



DEPARTMENT OF HEALTH & HUMAN SERVICES

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RE: NVAC – May 11 & June 5-6, 2007 meetings

Dear Dr. Agwunobi:

First let me offer you my congratulations on your new position. The support you have given the Committee over the last two years has done much to move important issues surrounding immunization coverage and vaccine safety to the forefront and on behalf of the National Vaccine Advisory Committee (NVAC) I offer my sincere thanks and wish you well in your future endeavors.

The Committee has accomplished much since our last correspondence. On May 11, 2007, we held a meeting by conference call to review the problem statement developed by the Adolescent Immunization Working Group (attached). The purpose and goal of the manuscript, "The Promise and Challenge of Adolescent Immunization," is, as you suggested, not to outline solutions to issues raised but simply to raise issues of import so as to begin a national debate on these topics. After a brief discussion and clarification of some details as requested by both members of the Committee and the public, the attached version was approved and endorsed by the full Committee. I am currently working to have the document published in an upcoming issue of the Journal of the American Medical Association.

Unfortunately, important family obligations prevented me from attending the first day of our June meeting. I am pleased to report, however, that Dr. Cornelia Dekker filled the role of Acting Chair quite seamlessly.

During our two-day meeting, the Committee received many important presentations beginning with a presentation by Dr. Gina Mootrey (Centers for Disease Control and Prevention [CDC]) about the National Influenza Vaccine Summit. She informed the Committee of the record-high estimated vaccine production for the 2007-08 influenza season and noted that the Summit Statement emphasizes universal vaccination as opposed to vaccination for high-risk groups only. Dr. Mootrey also reviewed the 2006-07 influenza vaccine distribution data, which reveal a trend toward instability in the vaccine supply over time for some provider types while others remain constant. Finally, she highlighted recipients of the 2006 Summit Immunization Excellence Awards, who were chosen for their efforts to increase demand for vaccination through partnerships.

Dr. David Bell of the CDC reported important pandemic influenza-related developments that occurred at the recent World Health Assembly. In January 2007, Indonesia ceased

sharing its human H5N1 specimens with the World Health Organization (WHO) surveillance network on the grounds that it does not receive any benefit related to its sharing. Efforts to resolve the crisis resulted in the assembly crafting a compromise resolution that proposed multiple revisions to the terms of agreement for the WHO surveillance network. Most notably, the resolution called for a study of the extent to which a virus or gene can be considered a biological resource over which countries can claim sovereign rights. Dr. Bell informed the Committee that the U.S. Government is engaged in high-level discussion on this issue as it affects patenting and trading practices as well as health research.

Dr. Jeanne Santoli of the CDC next briefed Committee members on expectations for the 2007–08 influenza season. Highlights of the 2007 Advisory Committee on Immunization Practices influenza vaccination recommendations are the emphasis on the permissive component, changes to the two-dose recommendations for children not fully vaccinated the first year, and changes in language regarding timing of vaccination. Dr. Santoli then confirmed that vaccine production estimates are at a record high but added the caveat that these estimates are based on two variables: Production and, more important, demand. In closing, Dr. Santoli reviewed the public relations campaign for the upcoming influenza season, which is being driven by data obtained through focus group research.

Committee members next received an update from Ms. Emily Marcus Levine of the HHS Office of the General Counsel on the Omnibus Autism Proceeding in the U.S. Court of Federal Claims. The court proceedings officially began on June 11, 2007, with a series of test cases. All evidence presented will be subject to the *Daubert v. Merrell Dow Pharmaceuticals* case law that established a high standard of reliability for expert testimony on scientific matters. The test cases will be open to the public, and Ms. Marcus Levine informed Committee members on how they may stay abreast of the court proceedings.

Dr. Ben Schwartz of the NVPO presented the renamed Strategic Issues in Vaccine Research (SIVR) Program, formerly the Unmet Needs Program. In fiscal year 2007, the SIVR review process was streamlined, and a total of 31 projects were funded from a pool of approximately \$4 million. Improvements in SIVR Program monitoring, evaluation, and information sharing, including frequent progress reports and an SVIR-sponsored seminar series, are being considered. Dr. Schwartz closed by soliciting Committee member input on fiscal year 2008 priority topics, proposal review process, and timeline.

The second day of the meeting, presided over by NVAC Chair Dr. Gary Freed, opened with reports from representatives of various agencies, departments, and advisory committee representatives and stakeholder liaisons, as follows: National Vaccine Injury Compensation Program—Dr. Geoffrey Evans, Advisory Commission on Childhood Vaccines—Ms. Marguerite Evans Willner, Centers for Disease Control and Prevention—Dr. Melinda Wharton, National Vaccine Program Office—Dr. Bruce Gellin, Centers for Medicare & Medicaid Services—Dr. Jeffrey Kelman, United States Agency for International Development—Mr. Neal Brandes, Department of Veterans Affairs—Dr. Ronald Valdiserri, and America's Health Insurance Plans—Ms. Barbara Lardy.

These reports were followed by an update on the National Vaccine Plan. Dr. Ray Strikas (NVPO) reviewed recent plan developments, beginning with a March 20, 2007, interagency meeting to draft recommendations for the plan. Followup discussions with the Assistant Secretary of Health clarified the purpose of the plan and the need to align it with HHS Healthy People 2010 goals. After a review of international vaccination plan components that revealed consonance with the draft U.S. recommendations, a subsequent interagency meeting was held on June 5, 2007. Lead and contributing agencies nominated in this meeting will work with the NVPO to draft the National Vaccine Plan. Dr. Strikas noted that the development process will include stakeholder involvement and a review by NVAC.

NVAC Subcommittee representatives then presented summaries of their meetings. Dr. Andrew Pavia summarized the joint meeting of the Subcommittee on Vaccine Safety with the Subcommittee on Public Communication, Consultation, and Participation. Their meeting focused on NVAC's role in development of the Immunization Safety Office's (ISO) research agenda. Based on the recommendations of the Institute of Medicine, the ISO has asked NVAC to conduct a scientific review of the research agenda and to obtain input from public stakeholders. After establishing this review panel, next steps are to develop a clear charge to the review panel, refine the role of the public, and develop a mechanism for industry consultation.

Dr. Ben Schwartz, representing the Subcommittee on Vaccine Development and Supply, presented on the topic of establishing and changing vaccination schedules. The Subcommittee specifically explored what research infrastructures currently exist in the United States to generate data on immunization and how can these data can be used to change the vaccination schedule. The Subcommittee also responded to the request for additional research priorities for the SIVR Program with the suggestion of standardized vaccine assays as a new topic area.

The chair of the Subcommittee on Immunization Coverage, Dr. Jon Almquist, reviewed the topics covered in this group's meeting: Efforts at the American College of Obstetrics and Gynecology to educate its members regarding immunization, publication and implementation status of NVAC's Progress Report on Immunization Information Systems, vaccine payment issues, and strategic planning at CDC for vaccine coverage assessment. The Subcommittee also discussed the SIVR Program and added two research areas for consideration: Improving adult immunization rates and improving immunization assessment and immunization information systems. Dr. Almquist concluded with an acknowledgment of Dr. Alan Hinman as outgoing Subcommittee chair.

Committee member Dr. Lance Gordon updated the other members on the Adolescent Immunization Working Group's progress to date. The "problem statement" paper reviewed by NVAC is in review at *JAMA*, and the Working Group is now developing draft recommendations to address a full range of topics relevant to adolescent immunization. Dr. Gordon noted that forthcoming data from the teen module of the National Immunization Survey will be valuable for informing the Working Group's recommendations.

Dr. Guthrie Birkhead, Chair of the Vaccine Financing Working Group, reported on the activities of this ad hoc group formed in 2006. To date, the Working Group has focused primarily on childhood immunization and has engaged in data gathering from various sources, including CDC-sponsored studies of vaccination financing. The expected outcome of the current data-gathering phase is a white paper that will likely come before the full Committee for review in February 2008.

Please feel free to contact me with any questions or concerns you may have in regard to any of the Committee's activities. The next NVAC meeting is scheduled for October 22-23, 2007. Again, please accept my congratulations and best wishes.

Sincerely yours,



Gary L. Freed, MD, MPH
Chair, National Vaccine Advisory Committee

Enclosure

The Promise and Challenge of Adolescent Immunization

Adolescent Working Group of the
National Vaccine Advisory Committee

Approved by NVAC – May 11, 2007

The National Vaccine Advisory Committee (NVAC) created a working group to address issues related to adolescent immunization. In response to a request from the Assistant Secretary for Health, this Working Group conducted an assessment of the current landscape of adolescent immunization and identified issues that will require national attention in the coming months and years if current and future recommended adolescent immunizations will be used to their potential. Following identification and the achievement of a national consensus on the issues to be addressed, the NVAC, through its Adolescent Working Group, will receive input from a variety of stakeholders to develop policy recommendations to address these issues.

There is now a unique and important opportunity through immunization to reduce morbidity and save lives of adolescents in the United States. Adolescents hold the promise of a productive and satisfying adulthood, but this promise may be threatened by a variety of preventable health conditions. Several health issues are of national concern for the adolescent population, including obesity and substance abuse. However, many of these problems are frustrating because there are no clear and effective actions which, if implemented, can impact virtually the entire age group. Conversely, vaccine preventable diseases are unique in that they are both serious *and* readily preventable.

Our country has a long history of using immunizations to protect individuals and populations at both ends of the age spectrum, but little experience between those ranges. Now, several new vaccines have created an imperative to reach the adolescent population and to protect them against a group of significant – but eminently preventable – diseases, thereby increasing the chance of our youth to enjoy long and productive lives. However, to achieve the promise of these new preventive health interventions our nation must focus on effective vaccine delivery to this population.

Specifically, three new vaccines are now available and recommended for adolescents that prevent a total of 5 diseases that can have a range of devastating health consequences.¹ Individual vaccines protect against meningococcal meningitis and human papilloma virus and a combined vaccine protects against tetanus, diphtheria and pertussis. All three vaccines have been shown to be safe and effective.

THE DISEASES NOW PREVENTABLE THROUGH ADOLESCENT IMMUNIZATION

Meningococcal Vaccine

Meningococcal disease is a bacterial infection that is a leading cause of meningitis among children 2 – 18 years of age in the United States and a cause of severe and devastating sepsis.² Of the 1,400-2,800 individuals in the U.S. who contract meningococcal disease each year, 10-14% will die despite aggressive treatment. Of those who survive, debilitating side effects are common, including loss of limbs, deafness, mental retardation, seizure disorders, and strokes. The meningococcal conjugate vaccine was licensed in 2005 and is recommended for all children at their routine recommended early adolescent visit (11-12 years of age) as well as those entering high school and for college freshmen living in dormitories.^{3,4}

Human Papilloma Virus Vaccine

In 2003, more than 11,000 women were diagnosed with, and almost 4,000 women died from, cervical cancer in the United States each year. The overall incidence of cervical cancer was 8.1 per 100,000 women. Almost all cervical cancers are caused by the human papillomavirus.⁵ The recently licensed HPV vaccine was shown in clinical trials to provide close to 100% protection against cervical cancer precursor lesions due to the two types of human papillomavirus (types 16 and 18) that cause 70% of cervical cancer as well as genital warts due to two types (6 and 11) that cause 90% of genital warts. The vaccine is recommended to be given to 11-12 year old adolescent girls in a three-dose series over six months. Previously unvaccinated females 13-26 years of age are also recommended to receive this vaccine.⁵

Tdap Vaccine

The combined Tdap vaccine protects against tetanus, diphtheria and pertussis.⁶ Despite substantial success in vaccinating infants against these diseases, coverage is not complete, and protection against pertussis appears to wane after 5 – 10 years. Consequently, a large proportion of reported cases of pertussis in the United States are now found in the adolescent age group, and many outbreaks occur in school settings where adolescents congregate. Further, adolescents are now a reservoir of disease which can infect infants. A large proportion (38%) of adolescents in Massachusetts with pertussis reported prolonged coughing of at least one month at the time of diagnosis, resulting in multiple health care visits as well as school absenteeism.⁶ In 2006, the Advisory Committee on Immunization Practices (ACIP) recommended that “adolescents aged 11-18 years should receive a single dose of Tdap instead of tetanus and diphtheria toxoids vaccine (Td) for booster immunization against tetanus, diphtheria, and pertussis.”⁶ The preferred age for receiving the vaccine is 11-12 years.⁷

A NEW ERA IN ADOLESCENT IMMUNIZATION

Understanding and acting upon the imperative of ensuring that these new vaccines as well as the previously recommended vaccines are administered to the adolescent population requires a paradigm shift on the part of health care providers, policy makers, and parents alike. Historically, vaccination has been framed as an intervention for young children, while behavioral health challenges like nutrition and sexual behavior are illustrative of key issues that compromise adolescent health. Indeed, vaccinations for young children *are* important. And the behavioral health challenges that face adolescents *are* critical. But at the same time, there are now immunizations that can prevent serious and life-threatening diseases among adolescents.

The ability to effectively prevent significant morbidity and potential mortality, especially among a population that constitutes our Nation's future, creates an imperative to make adolescent vaccination a national health priority.

Adolescent Health Care Utilization

Ensuring that there exists an effective means of delivering these vaccines is a necessary precursor for high vaccine coverage rates. Unfortunately, unlike infants, the delivery of preventive care for adolescents is more complex. The imperative to provide and promote adolescent vaccination will require the support of an infrastructure for this to be accomplished effectively and at a reasonable cost.

The unfortunate reality is that fewer adolescents, compared with other pediatric age groups, access the medical system for preventive care, either in public or private delivery venues. When they do access the health care system, it is most often for acute care.⁸ If the U.S. is to achieve high rates of vaccine coverage for adolescents, there will need to be a system that meets their needs and fits their patterns of behavior.

Currently, the utilization of the existing private or public health preventive care infrastructure to achieve high vaccination coverage rates for these new vaccines among adolescents is woefully inadequate. Adolescents access a patchwork of sites and services for health information and health care; in fact, research to date is mixed on the extent to which adolescents get health care – particularly preventive care - at all. Recent analyses of national data suggest that over 30% of adolescents receive no health care in a 12 month period.⁹ Although more than 50% do have some type of visit to a primary care provider, the probability of having a primary care visit in a given year declines substantially with increasing age.⁸ A study of medical records from Harvard Pilgrim Health Care, demonstrated that most visits by adolescents (73%) were for acute, not preventive care. Within this insured population, all with assigned primary care providers, 33% of 11 year olds had no preventive care visits in any given year. This number increased to 44% for those 17 years of age. Even fewer adolescents have the three health visits required to complete the HPV vaccine series.¹⁰ Thus, even in a “best case” scenario of insured children in a well-organized health care delivery system, with assigned primary care providers, preventive care is markedly underutilized and not sufficiently organized to reach desired immunization rates.

Other research has shown that adolescents self-report a much higher rate of preventive visits in a given year.¹¹ However, this finding is not supported by billing data from the Health Plan Employer Data Information Set (HEDIS), in which a study demonstrated that only 34% of adolescents had a preventive visit over a 12-month period.¹² This apparent contradiction may be the result of adolescents erroneously perceiving health care visits in general to be preventive when many of them are, in fact addressing specific health concerns. Another possibility is that physicians may be providing preventive services but coding the visit for something other than well care when preventive care is not covered by insurance. Regardless, it appears likely that adolescents overestimate their own use of preventive care.

Adolescents do, however, identify unmet needs in their own health care use; in the National Longitudinal Study of Adolescent Health, almost 20% reported that there was a time in the past year when they thought they should obtain medical care, but did not.¹³ Bringing adolescents into the health care system by promoting vaccinations could be thought of as an invitation that brings them into the system for other important health and health care messages and activities, including important advice and screening as they transition into adulthood.

New Ideas for Old Problems

The issues surrounding adolescent immunization compel our nation to consider new ways of looking at old problems. Although adolescents have long not utilized preventive health care, it is now even more important they do so. This results in the need to raise new issues that warrant public debate including the identification of where fiscal and programmatic responsibility lies within the government (e.g., local, state, federal) and the private sector to achieve preventive health goals for this age group. Further, levels of responsibility for adolescent immunization across and among diverse entities (i.e., public health and educational systems) must be considered.

In order to create a system for adolescent immunization, we have to assess the motivation and obstacles for participation across potential settings, identify real and

potential logistical issues, and assess funding constraints and solutions. It is likely that unprecedented collaborative efforts and creative approaches may be necessary to achieve recommended vaccination rates among the adolescent population.

ISSUES TO ADDRESS

There are several unique issues that challenge the U.S. health care system to fully vaccinate the adolescent population. These challenges must be acknowledged, evaluated and discussed openly if our nation is to create an accessible and effective network for adolescent vaccination. Among those topics with unique applications to adolescent immunization are venues for vaccine administration, consent for immunizations, communication, financing, surveillance, and the potential for school mandates.

Venue

There exist limited entry points used regularly by adolescents to enter the health care system. Helping adolescents move into a system of care would require both increasing utilization at the entry points that do exist and also creating new, and more easily accessible entry points – some of which will necessarily fall outside of what we typically consider the traditional health care system.

Although physician offices can provide vaccines to a significant portion of adolescents, without a significant change in health care seeking behavior patterns and greater attention being paid to missed opportunities for immunization in this age group, other venues must be considered to reach national immunization goals and assure maximum protection.

The question therefore arises as to what aspect of the health care community best serves to identify, capture and provide service to adolescents. Certainly, vaccinations have long been the purview of the primary care physician. However, in the case of adolescents' health care utilization patterns, this venue may actually not be the ideal

location for all adolescents. Additional health care settings likely to provide additional access include pharmacies, family planning and sexually transmitted infection clinics, obstetrician-gynecologist offices, emergency departments, teen clinics and health departments. Each venue must be evaluated to assess its potential in both attracting critical numbers of adolescents as well as supporting the necessary infrastructure for their immunization with all recommended vaccines for this age group. However, these sites will not replace the role of the primary care physician in the delivery of comprehensive preventive care.

When considering locations where adolescents congregate and may be available to receive health care, schools are frequently cited as an obvious locale. Vaccinating adolescents in schools has a number of obvious challenges (e.g., organization, financing) that warrant substantial study and consideration over whether this is a potential “best” venue. Therefore, the advantages and disadvantages of school-based vaccinations for adolescents have to be assessed empirically and fully.

Likely none of these potential venues, by itself, attracts a significant enough proportion of adolescents on which to base a population-wide strategy. Public discourse is also needed to consider the public and private investment required to explore approaches to improving access/availability and perhaps most importantly, to create the productive collaborations without which a move toward achieving full adolescent vaccine coverage cannot succeed.

Consent

The ability of adolescents to consent for health care – including vaccinations – differs substantially by state and by health condition.¹⁴ This variability could have a significant impact on our nation’s ability to achieve immunization coverage in this age group.

Therefore significant and potentially controversial issues arise upon making a vaccination available to adolescents – especially in nontraditional settings. For example, some states may allow adolescents to consent to receive their own vaccinations, but others may not. Although consent requirements are the purview of states, there may be

utility in the provision of a federal template for recommendations on the issue. It is also possible that in some states new vaccines which protect against sexually transmitted diseases may have different consent status than other vaccines, as does treatment for sexually transmitted infections. A review and examination of consent laws as they exist and pertain to adolescent vaccines in the context of creating the infrastructure necessary to achieve high levels of adolescent vaccination must be conducted.

Communication Specific to Adolescents

A new approach to communication and new communications materials is necessary to ensure that the public, providers, parents and the adolescents themselves understand the need and the appropriate timing of these vaccinations. In the infant and childhood vaccine setting, education and information are geared toward parents. However, if adolescents are receiving care with or without parental involvement, information must be focused on the adolescents themselves in addition to parents and providers. Knowledge about reaching adolescents should be garnered from other health and health care areas and brought to bear on vaccine issues. Convincing adolescents and young adults to engage in preventive behaviors is difficult. It is unknown whether the need for an injection will be even more challenging to disseminate than other messages. Current policies and programs have not been successful in immunizing a significant portion of adolescents with the previously recommended tetanus booster. Especially in the case of those vaccines against STIs, it will be critical to ensure that adolescents understand the limitations of the vaccines and continue to protect themselves in other ways.

Financing

Financing issues regarding adolescent immunization are unique in two specific areas, the cost of adolescent vaccines, and the rate of insurance coverage for adolescents.

These new vaccines for adolescents are among the most expensive vaccines recommended today for any age group. Their aggregate estimated price in the private sector is approximately \$500. As such, their inclusion in the recommended

immunization series has the potential to put a significant strain on both the public and private financing sectors. These costs, when combined with the fact that fewer adolescents have insurance coverage (public or private) for preventive services than other children must be addressed if we as a nation hope to realize the promise of these vaccines.^{15,16} Otherwise, the financial barriers for adolescents themselves, as well as the providers who may also incur significant financial burden associated with these vaccines, may impede implementation of these recommendations.

In the public sector, a smaller proportion of adolescents, compared with infants, are eligible for the federal Vaccines For Children program. Thus, greater strain on state budgets will likely result if these recommendations are to be fully implemented.

Surveillance

Experts worldwide recognize surveillance as important to effective implementation and evaluation of public health programs.¹⁷⁻²⁰ U.S. surveillance systems have constrained capacity to yield data related to disease burden, vaccination coverage, and vaccination impact among adolescents. For example, while data pertaining to adolescents will be collected through the National Immunization Survey for the 4th quarters of 2006 and 2007, these data will not be state-specific. Furthermore, there is no funding source for future, more comprehensive surveillance critical to guiding program planning and policy.

Well-defined national vaccination coverage targets are needed for adolescents. A limited number of goals for coverage among adolescents aged 13-15 years were included in the *Healthy People 2010*.²¹ However, future goals should be defined clearly.

For surveillance systems to work, many healthcare providers delivering immunizations to adolescents in communities and other settings (e.g., military, corrections facilities, colleges) will require education regarding the importance of disease reporting, adverse event reporting, and participating in immunization information systems (IIS). In turn,

most states need to strengthen these systems and healthcare quality measures linked to IIS warrant consideration.

School Mandates

School entry requirements, or mandates, have proven to be an effective mechanism to raise immunization rates among children in the U.S.²²⁻²⁴ These new adolescent vaccines raise the issue as to whether such laws should be considered as part of a strategy for achieving high immunization rates. As school entry requirements are under the purview of individual states, there is no federal legislative role in this process. However, states have relied on guidance from specific federal agencies regarding such requirements in the past. Because some of these new vaccines differ from older vaccines with regard to the nature of transmission of the disease they prevent, they raise novel legal and policy issues that must be addressed to determine if a school mandate strategy should be implemented.

MOVING FORWARD

The National Vaccine Advisory Committee will move forward expeditiously to develop recommendations for the nation to address the most acute issues regarding adolescent immunization as outlined in this problem statement. (Table 1)

Our nation is in a new position regarding the health care of adolescents. With increasing challenges to their health, including obesity, diabetes, sexually transmitted diseases and poor mental health, adolescents are vulnerable as they grow into adults. With three new vaccines available to combat five serious diseases there is an opportunity to prevent these specific illnesses, help adolescents increase their health care access and to support their growth and development to productive adults. There is also unique opportunity to establish a culture of immunization among adolescents that may lead them to pursue immunization as adults as well as eventually for their own children in greater numbers. Now, our nation must find the ways to ensure the promise of these new preventive measures are fulfilled. Some of these issues raised will require

additional information to determine the best course of action. For the future of our nation, the time to begin this process is now.

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Table 1.

The Most Acute Issues Facing Successful Adolescent Immunization

1. Modifications in the adolescent health care infrastructure to support the additional needs generated by new vaccines.
2. Development of additional venues to supplement the current adolescent healthcare infrastructure for immunization.
3. Standardization and clarification of consent laws for the administration of vaccinations to minors.
4. Creation of novel communication strategies to facilitate information dissemination to the parents, guardians and the adolescents themselves on the importance of immunization.
5. Generation of financial strategies for the public and private sector to make administration of immunizations to adolescents financially viable to patients and providers.
6. Development of long-term surveillance strategies to assess disease burden, vaccination coverage, and vaccine impact among adolescents.