This workshop was the second in the President’s Cancer Panel’s (PCP, the Panel) 2012-2013 series, *Accelerating Progress in Cancer Prevention: The HPV Vaccine Example*. During this workshop, the Panel heard expert testimony and moderated discussions regarding communication and policy strategies for increasing awareness and uptake of the human papillomavirus (HPV) vaccine. The meeting was divided into four discussion sections.

**President’s Cancer Panel**
Barbara Rimer, Dr.P.H., Chair
Owen Witte, M.D.

**National Cancer Institute (NCI), National Institutes of Health (NIH)**
Abby Sandler, Ph.D., Executive Secretary, PCP

**Meeting Co-Chairs**
Noel Brewer, Ph.D., Associate Professor, Health Behavior, Gillings School of Global Public Health and Lineberger Comprehensive Cancer Center, University of North Carolina
Robert Croyle, Ph.D., Director, Division of Cancer Control and Population Sciences, NCI

**Participants**
Kenneth Alexander, M.D., Ph.D., Professor of Pediatrics, Chair, Section of Pediatric Infectious Diseases, The University of Chicago
Michael Brady, M.D., Chair, Department of Pediatrics, Nationwide Children’s Hospital
Janine Cory, M.P.H., Senior Health Communications Specialist, Centers for Disease Control and Prevention
Amanda Dempsey, M.D., Ph.D., M.P.H., Associate Professor of Pediatrics, Children’s Outcomes Research Program, University of Colorado School of Medicine
F. Reed Dulaney, III, President, Dulaney Industries, Inc.
Bruce Gellin, M.D., M.P.H., Deputy Assistant Secretary for Health, U.S. Department of Health and Human Services, Director, National Vaccine Program Office
Lenora Johnson, Dr.P.H., Director, Office of Communications and Education, National Cancer Institute
Judith Salmon Kaur, M.D., Professor of Oncology, Mayo Comprehensive Cancer Center
Julie Leask, Ph.D., M.P.H., Senior Research Fellow, Australian National Centre for Immunisation, Research and Surveillance, University of Sidney
Doug Lowy, M.D., Deputy Director, National Cancer Institute
Amy Middleman, M.D., M.S.Ed., M.P.H., Associate Professor, Department of Pediatric Medicine, Adolescent Medicine, Texas Children’s Hospital
Cynthia Rand, M.D., M.P.H., Associate Professor, Department of Pediatrics, University of Rochester Medical Center
Mitchel Rothholz, R.Ph., M.B.A., Chief Strategy Officer, American Pharmacists Association
Debbie Saslow, Ph.D., Director, Breast and Gynecologic Cancer, American Cancer Society
OPENING REMARKS—DR. BARBARA RIMER

On behalf of the Panel, Dr. Rimer welcomed invited participants and other attendees to the meeting. She introduced fellow Panel member Owen Witte and acknowledged recently nominated member Mr. Hill Harper, who was unable to attend the workshop. She then provided a brief overview of the history and purpose of the Panel, and described the aims of the current series of meetings. She emphasized the importance to the Panel members of generating actionable recommendations related to HPV vaccination, in part based on input received through the series workshops. The first workshop of the series focused on basic science and epidemiology related to the HPV vaccine. Future workshops will address clinical aspects of HPV vaccination and global issues. Dr. Rimer also introduced the meeting co-chairs, Drs. Noel Brewer and Robert Croyle, as well as Robert Mittman, the workshop facilitator.

SERIES OVERVIEW

DR. DOUGLAS LOWY

HPV-ASSOCIATED DISEASES AND THE HPV VACCINE: STATE OF THE SCIENCE

BACKGROUND

Dr. Lowy is deputy director of the National Cancer Institute and chief of the Laboratory of Cellular Oncology in the NCI Center for Cancer Research. He received his medical degree from New York University School of Medicine and trained in internal medicine at Stanford University and dermatology at Yale. Dr. Lowy’s research includes the biology of papillomaviruses and the regulation of normal and neoplastic growth. The papillomavirus research is carried out in close collaboration with John T. Schiller, Ph.D., with whom he has co-authored more than 100 papers over the past 25 years. Their laboratory was involved in the initial development, characterization, and clinical testing of the virus-like particles that are used in the two U.S. Food and Drug Administration (FDA)-approved HPV vaccines. Dr. Lowy is a member of the National Academy of Sciences and is also a member of the Institute of Medicine. He and Dr. Schiller have received numerous honors for their pioneering work, including the 2011 Albert B. Sabin Gold Medal Award.

KEY POINTS

- HPV causes several types of cancer. In the developing world, cervical cancer is the most common HPV-associated cancer. However, in the United States, the number of HPV-associated noncervical cancers is higher than the number of cervical cancers. In addition, males in the United States bear a larger proportion of the burden of HPV-associated cancers compared with men in the developing world; 30 percent of HPV-associated cancers in the United States occur in men, compared with less than 5 percent of cases in the developing world.
- Approximately 85 percent of global cervical cancer cases and 88 percent of cervical cancer deaths occur in the developing world.
Differences between the United States and the developing world exist in part because high rates of Pap screening in the United States have reduced the incidence of cervical cancer by approximately 80 percent. In addition, the U.S. incidence of HPV-associated oropharyngeal cancer increased more than threefold between 1988 and 2004.

In the United States, most of the $8 billion spent on HPV-associated diseases each year is attributable to cervical cancer screening.

In the developing world, the main goal of HPV vaccination is to prevent cervical cancer. In the United States, the goal of HPV vaccination is to prevent the spectrum of HPV-associated diseases, including several cancers, genital warts, and recurrent respiratory papillomas.

HPV-associated cancers do not have validated public health interventions for secondary prevention, with the exception of cervical cancer screening. HPV vaccination is the main validated public health approach to prevent noncervical HPV-associated cancers.

There is some overlap between the cases of HPV-associated cancers that could be prevented through vaccination and the cases that could be prevented through cervical cancer screening; however, there are key differences between these approaches. Vaccination is a primary prevention intervention that targets adolescents. Cervical cancer screening is a secondary prevention intervention that targets adult women.

The HPV vaccines are noninfectious subunit vaccines composed of HPV L1 capsid proteins. Both available vaccines are multivalent: Cervarix (GliaxoSmithKline [GSK]) is composed of L1 protein from HPV 16 and 18, while Gardasil (Merck) is composed of the L1 protein from HPV 6, 11, 16, and 18.

The HPV vaccines have excellent safety records, similar to those of other licensed vaccines. However, the message that these vaccines are safe has not been sufficiently conveyed. The Centers for Disease Control and Prevention (CDC) has two systems that monitor vaccine safety: the Vaccine Adverse Events Reporting System (VAERS) and the Vaccine Safety Datalink (VSD). VAERS is a passive reporting system with no control group or denominator while data for VSD are actively collected and include control group data. A publication based on VAERS data that found disproportional reporting of syncope and venous thromboembolic events with HPV vaccination has received more media attention and been cited more extensively in the scientific literature than has a more recent publication based on the more robust VSD data, which found no evidence for increased risk of prespecified adverse events following HPV vaccination.

Cervarix is approved for females ages 10 to 25 for prevention of cervical cancer and its precursors. Gardasil is approved for females ages 9 to 26 for prevention of cervical, vulvar, and vaginal cancers and their precursors. Gardasil also has been approved for both males and females ages 9 to 26 for prevention of anal cancer and its precursors, as well as prevention of genital warts.

HPV vaccines are more immunogenic in young adolescents (age 10-15) than in the older age groups in which efficacy trials have been conducted (age 16-23). Young adolescents who received two doses of the vaccine (at 0 and 6 months) exhibited similar serum antibody titers as did those from the older age group who received the recommended three doses.

Among women who received all three doses of the HPV vaccine and were HPV negative during the vaccination period, the efficacy of the vaccine with respect to various clinical endpoints was close to 100 percent. Efficacy among a similar cohort of men was somewhat lower, somewhere between 75 and 90 percent. However, vaccine efficacy was substantially lower among women who were exposed to HPV prior to vaccination. These results provide evidence for the importance of vaccinating prior to sexual debut.
Current evidence indicates that the duration of protection imparted by either vaccine is at least eight years. Studies have shown that protection lasts years beyond the time when serum antibody titers have plateaued, which suggests that protection is likely to last even longer.

Pharmaceutical companies cannot make claims about vaccine efficacy that go beyond FDA-approved indications. Others (e.g., public health officials) are not subject to this restriction, but any claims made about “off-label” indications should be balanced and responsible.

The CDC Advisory Committee on Immunization Practices (ACIP) makes federal vaccine recommendations. Cervarix is recommended for routine vaccination for girls, while Gardasil is recommended for both genders. The primary target age is 11-12-year-olds, with catch-up vaccination recommended through age 25 (Cervarix) or 26 (Gardasil). The American Cancer Society (ACS) recommends that catch-up vaccination be done up to only 18 years of age because of the lower cost-effectiveness of vaccinating older individuals.

The HPV vaccines are covered through the federal Vaccines for Children (VFC) Program, which serves children less than 19 years of age who are Medicaid eligible or uninsured or who are American Indians/Alaska Natives.

In Australia, where female vaccination rates have been high since 2007, there has been a drastic reduction in genital warts among young women and young heterosexual men. However, a similar reduction has not been observed among men who have sex with men. There also has been a drastic reduction in cervical dysplasia among girls younger than 18 years old and a modest reduction among women 18 to 20 years of age. However, no reduction has been observed among women older than 20, which likely reflects the decrease in efficacy when the vaccine is administered after HPV exposure.

Recurrent respiratory papillomatosis (RRP), which is caused by HPV 6 and 11, could be prevented by Gardasil. It is a rare disease but can be serious when it occurs in young children. Changes in RRP due to vaccination would likely be evident sooner than changes in cancer rates.

It is highly plausible that the HPV vaccine will prevent HPV-associated oropharyngeal cancer. However, the natural history of oral/oropharyngeal HPV infection has not been fully elucidated, and no precursor lesion for HPV-associated oropharyngeal cancer has been identified to date. In contrast, precursor lesions have been identified for each of the cancers included as indications for the HPV vaccine, and FDA approval for these indications was based on prevention of these precursor lesions.

An NCI-conducted trial of Cervarix found that the vaccine prevents oral HPV infection with high efficacy (>90%) among women, but results were somewhat ambiguous and the relevance of these results to men and/or Gardasil is unknown.

Some countries are implementing a modified, two-dose schedule for the HPV vaccine, but the United States is continuing to recommend the three-dose schedule.

Merck is conducting a Phase III trial of a nine-valent HPV vaccine. If successful, this vaccine could potentially prevent 90 percent of cervical cancer cases, which may make it possible to safely reduce (but not eliminate) cervical cancer screening.

OPENING ROUNDTABLE

Participants introduced themselves and were asked to state the intervention they thought would have the biggest impact on HPV vaccination rates. Several participants emphasized the need to increase support and enthusiasm among providers for the vaccine. Interventions related to this goal could include provider education (e.g., academic detailing, continuing medical education), targeted communication with primary care providers, and elimination of financial barriers to stocking and administering the vaccine. The potential benefit of expanding the types of providers who can give the vaccine (e.g., pharmacists, dentists) also was mentioned, as was the need to increase overall preventive health services for adolescents. Other participants stated that outreach and/or media coverage is needed to educate the public about the vaccine,
particularly the fact that it prevents cancer. Community partnerships also could be utilized to find local solutions for increasing vaccine uptake. Some participants posited that schools provide a good venue for educating parents/adolescents about the vaccines; requiring vaccination for school entry also may increase uptake. It also was suggested that the availability of a vaccine that could prevent all HPV-associated cancers with a single dose would increase the attractiveness and uptake of the vaccine. Roll-out of the vaccine also might be improved if resources and tools were available to identify individuals eligible for vaccination and/or those who have received one or more vaccine doses.

SESSION ONE: OVERVIEW OF CURRENT REALITIES REGARDING HPV VACCINATION

DR. ANNE SCHUCHAT

HPV VACCINATION: OVERVIEW AND CURRENT REALITIES

BACKGROUND

Dr. Schuchat is director of the CDC National Center for Immunization and Respiratory Diseases. An internist and epidemiologist, she has extensive research, program, and policy experience in infectious diseases and immunization. Dr. Schuchat oversees the Vaccines for Children Program and has made important research contributions to accelerating uptake of new and underutilized vaccines. She spearheaded CDC’s guidelines on perinatal group B streptococcal disease prevention in the 1990s. Dr. Schuchat served as CDC’s Interim Deputy Director during 2009, as well as CDC’s Chief Health Officer for the H1N1 pandemic response. Dr. Schuchat was elected to the Institute of Medicine in 2008. She has been a member of the board of the GAVI Alliance (formerly The Global Alliance for Vaccines and Immunisation), representing technical and health research institutes since 2010.

KEY POINTS

- National Immunization Survey (NIS) results, released in August 2012, indicate that HPV vaccine uptake has lagged behind that of other recommended adolescent vaccines. Between 2006 and 2011, rates of Tdap (tetanus-diphtheria-acellular pertussis) and meningococcal vaccination among U.S. adolescents (13 to 17 years of age) increased from approximately 10 percent to more than 70 percent. However, since 2008, the year after the HPV vaccine was approved, the annual increase in HPV vaccination among girls has been about half of what is observed for the other adolescent vaccines. Less than half of girls in this age range have initiated the HPV vaccine series and less than one-third have received all three doses. Furthermore, rates of HPV vaccination appear to have plateaued between 2010 and 2011. HPV vaccination rates also are low among boys, although available data predate the recommendation that the HPV vaccine should be routine for adolescent boys.

- Among U.S. adolescents 13 to 17 years of age, 46.2 percent have private insurance that covers vaccination. Additionally, VFC covers approximately 40 percent of teenagers in this age group, including those who are Medicaid eligible, uninsured, or American Indians/Alaska Natives. Some underinsured adolescents also are able to obtain vaccines through VFC if they receive care through federally qualified health centers. For most vaccines provided through VFC for Medicaid-eligible or uninsured children/adolescents, the vaccine is provided by the government but administered by private providers. VFC covers the cost of the vaccine, but not costs for vaccine administration.

- There are differences in HPV vaccine uptake among racial/ethnic groups. In 2011, blacks and Hispanics were significantly more likely than non-Hispanic whites to receive the first dose of the HPV vaccine, but black girls were significantly less likely than Hispanic and non-Hispanic white girls to complete the vaccine series. This suggests that racial/ethnic minorities are not opposed to receiving the vaccine, but have barriers to receiving all three doses.
There also are socioeconomic differences in HPV vaccine uptake. Girls from households with incomes below the poverty level are significantly more likely to receive the first or third dose of the HPV vaccine than are girls from households with incomes at or above the poverty level. This is the opposite of what is observed for other adolescent vaccines: girls living at or above the poverty level are more likely to have received the Tdap or meningococcal vaccines (although differences based on socioeconomic status are smaller for these vaccines). The reasons for the socioeconomic disparities in HPV vaccine uptake are unclear.

NIS surveyed parents about their intentions to vaccinate their daughters or sons against HPV in the next 12 months. Between 2008 and 2011, the percentage of parents who reported having had their daughters vaccinated increased from 37.2 percent to 53 percent. However, the percentage reporting that they were not likely to have their daughters vaccinated in the next 12 months changed little over the same timeframe (26% in 2008 versus 25.1% in 2011). Among parents of girls, the top five reasons given for not vaccinating were: (1) the vaccine is not needed or necessary (23.2%), (2) the girl is not sexually active (19.5%), (3) concern about safety/side effects (19.3%), (4) lack of knowledge (15.2%), and (5) not recommended by physician (9.6%). These results suggest that there is a lot of confusion about the vaccine among parents that could potentially be addressed through interactions with a doctor or nurse.

In-depth interviews with providers indicate that there is “vaccine hesitancy” among physicians related to the HPV vaccine. Providers perceive that parents are resistant to having their children vaccinated and are unwilling to strongly promote the vaccine. This contrasts with what is observed for infant and toddler vaccines; physicians are committed to promoting these vaccines and have developed strategies for discussing them with parents.

Experiences with other adolescent vaccines suggest that significantly higher rates of HPV vaccination would be achievable if the vaccine were offered/accepted when other adolescent vaccines were offered. Among adolescents, 85.3 percent have received the Tdap vaccine and more than 70 percent have received the meningococcal vaccine. These data also indicate that widespread vaccine coverage can be achieved using the medical home model (i.e., school-based vaccination is not essential).

**DR. NOEL BREWER**

**BEHAVIORAL SCIENCE AND HPV VACCINE UPTAKE**

**BACKGROUND**

Dr. Brewer studies the psychology of medical decisions about vaccination and medical tests. His current work focuses on receipt of HPV vaccine, risk communication about genomic tests, and harms from medical screening. Dr. Brewer is associate professor of health behavior at the University of North Carolina (UNC) Gillings School of Global Public Health. He has appointments with UNC’s Lineberger Comprehensive Cancer Center, Department of Psychology, and Center for Genomics and Society. As a member of the Food and Drug Administration’s Risk Communication Advisory Board, he co-edited their recently published book, *Communicating Risks and Benefits: An Evidence-Based User’s Guide*. He is associate editor of *Health Psychology Review* and serves on the editorial boards of the *Journal of Behavioral Medicine* and *Medical Decision Making*.

**KEY POINTS**

- Several commonly cited concerns about the HPV vaccine are not consistent with research results. To date, none of the studies conducted have found that HPV vaccination promotes sexual activity (i.e., sexual disinhibition), although some studies have found that parental belief in sexual disinhibition is used as a justification for the decision not to vaccinate. Another concern among policymakers is that
parents are against the vaccine; however, study results indicate that although there are parents who are not supportive of the vaccine, they are a minority (median of 10% across eight studies). Pain is another concern that has been raised, but parent surveys indicate that the pain caused by the HPV vaccine is less than or equal to that caused by other adolescent vaccines.

- A systematic review and data from the Health Information National Trends Survey (HINTS) indicate that more than two-thirds of those surveyed know that HPV is a common virus and that it is sexually transmitted. However, less than half of people know that HPV causes cervical cancer, and most studies have found that less than half of people are aware that HPV causes health problems in males.
- Available data indicate that most white parents of girls (87%) have heard of the HPV vaccine. Awareness of the vaccine is somewhat lower among African-American parents of girls (68%). Only 21 percent of parents of boys reported knowing that the vaccine was for boys. Among men who have sex with men, 73 percent reported knowing about the vaccine compared with 63 percent of heterosexual men. More up-to-date data on vaccine awareness are needed.
- Research to date suggests that a physician recommendation is a strong predictor of vaccination (median odds ratio of 10 based on four studies). Additional studies are needed to clarify factors that influence the impact of a physician recommendation to vaccinate.
- Other predictors of HPV vaccine uptake include anticipated regret (i.e., anticipation that something terrible will happen if a child is vaccinated or not vaccinated) and previous vaccination. Additional studies are needed on predictors of uptake, particularly among high-risk populations.
- There are no national data on parental acceptance of requiring HPV vaccination for school entry. Available (non-national) survey results indicate that approximately 44 percent of parents support such a requirement. The level of support increases to nearly 90 percent if there is an opportunity to opt out of the requirement.
- The CDC Community Guide to Preventive Services includes several recommendations for increasing uptake of preventive vaccines. Recommendations to enhance access to vaccination services include conducting home visits, reducing client out-of-pocket costs, and implementing vaccination programs in schools, child care centers, and Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) settings. Recommendations to increase community demand for vaccinations include client/family incentive rewards, client reminder and recall systems, and vaccination requirements for child care, school, and college attendance. Recommended provider- or system-based interventions include immunization information systems, provider assessment/feedback, provider reminders, standing orders, and community-based interventions.
- Three ideas for increasing uptake of the HPV vaccine were presented. The first was to create a national program to provide adolescent vaccines free of charge to all children in schools. The second was to harmonize state laws so that pharmacists in all 50 states can administer the HPV vaccine. The third was to integrate adolescent vaccines into the AFIX (Assessment, Feedback, Incentives, and eXchange) program, a quality improvement program that currently focuses on childhood vaccines.

SESSION ONE MODERATED DISCUSSION

KEY POINTS

- Uptake of the HPV vaccine differs across geographic regions of the United States. Although some states have higher rates of HPV vaccination than others, only 11 states increased their rates of vaccination between 2010 and 2011 (compared with 35 states that increased levels of Tdap vaccination). In general, New England states have higher rates of HPV vaccination, while states in the Southeast have significantly lower coverage. This is of concern because the Southeast has the highest rates of cervical cancer in the country. Uptake of adolescent vaccines is uneven within some states.
(e.g., a state may have higher than average rates of Tdap vaccination but lower than average rates of HPV vaccination).

- A few states have had notable increases in HPV vaccination over the past few years, including Hawaii and South Dakota. In South Dakota, rates of HPV vaccination have been high because the governor strongly supports the vaccine. The vaccine has been provided free of charge to all eligible recipients in the state. However, there is no longer funding available for this program, so rates may fall in coming years. The high rates of HPV vaccination in South Dakota are encouraging, but the state also has relatively low rates of Tdap vaccination. The goal should be to increase uptake of all adolescent vaccines.

- The HPV vaccine is more expensive than other adolescent vaccines, especially when the cost of all three recommended doses is taken into account. However, the effect of the cost of the vaccine on uptake is unclear. The vaccine is covered by VFC, and the Affordable Care Act requires new and updated plans since September 2010 to cover all ACIP-recommended vaccines with no copays or deductibles.

- CDC has three goals with respect to HPV vaccination: improve initiation, reduce disparities, and improve completion. The U.S. recommendation continues to be for three doses of the vaccine, but it is possible that evidence will eventually show that fewer doses are required to impart protection.

- Several recent and ongoing efforts will provide insight into the efficacy of two doses of the HPV vaccine. One study found that two doses six months apart in younger adolescents resulted in an immune response similar to what was observed in the older adolescents and young women who received three doses as part of the original efficacy trials. In addition, two Canadian provinces, Switzerland, and Mexico have adopted two-dose schedules for the vaccine; monitoring these populations will be informative, but it will take considerable time to get a sense of the impact of these schedules on clinical outcomes. Merck initiated a clinical trial in India testing two versus three doses, but political problems have interfered with the trial, so it is unclear if and when data will be available.

- State immunization registries can play an important role in vaccine uptake. For the HPV vaccine, the use of reminder/recall can help achieve high completion rates. For example, New York City, which has a strong registry, has a very high HPV vaccine completion rate. Other system-level interventions, such as electronic health records, also have potential to help with identifying those eligible for vaccination and reminding people to complete the dosing schedule. However, these types of interventions will not be beneficial unless providers are supportive of the vaccine.

- Several reasons given for not receiving the HPV vaccine (e.g., not necessary, not needed, not recommended) are the same reasons people have given for forgoing cancer screening. Experience in cancer screening has shown that these attitudinal barriers can be addressed by working with physicians and educating the public.

- CDC researchers conducted qualitative, in-depth interviews with pediatricians and family practitioners regarding the HPV vaccine. Providers repeatedly stated that they were not willing to “go to the mat” for the HPV vaccine and often viewed questions from parents about the vaccine as a sign of reluctance or resistance. Providers also demonstrated a surprising lack of knowledge about the endpoint of the vaccine, particularly for boys. Most knew that the vaccine prevents cervical cancer, but few knew facts about incidence or prevalence of cervical cancer that could be compelling to parents making a decision about whether to vaccinate their children.

- Many members of the general public are completely unaware of HPV, particularly its role in men’s health. There also is little understanding of how widespread HPV infection is. It is estimated that four in five women will develop HPV infection during their lifetime. Even women who have only one sexual partner in their lifetime have an approximately 50 percent chance of becoming infected.

- A media blast that presents the HPV vaccine as an anti-cancer vaccine might get the attention of the general public, including adolescents. Health care providers also are influenced by mass media.
Many pediatricians may not be aware of the noncervical cancers that can be caused by HPV, in part because the associations of HPV with these diseases have been made more recently. There is an opportunity to educate practitioners about HPV-associated noncervical diseases. It is important that educational messages come from sources other than pharmaceutical companies; both physicians and parents are skeptical about messages that originate with the vaccine manufacturers. Australia utilized a framework created by the British Psychological Society to engage providers regarding the HPV vaccine. The framework outlines the domains that need to be considered as providers implement evidence-based practices.

Messaging about the vaccine needs to emphasize at least three things: the vaccine should be administered to 11- to 12-year-olds (prior to first sexual activity); the vaccine is noninfectious; and immune responses to the vaccine are stronger in younger girls compared with older girls. There are parents who are not opposed to the vaccine but put off vaccination because they do not recognize the potential consequences of doing so.

Parents have become more accepting of the HPV vaccine over the past several years, but physicians may not be aware of this shift in attitudes. They still may be acting based on the resistance to the vaccine they observed right after the vaccine was approved. One study, which has not yet been published, found that physicians underestimated the importance of the HPV vaccine to parents.

Initiatives that focus on the whole adolescent vaccine platform have been more effective than those focusing on the HPV vaccine. Physicians may be undermining uptake of the HPV vaccine by expecting hesitancy from parents rather than assuming that all adolescent vaccines will be given. However, it was noted that parents more often have questions about the HPV vaccine than about other vaccines because they have heard it mentioned in the media. Even if they do not have strong feelings about the vaccine, they may ask for more information because they have heard it discussed.

It may be possible to utilize nurses to increase acceptance and uptake of the HPV vaccine. CDC is planning to do formative research on nurses and eventually develop nurse-targeted training and tools. Nurses can help remind providers to offer the vaccine, regardless of the reason for the patient’s visit, and also can administer the vaccine if standing orders are utilized. Studies have shown that parents prefer that the second and third doses of the vaccine be administered by a nurse rather than a doctor.

It also may be useful to increase awareness and acceptance of the HPV vaccine among all nurses, not only those who may be administering it. Many people interact with nurses outside of the health care system and may ask for their input on the vaccine.

A ten-year study called Native Web illustrated the importance of nurses. The program involved training nurses to do clinical breast exams and Pap smears and found that nurses were better than physicians at getting adequate Pap smears. In underserved communities, nurses are often the most consistent and trusted caregivers.

For many vaccines, uptake is highest among Hispanics. The reason for this is not known, but it suggests that there is high cultural acceptance of vaccines among this population.

Involving dentists in HPV vaccine administration may help increase uptake. Many dentists may be proactive about offering the vaccine if reimbursement rates are adequate. A statement from the American Dental Association about the importance of the HPV vaccine for oral health could have a positive impact.

In the United States, some people may be uncomfortable talking about the HPV vaccine because of the stigma of HPV as a sexually transmitted disease. It may be helpful to remind people that it is possible to contract the virus via sexual contact that does not include intercourse.

Some parents and adolescents may be more motivated to prevent oral or genital warts, which may occur within a relatively short timeframe, than cancer, which they may view as a distant concern.

Many parents are not aware that the vaccine is recommended for 11- to 12-year-olds.
One study found that if a woman had been previously diagnosed with genital warts, she would be more likely to have her daughter vaccinated. However, neither diagnosis of cervical cancer nor having had an abnormal Pap smear were associated with increased willingness to have a daughter vaccinated.

When one participant was diagnosed with an HPV-associated cancer, many of his friends were concerned about their own risk of HPV-associated diseases and would have been willing to be vaccinated if a vaccine had been appropriate for them. However, the same friends were hesitant about having their children vaccinated against HPV because of concern about potential risks.

Although it may be desirable to improve public awareness of and attitudes about the HPV vaccine, it is important to think about whether this is necessary in order to increase vaccine uptake. If the evidence suggests that a strong clinician recommendation is a powerful predictor of uptake, then it may not be necessary to invest significant resources into modifying public awareness and knowledge. Consideration should be given to what is the most direct and effective way to increase uptake.

SESSION TWO: SYSTEM INTERVENTIONS TO INCREASE UPTAKE OF HPV VACCINE

DR. BRUCE GELLIN

SYSTEMS PERSPECTIVE ON INCREASING VACCINE UPTAKE

BACKGROUND

Dr. Gellin, Director of the National Vaccine Program Office (NVPO), is one of the nation’s top experts on vaccines and infectious diseases. NVPO was created by Congress to provide leadership and coordination among federal agencies and other immunization stakeholders, including states and municipalities, health care providers, and private-sector entities such as vaccine manufacturers. Before joining NVPO in 2002, Dr. Gellin was director of the National Network for Immunization Information, an organization he founded to provide up-to-date, authoritative information about vaccines and immunizations. Dr. Gellin has broad experience in public health aspects of infectious diseases and has held positions at the National Institute of Allergy and Infectious Diseases at the National Institutes of Health, CDC, the Rockefeller Foundation, and The Johns Hopkins University Bloomberg School of Public Health. In addition, he has been a regular consultant to the World Health Organization. He is board certified in internal medicine and infectious diseases and is currently on the faculty at George Washington University School of Medicine and Vanderbilt University Schools of Medicine and Nursing.

KEY POINTS

- NVPO provides coordination and leadership among the various federal agencies working together to achieve the goals of the National Vaccine Plan. The National Vaccine Plan provides a framework, including goals, objectives, and strategies, for pursuing prevention of infectious diseases through immunizations. The plan aims to achieve five broad goals related to research and development, vaccine safety, communications, supply and demand, and global disease prevention.

- When addressing vaccine implementation and uptake from a systems perspective, there are unique challenges and issues that need to be accounted for at each level of the system (e.g., basic science, research and development, recommendations and communications, impact measurement). Effectively increasing vaccine uptake will require determining the level of the system at which intervention will have the greatest impact and focusing efforts at that level.

- An article entitled “Big Med,” by Atul Gawande, featured in the New Yorker in August 2012 discusses how health care guidelines and recommendations do not reach providers in a uniform
manner. Every physician has his or her own way of doing things, and the quality of care delivered varies greatly, even within the same medical institution. This issue needs to be addressed in order to improve vaccine uptake.

- Schools have potential to play an important role in increasing uptake of the HPV vaccine. However, schools need to be viewed as a location for delivery, not as deliverers of vaccines. Schools are another element of the immunization system that present their own set of challenges, thus requiring focused attention and consideration.
- A few years ago, the National Vaccine Advisory Committee released recommendations on adult immunizations. These recommendations may be a useful resource to help determine specific aspects of the immunization system on which to focus.

MS. SHANNON STOKLEY

VACCINATION REQUIREMENTS FOR SCHOOL ENTRY

BACKGROUND

Ms. Stokley received an M.P.H. in epidemiology from San Diego State University and began her public health career with the San Diego County Infant Immunization Initiative assessing vaccination coverage at the community and provider levels. In 1996, she joined the National Immunization Program at the CDC. During the past 15 years, Ms. Stokley has analyzed national surveys to assess vaccination coverage levels, conducted surveys of physicians to assess barriers to implementing vaccine recommendations, and conducted studies to evaluate strategies to improve vaccination coverage. Since 2006, she has served as the team lead for the Adolescent Vaccination Team within the National Center for Immunization and Respiratory Diseases.

KEY POINTS

- The main purpose of a vaccine requirement for school entry is to prevent and control disease, not to reach an immunization target. The first vaccine requirement implemented was for smallpox; over time, requirements have been added for measles, pertussis, and varicella. Vaccine requirements are typically created for diseases that are easily transmitted, especially within the school environment, and have potential to cause high absentee rates. However, there also are requirements for some diseases that are less transmissible, such as tetanus and hepatitis B.
- Vaccine requirements are created at the state level. States vary in how they create requirements; some are created through statutes while others are administrative rules adopted by the health or education department. All states have at least one type of opt-out provision (exemption). There are three types of exemptions: medical (51 states), religious (47 states), and philosophical (18 states). Every state has a medical exemption; if a child has a medical contraindication, he or she cannot be forced to receive that vaccine. Mississippi and West Virginia are two states that do not allow either religious or philosophical exemptions. California and Arizona also do not have religious exemptions, but they do have philosophical exemptions that encompass religious reasons for refusing vaccination.
- The ease of obtaining an exemption varies by state. Some states require notarized letters, letters from clergy, discussions with physicians, and/or education on the consequences of obtaining an exemption. However, other states, such as California, only require a form to be filled out and signed by a parent. Thus, securing an exemption does not necessarily mean that a parent is strongly against a vaccine.
- Enforcement of vaccine requirements is conducted at the school level, usually by a school nurse or other staff member (in schools where there is no nurse). This can impose a tremendous burden on the school. Students may be excluded from school if they are noncompliant, and exempt students may be excluded during an outbreak of vaccine-preventable disease. The exclusion of students from school
poses a financial issue as schools are paid based upon attendance. Additionally, the level of enforcement varies depending on the attitudes of school personnel (e.g., school nurse, principal, superintendent).

- If a vaccine is required for attendance, states must provide that vaccine at no cost for students unable to pay. An HPV vaccine requirement could be costly for states.
- The Association of Immunization Managers (AIM) issued a position statement on vaccine requirements based on experiences with HPV vaccine. The statement maintains that requirements should be used sparingly, approached cautiously, and considered only after an appropriate vaccine implementation period. Requirements must be evaluated carefully, with epidemiologic, economic, and ethical concerns taken into account. Requirements must be pursued through existing state processes. Measures to add or alter exemptions must be carefully coordinated with state immunization policies and goals. This and other position statements should be considered when deciding whether to pursue a requirement.
- Gardasil was licensed in June 2006. Three months later, Michigan was the first state to introduce legislation requiring HPV vaccination of girls entering 6th grade. In the history of vaccines, such legislation has never been introduced so quickly following licensing. In February 2007, the Texas Governor implemented an executive order requiring vaccination of girls entering 6th grade. The law was overturned by state legislature. The Texas Governor bypassed the traditional vaccine requirement process within his state, which resulted in passage of a law that expressly prohibits schools or the Executive Commissioner of the state’s Health and Human Services Commission from requiring HPV for school entry. To date, legislators in 24 states and Washington, DC have introduced bills requiring HPV vaccination for entry into middle school; only two (Virginia and Washington DC) have passed the requirement. However, those requirements include broad opt-out provisions.
- Currently, 41 states have a Td/Tdap vaccine requirement; 13 states have a meningococcal vaccine requirement; 2 states have an HPV vaccination requirement; and 7 states have an HPV education requirement. While only a few states have an HPV vaccination or education requirement, HPV vaccination should be promoted during students’ visits for school-required vaccines.

DR. MICHAEL T. BRADY

THE HPV VACCINE EXAMPLE 2012-2013

BACKGROUND

Trained in pediatric infectious diseases, Dr. Brady has been in practice since 1983. His areas of specialization include HIV infection, vaccines, health-care-associated infections, and perinatal infections. Dr. Brady is chair and professor of pediatrics at The Ohio State University and Nationwide Children’s Hospital. He has been a member of the American Academy of Pediatrics (AAP) Committee on Infectious Diseases since July 2005 and has chaired this committee since July 2010. He is the AAP liaison to the CDC Advisory Committee on Immunization Practices.

KEY POINTS

- The HPV vaccine has not reached the same coverage levels as the Tdap and meningococcal vaccines among U.S. adolescents. Various issues affect HPV vaccine uptake. Promoting the vaccine as a sexually transmitted infection (STI) vaccine versus a cancer vaccine can have an impact on provider attitudes. Many pediatricians are uncomfortable discussing sexual issues, and some view promoting the vaccine as condoning sex.
- The dosing schedule of the vaccine (three doses in six months) also poses a barrier to uptake. Physicians rarely see adolescents that frequently.
Administering the vaccine prior to sexual debut provides greater benefit, but is harder to sell. Additionally, administering the vaccine initially to only girls proved to be problematic. The practice created false public perceptions of the vaccine. There is a lack of knowledge about HPV among both patients and providers. Safety concerns about the vaccine have been magnified by misperceptions and fallacies on the Internet and by the media.

Other barriers to vaccine uptake include lack of an HPV vaccine requirement for school entry, vaccine hesitancy, the cost of the vaccine, and the time required for physician-patient discussions.

Providers have the strongest impact on the decision to vaccinate; thus, providers should be educated on HPV and the benefits of the vaccine. The vaccine needs to be marketed as a cancer vaccine that is gender neutral. The stronger immune response to the vaccine among younger adolescents should be highlighted, and the notion that HPV vaccination leads to sexual activity should be dispelled. Misperceptions and fallacies on the Internet should be countered with information from nongovernment/nonindustry sources.

Access to the HPV vaccine needs to be improved. An alternative vaccination schedule (e.g., yearly) needs to be considered. There is some evidence that if given yearly, the vaccine results in equal or better antibody responses than with the three doses in six months schedule. Schools and pharmacies should be considered as alternative locations for administration of the vaccine. Immunization should occur at every opportunity, such as visits to the emergency room or urgent care facilities. Improved recall systems (e.g., text messaging) could also help improve vaccine uptake. Lastly, cost needs to be eliminated as a barrier.

AAP prefers that all vaccines be administered in the “medical home.” If vaccines are administered outside the medical home, AAP advocates for communication of vaccine administration to the medical home in a timely fashion, the next business day if feasible.

The HPV vaccine for female adolescents was added as a Healthcare Effectiveness Data and Information Set (HEDIS) measure in 2012. HEDIS is a set of performance measures developed by the National Committee for Quality Assurance and is widely used in the managed care industry. In general, AAP does not formally endorsed HEDIS measures; however, AAP would be supportive of HEDIS measures that are congruent with AAP policies. AAP has a policy statement recommending HPV vaccination for all adolescents.

MR. MITCHEL C. ROTHHOLZ

SYSTEM INTERVENTIONS TO INCREASE UPTAKE OF HPV VACCINE: PHARMACIST PERSPECTIVE

BACKGROUND

Mr. Rothholz is a pharmacist currently serving as chief strategy officer for the American Pharmacists Association (APhA). In his current position, he is responsible for the strategic oversight of Association initiatives, including implementation of APhA’s strategic plan, evaluation and management of strategic alliances, establishment of Association policy and communications, and fostering of collaborative partnerships within the Association as well as with the external community. He also serves as secretary for the Joint Commission of Pharmacy Practitioners and facilitates the profession of pharmacy’s immunization initiative. He is a 1984 graduate of the University of Florida College of Pharmacy and has worked as an Association executive for more than 28 years. In 2005, he earned a master’s degree in business administration in health care management from Regis University. He has practical experience in community (chain and independent) pharmacy, nursing home, hospital, and managed care practice settings.
KEY POINTS

- APhA advocates an “immunization neighborhood” model for increased uptake of the HPV vaccine. The goal of an immunization neighborhood is collaboration, coordination, and communication among stakeholders to provide the public with a choice of where to get vaccinated.

- The HPV vaccine is a three-dose series. Initial evaluation/education and first dose administration could be done by a medical provider, with a pharmacist administering the remaining two doses. Documentation of the doses given by a pharmacist would be sent to the medical provider.

- The authority of pharmacists to administer the HPV vaccine varies by state. Pharmacists have authority to administer the HPV vaccine by prescription and/or protocol in 43 states. Many states also place restrictions on the age groups that can be vaccinated by a pharmacist. Each state has different age restrictions, which creates a barrier to uniform uptake of the vaccine.

- In July 2011, CDC sent out guidance to their state awardees to try to resolve two barriers to pharmacist involvement in VFC. First, the guidance clarified that pharmacists can become VFC-registered providers in accordance with state law. If a pharmacist is granted the authority to administer the vaccine by state law (whether by prescription, protocol, or prescribing authority), the pharmacist is eligible to become a VFC-registered provider within the state. Second, the guidance clarified that specialty providers (which includes pharmacists/pharmacies) enrolled in the VFC program, at the discretion of the awardee, could limit their VFC practice to particular relevant vaccines. For example, if a state provider wanted to administer only adolescent vaccinations, they could become a recognized VFC provider for the adolescent population.

- In some states, providers must be recognized as Medicaid providers in order to participate in the VFC Program. Obtaining this recognition is difficult for pharmacists. The VFC reimbursement rate for vaccines is also a barrier to participation.

SESSION TWO MODERATED DISCUSSION

KEY POINTS

- CDC looked at the relationship between school mandates and HPV vaccination coverage by state. At the time the data were collected, five states had implemented an education requirement for the HPV vaccine (i.e., schools were required to disseminate information about the vaccine to the parents of incoming students) and one state had implemented an HPV vaccine requirement for school entry (because of the low sample size, this state was analyzed in a group with the states with education requirements). There was no association between these requirements and HPV vaccine uptake. Rates of meningococcal and Td/Tdap coverage were higher in states that had school entry requirements for those vaccines. The ten states with education requirements for the meningococcal vaccine had similar vaccine coverage as states with no requirement. These data suggest that educational requirements do not have a significant impact on vaccine uptake. North Carolina implemented an educational requirement, but statewide data indicate that only 10 percent of parents received information on the HPV vaccine from schools.

- There is some evidence that the presence of a school entry requirement for any vaccine may increase HPV vaccine coverage: higher HPV vaccine coverage was observed in states with a Tdap vaccine school entry requirement. However, this trend is not uniformly observed. For example, in New York City, teens getting their required Tdap vaccine were not getting the HPV or meningococcal vaccines. There was an effort to educate providers to take advantage of the opportunity to provide all three adolescent vaccines; this resulted in an increase in meningococcal vaccine coverage but did not significantly increase rates of HPV vaccination.
NIS data show higher uptake of the HPV vaccine among African-American and Hispanic girls than among non-Hispanic white girls. However, there are other data showing that African-American girls are less likely to get the first dose of the vaccine. The reasons for these seemingly conflicting data are unknown, although it was noted that the difference may be related to when the data were collected. Also, local trends in uptake may not always mirror national trends. Local trends need to be taken into account when developing local strategies to increase vaccine uptake.

There are cultural differences in the way populations view primary prevention and immunization. Also, some populations may distrust mechanisms used to distribute vaccines. It may be important to separate factors due to culture from those due to socioeconomic status.

Poor women are most likely to die from cervical cancer and are least likely to receive consistent health care. The Indian Health Service (IHS) has a major emphasis on HPV vaccination, but many Native women are not receiving health care at IHS facilities.

Australia does not have stark differences in HPV vaccination rates among socioeconomic groups. This is thought to be because the vaccine is made freely available through schools. Also, there are systems to follow up with those who have not been vaccinated. Reminder/recall systems may be a cost-effective way to increase completion of the HPV vaccine series.

The proportion of people who are not vaccinated solely because of economic barriers is likely very small. For most people, the decision whether or not to vaccinate is based on several factors, including economics, motivation, and logistical challenges (e.g., time off from work). The Affordable Care Act should eliminate the economic barrier to vaccination for insured patients because, as a preventive service, the HPV vaccine should not be associated with a copay.

In the United States, overall rates of HPV vaccination are lower than they should be in all demographic groups; thus, efforts are needed to increase vaccination among all populations. There may be benefit to developing interventions to increase completion of the vaccine series among minority populations. Education may be one way to motivate people to get their second and third doses, although access barriers also need to be addressed.

High rates of Tdap and meningococcal vaccination suggest that there is an opportunity to increase HPV vaccination coverage. High levels of Tdap and meningococcal vaccination are observed among minority populations, suggesting that these populations are open to vaccination. Perhaps the importance of the HPV vaccine needs to be stated more clearly when adolescents receive their other vaccines.

Reminder/recall systems are effective but they can be expensive for providers. Generating letters and paying for postage can be costly. Follow-up phone calls are also an option, but phone numbers can be disconnected or changed—a fairly common occurrence among disadvantaged populations.

One potential strategy for targeting high-risk populations would be to conduct mother-daughter interventions to increase cervical cancer screening for mothers and HPV vaccination for daughters.

Low rates of HPV vaccination among males are striking, although it should be noted that 2011 NIS data were collected before the vaccine was recommended as routine for males. Future NIS data will show whether this recommendation has increased HPV vaccination among males. There is preliminary evidence that uptake among males is increasing in some areas, such as New York City.

A strong supporting infrastructure must be put into place for vaccine providers. It is important that reimbursement rates for vaccination are high enough to cover the costs of providers. The increases in Medicaid administration fees for preventive services that will occur in 2013 and 2014 as a result of the Affordable Care Act may help improve vaccination rates.

Ideally, adolescents would receive vaccinations within their medical home (i.e., the office of their primary care provider). This provides an opportunity for physicians to provide other preventive care services. However, the medical neighborhood model is another approach to increasing uptake of
vaccines. With this model, providers other than the primary care provider (e.g., pharmacists) would be able to administer the vaccine. Collaboration, coordination, and communication among all providers within the medical neighborhood are crucial to the success of this model, and system-level support (e.g., central vaccine registry) is also needed. The goal of this approach is to make it easier for patients to get the vaccinations they need.

- Some pediatricians are uncomfortable with the medical neighborhood model because they are concerned that opportunities to provide comprehensive care will be missed if adolescents receive vaccinations outside of the medical home. However, proponents of the medical neighborhood model argue that vaccines should be as accessible as possible in order to optimize uptake; an effective strategy must take into account the ways that adolescents seek out medical care. The impact of immunization outside of the medical home on the delivery of medical care within the medical home should be studied.

- Pharmacists and others who deliver vaccines within the medical neighborhood should encourage patients to see their primary care providers for other care. One option that might be acceptable to pediatricians would be to have pediatricians (or other primary care providers) deliver the first dose of the vaccine and have subsequent doses administered by another type of provider (e.g., pharmacists). This approach may be acceptable to parents. Studies have indicated that parents want their children to receive the first dose of the HPV vaccine from their pediatricians or family doctors so that they can talk to the doctors about the vaccine. They are, however, willing for their children to receive the second and/or third doses from someone else within or outside the medical home.

- Pharmacists in some states can gain access to and enter data into state immunization registries.

- The most effective way to increase HPV vaccine uptake may be to create local interventions that are appropriate to local conditions. School-located vaccination may make sense in some areas but not in other areas. A single national approach likely will not be effective in all regions; however, national policies supportive of implementation of local interventions should be adopted.

- Support should be provided for immunization information systems. These systems should be bidirectional, allowing providers to both enter and access information about the vaccination status of their patients. Interoperability between immunization registries and electronic health records is also an important consideration. Australia has a national immunization registry for children under the age of five and for the HPV vaccine; this resource has contributed to that country’s success with vaccination coverage.

- Incentives for HPV immunization should be created for both providers and patients. Several incentive models have been applied to immunization. In some places, a family receives a check if their child receives all of his/her childhood vaccines. Some health plans give providers a bonus if the information they enter in the vaccine database indicates that a child of certain age is up to date on his/her vaccinations. Incentives must be carefully designed to ensure that they promote the desired outcomes.

- In the United Kingdom, regional health trusts are responsible for vaccination of defined groups of children. The trusts are paid when certain targets are reached. This system has resulted in high vaccine coverage.

- Many health communications approaches in the past focused on direct communication to target audiences, which was an inefficient approach. Public health researchers learned that indirect strategies, such as communications focused on policy change, were often more effective. For example, clean indoor air ordinances were more cost-effective in reducing tobacco exposure than were many direct communication efforts. Communities can be engaged to mobilize policy changes that support systems changes.

- Physicians and medical professional societies will need to be enthusiastic and supportive of HPV vaccination in order for meaningful changes to occur.
Health and vaccination are not the highest priorities for schools. Schools are focused on educating students and also devote substantial resources to transporting and feeding students. The majority of schools do not have health centers, which creates a logistical challenge for large-scale school-based vaccination. In Chicago, school-located immunizations are provided through contracts with different agencies, not through the school health system. Private insurance companies and Medicaid are billed. It is difficult to develop incentives for schools, but it is important to try to match immunization activities to the school’s agenda rather than try to make the school conform to a public health agenda.

Parental acceptance of school-located vaccination may depend on the vaccine. Qualitative research conducted by CDC suggests that parents are more likely to accept flu vaccination within schools than other types of vaccines. They feel that adolescent vaccines like Tdap and the meningococcal vaccine should be administered by physicians.

School-based HPV vaccination was easily accepted in Australia. There were some logistical challenges associated with implementing HPV vaccination in schools that did not have existing vaccine programs, but a good working relationship between the education and health sectors in Australia helped get it done. Providing incentives to schools was not found to effectively increase vaccination rates, but sending consent forms to parents a second time was beneficial.

One study found that 44 percent of parents who provided consent for their children to be vaccinated at school had not indicated in a previous survey that they would be willing to use a school-based vaccination program. This illustrates what has been shown previously—that asking people what they will do in a hypothetical situation is often a poor predictor of their behavior if that situation arises.

Researchers should be cautious about the inferences they make from research results. For example, few data exist about the nature of conversations between physicians and parents regarding the HPV vaccine. Direct observation of clinician-patient interactions in the areas of clinical trials recruitment, mammography, and smoking cessation have revealed that much of the variance in behavior in these areas could be accounted for by poor physician communication skills (e.g., physician not showing a strong interest, making a weak recommendation, failing to use evidence-based strategies).

CDC has expanded the AFIX system to a national scale and allows state health departments to implement the program. It may be possible to refine this system to improve uptake of adolescent vaccines.

PUBLIC COMMENT

KEY POINTS

The Washington, DC HPV vaccine school mandate has been met with hostility by parents, particularly minority parents, who feel that the vaccine has been forced upon them. Parents report vaccinating out of fear, not of HPV-associated disease but of repercussions related to government benefits or school attendance. Community-based partnerships can help with vaccine acceptability and uptake. Parents need to be involved in discussions and decisions about these types of issues.

Georgetown University has a school-based clinic in the Anacostia area. Another program has a van that goes to schools to provide vaccinations to students. Another resource that has been helpful to families in the Washington, DC area is a resource list of private providers who will accept DC Alliance insurance, a public insurance program for District residents.

Gynecologists could be strong advocates for HPV vaccination since they diagnose and treat HPV-associated diseases. They could partner with primary care providers to facilitate conversations about sexual health with mothers and young women.

One strategy for improving support for the HPV vaccine among providers would be to target trainees by introducing curricula into medical schools and/or residency programs.
SESSION THREE: COMMUNICATION STRATEGIES TO MODIFY KNOWLEDGE, ATTITUDES, AND BEHAVIORS REGARDING HPV VACCINATION

DR. AMANDA F. DEMPSEY

TAILORED MESSAGING AS A STRATEGY TO INCREASE HPV VACCINATION

BACKGROUND

Dr. Dempsey is a pediatrician-researcher with nine years of research experience related to HPV vaccine implementation and potential clinical effects. As an associate professor of pediatrics at the University of Colorado, Denver, she divides her time between outpatient general pediatrics duties, resident and medical student teaching, and research of vaccine implementation issues among adolescents and young adults.

KEY POINTS

- The various barriers to HPV vaccine uptake can be categorized into two broad groups: attitudinal and logistical. Attitudinal barriers mainly affect the decision to initiate the vaccine series. Patients or parents must decide that the vaccine is worth any potential risks they might perceive. Efforts should be made to change attitudes in order to overcome these barriers. Studies have shown that parents and patients want more information to help in the vaccination decision. Logistical barriers are related to vaccine series completion. Patients need to remember to complete the series and must want to access care. Providing information and removing systems barriers will help improve series completion.

- Tailoring and targeting information are distinct activities. Targeting is population-based personalization; for example, health care professionals give specific messages to a large proportion of the population (e.g., males or the elderly). Tailoring is individual-level personalization. It is more labor-intensive, but may result in better compliance. Tailored messaging is focused more on changing attitudinal barriers but could be applied to logistical barriers as well.

- Tailored messaging has three main components: personalization, feedback, and content matching. Personalization may include integration into materials of a patient’s name or pictures and information related to the patient’s ethnic background. Feedback is used to demonstrate that the provider is listening (e.g., the provider summarizes concerns shared by the parent/patient). Content matching is the most important aspect of tailoring. It involves assessing which issues are most important to each person and producing messages related to those topics.

- VaxFacts HPV was a pilot study that involved 72 mothers. The mothers were divided into two arms (an intervention and a control group). Mothers in the control arm received the CDC Vaccine Information Statements. Mothers in the intervention group filled out a computer-based preintervention questionnaire covering 21 items identified in the literature as potential attitudinal barriers to HPV vaccination. The questionnaire also collected demographic and historical health information related to HPV infection. An automated tailoring engine processed the survey responses and immediately created a two-page tailored brochure that was printed and given to the mother. The brochure was tailored on multiple levels—pictorially based on the patient’s ethnicity and textually based on past vaccination behavior, past HPV history, potential barriers identified through the questionnaire, and the daughter’s name. For example, one mother could receive a brochure that addressed concerns of vaccination at a young age, while another mother could receive a brochure that addressed questions about vaccine effectiveness.

- The main outcome of this study was change in vaccination intention. The only statistically significant finding was on intentional change. Mothers were asked about their intention to have their daughters receive the vaccine over the coming year. Mothers in the intervention group reported a significantly higher intention of bringing in their daughters for the vaccine than did mothers in the control group.
- Teen VaxScene is an ongoing study of a web- or kiosk-based intervention for parents of adolescents. This large, randomized controlled trial (200 people per arm) targets the entire adolescent vaccine platform (HPV, flu, meningococcal, Tdap). The study tailors information on multiple levels based on survey responses. The website includes tailored pages on each of the four vaccines. There are also tailored vignettes. Users have the option to read vignettes describing how individuals have made the vaccination decision. Vignette photos are tailored to match a participant’s age, gender, and race. The intervention website is complete, but data are not yet ready for analysis. Outcomes measured as part of this study will be changes in vaccine intention and changes in vaccine uptake over a two-year time period.

- Grant applications have been submitted in hopes of securing funding to conduct VaxFacts Latina. This study will look at the use of tailored messaging in the Latina population in an effort to reduce disparities in HPV vaccination.

DR. JUDITH SALMON KAUR

SPIRIT OF EAGLES

BACKGROUND

Dr. Kaur is the medical director of Native American Programs of the Mayo Clinic Comprehensive Cancer Center and principal investigator for the Spirit of Eagles program. A medical oncologist with a specialization in women’s cancer, including cervical cancer, she is a member of the National Cancer Advisory Board.

KEY POINTS

- American Indian and Alaska Native (AI/AN) populations have high incidence rates for some cancer sites and poor survival rates for most cancers.

- Spirit of Eagles is one of 18 NCI-funded Special Population Networks focused on increasing cancer awareness among tribal Nations and organizations throughout the United States. The program plays a role in education and advocacy, provides small grants to communities, works with leadership organizations, and provides scholarships for young researchers. Cancer survivors have played an important role in the Networks in terms of communicating the importance of screening and prevention.

- Spirit of Eagles relies on community partners to determine how to engage communities to deliver health messages. Utilizing community health representatives is one way to engage Native American populations. In Alaska, these representatives are called Community Health Aides and Practitioners (CHA/Ps). In the lower 48 states, they are called Community Health Representatives. These health workers assist with transporting patients to medical appointments and, if they are well connected, are able to effectively deliver health messages.

- Spirit of Eagles has developed programs that have resulted in decreased invasive cervical cancer rates among AI/AN populations. However, it is important to note that for some communities a uniform approach to cancer prevention does not work. There are some Native areas in the country that have outstanding health programs and are well staffed, but other areas have poor resources and need a more intensive approach to solving health care problems.

- Spirit of Eagle’s main priority for HPV vaccination is to vaccinate young women prior to sexual debut to maximize the benefit of the vaccine. Girls are sexually maturing faster than they have in the past; therefore, the focus needs to be on younger populations. Messages and policies that encourage continued cervical cancer screening need to be encouraged. Additionally, regular cervical cancer
screening needs to be encouraged and provided for all women regardless of whether or not they receive the HPV vaccine series.

MR. JOHN STRAND

MARKETING THE HPV VACCINE

BACKGROUND

Mr. Strand leads a 50-person team that provides social marketing, strategic communications, consumer research, and evaluation services to help clients design and implement programs that influence hard-to-change behaviors. He advises government and nonprofit agencies, foundations, academic institutions, and community-based organizations on addressing issues such as obesity prevention, access to health care, energy efficiency, pollution prevention, educational equity, workplace safety, and tobacco cessation. His current projects include a $28 million media campaign for the CDC to support environmental changes in communities to reduce prevalence of obesity and tobacco use and campaigns to promote childhood and adolescent immunizations.

KEY POINTS

- Effective marketing of vaccination requires taking into account the role of providers and parents, behavioral determinants, risk communication, and the systems involved (e.g., public health, policy, costs/payments, supply and demand). Outreach and communication efforts are focused on addressing the key determinants of behavior. In the case of the HPV vaccine, these determinants are social norms, perceived self-efficacy, and issues of salience and severity. Risk communication principles are applied to provide clear and actionable health messages to the targeted population. Information is provided in different formats and in different degrees of complexity to meet the needs of all individuals.

- The HPV vaccine requires different marketing strategies than those used for other adolescent vaccines. With HPV, there is a lack of disease visibility and immediacy for both parents and providers. The vaccine incurs higher costs, and routine health checkups are no longer a normal occurrence for patients. The vaccine manufacturers also play a role in the marketing of the vaccine, thus influencing perceptions in the marketplace. Additionally, the issue of adolescent sexuality can result in hesitancy on the part of providers and the willingness of parents and providers to wait until a later age to give the vaccine.

- Many opportunities are available to market the HPV vaccine; the best strategies will depend on the available budget and timeframe. Marketing involves four Ps: product, price, place, and promotion. Success of a marketing strategy depends on aligning these four Ps. The product, the HPV vaccine, is a cancer vaccine but is associated with a sexually transmitted infection. Price includes monetary costs in addition to all other perceived costs (e.g., convenience, discomfort, stigma). Perceived costs impact populations differently. Those costs must be mitigated as much as possible to improve the cost-benefit ratio of the vaccine.

- There is segmentation among providers and parents. Each provider can have a different view of the vaccine. Parents also have varying views and levels of comfort in discussing the vaccine with providers. Another consideration is the age at which it is appropriate to discuss these issues with children/adolescents.

- Policymakers are an important audience to consider when promoting the HPV vaccine. Public-private partnerships also play a role in promotion of the vaccine. Public (or community) organizations can contextualize issues around the vaccine for the communities they serve.
DR. JULIE LEASK

STRATEGIES TO ADDRESS ANTI-VACCINE VIEWS AND MISINFORMATION

BACKGROUND

Dr. Leask is a social scientist specializing in immunization. She is a senior lecturer at the Sydney School of Public Health, University of Sydney, and a senior research fellow at the Australian National Centre for Immunisation Research and Surveillance. Dr. Leask leads a program of research examining determinants of vaccine uptake and improving risk communication. She has advised governments in Australia, the United States, and New Zealand; the Decade of Vaccines Collaboration; the U.S. Institute of Medicine; the National Health and Medical Research Council (NHMRC); and the Australian Academy of Science. Dr. Leask is a member of an international think tank on Motivators of Trust in Vaccination and an investigator with an NHMRC Centre of Research Excellence: Immunisation in Understudied and Special Risk Populations.

KEY POINTS

- Four groups of parents and patients should be considered when developing HPV vaccine communication strategies: those who have actively decided to be vaccinated; those who have passively decided to be vaccinated; those who have actively decided not to be vaccinated; and those who have passively decided not to be vaccinated. Those who have actively decided not to be vaccinated may or may not be against vaccination in general.

- There are two major types of anti-vaccine groups: radicals and reformists. Radicals tend to oppose all vaccines and may have radical beliefs about disease prevention, be conspiratorial in their approach, and have low trust in government. Reformists are often opposed to a particular vaccine because of an adverse event they have attributed to the vaccine. Anti-vaccine activism occurs across community, political, traditional, and online media platforms. The social media environment is particularly ripe for anti-vaccine messages.

- The best approach to addressing radical anti-vaccine groups is to not give them any attention—aggressive attempts to stop them are not successful. On the other hand, it is a good idea to listen to reformists. They are exquisitely sensitive to weaknesses within the health care system and may have important issues about vaccine safety to share.

- Communication goals need to be realistic when targeting parents who have actively decided not to have their children vaccinated. These parents are usually against a lot of vaccinations, and their views will not be easily shifted.

- An important group to target is that composed of people hesitant about the HPV vaccine. These people are seeking information, especially online. Narratives and providers are the strongest mediators of anti-vaccine messages. The strategy used to address hesitant parents and patients is to reframe debates toward protection. Vaccine champions increase support among parents and providers. People who passionately advocate for vaccination within their organizations, communities, and institutions are important in creating positive perceptions of vaccines. These individuals are also influential with providers.

- Provider communication plays an important role in the decision to vaccinate. The Australian National Centre for Immunisation Research and Surveillance developed a communications framework for health care professionals. This resource helps providers to be competent and confident, and to communicate well. It includes tailored strategies (e.g., for unquestioning acceptors, those who are hesitant, or refusers) informed by motivational interviewing, shared decision-making, and principles of valid consent.
Dr. Spring Cooper Robbins at the University of Australia is developing an HPV vaccine decision aid for adolescent girls to use with their parents. This decision aid will be tested in a study in Australia.

Minimizing the structural barriers to vaccination is the most effective way to increase coverage and make communication issues secondary. The number of individuals who passively decide not to be vaccinated should be as small as possible. Removing barriers will help these individuals decide, either actively or passively, to be vaccinated.

SESSION THREE MODERATED DISCUSSION:

KEY POINTS

- The influence of anti-vaccine groups on parental decisions to vaccinate is complicated and often overestimated. Experience in Australia has shown that aggressive attempts to silence or counteract anti-vaccine groups draw more attention to the groups and may not have the intended effects. Vaccine proponents should exhibit respect for all people and have respectful discussions with people who believe they have had an adverse event associated with vaccination. These types of interactions will help gain the trust of the general population. The U.S. National Vaccine Program has provided opportunities for public representation on some advisory committees in an attempt to hear different points of view. Experiences with this practice have been mixed, but the effort has led to the recognition among those involved that most people are trying to do what is best for their children.

- The Australian government has developed HPV vaccine information campaigns similar to those developed by the U.S. government. It has not done anything specific to counteract anti-vaccine messages. However, there is some innovative investigator-initiated research ongoing in Australia focused on fostering communication between adolescents and parents and increasing self-efficacy.

- HPV vaccine coverage among aboriginal populations is lower than that among the general population in Australia (54% versus 74%). This is in large part because aboriginal populations have lower school attendance and reside in remote locations. Engagement of these communities in culturally appropriate ways poses the same challenges as engaging Native populations in the United States.

- For physicians, the most resonant message may relate to the salience of HPV-related diseases for their patients and the ability of the HPV vaccine to prevent these diseases. Epidemiological evidence should be used to support this messaging.

- One problem is that many pediatricians think that delaying the vaccination is acceptable. A potential communications strategy would be to appeal to pediatricians’ guilt by telling them that they are responsible for helping their patients avoid serious future health problems.

- If providers can identify the most pressing concerns of particular parents/patients ahead of time, this could reduce the time needed during the appointment to discuss concerns. Efforts also should be made to improve the ways in which providers are offering and recommending the vaccine so that the importance of getting the vaccine during the recommended age range is communicated. It would likely be more effective to assume that patients are going to get the vaccine rather than to assume that parents will refuse or be hesitant to have children vaccinated.

- In conversations between providers and parents, the most important factor is not necessarily what the provider says, but how he or she interacts with the parent. It is important that providers demonstrate that they are listening to parents and interested in their concerns. The way providers respond to parent concerns can increase trust and confidence. Parents often are influenced by whether or not providers have vaccinated or would vaccinate their own children.

- One strategy that may help parents choose to have their children vaccinated against HPV would be to remind them that they already may have vaccinated their children against a disease that is primarily
sexually transmitted (i.e., hepatitis). Many people tend to default to the decisions they have already made in the past.

- Tools to support parent-provider conversations should be tested with regard to HPV vaccination. Some options might be question prompt sheets (similar to those that have been used to help cancer patients articulate questions to their physicians) and brief, waiting-room questionnaires. It may be possible to have productive conversations about vaccination in less time if the conversations are targeted to parents’ most pressing concerns.

- In order to move people from the “passive nonvaccinators” to “passive vaccinators” group, it will be necessary to change social norms surrounding HPV vaccination. It also may be necessary to make policy changes (e.g., standing orders) to make HPV vaccination the default. School mandates and public service announcements that indicate how many people have been vaccinated may be one way to normalize HPV vaccination. One way to increase the number of people who passively choose to vaccinate is to offer the vaccine in a group with other adolescent vaccines. In North Carolina, parents were more likely to consent when offered three adolescent vaccines (HPV, meningococcal, and flu) than when offered only the HPV vaccine. Another example of this approach is a consent form that includes an “all vaccines that apply” option.

- Mothers are the primary decision makers about childhood vaccines. In some cultures, fathers may play a gatekeeper role in decisions about adolescent vaccines, but mothers are still heavily involved. Grandparents also may play a role in vaccination decisions.

- It may be helpful to consider efforts to increase HPV vaccination within a general behavioral context. For patients, the decision to vaccinate (or at least to initiate the vaccine series) is a single decision. However, provider behaviors surrounding HPV vaccination are repeated on a regular basis (i.e., chronic), so these behaviors may be more amenable to influence from altered norms, policies, and guidelines. When developing a communication strategy, it is important to consider whether a proactive versus reactive strategy is more appropriate; the appropriate strategy may differ depending on the domain (e.g., context, audience, long-term versus short-term goal) being addressed. Resistance to change is best counteracted with development or use of trusted sources of information. These sources of information could include clinicians or other vaccine champions (e.g., celebrities, teachers).

- Missteps during the initial rollout of the HPV vaccine have affected uptake. It was not presented as an anti-cancer vaccine and subsequently became viewed primarily as a “sex vaccine.” Also, mandates were pushed forward prematurely and inappropriate lobbying was done. It should have been presented as a vaccine to be given along with all other routine vaccines. However, despite these missteps, improvements in uptake are possible. Childhood vaccines are widely accepted in the United States, despite concerns by some groups about the link with autism. Low uptake of the HPV vaccine likely is not primarily because of the anti-vaccine movement; it is more likely tied to weak provider recommendations.

- Anti-vaccination sentiment may influence policy discussions and decisions (i.e., make policy makers hesitant to address related issues). It may be helpful to counteract these viewpoints with positive narratives in these settings. There already are a number of supportive policies and programs (e.g., Affordable Care Act, VFC). Careful consideration should be given to what additional policies are needed. Policies related to administration of the vaccine by pharmacists may be one opportunity, but it is possible that the most effective efforts will be in other domains, such as physician education.

- CDC is interested in studying adolescents’ views on the vaccines and developing interventions for this age group. Parents often are comfortable with older adolescents playing a part in the decision to be vaccinated. For younger adolescents, parents are the primary decision makers, but there may be opportunities to educate this age group. Adolescents can contribute to social normalization via their
social media interactions. In Australia, adolescent girls have had a desire for more information about the vaccine and a desire to engage in decision making.

- Adolescents can consent for testing and/or treatment of sexually transmitted diseases as well as for pregnancy testing and/or termination of pregnancy. However, in many states, teens cannot consent to receiving the HPV vaccine, which prevents a sexually transmitted disease. A survey conducted by CDC indicated that younger adolescents prefer to have their parents involved in decision making about the HPV vaccine, although older adolescents may be more willing to make the decision on their own. Another study found that adolescent girls are interested in getting the HPV vaccine but that there is less interest among adolescent boys.

- In many fields, early behavioral research focused on identification of knowledge gaps, but these knowledge gaps may or may not have been important in terms of influencing behavior. Researchers should try to identify as early as possible the factors that have an impact on behavior (i.e., decision to receive the HPV vaccine) so that resources are not unnecessarily devoted to research and activities in other areas.

- Social media will become increasingly powerful for health messaging as the younger generations who engage more heavily in social media become parents.

- A group in Kentucky led by Dr. Baretta Casey has developed an initiative called “Cause the Movement.” As part of this initiative, they developed an application that links to people’s Facebook accounts and uses information about the user’s location and friends to personalize messages about numbers of cervical cancer deaths, cervical cancer screening, and HPV vaccination. This is being used as an educational tool and also as a way to build coalitions to support policy change.

- Unless there are proactive efforts to populate social media with accurate, relevant information, these domains tend to become populated with negative or inaccurate health messages. There has not been enough research on the influence of social media on vaccination decisions, although a recent issue of Vaccine focused on this and related topics. The public health sector needs to think about ways to mobilize support within social media domains.

- The anti-vaccine movement has effectively used personal narratives to make its case. Vaccine proponents (e.g., CDC, NCI, ACS, professional organizations) need to create narratives that illustrate their message. These could be video-based and should be disseminated via the Internet. Pharmaceutical companies should not be involved in creating these narratives, since this would likely make the public skeptical of the motives behind the narratives. CDC has developed fact sheets with personal stories of people affected by vaccine-preventable diseases, including HPV.

- Rather than viewing current rates of HPV vaccination as a failure, they should be framed as a success with the opportunity for improvement. The vaccine has not been available for very long, and already more than half of age-eligible girls have received at least one dose. People may be more enthusiastic about joining a successful public health effort than one that has been framed as a failure.

- Providers may benefit from tools that demonstrate effective conversations about HPV vaccination, but it is more important to educate providers so that they strongly support the vaccine. Effective messaging will not be effective if physicians are not convinced that their patients should be vaccinated. Providers need to be made aware of recent data on duration of protection and the importance of vaccinating 11- to 12-year-olds. There also should be messaging about the importance of series completion.

- The upcoming PCP report presents an opportunity for communication about the HPV vaccine. Panel members, workshop participants, and other stakeholders should consider ways to leverage the report release to promote coordinated activities to promote vaccine uptake.
SESSION FOUR: IDENTIFYING PARTICIPANT PRIORITIES

Key themes that emerged during the workshop were identified, including strategies for increasing support for the HPV vaccine among providers and parents and other opportunities to increase access to the vaccine. Invited participants discussed which strategies and activities should be given priority in efforts to reduce the burden of HPV-associated diseases. The priorities recommended by invited participants will be considered by the Panel as it develops recommendations for its annual report.

KEY POINTS

- A provider-focused communication campaign should be conducted and tools should be developed to facilitate physician-parent/patient communication. The HPV vaccine should be framed as an anti-cancer vaccine (i.e., vaccine that protects against multiple cancers), and the focus should primarily be on the principal target group (i.e., less emphasis on catch-up vaccination). This campaign should not be conducted by pharmaceutical companies.
- Incentives should be established for providers to promote use of the HPV vaccine. As part of this, practice goals should be set and monitored. It may be possible to use or modify existing quality improvement practices (e.g., AFIX) for this purpose.
- Relevant professional societies should work together to develop a joint statement about the importance of HPV vaccination.
- There should be investment in electronic health records and vaccine registries to facilitate reminder/recall as well as exchange of information among providers regarding vaccination status.
- A consumer-focused communication campaign should be conducted (e.g., public service announcement, digital storytelling). This campaign should focus on vaccination for both girls and boys and could make use of social media.
- The pool of providers permitted to administer the vaccine should be expanded. For example, pharmacists and dentists should be allowed to administer at least the second and third doses. This may require state-level policy changes.
- Efforts should be made to facilitate school-located vaccination. State-level policy changes—such as streamlining Medicaid billing and modifying FERPA (Family Educational Rights and Privacy Act) requirements—would likely be critical for this. Compilation of information for school district legal teams and creation of standard consent forms also would be helpful.
- Vaccine champions across diverse sectors should be mobilized, including champions with influence at the local level.
- Efforts to increase HPV vaccination rates should be implemented in the context of an adolescent platform that includes other adolescent vaccines (i.e., Tdap, meningococcal) and other preventive health services.
- Evidence-based interventions (e.g., Guide to Community Preventive Services) should be used to enhance vaccine uptake.
- HPV vaccines should be included as part of the curriculum for health-related professional schools (e.g., medical school, nursing school), as well as on board certification tests.
- HPV vaccination should be a requirement for school entry.
- Vaccine manufacturers should submit data to FDA regarding the efficacy of simpler dosing schedules (e.g., fewer than three doses, different dose intervals).
- Parental incentives for vaccination should be established (e.g., payment/reimbursement from health insurance companies).
- More HPV vaccines should be provided free of charge (to both patients and providers).
PUBLIC COMMENT

- Dr. Oz is planning to tape a show on HPV and cervical cancer. Although it is unclear whether the vaccine will be discussed, this illustrates that there is interest among the public in this topic.
- One member of the public’s pediatrician’s office has posted signs indicating that the practice will not see patients who refuse to receive childhood vaccines.
- It is important to keep vulnerable populations (e.g., immigrants, Spanish-speaking communities) in mind when developing strategies to increase vaccine uptake. Huntsman Cancer Institute investigators worked with community groups and a radio station in the Yakima Valley of Washington State to develop a radio novella, which combined digital storytelling and PSA-like elements. It was well received.
- NCI or other national stakeholders should send representatives to speak at meetings of relevant professional organizations (e.g., AAP, AAFP) to emphasize the importance of the HPV vaccine. Including a cancer survivor as part of the presentation also could be powerful. It also may be effective to work with minority medical associations (e.g., Association of American Indian Physicians) to target high-risk populations.
- Although overall cervical cancer mortality rates are decreasing in the United States, mortality rates among foreign-born women are increasing. There should be interventions focused on this population.
- Consideration should be given to how gynecologists can help with improving knowledge of HPV-associated diseases and the vaccine among providers. ASCCP has a speaker’s bureau that has helped improve knowledge among providers, but this organization is sponsored by pharmaceutical companies, which is not preferable.
- Support should be provided for efforts to disseminate information about the evidence-based practices outlined in the Community Guide.
- Pediatricians should be considered as an additional target audience when developing tools for outreach via social media.
- A representative for Merck thanked the Panel and participants for the opportunity to attend the meeting and hear about what they think pharmaceutical companies should and should not be doing to promote HPV vaccine uptake.

CLOSING REMARKS

Drs. Rimer, Witte, Croyle, and Brewer thanked the participants for their contributions to the workshop. Dr. Witte also urged participants to submit any additional input via email. Dr. Croyle expressed an interest in talking further, particularly with representatives from government agencies, about coordinating activities related to HPV vaccination.
CERTIFICATION OF MEETING SUMMARY

I certify that this summary of the President’s Cancer Panel meeting, Achieving Widespread HPV Vaccine Uptake, held September 13, 2012, is accurate and complete.

Certified by: ________________________________ Date: __________________

Barbara K. Rimer, Dr.P.H.
Chair
President’s Cancer Panel