RSV. They discovered that children under the age of three months were significantly less likely to develop an immune response to the presence of RSV. This suggests the need for physicians to be even more vigilant in their efforts to screen infants in this age group.

Banjeri et al. (2009)[44] sought to determine the relative benefits of utilizing palivizumab to reduce hospital admissions among infants by administering the dosages before the beginning of the RSV season. As mentioned, palivizumab is not a vaccine but an immunoprophylactic agent. It prevents or attenuates RSV infection in high-risk individuals. For example, the Inuit are a people who live in the Arctic regions of Alaska, Canada and Greenland. An intervention was tested to determine whether the use of palivizumab prophylaxis could reduce the costs associated with hospitalization for RSV among Inuit children less than six months old and children less than one year old in general, and by urban and rural status. Cost savings were generated across all variables.

However, in a related article, Banjeri et al. (2009)[45] expanded this research question in order to identify the factors that were related to hospitalization. Several factors were identified as having a positive correlation with the likelihood of hospitalization. Children/infants of women who smoked during pregnancy had a significantly higher chance of hospitalization admission. Children who were raised in rural areas rather than in the one town in the study were also at greater risk of hospitalization and/or complications from RSV. Race/ethnicity was also an operative factor. Children whose mothers and fathers were Inuit had a greater risk of hospitalization. Children reared in overcrowded living conditions, children who were not breastfed, and adopted children who were not breastfed, were predicted to have a significantly higher risk of RSV-related hospitalizations.

Multiple factors were also identified as related to RSV based on another study. Moore et al. (2009)[46], in an analysis of respiratory viral infections in children from 1992 to 2005 in Western Australia, identified several correlates of hospitalization. Of 32,741 specimens screened, RSV was detected in 18.6 percent of cases, influenza Virus A in 5.1 percent of the specimens, and parainfluenza in 3 to 4 percent of the specimens. Thus, as in the United States, RSV was the most common respiratory virus. Interestingly, RSV manifested itself differently by ethnicity. Aboriginal and non-aboriginal children experienced differences by age and viral season.

Karr et al. (2009)[47] analyzed the relationship of RSV to acute bronchiolitis among 2,604 infants in Washington State. While the model specified included race/ethnicity, mother's education, and smoking during pregnancy as well as air pollution, the analyanalysis revealed that RSV bronchiolitis hospitalization was higher for infants who lived within 150 miles of a highway. It must be noted that the authors emphasized the need for additional research in this area.

Severe RSV has been linked with asthma. However, the pathway appears to be a nonlinear one. For example, Pippo-Savolainen et al. (2007)[48] sought to identify the relationship between RSV, asthma, and blood eosinophilia, which is defined as having a high count of eosinophils (white blood cells of the immune system). From infancy to adulthood, the researchers discovered that there was no relationship between blood eosinophilia and the development of asthma. Yet, the data were also cross-tabulated to determine whether infants with RSV bronchiolitis experienced a lower level of blood eosinophilia. The additional analysis revealed that while RSV was associated with fewer eosinophils, this relationship did not predict wheezing/asthma. There was, however, a relationship between increased eosinophilia during the recovery period and a higher probability of asthma at ages two to three years, but not thereafter.

There are other pathways by which RSV infection may also enhance asthma risk. Matsuse, et al. (2007)[49] examined the role of pulmonary dendritic cells upon allergies/ asthma when RSV infection occurs. Pulmonary dendritic cells are leukocytes that help to organize and coordinate some of the pulmonary system's immune responses. These cells perform the task of surveillance of antigen-exposed areas. The number and behavior of pulmonary dendritic cells are affected by the presence of cysteinyl leukotrienes. Researchers Peters-Golden et al. (2006)[50] define cysteinyl leukotrienes (CysLTs) as "a family of inflammatory lipid mediators synthesized from arachidonic acid by a variety of cells, including mast cells, eosinophils, basophils, and macrophages." When an RSV infection occurs, it can cause the quantity of cysteinyl leukotrienes to increase, thereby altering the number and functioning of pulmonary dendritic cells. Utilizing mice infected with RSV, the research team found that airway inflammation did accompany RSV as a result of higher levels of pulmonary dendritic cells caused by higher levels of cysteinyl leukotrienes.

Similarly, Murai et al. (2007)[51], in a study of 70 children with RSV, discovered that one factor associated with airway inflammation was the existence of higher levels of interleukin-4 (IL-4), interleukin-10 (IL-10), and Regulated on Activation, Normal T Expressed and Secreted (RANTES aka CCL5). Il-4 is a cytokine that coaxes T cells (Th0 cells) into becoming Th2 cells. IL-10 is an anti-inflammatory cytokine. RANTES is defined as a cytokine that attracts eosinophils, monocytes, and lymphocytes. Tian et al. (2009)[52] also confirmed that RANTES levels affect asthma in children who had RSV bronchiolitis. Silver et al. (2009)[53] found that severe RSV bronchiolitis can be linked with too little plasmacytoid dendritic cells in the blood, thereby creating allergies and/or asthma. Whether asthmatic children are at greater risk of RSV, or RSV is a causal agent in asthma, the research therefore reveals that correlations do exist.

In addition to co-occurring conditions, acquisition of RSV is also associated with a number of other factors. For example, children living in rural communities without in-house water service are at greater risk of an RSV infection that results in hospitalization. Hennessy et al. (2008)[54], in an analysis of data from Alaska Native children for the period of 2000 to 2004, found that homes without in-home water service had higher rates of hospitalization for not only RSV, but other infectious diseases as well. This research confirms earlier findings by Ryder et al. (1985)[55] who, in a now classic study, asserted that RSV was one of several viruses and bacterial diseases associated with a poor water supply.

Differences in access to high quality medical care also comprises a social determinant of health care that affects hospitalization rates from RSV. For example, Eick et al. (2008)[56] unsuccessfully sought to identify the 200 to 400 percent higher rate of RSV hospitalizations among Navajo and White Mountain Apache infants as a function of an inadequate supply of viral-neutralizing antibodies in Native American/American Indian mothers. However, the hypothesis proved false, leaving the documented disparities unexplained. Yorita et al. (2007)[57] identified a similar pattern among Native Hawaiians and Pacific Islander children. Despite lower reported RSV prevalence rates than across the country, RSV hospitalization rates for this ethnic group exceeded those of other ethnic groups in Hawaii. Carville et al. (2007)[58] identified ethnic disparities between Aboriginal and Majority children in Australia. With a viral infection rate that was 1400 percent higher for aboriginal children than for their non-aboriginal counterparts, the data suggest that social determinants of health outcomes may be operative.

Further support for the thesis that social determinants of health may serve as risk factors for RSV hospitalization is introduced by Reeve et al. (2006)[59]. Seeking to identify some of the variables explanatory of the higher incidence of RSV hospitalization among aboriginal infants, the researchers applied multiple logistic regression to data from 271 children with RSV-associated lower respiratory tract infection. The analysis revealed that low birthweight as defined by a weight of no less than 2500g at birth, single mother status, maternal tobacco use, and low birth order in combination with older siblings were variables that both singularly and collectively contributed to RSV hospitalization.

RSV and African Americans

The existence of RSV disparities among other ethnicities raises the question of whether documented evidence of RSV disparities exists for African Americans. As one examines the correlates of hospitalization from RSV infections, one would hypothesize that such disparities may exist since African American communities embody many of the risk factors for RSV. The subsections that follow introduce data regarding some of these variables.

Premature Births and African Americans

As is known, preterm births are defined as any live birth that takes place before 37 completed weeks of gestation occurs. In contrast, preterm births can be further subdivided into: late preterm infants (born after 34 to 36 completed weeks gestation); moderately preterm (born at 32 to 36 weeks gestation); and very preterm (born at less than 32 weeks gestation). Data from the National Center for Health Statistics reveals that African American babies are over-represented in each of these categories.

While the data for moderately preterm are missing, Table 2 confirms that African American infants are at significantly higher risk of RSV as a result of prematurity than is the case with their counterparts of other ethnicities. For example, the State of Florida has the longest RSV season in the United States (30 weeks). As Table 3 on page 32 indicates, even within the State of Florida, African American premature infants are at a greater risk of RSV because of earlier gestational age at birth.

Table 2: Preterm, Late Preterm, Moderately Preterm, and Very Preterm - Birth Rates by Race/ Ethnicity (2004-2006)

	Caucasian	African American	Latino/ Hispanic	Native American	Asian	Total
Preterm >37 weeks	11.6	18.3	12.1	14.1	10.7	12.7
Late Preterm (34-36 weeks)	8.6	11.7	8.8	10.1	7.9	9.0
Moderately Preterm (32-36)	--	--	--	--	--	--
Very preterm (>32 weeks)	1.6	4.1	1.8	2.1	1.0	2.0

Source: March of Dimes. Peristats. Preterm Birth, United States 1996-2006 as taken from the National Center for Health Statistics, final natality data. Accessed July, 2010.

Table 3: Florida County Resident Births - Column Percentages (2008)

	Mother's Race									
	Number/Percent of All Births to Mothers by Race/Ethnicity									
Gestational Age of Infant	**White (#)**	**White (%)**	**African American (#)**	**African**	**Other Non-White (#)**	**Other Non-White (%)**	**Unknown Ethnicity (#)**	**Unknown Ethnicity (%)**	**Total (#)**	**All Births (%)**
< 20 weeks	33	< 0.1%	45	0.1%	5	< 0.1%	1	0.2%	84	< 0.1%
20-28 weeks	1,329	0.8%	1,051	2.0%	116	1.0%	7	1.3%	2,503	1.1%
29-31 weeks	1,696	1.0%	932	1.8%	131	1.1%	7	1.3%	2,766	1.2%
32-33 weeks	2,879	1.7%	1,385	2.7%	208	1.7%	3	0.6%	4,475	1.9%
34-36 weeks	15,482	9.2%	6,540	12.7%	1,065	8.8%	30	5.8%	23,117	10.0%
37+ weeks	145,964	87.1%	41,346	80.5%	10,518	87.3%	467	90.0%	198,295	85.7%
Unknown	104	0.1%	63	0.1%	0	0.0%	4	0.8%	177	0.1%
All Gestational Age	167,487	100.0%	51,362	100.0%	12,049	100.0%	519	100.0%	231,417	100.0%

Source: Florida Department of Health, Office of Vital Statistics, Florida Birth Certificate
Data Notes: The number and percent of preterm live births by LMP uses calculated gestational age based on date of last menstrual period (LMP) and the date of delivery. Some missing data are estimated for completeness. These estimates will vary from those estimated using gestational age based on obstetrical consultation. Data are for Florida residents only.

Based upon such disparities, the 2009 Red Book modifications regarding recommended dosages may have a disproportionate impact upon African American infants. Additionally, the disparities may be even greater than suggested by the data. This is because anecdotal data indicate that some African American babies that are late preterm may be reported as full-term because of a greater ability to go to the Well Newborn Nursery. In contrast, their Majority counterparts are more likely to have problems if born four weeks early. Thus, research is needed that triangulates prematurity reporting by race/ethnicity as a part of a broader study that determines whether disparities are occurring in access to palivizumab as a result of inaccurate reporting and other factors.

African Americans and Low Birth- Weight

While a higher prevalence of prematurity alone places African American children at a greater risk of RSV, prematurity can conjoin with low birthweight as an RSV factor. Additionally, low birthweight in full term infants can also increase the risk of RSV. As is known, low birthweight infants weigh less than 2500 grams or 5-1/2 pounds and very low birthweight infants weigh less than 1500 grams or 3-1/3 pounds.

Table 4 provides data on birthweight by race/ethnicity. As Table 4 indicates, in 2008, 7.3 percent of Caucasian babies were low birthweight relative to 11.8 percent of African American infants. Indeed, African American infants were significantly more likely to have low birthweight than were infants of any other ethnicity. Such a trend held true whether the infants were preterm or full term.

Table 4: Summary of Trends in Infant Health Indicators by Race/Ethnicity

Race/Ethnicity and Year		Birthweight			Preterm <37 weeks gestation		Full Term LBW 37 weeks or more	
			Low <2500 g	High >4000 g	Number	%	Number	%
		Number	%	%				
White, Non-Hispanic	2008	454,618	7.3	7.9	429,778	10.1	378,753	3.2
	2007	432,839	7.4	7.9	387,312	10.7	361,773	3.3
	2006	400,559	7.5	7.9	353,464	11.0	335,333	3.3
	2005	348,059	7.5	7.9	308,337	11.5	291,242	3.4
	2004	332,226	7.4	8.3	292,984	11.6	277,886	3.4
	2003	313,259	7.4	8.6	307,196	10.4	263,631	3.5
	2002	290,780	7.2	8.6	287,479	10.3	244,574	3.4
	2001	297,100	7.2	9.1	255,580	10.5	218,099	3.6
	2000	307,961	7.0	9.5	273,140	9.9	239,054	3.4
	1999	303,694	7.2	9.6	299,352	10.1	257,129	3.4
Black, Non-Hispanic	2008	257,481	11.8	4.1	240,327	13.7	204,303	5.3
	2007	239,740	11.8	4.4	219,013	14.6	192,549	5.6
	2006	219,479	11.8	4.4	196,468	14.6	177,338	5.6
	2005	168,091	11.9	4.6	146,145	15.1	134,993	5.8
	2004	160,560	11.6	4.7	140,122	15.0	129,601	5.9
	2003	154,776	11.5	4.7	153,841	13.8	123,990	5.7
	2002	141,637	11.4	4.7	141,208	14.1	113,263	5.6
	2001	145,344	11.0	5.0	118,316	13.5	94,572	5.8
	2000	141,127	11.1	5.3	121,295	13.5	97,851	5.7
	1999	128,111	11.1	5.1	127,285	13.5	102,831	5.6
Hispanic	2008	311,488	6.8	6.8	295,737	11.9	255,456	2.8
	2007	293,201	6.7	6.9	272,561	11.8	239,097	2.9
	2006	284,320	6.9	6.9	260,324	12.1	231,089	3.0
	2005	149,300	6.3	7.8	134,746	11.5	123,570	2.8
	2004	144,387	6.2	7.8	136,909	11.4	117,247	2.7
	2003	134,412	6.0	8.1	130,985	10.6	109,556	2.7
	2002	116,561	5.7	8.2	114,915	10.6	96,461	2.5
	2001	112,157	5.8	8.4	87,883	10.8	71,902	2.7
	2000	112,890	5.8	8.6	92,732	10.5	78,036	2.7
	1999	78,522	5.7	8.9	76,136	10.5	63,632	2.7

Table 4: Summary of Trends in Infant Health Indicators by Race/Ethnicity—*Cont'd*

Race/Ethnicity and Year		Birthweight			Preterm <37 weeks gestation		Full Term LBW 37 weeks or more	
			Low <2500 g	High >4000 g	Number	%	Number	%
		Number	%	%				
American Indian/ Alaska Native	2008	10,197	7.4	9.3	9,497	12.8	8,073	2.8
	2007	11,490	7.2	9.5	10,551	12.3	9,112	2.9
	2006	10,262	7.5	9.4	9,150	12.4	8,098	3.2
	2005	8,658	7.4	10.4	8,364	12.2	7,338	3.3
	2004	8,552	7.1	10.0	8,792	12.1	7,104	3.3
	2003	7,583	7.0	10.6	9,172	11.2	6,438	3.2
	2002	6,570	6.7	10.9	7,221	10.9	5,554	3.2
	2001	6,201	6.5	11.5	6,484	11.6	4,903	3.0
	2000	7,333	6.3	11.9	6,955	11.3	6,074	2.8
	1999	6,481	7.2	12.4	7,165	11.5	5,486	3.3
Asian/Pacific Islander	2008	35,228	7.6	4.7	34,104	9.2	30,470	3.8
	2007	34,811	7.6	5.0	32,945	8.9	30,274	4.1
	2006	31,476	7.8	5.2	29,431	9.2	27,282	1.2
	2005	18,642	7.8	5.2	17,221	9.2	16,181	4.4
	2004	16,274	7.9	5.7	14,953	9.6	13,902	4.7
	2003	15,394	8.0	5.4	11,737	9.9	9,988	41.2
	2002	16,669	7.9	5.8	10,029	10.2	8,437	4.1
	2001	16,610	7.8	6.2	8,936	11.0	7,444	4.0
	2000	17,052	7.4	6.5	10,078	10.1	8,626	3.8
	1999	9,957	7.4	6.7	9,595	11.0	8,087	3.7
Multiple Races	2008	11,462	7.9	7.2	11,160	8.8	9,884	4.0
	2007	9,848	8.2	7.2	9,496	9.7	8,475	4.3
	2006	8,946	7.8	7.1	7,536	9.7	7,726	4.6
	2005	4,160	7.9	7.2	3,821	8.0	3,566	4.8
	2004	3,008	7.4	7.2	2,796	6.2	2,659	5.2
	2003	41,994	8.3	7.0	--	--	0	--
	2002	0	--	--	--	--	0	--
	2001	0	--	--	--	--	0	--
	2000	0	--	--	--	--	0	--
	1999	0	--	--	--	--	0	--

Source: Polhamus B, Dalenius K, Mackentosh H, et al. Pediatric Nutrition Surveillance 2008 Report. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2009.

As Table 4 indicates, African Americans also have the highest rate of low birthweight in the United States. Since 1999, the number and percent of low birthweight African American babies born has increased. While the rate of increase has not equaled and/or exceeded that of Latinos, the direction of the change signals the need for multiple interventions to contain and decrease this trend. This data would suggest that African American infants may be at greater risk of hospitalization from RSV infection.

Breastfeeding

Over recent decades, an abundance of research has emerged regarding the benefits of breastfeeding. Whether measured using the Breastfeeding Attrition Prediction Tool, the Modified Breastfeeding Evaluation Scale, the Breastfeeding Self-Efficacy Scale, the Iowa Infant Feeding Attitude Scale or another instrument, both current as well as classic research reveal that this very natural act contributes to the wellness of babies.[60]

Neault et al. (2007)[61], in a five-year study, analyzed data on the infants of nearly 3,600 immigrant women. Utilizing CHI-Square tests and logistic regression, these researchers found that the breastfed infants in the study attained a weight that was significantly higher than that of the babies who were not breastfed. Moreover, these infants did not have a greater prevalence of overweight. Additionally, and of particular importance to this project, significantly fewer mothers of the breastfed babies described their children as having only fair or poor health. The health status of the child is, as mentioned, a significant predictor of absenteeism, tardiness, and job separation among women and/or men who are the custodial parent.

These findings are confirmed by other researchers. For example, Moschonis et al. (2007)[62], using a 2,374-person sample of infants and young children in Greece, identified breastfed children as being 49 percent and 50 percent less likely to become overweight over the course of the study. A study by Procter and Holcomb (2007)[63] further refines our understanding of the linkages between breast-fed status and the overall health of infants. These researchers argue that breastfeeding is most protective when the period of breastfeeding is of longer duration. Obesity reduction is not the only benefit associated with breastfeeding. Other findings regarding breastfeeding and its benefits are described in Table 5.

Table 5: Other Health Benefits of Breastfeeding

- The Agency for Healthcare Research and Quality (AHRQ) found that there are benefits for both mother and child when the mother breastfeeds. For example, breast-feeding helps in protecting the infant from developing otitis media, gastroenteritis, severe lower respiratory infection, and necrotizing enterocolitis.

  Source: Breastfeeding and maternal and infant health outcomes in developed countries. Rockville (MD): Agency for Healthcare Research and Quality; 2007. AHRQ Publication No. 07-E007.

- Infants who are breastfed have stronger immune systems based upon research by Heinig (2001). This suggests that RSV is a lower risk in breastfed babies (Cohen et al., 1995).

  Sources: Heinig MJ. Host defense benefits of breast-feeding for the infant. Effect of breastfeeding duration and exclusivity. Pediatric Clinics of North America. 2001; 48:105-123.

  Cohen R, Mrtek MB, Mrtek S. Comparison of maternal absenteeism and infant illness rates among breast-feeding and formula-feeding women in two corporations. American Journal of Health Promotion. 1995; 10(2):148-153.

- Children who are breastfed as infants have higher academic achievement according to Anderson et al. (1999). Thus, their employed parents are less likely to miss work in order to address underachievement.

  Source: Anderson J, Johnstone B, Remley D. Breast-feeding and cognitive development: A meta-analysis. American Journal of Clinical Nutrition. 1999 70(4):525-535.

- Breastfeeding is also correlated with lower rates of sudden infant death syndrome, childhood obesity, Type 2 diabetes, and leukemia. Mothers also reap the benefits of breast-feeding in their health status. For example, mothers who breast-feed are at a decreased risk for Type 2 diabetes, as well as breast and ovarian cancers.

  Source: Ibid.

In addition, infants born to breastfeeding mothers experience a range of other health benefits.[68] As mentioned, the protective impact of breast milk extends to RSV. Bulkow et al. (2002)[69] in an analysis of RSV risk factors, found that breastfeeding reduced the risks of RSV hospitalization among Alaska Native infants. Both the U.S. Department of Health and Human Services [70] and the American Academy of Pediatrics[71] recommend breastfeeding as a protective factor among children and youth in the United States. However, data on breastfeeding behaviors suggest that African American women are less likely to breastfeed their newborns and infants.[72] Even when they do breastfeed, African American women do so for shorter periods of time. Table 6 describes breastfeeding behaviors by race/ethnicity. This data also suggest that African American infants and children may be at greater risk of RSV as a result of the lower rates of breastfeeding.

Table 6: Summary of Trends in Breastfeeding Indicators by Race/Ethnicity: 1999-2008

Race/Ethnicity and Year		Breastfeeding					
		Number	% Ever Breastfed	Number	% Breastfed At Least 6 Months	Number	% Breastfed At Least 12 Months
White, Non-Hispanic	2008	633,996	58.1	320,701	20.7	362,686	12.4
	2007	638,951	55.9	328,452	19.3	349,226	11.7
	2006	559,606	56.6	282,443	20.0	293,598	13.3
	2005	535,489	55.4	273,609	19.7	299,095	13.0
	2004	577,914	53.8	295,108	18.8	310,618	12.7
	2003	479,220	52.6	237,240	19.3	255,873	13.5
	2002	427,916	51.0	235,051	18.6	243,022	12.1
	2001	291,524	50.6	168,134	20.1	165,987	13.3
	2000	428,481	48.5	246,974	18.7	228,170	11.9
	1999	428,232	49.0	256,561	18.1	228,248	11.7
Black, Non-Hispanic	2008	386,593	50.2	173,724	20.2	210,318	12.9
	2007	401,429	46.9	186,767	18.2	206,657	11.3
	2006	362,220	47.3	165,104	18.2	177,375	11.9
	2005	327,559	46.4	152,600	18.4	374,080	12.0
	2004	354,100	42.6	163,265	16.3	190,170	11.0
	2003	296,353	41.6	140,154	16.3	160,412	10.7
	2002	267,397	40.0	135,737	15.2	148,196	9.0
	2001	144,375	36.1	73,220	14.0	78,159	9.6
	2000	258,475	34.5	133,425	13.3	131,564	8.2
	1999	244,816	35.3	130,327	12.9	123,557	7.9
Hispanic	2008	586,634	73.8	298,029	37.9	395,950	29.1
	2007	601,022	72.4	305,954	36.4	362,706	26.8
	2006	525,929	72.9	275,991	35.6	336,971	26.3
	2005	455,203	71.1	245,636	33.5	314,397	25.7
	2004	453,498	68.7	232,953	33.8	276,523	27.3
	2003	398,490	68.0	194,066	33.5	246,698	25.9
	2002	254,397	67.5	144,220	28.7	158,724	15.3
	2001	90,392	68.4	54,085	63.8	50,918	20.3
	2000	171,314	65.5	94,827	30.1	92,202	17.9
	1999	155,326	62.8	86,781	27.7	82,517	16.8

Table 6: Summary of Trends in Breastfeeding Indicators by Race/Ethnicity: 1999-2008 — *cont'd*

Race/Ethnicity and Year		Breastfeeding					
		Number	% Ever Breastfed	Number	% Breastfed At Least 6 Months	Number	% Breastfed At Least 12 Months
Hispanic	2008	586,634	73.8	298,029	37.9	395,950	29.1
	2007	601,022	72.4	305,954	36.4	362,706	26.8
	2006	525,929	72.9	275,991	35.6	336,971	26.3
	2005	455,203	71.1	245,636	33.5	314,397	25.7
	2004	453,498	68.7	232,953	33.8	276,523	27.3
	2003	398,490	68.0	194,066	33.5	246,698	25.9
	2002	254,397	67.5	144,220	28.7	158,724	15.3
	2001	90,392	68.4	54,085	63.8	50,918	20.3
	2000	171,314	65.5	94,827	30.1	92,202	17.9
	1999	155,326	62.8	86,781	27.7	82,517	16.8
American Indian/Alaska Native	2008	16,863	64.3	9,094	26.9	11,850	17.9
	2007	17,289	63.1	9,643	26.3	11,871	17.8
	2006	16,182	65.8	7,776	29.8	9,852	20.9
	2005	13,272	61.5	6,889	24.7	8,496	17.7
	2004	14,683	62.4	7,644	20.8	8,642	15.9
	2003	11,858	55.7	6,014	22.3	7,576	17.4
	2002	9,141	58.6	5,214	21.5	5,562	12.1
	2001	5,817	52.2	3,395	22.9	3,260	15.2
	2000	10,134	53.2	6,193	23.2	5,892	17.0
	1999	7,583	55.9	4,730	25.3	4,453	19.2
Asian/Pacific Islander	2008	44,857	63.4	21,555	29.8	27,302	20.5
	2007	42,994	60.4	19,522	28.7	23,260	18.6
	2006	37,151	59.7	17,280	29.7	20,982	19.2
	2005	39,048	59.4	16,941	29.6	21,245	20.0
	2004	43,207	58.8	22,061	23.6	18,164	19.4
	2003	38,507	53.6	19,516	21.8	20,863	13.0
	2002	32,440	51.0	17,442	21.7	17,343	12.2
	2001	10,641	55.3	6,566	24.6	6,190	16.3
	2000	24,294	54.5	15,091	20.9	14,523	12.6
	1999	18,578	50.3	11,122	20.7	10,078	13.0

Table 6: Summary of Trends in Breastfeeding Indicators by Race/Ethnicity: 1999-2008 — *cont'd*							
Race/Ethnicity and Year		**Breastfeeding**					
		Number	**% Ever Breastfed**	**Number**	**% Breastfed At Least 6 Months**	**Number**	**% Breastfed At Least 12 Months**
Multiple Races	**2008**	46,485	59.9	24,896	19.8	28,924	12.1
	2007	39,636	58.3	21,044	19.5	23,284	11.8
	2006	32,199	58.5	16,430	19.4	16,338	12.0
	2005	21,346	57.3	9,559	19.1	10,693	12.9
	2004	2,117	50.8	811	19.6	1,209	10.9
	2003	0	--	0	--	0	--
	2002	0	--	0	--	0	--
	2001	0	--	0	--	0	--
	2000	0	--	0	--	0	--
	1999	0	--	0	--	0	--
Source: CDC, 2008 Pregnancy Nutrition Surveillance. Table 19D: Summary of Trends in Breastfeeding Indicators by Race/Ethnicity. 2009.							

Overcrowding/Sibling Risks and RSV

Bulkow et al. (2002)[73] identified household crowding as a risk factor for RSV-related hospitalizations. American Household Survey data from 2005 that was analyzed by ICF International indicate that overcrowding is more probable among African Americans than among their Caucasian counterparts. Table 7 summarizes this data.

Table 7: Persons Per Room, By Ethnicity and Race (2005)			
Indicator	**Ethnicity/ Race**	**2005**	
		Households	**%**
Less than One Person per room	Latino	9,910,528	88
	Caucasian	78,030,766	99
	African American	12,707,767	97
One or More Persons per room	Latino	1,339,152	12
	Caucasian	698,964	1
	African American	340,683	3
Source: Blake KS, Kellerson RL and Simil A. Measuring Overcrowding in Housing. September 2007, p 12-13. (Prepared for the U.S. Department of Housing and Urban Development, Office of Policy Development and Research.			

The American Academy of Pediatrics has also identified the presence of siblings as a risk factor.[74] African Americans, like Latinos, have higher fertility rates and larger family size. Table 8 describes the fertility rates of women by race/ethnicity.

Table 8: Fertility Rates by Race/Ethnicity, 207

Race/ Ethnicity	Caucasian	African American	Latino
Live births per 1,000	60.1	71.6	102.1

Source: U.S. National Center for Health Statistics, National Vital Statistics Reports (NVSR), Births: Final Data for 2006, Vol. 57, No. 7, January 7, 2009 and Births: Preliminary Data for 2007, Vol. 57, No. 12, March 18, 2009.

As a result of the above data, it also appears that having a greater number of siblings is another risk factor for African Americans.

Asthma and RSV

As mentioned, findings regarding the relationship between asthma and RSV are not definitive. For example, Lee et al. (2007)[75] sought to clarify the relationship between RSV and asthma by analyzing data from 455 infants with a parent and/or sibling who had asthma. Children with RSV as well as other respiratory infections in the sample were more likely to experience wheezing and other symptoms that signaled the presence of asthma. In contrast, Dunder et al. (2007)[76], using a sample of 637,922 children, reached quite different conclusions. Selecting asthma medication use at ages three to sixteen years as a proxy measure for asthma, these researchers found no relationship between RSV infection and the development of asthma.

Thus, research is needed to characterize the exact relationship between RSV and asthma. However, sufficient evidence does currently exist to demonstrate that whether asthma is an antecedent or additional co-morbid variable, some degree of correlation exists between RSV and asthma. This suggests that asthma may also be a risk factor that is associated with the possibility of disparate RSV prevalence rates in the African American community.
Table 9 below provides an overview of data on asthma by race/ethnicity.

Table 9: Prevalence Asthma Rates By Race/Ethnicity

2007	Caucasian	African American	Latino
% of Adults	7.7	7.9	5.6
% of Children (<18 yrs)	7.4	15.5	9.3

Source: Centers for Disease Control and Prevention. 2007 National Health Interview Survey (NHIS) Data. Table 4-1 Current Asthma Prevalence Percents by Age, United States: National Health Interview Survey, 2007. Compiled 9/19/2008.

As Table 9 indicates, African American children are at a significantly higher risk of asthma.

Environmental Pollutants

Over recent decades, an entire movement known as environmental justice has highlighted the fact that air, water, and other pollutants can have a disparate impact among Americans. This is also the case in African American communities where good health can be compromised due to pollution. Table 10 describes some of these ongoing disparities.

Table 10: African American Communities and Pollutants

Lower-income African American neighbor-hoods experience 150% higher levels of polluted air than other higher-income communities. Source: Downey L, Hawkins B. Race, income, and environmental inequality in the United States. Social Perspective. 2008;51(4):759-781.
African Americans have a high rate of lung cancer - 73.5 per 100,000 compared to 63.8 per 100,000 for their Majority counterparts. Source: National Cancer Institute. SEER Cancer Statistics Review 1975-2007. SEER Incidence, Age-Adjusted Rates and Trends By Race/ Ethnicity and Sex. See http://seer.cancer.gov/csr/1975_2007/browse_csr.php?section=15 &page=sect_15_table.21.html.
Approximately 68% of African-Americans live within 30 miles of a coal-fired power plant – the distance within which the maximum effects of the smokestack plume are expected to occur. Source: Energy Justice Network. Energy and Environmental Justice Fact Sheet. Accessed 5/10/10 at http://www.energyjustice.net/ej/.
Air pollution is related to rising asthma rates. Although African Americans represent 12.7% of the U.S. population, they account for 26% of asthma deaths. **Source:** American Lung Association. Lung Disease Data in Culturally Diverse Communities: 2005. Lung Disease Data at a Glance: Asthma, available at http://www.lungusa. org.

Research by Karr et al. (2009)[81] also reveals that air pollutants are causally related to bronchiolitis, which can lead to hospitalization for RSV. Thus, the disproportionate air quality in many African American communities also suggests that African American infants and children and other vulnerable populations may be at greater risk of hospitalization for RSV.

Other Variables

Other risk factors for RSV are also disproportionately associated with African Americans. Persons with a compromised immune system are at greater risk of RSV. HIV infection, a condition that impacts the immune system, is more common among African American children as Table 11 indicates.

Table 11: Estimated Number of Cases of HIV/AIDS Among Children Under 13 by Race/Ethnicity (2007)

White	African American	Latino	Asian	American Indian/ Alaskan Native	Native Hawaiian/ Other Pacific islander
10,836	19,309	6,183	308	177	39

Source: Centers for Disease Control and Prevention. HIV/AIDS Surveillance Report, 2007. Vol. 19. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2009:12. http://www. cdc.gov /hiv/topics/surveillance/resources/reports/.

Additionally, infant mortality rates due to HIV/AIDS are also higher among the African American population in the United States (13.5 per 1,000 compared to 5.7 per 1,000 for Caucasians and 5.5 per 1,000 for Latinos).[82]

Table 12: African Americans and Tobacco, 2008					
	Caucasian	African	American Indian/ Alaska Native	Asian	Hispanics/ Latinos
% of Current Smokers age 18 and over	22.0%	21.3%	32.4%	9.9%	15.8%

Source: DC. Adult Cigarette Smoking in the United States: Current Estimate. Centers for Disease Control and Prevention. Cigarette Smoking Among Adults and Trends in Smoking Cessation—United States, 2008. Morbidity and Mortality Weekly Report 2009;58(44):1227–1232 [accessed 2009 Nov 16].

Tobacco smoke is also a risk factor for RSV. Table 12 summarizes tobacco use patterns on an inter-ethnic basis. As Table 12 reveals, while both Caucasians and Native Americans/American Indians have higher rates of tobacco use than African Americans, the percent of African Americans who use tobacco is 21.3 percent.

Children who are enrolled in daycare are at greater risk of RSV.[83] African American children are more likely than Caucasian or Latino children to attend daycare. Approximately, 30 percent of African American children of working mothers attend day care compared to 24 percent and 10 percent of their Caucasian and Latino counterparts, respectively. Moreover, full-time day care enrollees are more likely to be African American (58%) than Caucasian (36%) and/or Latino (34%).[84]

Despite the circumstantial data that support the hypothesis that African American infants may be at greater risk of RSV, very little research has been completed regarding this issue. Moreover, the empirical studies that have been completed are counter-intuitive. For example, Hall et al. (2009)[85] found that while 39 percent of children who tested positive for RSV were African American, only 29 percent of hospitalized children were African American. In contrast, 36 percent of the children who tested positive for RSV were Caucasian in the sample. However, 55 percent of the children who were hospitalized for RSV were Caucasian. While the authors interpreted these differences as suggesting that the African American children accessed health care more quickly and/or embodied a biogenetic difference, such data may also suggest that African American children diagnosed with RSV were not provided the level of treatment which they needed, i.e. hospitalization. African American children had a prevalence rate that was 200 percent higher than their representation in the overall population as indicated by the fact that 39 percent of the pool of children testing positive for RSV were African American. This study signals an immediate need for well-designed research that not only captures prevailing detection and treatment disparities, but which also identifies differential causes of RSV infection for African American, Latino and Asian children. These are groups for whom inadequate RSV data are available.

This need is further accentuated when data are examined by selected states. For example, the State of Louisiana, a state that is 32.0 percent African American[86] and which includes numerous risk factors for RSV in African American communities, had RSV hospitalization rates of 7.9 per 1,000 for Caucasians and 6.8 per 1,000 for African Americans. This data again raise the question of whether African American children who need hospitalization for RSV are being admitted.

The same trend of higher hospitalization rates for Caucasian infants with RSV infection is also observable in the State of California. Sangaré et al. (2006)[87] analyzed hospital discharge records for children under the age of one who were Medi-Cal enrollees. Medi-Cal infants, a group that qualifies for services by virtue of lower income status, had an RSV hospitalization rate that was 103 percent higher than for their non-Medi-Cal counterparts. However, the hospitalization rates were 34.9 per 1,000 live births for Caucasian, and 27.9 per 1,000 live births for African American infants. Similarly, the hospitalization rates were 21.8 per 1,000 live births for Latino infants, 12.5 per 1,000 live births for Asian/Pacific Islanders, and only 12.2 per 1,000 for American Indian/Alaska Natives. As research introduced earlier indicates, Native Americans and Alaskan Natives have some of the highest RSV rates in the country.[88] Yet, in California, hospitalization rates for these infants were the lowest in the study.

Morris et al. (2005)[89], analyzing data from a sample of 1,591 extremely low birthweight infants with RSV as well as other infectious diseases, found no differences in re-hospitalization rates by race when all factors were held equal. Control variables included age, gender, hospital, mother's education, household income, clinical condition, and insurance type. This well-designed study identified income and co-occurring medical conditions as the primary explanatory factors for different re-hospitalization rates. However, it is also possible that racial differences in re-hospitalization rates may have disappeared by including controls for hospital site. Certain characteristics of a hospital are associated with high rehospital-ization rates, i.e., hospital ownership, years of experience of the staff, staffing composition, etc. If these things come together in such a way that the hospital is a low-performing one, disparate rates of hospital readmissions will result, but the causes may be institutional and not based solely upon patient-level variables. Multi-level modeling, and/or hierarchical linear modeling are more appropriate statistical techniques for capturing demographic, hospital, and community characteristics as correlates of disparities. Again, this study highlights the need for not merely more research, but the re-specification of the models used for answering questions regarding RSV disparities.

Finally, Iwane et al. (2004)[90] also analyzed the relationship between hospitalization rates and RSV among 592 children less than five years old by race/ethnicity and viral infections. This study confirmed the intuitive conclusion that, given the risk factors associated with African Americans, Latinos, and other medically underserved populations, RSV-infected children would have higher and not lower rates of hospitalization.

FINDINGS AND RECOMMENDATIONS

Based upon the overview of RSV prevalence and incidence, prevention and treatment, epidemiologic considerations and possible disparities, a number of areas of need exist. In this section, the Consensus Panel summarizes and expands the discussion of needs and makes recommendations based upon these needs.

Priority Recommendations

While the Consensus Panel throughout this paper makes a number of recommendations regarding the diagnosis and treatment of RSV, there are four main areas that are considered top priority issues. These recommendations have been outlined in the subsections below.

PRIORITY RECOMMENDATION 1: The Consensus Panel recommends that evidence be provided by AAP/COID regarding the change in clinical guidelines defining the appropriate dosages of RSV immune-prophylaxis. The Consensus Panel also proposes that additional research and/or empirical evidence be established and disseminated to support the current clinical recommendations regarding the number of doses of immunoprophylaxis that should be given.

The Consensus Panel specifically recommends that more research is needed to confirm when fewer doses will achieve the same effect as a full season of prophylaxis. The research should also more explicitly provide evidence regarding the point at which eligibility can be best ended. This evidence must conclusively demonstrate the terms that should determine when immunoprophylaxis should or should not be used.

PRIORITY RECOMMENDATION 2: In order to improve the accuracy of RSV prevalence data, the Consensus Panel recommends that the Centers for Disease Control and Prevention make RSV a reportable disease.

As is known, reportable disease status confers a number of advantages in addressing key issues. A reportable disease is defined as a condition or disease that is usually contagious and/or serious that must be reported to federal, state, or local health entities in order to track patterns of progression. National notifiable or reportable diseases identified by the CDC for 2010 include: active tuberculosis, viral hepatitis, syphilis, gonorrhea, AIDS/HIV, cholera, influenza-associated pediatric mortality, malaria, measles, pertussis, rubella, small pox, tetanus, yellow fever and many others. National non-contagious diseases are also reported. For 2010, the CDC has identified cancer, elevated blood lead levels, pesticide-related illness, silicosis and waterborne disease as reportable diseases.

RSV does not currently have reportable disease status. Each state's list of reportable diseases differs since the reporting of these diseases is mandated by state laws or regulations. Ultimately, the CDC and the Council of State and Territorial Epidemiologists (CSTE) will determine which diseases are listed and which may be removed due to a decline in incidence. The state public health departments also work with the CDC to identify national reportable diseases.

The Consensus Panel recommends that state health departments be made aware of the seriousness of RSV and add it to the notifiable disease state lists. The Consensus Panel also suggests that State Public Health Departments be included as partners in urging the CDC to monitor the prevalence and incidence of RSV for inclusion on the national registry of reportable diseases.

PRIORITY RECOMMENDATION 3: The Consensus Panel recommends that research be completed to assess the role that "tiers of care" may play in reducing access to this highly critical immunoprophylaxis on a state-by-state basis.

One of the problems with the current RSV prophylaxis guidelines is that they create tiers of care. These tiers of care vary depending upon the individual health maintenance organizations and health insurance entities in general, as well as public and private insurers. Moreover, in some states, practice guidelines regarding RSV prophylaxis differ among private and public insurers. In this regard, a state-by-state analysis of current guidelines is needed to determine which guidelines can create disparities in the provision of RSV care.

These two-tier systems do not merely apply to the insured and the uninsured even within the insured population, a dichotomous effect is observable. The Consensus Panel recommends that a case study be completed regarding the introduction and institutionalization of polyclonal pneumococcal vaccine. The case study will identify groups that were excluded based on financial decisions. The information can then be used to ensure that such exclusions are not replicated in terms of the RSV prophylaxis in any state.

PRIORITY RECOMMENDATION 4: The Consensus Panel recommends that persons knowledgeable about RSV participate in the current ICD-10 coding discussions in order to minimize the risk of RSV miscoding.

Even with the use of the physician training on RSV recommended by the Consensus Panel, coding problems may emerge. ICD-9 coding is woefully inadequate in terms of actually identifying that an RSV diagnosis has been made. Indeed, many newer therapies have not been included in ICD-9 because it utilizes an historical basis for code assignment. However, the revised coding ICD-10 is currently being completed. The committee charged with this task is seeking to identify some of the more common constraints of ICD-9. Thus, the Committee will welcome input regarding RSV. Incorrect coding will, of course, obscure the severity of the problem.

In addition to these priority recommendations, the Consensus Panel also introduced supplemental findings in several other areas. The subsections that follow describe other concerns.

RSV Surveillance and Measurement

The advent of the information age has elevated the need for expert surveillance and rapid data analysis so that health threats can be quickly captured, identified, and remediated. In response to this need, the federal sector now collects data through an abundance of surveys, electronic surveillance systems, and other mechanisms. However, consistent with the Minority Health and Health Disparities Research and Education Act of 2000, the federal sector has mandated that data collected be disaggregated by race/ethnicity and other variables so that baseline and ongoing disparities can be identified and tracked. The Minority Health and Health Disparities Research and Education Act specifically requires the National Academy of Science (NAS) to "conduct a comprehensive study of the Department of Health and Human Services´ data collection systems and practices, and any data collection or reporting systems required under any of the programs or activities of the Department, relating to the collection of data on race or ethnicity, including other Federal data collection systems (such as the Social Security Administration) with which the Department interacts to collect relevant data on race and ethnicity." [And] "prepare and submit ...a report that: (1) identifies the data needed to support efforts to evaluate the effects of socioeconomic status, race and ethnicity on access to health care and other services and on disparities in health and other social outcomes and the data needed to enforce existing protections for equal access to health care; and (2) examines the effectiveness of the systems and practices of the Department of Health and Human Services described in subsection (a), including pilot and demonstration projects of the Department, and the effectiveness of selected systems and practices of other Federal, State, and tribal agencies and the private sector, in collecting and analyzing such data."

Yet, despite its status as one of the nation's primary causative agents of acute illnesses, the surveillance and tracking systems that are used for RSV are both under-developed and, as discussed, collect data in such a way that can introduce systematic bias. Accordingly, the Consensus Panel makes the following additional recommendations.

RSV Surveillance and Tracking Recommendations

RECOMMENDATION 1. The Consensus Panel recommends that RSV tracking and surveillance methods be revisited by the public sector so that the prevalence and incidence of RSV can be more accurately tracked.

RECOMMENDATION 2. The Consensus Panel proposes that a list of RSV symptoms be included in the key national surveys that collect data on infants. The inclusion of such symptoms will allow data to be collected even when no formal diagnosis of RSV has been made.

RECOMMENDATION 3. The Consensus Panel proposes that the Centers for Medicare and Medicaid Services (CMS) establish quality metrics for infants enrolled in Medicaid that extend RSV testing to a larger number of infants with symptoms of viral infection.

RECOMMENDATION 4. The Consensus Panel suggests that the need to determine whether disparities in the incidence and prevalence of RSV among African Americans and other racial/ethnic groups exist is extremely urgent. In this regard, we propose that the Centers for Disease Control and Prevention fund a meta-analysis of existing publications as a form of exploratory research to seek evidence of disparities. Simultaneously, we propose that CMS fund a retrospective study of its claims data to determine whether evidence exists of racial/ethnic disparities in the screening, prevention, diagnosis and treatment of RSV over the past. NMA and NBNA are available to participate in these efforts.

RSV Prevention, Diagnosis, and Treatment

The absence of an RSV vaccine places RSV immunoprophylaxis at the center of the issues of RSV prevention. In order to clarify those variables that support such a conclusion, it is necessary to briefly review some of the recommendations that were made by the Consensus Panel regarding palivizumab in general. The Panel also made recommendations to address specific barriers to the use of palivizumab that may support RSV health disparities.

RECOMMENDATION 1. The Consensus Panel recommends that practice guidelines be simplified to support maximum care.

Current American Academy of Pediatrics Committee on Infectious Diseases RSV guidelines remain complex. These complicated guidelines can lead to forgetfulness and/or confusion by pediatricians and/or neonatalogists. Thus, the Consensus Panel recommends that a RSV Relative Risk Scale be formulated and used by practitioners in identifying at-risk patients who may benefit from RSV prophylaxis. Such a scale is already in use in Canada. Table 13 is an example of that scale.

Table 13: Canadian RSV Risk Scoring Tool

	Point Value	Score	Point Value
Question	**Yes**		**No**
Born in Nov, Dec or Jan	25		0
Infant or siblings in daycare	17		0
>5 individuals in the home	13		0
Small for gestational age	12		0
Immediate family history without eczema	12		0
Male	11		11
>2 smokers in the home	10		0
TOTAL SCORE:	**100**		**0**
Low Risk:		0–48	
Moderate Risk:		49–64	
High Risk:		65–100	

Source: Latchman A, Pinelli J, Daudji A, Rawof S and Paes B. Predictive Value of the RSV Risk Scoring Tool in the Term Infant in Canada. Poster Session 2. Canadian Paediatric Society 85th Annual Conference. June 24-28, 2008.

Even when a Relative Risk Scale is used, the cost of prophylaxis should be weighed against the risk of severe RSV disease requiring hospitalization as well as associated aftercare costs to the family and health system. Documented long-term consequences must also be considered.

RECOMMENDATION 2. The Consensus Panel recommends that CMS commission a baseline study to determine whether current guidelines regarding the use of palivizumab have been followed in general among infants receiving care through Medicaid.

There are clear cases in which palivizumab should be administered to reduce the chance of infection with RSV. Palivizumab has been associated with a reduction in RSV-related hospitalization risk among patients who have congenital heart disease. However, the degree and severity of the heart disease may contribute to whether RSV prophylaxis is indicated.

African Americans are 12.8 percent of the overall population[91], but are approximately 22 percent of the country's 60 million Medicaid beneficiaries[92]. The data gathered by CMS from its contractors can be used to assess the level of physician and/or health plan compliance with both current and past clinical guidelines regarding the use of palivizumab.

Children whose status involves post-cardiac transplantation, extracorporeal membrane oxygenation, or bypass, are also at higher risk for RSV and should be provided with prophylaxis.[93 94] Patients who have congenital abnormalities of the airway, and/or diminished respiratory function should also receive prophylaxis. Congenital diaphragmatic hernia suggests a need for this prophylaxis as well. Similarly, patients with cystic fibrosis, alpha one antitrypsin, or any one of the other deficiencies which compromise the lung milieu should be considered.

RECOMMENDATION 3. There is also a need for research to determine whether disparities exist in the rates of recurrent RSV infection. Again, the Consensus Panel recommends that CMS be asked to support this research since it can be conducted using Medicaid claims data.

RSV is not a single entity antigenic virus. Because of the existence of an A type and B type RSV, it is possible for a child to have two separate RSV infections within the same season. The probability is much greater among certain classes of individuals who may not have complete immunologic competency.[95]

In addition, a recurrent infection is possible for RSV A or B type. The Consensus Panel suggests that research be conducted so that the nature of these risks can be better characterized.

RECOMMENDATION 4. The Consensus Panel is uniquely sensitive to cost as a barrier to accessing this prophylaxis and recommends that measures be taken to increase the cost effectiveness of treatment.

The Consensus Panel recommends that meetings be held to identify win-win strategies to reduce per unit costs without decreasing the level of profitability that is needed to sustain production of palivizumab and future research and development. It is estimated that palivizumab costs approximately $1,250 a vial. However, the price varies according to how much one buys, which group purchasing organization the vendor uses, a specific hospital's affiliation, and other factors. The Consensus Panel recommends that a Strategic Plan be developed by key stakeholders to identify methods that can be used to reduce the mean costs of a vial. For example, NICUs at hospitals reduce costs through batch doses. This approach can decrease costs by 1/3 to 1/2 since two or three babies may be served from a single vial.

Minority-serving physicians and/or hospitals may require training so that batch dosing can be maximized in achieving approappropriate immunoprophylaxis. These returns to scales can also be generated through the establishment of RSV prophylaxis clinics which serve the largest number of babies per vial so that cost-effectiveness of their immunoprophylaxis is maximized. However, the Consensus Panel recommends that outreach and education be directed to the parents of at-risk infants and babies so that the elevated costs due to missed appointments are minimized. This is important since parents who fail to adhere to clinic appointments place their babies at risk because the appropriate immune-prophylaxis dosage is not received.

RECOMMENDATION 5. The Consensus Panel recommends that as an insurer for a large percent of multiple risk babies, the Centers for Medicare and Medicaid Services (CMS) define standards for Medicaid managed care plans and/or fee-for-service providers that decide access to RSV prophylaxis based upon recommendations by the child's physician.

CMS carefully measures the quality of care offered by providers. The Consensus Panel recommends that RSV treatment quality measures be integrated into the publicly available report cards for Medicaid providers. When infants are admitted to the NICU, access and timely administration are not problematic. However, following discharge and particularly at the level of the first pediatrician visit as well as subsequent visits, physicians encounter multiple hurdles that must be navigated in order to obtain authorization to deliver the drug. These difficulties are encountered in applying for the drug at every encounter. For example, because the managed care model is a capitated one, these insurers are required to more closely scrutinize requests for immunotherapy for RSV prophylaxis. It is therefore important to have data on the denial rules and rates for various health plans. CMS is perfectly positioned to require that such data be submitted as a quality measure.

However, data are also needed regarding how fast requests are processed and, if a request is denied, how rapidly that request can be re-considered. If denials are not processed quickly, the delay may leave an infant unprotected for much of the RSV season. Therefore, the Consensus Panel also recommends that CMS track denials so that families with infants and young children can see what denial rates are for various Medicaid managed care providers.

RECOMMENDATION 6. The Consensus Panel recommends that an extensive social marketing campaign be launched to educate the country in general regarding RSV.

Social marketing strategies have been successfully used to promote breastfeeding, educate the public about the H1N1 epidemic, and achieve other goals. The Consensus Panel recommends that a widespread social marketing campaign be used to promote awareness of RSV. This campaign should be directed towards all key publics, including parents and the entire public health infrastructure. Neither RSV prevention nor improvements in treatment can occur unless the public is aware of the ongoing risks. The Consensus Panel also recommends that highly visible individuals be used as spokespersons in this effort.

It is important to note that the producer of this prophylaxis does educate the public by planning local specials about children who are re-hospitalized in the pediatric intensive care unit and placed on ventilators. They also use case scenarios and other strategies to increase RSV awareness in the community. These efforts emphasize hand washing, breastfeeding, decreased smoking, decreases in crowded living conditions, and other preventive strategies. However, a publicly funded nationwide campaign is recommended.

RECOMMENDATION 7. The Consensus Panel also recommends that the processes associated with care transitions be strengthened to prevent the re-hospitalization of at-risk babies.

For the most part, neonatologists direct considerable attention toward follow-up. In some cases, they attempt to set up as many appointments as possible after the babies are discharged from the hospital. The care transition process involves transitioning the child to their primary care physician. Yet, stronger care transition practices are needed for children who are born two months before the onset of RSV season, and/or six months before the onset of the RSV season. These are the specific groups who can be poorly transitioned unless a structured system is in place. Improved transitions may be particularly needed for infants born into a rural environment where physicians may encounter fewer children born in their practice who are at risk of RSV. Some rural communities have addressed this issue through the use of a high risk follow-up system. Such a system identifies high-risk infants and tracks them from the moment of discharge.

As part of an improved system of care transitions, the Consensus Panel recommends that the health care system be more aggressive in identifying babies for different follow-up issues. We recommend that hospitals qualify babies for follow-up programs at the time of discharge. By making discharge communications more effective, rehospitalizations can be reduced.

Education and Training of Parents, Physicians and/or Providers

While a comprehensive needs assessment has not yet been conducted, anecdotal data suggest that tremendous illiteracy exists among parents and the public in general about RSV. The Consensus Panel's preliminary investigation indicates that even physicians, nurses, and/or other providers may be inadequately informed about RSV. As a result, education and training of parents and medical professionals is needed. Several recommendations were made regarding this issue.

RECOMMENDATION 8. Educate parents to ask their physicians, "Could it be RSV?" when selected symptoms are present.

Parents must be trained to support the identification of their child's disease as being RSV-related. They can do so by merely asking the physician about RSV. A proactive stance by parents can serve as a reminder to physicians to consider whether the child's symptoms suggest RSV.

RECOMMENDATION 9. The Consensus Panel also recommends that education be made available to increase providers' knowledge of the importance of RSV detection.

The level of familiarity with RSV among physicians, nurses, and other health care providers has not yet been assessed. The Consensus Panel recommends that funding be made available for NMA and NBNA to conduct needs assessments at their national conferences. These needs assessments can then be used to develop a comprehensive RSV training program to address RSV knowledge gaps among physicians and other providers.

RECOMMENDATION 10. The Consensus Panel also recommends that physicians and other health care professionals be provided with training to ensure that RSV is properly coded.

It is likely that coding errors have led to the underestimation of the problem of RSV. For example, H1N1 codes may sometimes be assigned by hospitals and/or emergency rooms when patients present with flu-like symptoms. With training, such coding errors can be addressed since RSV presents very differently from flu in terms of the amount of wheezing, the actual clinical presentation, and how the chest x-ray appears. However, it is easy for very busy medical personnel to misdiagnose and miscode "flu-like" symptoms as another influenza.

If the child is sick enough to require hospitalization, the probability of miscoding decreases as efforts are made to determine whether the child has a type of influenza or RSV. However, if the patient goes home as a result of efforts to ensure cost savings and cost containment, the baby won't be screened. Physician training can prevent errors of this type.

RECOMMENDATION 11. Engage in parental and provider education to increase compliance when palivizumab is approved for use.

While some research currently exists on Medicaid patients and/or minority patients and RSV, more is needed. In an article by Frogel et al. (2010), "A Systematic Review of Compliance with Palivizumab Administration for RSV Immunoprophylaxis" which was published in the *Journal of Managed Care and Pharmacy*[96], it was discovered that home-based programs are associated with higher prophylaxis compliance rates for RSV compared with clinics and/or office programs. RSV prophylaxis compliance rates were as high as 94 percent for home-based programs versus 64 percent for Medicaid infants and infants of minority descent, respectively, when they received their palivizumab doses through another program. Whether these infants received their doses at a clinic or office, depending on the definition of compliance, rates ranged around 61 to 100 percent for Medicaid patients in general, but were only 44 percent for infants of minority descent.

Reminders such as telephone calls to patients by caregivers, comprehensive multidisciplinary programs that include extensive counseling of the patients, calendars with sticker reminders, and education in the first language are also strategies that are associated with increased compliance with the necessary number of dosages. Several studies recommend educating parents on the benefits of RSV prophylaxis[97], alleviating transportation and language difficulties, recognizing cultural differences and biases, and clarifying misperceptions regarding the severity of RSV.

RECOMMENDATION 12. Train physicians to capture RSV risk factors in the medical histories of their patients.

Physicians can be trained to capture data regarding specific risks for use in the risk assessment. If, after the assessment of the individual patient's data, a provider determines that the patient is at high risk for RSV disease, complicated by the possibility of hospitalization, prophylaxis should be provided.

RECOMMENDATION 13. Educate physicians about RSV Prevention.

A pediatrician or primary care practitioner is the best person to determine and interpret relative risk factors. However, the Consensus Panel recommends that physicians receive training so that they will be better prepared to interpret risk. This training would reflect the findings from the needs assessment described in Recommendation 9.

RECOMMENDATION 14. Produce and disseminate RSV Prevention and Treatment Toolkits to parents of at-risk children.

There are many factors that put infants at risk of RSV. Parents should be well-informed of such risks if they are to identify and/or prevent RSV in their children. Children and infants that attend childcare[98] or have siblings in school[99], and those who are exposed to secondhand smoke[100], or those who are young at the beginning of the RSV season are most at risk of contracting RSV.

Given the well-known correlations between the quality of air and lung function, an environmental assessment of air quality is important for those patients with unique circumstances such as unwarranted air pollution caused by a residence being situated near an exhaust-producing area, i.e., parking lot, bus station, the use of a coal-burning stove, or the frequent use of a wood-burning fireplace. Parents must be educated regarding these and other conditions.

As mentioned, urban environments also contain different risk factors. For example, urban families are more likely to have a young child in daycare. However, efforts to reduce risks by isolation of the child and caregiver are not practical. As mentioned, smoking is a risk factor. Smoking cessation programs may therefore be listed in the toolkit.

The toolkit should inform parents of those risk factors which have a greater impact. For example, a larger family size with more than one school-age child is a risk factor. All parents who introduce their preterm babies into such as environment should be educated regarding the elevated risk. While no particular risk factor is unique in its predictive value, and many risk factors exist simultaneously, parents should be made aware that the greater the number of risk factors, the higher the likelihood of RSV hospitalization. However, the toolkit should train parents on preventive behaviors they can adopt (e.g., smoking cessation).

Other Prevention and Treatment Findings and Recommendations

In addition to focusing upon recommendations regarding expanding access to palivizumab, the Consensus Panel also had findings and recommendations in other areas related to RSV prevention and treatment. The subsections that follow briefly outline these areas of need and strategies for their remediation.

RECOMMENDATION 15. The Consensus Panel recommends that health information technology be used to support the early identification of patients who are at risk of RSV.

Whether the early identification of children at risk of RSV is tracked through a registry, individual health records, web-based tracking systems, or other means, it will be necessary to incorporate health information technologies. The Consensus Panel recommends that the NMA Health Information Technology Subcommittee partner with other experts on health information technology in order to identify the best processes that can be used to identify and track at-risk infants and children not only early in the flu season, but over the long run so that the progression of RSV residual effects can be assessed as a part of the early identification process. Thus, early identification can be combined with the generation of a paper trail on patients that track their care and their progress.

RECOMMENDATION 16. The RSV Consensus Panel recommends that an extensive media and outreach campaign be launched that addresses key correlates of RSV.

As discussed earlier, both systemic and behavioral factors can interblend in order to support a decrease in the prevalence and incidence of RSV. Through a media campaign in combination with group level and individual level outreach, a number of other prevention activities can be implemented. For example, the media and outreach campaign can be designed to increase awareness of RSV among at-risk communities. Additionally, the contents of the campaign can educate parents regarding the fact that pre-maturity, low birthweight and other factors place infants at risk of RSV. The importance of hand-washing, breast feeding, and a smoke-free environment should be integrated into the prevention messaging. This campaign should also educate parents and other segments of the public who have contact with high-risk infants who receive one dose of palivizumab regarding the importance of follow-up. Finally, the Consensus Panel proposes that messaging be delivered using a celebrity and/or other parent or family member whose life has been affected by RSV. This approach is consistent with research by Cram et al. (2003)[101] who discovered that preventive care programs can be boosted by a celebrity spokesperson. Specifically, they identified the "Katie Couric effect," in which the Today Show co-host underwent a televised colonoscopy that resulted in an increase in colonoscopies among the general public. Prevention messages can be delivered through videos, brochures, classes, online media, cell phones, and other communications devices. This recommendation reflects research by Samal et al. (2010)[102]. In this study, three modes of telecommunication were used (internet, texting and cell phone) to deliver information regarding an STD clinic. The study found that all three modes of contact were accepted as a form of health communication. Additionally, Winston et al. (2007)[103] found that telephone messages regarding pneumococcal vaccination in a diverse managed care population resulted in an increase in vaccinations among the targeted population. Finally, culturally competent materials must be presented.

Research

The need for additional research is a theme that was interwoven throughout the Consensus Panel discussions. Whether the issue was RSV prevalence and incidence RSV detection, and/or the extended discussion of RSV prevention and treatment, the need for research was identified. The recommendations that follow describe the types of research for which federal funding is needed.

RECOMMENDATION 17. The RSV Consensus Panel recommends that federal funding for RSV research be increased.

The findings from the literature regarding RSV reveal the existence of a number of knowledge gaps. Scientifically designed studies are needed to address these areas. The Consensus Panel recommends that federal funding be provided to support new RSV research.

RECOMMENDATION 18. The NMA/NBNA RSV Consensus Panel recommends that multiple research studies be completed to increase the evidence base for prevention and treatment.

Collectively, the Consensus Panel recommended that the types of research listed in Table 15 be completed.

Table 14: Recommendations Regarding Research

- First, the Consensus Panel recommends that the three versus five doses issue be revisited by CDC. This can be achieved in several ways. A literature review can be conducted of all current evidence that served as the basis for the modification of the clinical guidelines to support the changes in the dosage of palivizumab used. A re-analysis of data is also needed from the National Children Study that utilizes a statistical technique such as linear hierarchical modeling so that patient level, provider level, and community level variables can be integrated as explanatory variables in identifying the correlates of hospitalization and the long-term impacts of RSV.
- Second, the Consensus Panel recommends that CDC fund a study that tests a re-specified cost benefit model that uses findings from the above study to more accurately predict the cost-savings from the use of palivizumab. This model would assess the present value of the economic costs that would follow a child over the course of at least two decades.
- Third, the Consensus Panel recommends that Medicaid claims data from CMS be analyzed utilizing methods such as multiple logistic regression in order to determine whether the odds of receiving palivizumab, hospitalization and/or other RSV outcomes are significantly different for African American and other minority infants and children.
- Fourth, the Consensus Panel suggests that CMS fund a study that analyzes Medicaid claims data using bivariate and multivariate analysis in order to determine whether access to palivizumab differs across Medicaid managed care plans by race/ethnicity.

RECOMMENDATION 19. In addition to the retrospective studies described in Table 15, the Consensus Panel recommends that African Americans and other minorities be encouraged to increase their involvement in clinical trials.

Ultimately, the involvement of African Americans in RSV-related clinical trials will enhance RSV prevention and treatment. The Consensus Panel recommends that strategies be implemented to improve communications between universities and hospitals and community residents. One pathway to doing so involves building relationships with research institutions and community physicians. The Consensus Panel suggests that clinical trial education be taught in high school as a basis for the greater inclusion of African Americans not only in RSV clinical research, but in other studies as well. Moreover, physicians can be trained to design and implement a clinical trial.

As literature on clinical trials indicates, even the research from clinical trials can be flawed if the trial design is not carefully constructed. For example, the method of randomization can lead to distorted outcomes. This is true whether a coin toss, a table of random numbers, or a computer program is used in the randomization process. Numerous examples exist in health research regarding errors that have occurred as a result of the randomization process. Even the use of the cross-over design[104], a set of methods that alternate periods of treatment with periods of alternate treatment, can yield imperfect results. However, NMA and its partner have expertise in clinical trials and are perfectly positioned to expand their efforts to increase African American clinical trial participation by both physicians and consumers.

Advocacy

Advocacy is defined as "the act or process of advocating or supporting a cause or proposal."[105] In order to shift the Consensus Panel's recommendations from concept to policy, advocacy is needed. Several recommendations were made regarding the nature and type of advocacy that the issues explicit to RSV require.

RECOMMENDATION 20. The Consensus Panel recommends that NMA and NBNA partner with CMS and other key stakeholders to support awareness and use of RSV immunoprophylaxis.

Research by Thompson et al. (2003),[106] that was published in the *Journal of the American Medical Association* revealed several important results. The researchers found that RSV affects significant numbers of the elderly. Even more surprising, they discovered that mortality rates among the elderly from RSV actually exceed those from influenza. Thus, because a child infected with RSV can infect his/her grandparents and/or other relative, the pathway of prevention from the use of palivizumab may be multiplicative rather than linear. However, the parallel issues of RSV illiteracy across the general public, inadequate surveillance data, prevention and treatment barriers, and systematically integrated health disparities, also characterize the issue of RSV and the elderly. Accordingly, the Consensus Panel recommends that advocates for infants and children conjoin with advocates for the elderly on this issue. Once educated regarding issues that are remediable through advocacy, these partnerships and collaborations can engage in advocacy surrounding many issues. For example, consistency of care, consistency of the information provided, and consistency in the provider team that delivers care is an area that warrants advocacy. Similarly, one way of addressing the variations in treatment is through the use of treatment pathways. Treatment pathways are not clinical mandates. Thus, physicians are not professionally compelled to adopt and implement these approaches. Nevertheless, advocacy regarding the use of RSV treatment pathways can support improved treatment. This is because a set of orders, once written, will proceed through to other team members, thereby supporting a more standardized care regimen. Moreover, treatment pathways normally reflect evidence-based medicine – what works, what doesn't work. Physicians can serve as advocates within their own ranks for the use of treatment pathways. Physician advocacy can also include efforts to increase follow-up, compliance, and care transitions.

An even broader area in which advocacy is needed is in educating policymakers about RSV issues. These areas of concern may include RSV morbidities, the prevalence and magnitude of RSV, and documented long-term effects. Advocacy by partners such as Families USA, Women's Congress for a Cause, Children's Defense Fund, March of Dimes, Congressional Black Caucus Foundation, Hispanic Caucus, National Healthy Start Association, American Public Health Association, Food and Drug Administration, Centers for Disease Control and Prevention, National Institutes of Health, Environmental Protection Agency, National Black Family Coalition and others can also provide input as new clinical guidelines surrounding RSV, care coordination, and the administration of immunotherapy are crafted. The partnerships formed may also advocate for the use of interdisciplinary teams that may include physicians from different disciplines of nurses, nurse practitioners, and even community health workers.

The advocacy effort can focus upon the education of emergency room physicians, interns, physician assistants and nurse practitioners, registered nurses, federally qualified health clinics, and others. Advocacy for funding is also needed. For example, a clinical trial is needed regarding the efficacy of mobile nurses in improving the reach of a single vial of prophylaxis. Advocacy can take the form of holding meetings with HRSA and soliciting funding to educate medical and nursing students regarding the care of infants and/or seniors who are at risk of RSV.

Other advocacy issues include: 1) advocacy regarding the use of culturally-appropriate information; and, 2) adding the issue of RSV disparities to the agenda of the Academy of Pediatrics, Committee on Infectious Diseases (COID), Center for Disease Control's Advisory Committee on Immunization Practices (ACIP) and the Congressional Black Caucus Foundation (CBCF). Indeed, advocacy can be directed towards CMS, the Congress, members of insurance companies, and well-known researchers who design and implement clinical trials. In this regard, the Consensus Panel recommends that advocacy efforts use the approaches listed in Table 15.

Table 15: Suggested Advocacy Approaches

The Consensus Panel recommends that:

- Obstetrician/Gynecologists, nurse mid-wives and nurse practitioners play a role in reinforcing the importance of follow-up with the infant's Primary Care Physician for RSV immunoprophylaxis;
- A more efficient packaging of prophylaxis be implemented in order to reduce waste;
- Home-based programs for immuno-prophylaxis be advocated for as a cost-saving measure;
- The process for authorization of immunoprophylaxis be streamlined and expedited approval be used for the first outpatient dosage; and
- Other.

Indeed, the implementation of the strategies proposed by the Consensus Panel will require collaborative support.

Conclusions and Implications

Multiple recommendations and their corresponding rationales have been presented. However, a continuing theme is that RSV threatens the health of premature infants and that clinical guidelines should reflect the appropriate FDA-approved immunoprophylaxis treatment for premature babies during the RSV season. The threats associated with RSV infection as an acute health problem can be serious, particularly for infants, children, the elderly, and other vulnerable populations. Yet, RSV is virtually unknown among the public and may be inadequately screened for by primary care physicians and other health professionals. Thus, education directed towards the public in general is needed to increase awareness of this illness. Additionally, physicians, particularly those who serve at-risk populations, may also need re-education so that augmented systems can be implemented for its detection. However, from a public health perspective, RSV surveillance systems need improvements so that the data produced are more accurate.

Of particular importance, state and local level public health agencies are in need of data that accurately identifies whether current disparities exist in the detection and treatment of RSV infections. Finally, there is an urgent need for more research regarding the prevalence and treatment of RSV infections among African Americans, Latinos, Native Americans, Pacific Islanders and Asians. The recommendations of the Consensus Panel support the advocacy, research, education and training needed to identify and remediate RSV-related disparities.

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