



February 13–14, 2020, Meeting Minutes

Committee Members in Attendance

Robert H. Hopkins Jr., M.D., MACP,
FAAP; Chair
Debra Blog, M.D.
Melody Anne Butler, B.Sc.N., RN
Timothy Cooke, Ph.D.
John Dunn, M.D., M.P.H.
Leonard Friedland, M.D.
Molly Howell, M.P.H.
Mary Anne Jackson, M.D., FAAP, FPIDS,
FIDSA
Melissa Martinez, M.D., FAAFP
Cody Meissner, M.D., FAAP
Larry Pickering, M.D., FAAP, FIDSA
Robert Schechter, M.D.
Geeta Swamy, M.D.

NVAC Ex Officio Members

Limone Collins, M.D. (for Tonya Rans,
M.D.), Department of Defense (DoD)
Mary Beth Hance (for Jeffrey Kelman,
M.D., M.M.Sc.), Centers for Medicare
and Medicaid Services (CMS), *day one
only*
Troy Knighton, M.Ed., Ed.S., LPC,
Department of Veterans Affairs (VA)
Valerie Marshall, M.P.H. (for Marion
Gruber, Ph.D.), Food and Drug
Administration (FDA)
Justin A. Mills, M.D., M.P.H., Agency for
Healthcare Research and Quality
(AHRQ)
Barbara Mulach, Ph.D., National Institutes
of Health (NIH)
Mary Rubin, M.D., Health Resources and
Services Administration (HRSA)

Geetha Srinivas, D.V.M., M.S., U.S.
Department of Agriculture (USDA),
day one only, by phone

NVAC Liaison Representatives

Kim Martin (for James S. Blumenstock),
Association of State and Territorial
Health Officials (ASTHO)
Rebecca Coyle, M.S.Ed., American
Immunization Registry Association
(AIRA)
John Douglas, M.D., National Association
of County and City Health Officials
(NACCHO), *by phone*
Claire Hannan (for Kristen R. Ehresmann,
RN, M.P.H.), Association of
Immunization Managers (AIM)
Nathalie El Omeiri, Ph.D., Pan American
Health Organization (PAHO)
Hana El Sahly, M.D., Vaccine and Related
Biological Products Advisory
Committee (VRBPAC), *day one only,
by phone*
Jean-Venable “Kelly” Goode, Pharm.D.,
BCPS, FAPhA, FCCP, American
Pharmacists Association (APhA)
Christopher Regal, M.S., America’s Health
Insurance Plans (AHIP), *day two only*

Acting Designated Federal Officer

Ann Aikin, M.A., Communications
Director, National Vaccine Program
Office (NVPO), Department of Health
and Human Services (HHS)

Proceedings

Day One—February 13, 2020

Call to Order and Rules of Engagement—Ann Aikin, M.A., Acting Designated Federal Officer, Communications Director, NVPO, HHS

Ms. Aikin called the meeting to order at 9 a.m. and welcomed the participants. She briefly outlined the agenda and described key parts of the Federal Advisory Committee Act, its conflict-of-interest rules, and standards of ethical conduct for NVAC members. Ms. Aikin thanked the NVPO staff for their support in organizing the meeting and called the roll.

Office of Infectious Disease and HIV/AIDS Policy (OIDP) Update—Tammy R. Beckham, D.V.M., Ph.D., Director, OIDP

Dr. Beckham said the novel coronavirus (COVID-19) epidemic in China demonstrates the impact of infectious diseases on public health. The World Health Organization (WHO) convened a global forum on response to the disease, and HHS created a task force to address the potential spread. The Biomedical Advanced Research and Development Authority (BARDA) issued an open call for market research on countermeasures and rapid response measures, and NIH research is underway. Global and national efforts are needed to drive response to emerging infections and, ideally, to anticipate them. NVAC's advice shapes HHS' preparedness and thinking about policies, Dr. Beckham observed.

Work continues on the next National Vaccine Plan. Feedback from public comments and stakeholder interviews largely aligns with the recommendations already made by NVAC. Vaccine hesitancy, vaccine confidence, and immunization equity will be integrated into the 5-year plan that will put forth a vaccine strategy across the life span and will identify indicators of progress. Dr. Beckham expects the Plan to be final by late 2020.

HHS is working with public and private partners to increase human papillomavirus (HPV) vaccination rates. Among them is a faith-based initiative that targets the Southeast, where vaccination rates are lowest.

OIDP is updating other national strategies, including the Viral Hepatitis Action Plan, which prioritizes vaccination and will be finalized this summer. It is also creating the first *Sexually Transmitted Infections Federal Action Plan*, which will focus on the four most common sexually transmitted infections with the highest public health impact: chlamydia, gonorrhea, syphilis, and HPV. OIDP's efforts to address tick-borne diseases got a boost with the passage and funding of the Kay Hagan Tick Act in late 2019. Dr. Beckham noted that OIDP has a broad portfolio of conditions that are all relevant to each other and to immunization, and it is working to integrate approaches across offices and strategies.

Dr. Beckham said NVAC's input is crucial to HHS' ability to impact public health. She thanked Ms. Aikin and the rest of the OIDP staff for their hard work in support of NVAC and other Federal advisory committees.

Opening Remarks—ADM Brett P. Giroir, M.D., Assistant Secretary for Health, HHS

ADM Giroir said that despite advances in immunology and vaccines, vaccine hesitancy persists. In 2018, 140,000 people around the world died from measles. Already in the 2019–2020

influenza season, 12,000 people have died in the United States, at least 78 of whom were children. NVAC plays a critical role in the vaccine enterprise.

ADM Giroir outlined initial steps taken to prevent the spread of COVID-19, including deploying U.S. Public Health Service officers to assist the Centers for Disease Control and Prevention (CDC) and other agencies. The epidemic is a reminder of the need to continue supporting innovation in vaccine research, manufacturing, and response. Significant advances in the field since the emergence of severe acute respiratory syndrome (SARS) 17 years ago have helped speed up the timeline for vaccine development; it is estimated that a COVID-19 vaccine will begin clinical trials in 3 months.

Viral hepatitis, influenza, and other vaccine-preventable diseases remain leading causes of death and illness in the United States, underscoring the need for better vaccines. Some potential universal influenza vaccines have shown progress in clinical trials. In September, the President signed an Executive Order on modernizing influenza vaccines to support the effort.

To improve vaccine confidence, parents who are concerned about their children's health and safety should have the best, most credible information available, said ADM Giroir, which requires improving data systems, educating providers, supporting provider reimbursement for vaccine counseling, building in quality metrics that support system-wide changes, and working with private partners to counter misinformation on social media. The amplification of misinformation by those who do not understand or willfully ignore the science—and by foreign agents intent on causing confusion and discontent—must be addressed, and ADM Giroir said he is personally committed to combating the meddling into the nation's public health system.

NVAC's upcoming report on vaccine hesitancy and confidence will build on and strengthen the solid foundation of childhood vaccination rates in this country, ADM Giroir said. He expressed appreciation for NVAC members' work on these topics and on immunization equity issues.

ADM Giroir reiterated his strong support for increasing HPV vaccine uptake, which could prevent as many as 30,000 cancer cases per year. In the continued effort to enact NVAC's recommendations, in the past year, HHS has engaged a large number of integrated health delivery networks and large health systems and is launching a faith-based initiative throughout the Southeast to promote HPV vaccination through strategic collaborations. ADM Giroir has also worked with survivors and advocates to raise awareness about their stories through media; videos are available at [Vaccines.gov](https://www.vaccines.gov) and the [HHS YouTube channel](#). He has also written to leaders of professional associations, academic institutions, integrated delivery networks, and large health systems to prioritize the implementation of best practices to increase HPV vaccination rates. To reach young adults, ADM Giroir reached out to more than 20 colleges and universities in the Southeast, where the HPV burden is the highest. He also took part in various activities in support of HPV Prevention Week.

ADM Giroir welcomed the new NVAC members and thanked outgoing member Ann Ginsberg, M.D., Ph.D., for her service to NVAC. He said HHS takes the Committee's recommendations seriously and appreciates its feedback. He congratulated Dr. Beckham for her leadership of ODP, noting that the ODP portfolio encompasses seven of WHO's top 10 public health threats.

Chair's Welcome—Robert H. Hopkins Jr., M.D., MACP, FAAP, NVAC Chair

Dr. Hopkins welcomed the participants to the public meeting, which was accessible by webcast and telephone. He described the meeting proceedings and the agenda for this meeting. The

minutes of the September 17–18, 2019, meeting were approved unanimously by NVAC members.

Three new members joined NVAC as of this meeting: Debra Blog, M.D., Molly Howell, M.P.H., and Robert Schechter, M.D. Timothy Cooke, Ph.D., John Dunn, M.D., M.P.H., David Fleming, M.D., and Leonard Friedland, M.D. were reappointed. Dr. Ginsburg completed her term.

Written comments can be sent to NVAC for consideration by e-mail (nvac@hhs.gov). The agenda, minutes, and presentations of past meetings are available [online](#). In 2020, NVAC is scheduled to meet on June 9–10 and September 23–24. (See the appendix for a list of abbreviations used in this report.)

Experiences in the Field: Ebola Vaccine Implementation—Rosalind Carter, Ph.D., Center for Global Health, CDC

Dr. Carter described the emergence of Ebola virus and the steps to vaccine development in the face of the 2014 outbreak. Nine vaccine candidates are in clinical trials; one, recombinant vesicular stomatitis virus (rVSV), was effective in a study using a ring vaccination approach, in which the contacts of people diagnosed with Ebola virus, contacts of contacts, and health care workers who are potential contacts are vaccinated. That study demonstrated high vaccine efficacy, but the results did not reach statistical significance. However, WHO recommended rVSV vaccine be used in an expanded access framework, with informed consent, if no licensed product or other therapy was available. The vaccine has since been deployed in the Democratic Republic of Congo (DRC) and some neighboring countries.

Dr. Carter said it is important to invest in educating and sensitizing government leaders and other stakeholders about the vaccines and protocols throughout the process. WHO's expanded access framework was a novel concept for some. In the future, more consideration should be given to how to help regulatory and ethics agencies support novel protocols.

The cold-storage requirements were a significant barrier until the development of Arktek carriers that could maintain freezer temperatures during transport and up to a month in tropical climates. The vaccine and all related supplies were easily portable and replenished daily, requiring strong logistic support for field workers. Responders had to plan for limited infrastructure, relying on generators and multiple backup systems. Hiring and training vaccine teams was easy, as many were willing to learn. The investment in building capacity is expected to provide return for many years to come, Dr. Carter observed.

Organizers used microplanning to define target groups and identify those missing, at the individual level, to ensure effective ring vaccination and to make the best use of supplies when vaccine was limited. Frequent community engagement at all levels was key.

Following vaccination, safety monitoring procedures included having the staff and equipment available to address adverse reactions. Eventually, the protocol shifted to a passive reporting approach (except for pregnant women and infants), which might have affected detection of adverse events. Field workers collected data using digital tablets, but only aggregate data were available at the local level for analysis, limiting the public health options. Dr. Carter said data collection efforts should be designed to address public health needs. She pointed out that data systems for Ebola case reporting and vaccination are not harmonized.

Vaccination teams in the DRC have faced traumatic and dangerous situations, as the country is in the midst of a violent conflict. Public health has much to learn about security and safety in conflict settings. The public health community should learn from humanitarian aid partners about how to manage operations in insecure settings.

Notably, pregnant and lactating women were excluded from the original vaccine trials, so data were limited on use of rVSV vaccine in those populations. Ultimately, some countries, such as the DRC, determined that the vaccine benefits outweighed the risk in areas of active Ebola transmission. However, barriers to vaccine confidence remain, such as confusion about and opposition to selective vaccination, conspiracy theories and misinformation about the purpose and effects of the vaccine, and concerns about an unlicensed vaccine. Dr. Carter emphasized the need to invest time in building trust within the communities and to ensure that messaging responds to community concerns.

Additional Ebola vaccines are progressing toward licensure. Gavi, the Vaccine Alliance, will maintain an emergency stockpile of licensed vaccine for outbreaks. The U.S. Advisory Committee on Immunization Practices (ACIP) is reviewing target populations for vaccine. Questions remain about the durability of protection, the potential for multivalent vaccine, and the ideal vaccine strategy. Despite the speed of scaling up clinical trials in Africa, the vaccine candidate was not available until late in the epidemic—and such a timeline should be anticipated for other outbreaks, such as COVID-19. Dr. Carter said the ring vaccination trial demonstrated that trial design must be able to take advantage of cases that are still occurring. Bringing vaccine to where the cases are occurring and providing preventive vaccination along the path of an expanding outbreak—though imperfect—continues to be a successful model for responding to the current outbreak in the DRC.

Immunization Equity Subcommittee Update—Melody Anne Butler, B.Sc.N., RN, Co-Chair of the Immunization Equity Subgroup

Ms. Butler outlined the charge to the Subcommittee to review and make recommendations on vaccination disparities such as access, affordability, awareness, acceptance, and activation. She detailed the Subcommittee’s process, which includes a thorough literature evaluation and numerous presentations from subject matter experts on topics such as the following:

- Immunization disparities across the life span and the Vaccines for Children program
- Health literacy, vaccine hesitancy, and vaccine confidence among the public and providers
- Providers’ financial barriers to vaccination
- Role of immunization information systems and identifying populations at risk
- Successful efforts to reduce ethnic/racial disparities and rural disparities
- Medicare, Medicaid, and State policies
- Maternal immunization disparities
- Insurance coverage and 317 Coalition funding

The Subcommittee plans to present draft recommendations for consideration at the June 2020 NVAC meeting and then seek public comment. The final report and recommendations will be submitted for NVAC consideration at the September 2020 NVAC meeting.

What's Old Is New Again: Innovative Science

Intravenous (IV) Bacille Calmette-Guérin (BCG) Immunization Prevents Infection and Disease in Nonhuman Primates—Robert A. Seder, M.D., Vaccine Research Center, National Institute of Allergy and Infectious Diseases (NIAID), NIH

Tuberculosis (TB) remains a leading cause of death and a global health threat. The primary goal of vaccination is to prevent disease; ideally, it would also prevent infection, so there would be no disease reservoir in the lungs that could result in later infection. Dr. Seder outlined the qualities needed for a vaccine-elicited, T-cell response to protect against TB, in particular tissue-resident T cells in the lungs. Vaccines given intramuscularly (IM) might not reach the lung tissue. BCG vaccine has been in use for 100 years and protects against systemic TB starting in infancy, but it offers variable or no protection against pulmonary TB later in life. Dr. Seder described his work to determine whether alternate routes of BCG administration could prevent pulmonary TB.

Studies in nonhuman primates revealed that intradermal (ID) high-dose BCG vaccination offered slightly more protection against a TB challenge (6 months after vaccination) than the standard dose given by the ID route or aerosolized high-dose vaccine. IV high-dose BCG vaccination was dramatically more protective, resulting in sterile immunity in most of the animals treated. Vaccination by the IV route increased T-cell recruitment in the lungs, while the ID route did not. In the IV-vaccinated animals, T cells clearly overwhelmed TB throughout the lung. After about 6 months, researchers saw no residual BCG in the lungs, but the resident T cells remained.

Dr. Seder and colleagues seek to understand the mechanisms by which IV BCG vaccination prevents TB infection. Follow-up studies are also planned to assess the correlates of protection and durability of protection. Research conducted about 10 years ago demonstrated that IV malaria vaccination is more protective than subcutaneous vaccination in humans, and at least 10 studies have evaluated the feasibility of IV delivery in African countries. Further studies of IV BCG vaccination are planned, and Dr. Seder hopes to see clinical trials initiated later this year.

What's Old Is New Again: A New Twist on Measles Vaccines and Reduced Overall Childhood Mortality—Michael Mina, M.D., Ph.D., Center for Communicable Disease Dynamics, T. H. Chan School of Public Health, Harvard University

Evidence to date suggests that measles infection increases one's risk of any kind of infectious disease for the next 2–3 years. Dr. Mina said up to 50 percent of all childhood deaths from infectious disease might be associated with having had measles. The measles vaccine might prevent the immunological amnesia that is associated with measles infection.

Researchers observed that the introduction of measles vaccine in a given geographic area was associated with a dramatic reduction in deaths among children, regardless of cause. They hypothesized that the vaccine might boost the innate immune response or that measles infection affects immunological memory. In addition to the direct effect of the vaccine, which leads to immediate reductions in mortality among children, Dr. Mina and colleagues looked at data over time in populations before and after the introduction of the measles vaccine and saw the link between vaccination and lower mortality from all causes. They then determined that the cumulative incidence of measles infection predicts mortality from other infectious diseases in children, and the finding has borne out in assessments of multiple countries.

Through clinical retrospective reviews, Dr. Mina and colleagues identified 2,000 children in the United Kingdom who had measles and subsequently had more health care visits and more antibiotic prescriptions than controls. On the basis of findings in animal studies, they posited that although lymphocytes rebound after measles, the infection depletes the memory cells that carry

an individual's lifetime history of infections. Rebuilding the immunological memory takes a few years, and in that time, children are at increased risk of infectious disease. A study of unvaccinated children who had measles confirmed that they had lost 10–60 percent of their existing immunological memory, resulting in immunological amnesia. Dr. Mina concluded that immunological amnesia likely causes about half of all childhood deaths from infectious disease.

Using Synthetic Biology to Improve Vaccines—Gigi Kwik Gronvall, Ph.D., Center for Health Security, Johns Hopkins University

Synthetic biology and tools drive biomedical advances and transcend the biomedical field. They carry potential risks but also many positive uses. Synthetic biology offers an opportunity to combat longstanding problems in vaccine development. It can improve production of vaccine antigens, reduce costs, improve the immune response in the host, and speed up development.

One example of synthetic biology is the development of virus-like particles (VLPs), which mimic the natural introduction of a disease without the danger of replication. VLP vaccine platforms are easy to modify. Current VLP vaccine targets include malaria, influenza, and dengue viruses. Computational genomics accelerates data analysis, refining the epitopes and contributing to the design of VLPs.

Therapeutic interfering particles take over the body's virus replication machinery, resulting in production of less harmful cells. Gene editing technology (clustered regularly interspaced short palindromic repeats [CRISPR]-CRISPR-associated protein 9 [Cas9]) has been used, for example, to create a feedback loop that cuts the HIV virus genome, essentially acting as a vaccine that inactivates any viral genomes that arise. Investigators in the European Union have invested in recombinant attenuated bacterial vaccines that engineer existing bacteria to replicate and present antigen to the immune system. Others are engineering a vaccine that triggers the microbiome to elicit an immune response. Nucleic-acid-based vaccine strategies use messenger RNA prompt the body to develop its own vaccine-like antigens. (Moderna is developing a messenger RNA-based vaccine against coronavirus [CoV].)

Despite the promise these techniques offer, few companies are applying them because of the initial investment required and the regulatory burden associated with new techniques. Dr. Gronvall pointed out that synthetic biology could lead to more cost-effective manufacturing and would likely be suitable for distributed manufacturing, which is important to overall security and supply of countermeasures. She asked for input on how to encourage companies to take advantage of the novel science.

Discussion

Cody Meissner, M.D., FAAP, pointed out that the BCG vaccine in its current formulation is not ideal. Dr. Seder responded that efforts are underway to develop a subunit vaccine delivered by RNA. He believes the IV approach is worth pursuing as a way to get the vaccine to the tissue affected.

Dr. Meissner asked about the immune response following live-attenuated measles vaccine. Dr. Mina described results of some investigations and concluded that there is no evidence of infection with live vaccine.

In response to Dr. Schechter, Dr. Mina said that measles infection induces a severe immunodeficient state that lasts as long as 2 months, distinct from the long-term effects that cause immunological amnesia. IV immunoglobulin is among the few tools useful for mitigating acute

measles infection, but more study is needed to determine whether it would be useful for other pathogens in children who had measles. Dr. Mina pointed out that the mortality rate of measles is much higher when calculated along with subacute sclerosing panencephalitis and other complications of measles plus the predicted long-term effects of immunological amnesia.

CDC COVID 2019 Situation Update—Ram Koppaka, M.D., Ph.D., CDC

Dr. Koppaka described the emergence and spread of COVID-19 to date. CDC established an incident management system in early January. The immediate risk in the United States is low at present. CDC is putting out guidance on strategies for prevention and for managing possible shortages of personal protective equipment. CDC will upload the full genetic sequence of virus taken from infected U.S. patients to NIH's GenBank as the samples become available. Four common CoVs cause mild to moderate upper respiratory infections, usually in the fall and winter. In contrast, SARS-CoV emerged from China in 2002 and caused about 8,000 cases, with 774 known deaths. Middle East respiratory syndrome (MERS)-CoV arose in Saudi Arabia in 2012, causing 2,400 confirmed cases and 850 deaths.

COVID-19 was identified in China in December 2019, likely stemming from a large, live animal market, and appears to spread through person-to-person transmission by coughing, sneezing, or contact with infected surfaces. The prevention techniques recommended for influenza and other upper respiratory infections (e.g., handwashing and avoiding contact) apply to COVID-19. Current management approaches consist of supportive care for symptoms and management of complications. NIH is pursuing a vaccine and therapeutics.

Discussion

Dr. Koppaka clarified that antivirals in development could be effective against COVID-19, but there is no definitive evidence that any specific antivirals are effective now. It is not clear whether there is any association between COVID-19 and influenza, such as whether one predisposes to infection with the other, whether one can worsen the other, or whether coinfection is possible.

COVID-19 Vaccine Development: Opportunities and Potential Pitfalls

NIAID Response to SARS-CoV-2—Alan Embry, Ph.D., Division of Microbiology and Infectious Diseases, NIAID, NIH

NIH is accelerating research on SARS-CoV-2, the virus that causes COVID-19. It is evaluating cross-reactivity with existing SARS and MERS vaccine candidates and monoclonal antibodies (mAbs). In addition to the usual grant mechanisms, emergency supplemental funding is available for investigators to increase understanding of COVID-19, create medical countermeasures, and develop animal models for research. NIAID also specifically solicited applications to develop vaccines, therapeutics, and diagnostics for COVID-19. To facilitate research, viral isolate from the first U.S. patient with COVID-19 is available, and other patient samples will be available soon. Efforts are underway to develop reagents.

NIAID's Vaccine Research Center partnered with Moderna to create a vaccine candidate specific to COVID-19, which will begin trials soon. The vaccine stabilizes the virus in its prefusion state, which appears to be able to enable immunogenicity in animals. NIAID's Infectious Diseases Clinical Research Consortium will conduct trials.

Three severe CoV outbreaks have occurred in the past two decades, and the pandemic potential of CoV is obvious, so efforts are underway to develop a universal CoV vaccine. The Vaccine Research Center is making strides toward optimizing antigen design for potency and breadth, developing self-assembling nanoparticles and VLPs to increase immunogenicity, and creating

gene-based delivery systems for rapid response. Dr. Embry concluded that global collaboration and transparency are critical to vaccine development.

2019-nHCoV—Ralph Baric, Ph.D., Gillings School of Global Public Health, University of North Carolina

Dr. Baric explained that CoVs are jumping across species more rapidly than in the past. He believes that environmental conditions are affecting the rate at which the viruses can mutate and that the viral structure tolerates high rates of mutations, which allows for modular evolution. Studies have revealed a number of SARS-like bat CoVs, some of which theoretically can replicate in human cells and use human receptors. COVID-19 clearly originated in bats.

For long-term protection in humans, Dr. Baric suggests targeting the high-risk SARS-like CoVs that circulate in bats. The high-risk strains all use the same receptor for entry, grow in primary human airway cells, cause acute respiratory distress syndrome, affect the elderly more severely, and escape existing immune therapies. Similarly, a number of MERS-like CoV strains are poised to emerge in humans and have characteristics similar to the high-risk SARS-like CoV strains.

In the old model of virus emergence in humans, random mutations occurred, the virus spilled over from animals into humans, and the virus went through several rounds of replication before evolving into an epidemic strain. Now, viruses are capable of capitalizing on human or other animal receptors without any mutation. Genetically, the current human strains represent new SARS-like viruses different from any seen before.

Vaccine development faces complications. For example, animal models generally do not provide a good representation of the effectiveness of vaccines in aging humans. Use of adjuvants can drive a Th2 response that can be problematic. There is some evidence of antibody-dependent enhancement, which complicates the utility of a SARS-CoV vaccine.

Developing Antivirals Against Coronaviruses—Mark Denison, M.D., Vanderbilt University School of Medicine

Dr. Denison echoed the challenges to vaccine development for CoVs. His laboratory has been working for more than 5 years toward an antiviral candidate that would effectively target every CoV tested, with a high barrier to genetic resistance and a high fitness cost, and with the possibility of extending the therapeutic window for prevention, amelioration, or treatment. The ideal formulation could be used to stem transmission rapidly in a contained setting (e.g., a cruise ship) and should be available in oral form to ensure it is portable and accessible.

CoVs have the largest RNA genomes of any RNA family, the most proteins, and the most complicated mechanisms of replication. Multiple proteins work together, which is unprecedented for RNA viruses. CoVs can recapitulate a DNA-based, multiprotein replication enzyme. CoVs also have a unique capacity for regulating their own replication fidelity. Inactivating the virus' own "proofreading" capacity makes the virus sensitive to treatment compounds. Dr. Denison's laboratory received two nucleoside analogue compounds in development for testing that appeared to be active against the modified virus. One, remdesivir, dramatically reduced viral replication in in vitro models and showed broad activity against a wide variety of CoVs in different groups. Further testing revealed that it was difficult to generate resistance to the drug, and the resistance that was eventually generated was not very susceptible to the virus.

Dr. Denison noted that remdesivir was effective as prophylaxis in mouse studies and decreased virus titers when given early in infection, but, as with many drugs, it was not a very effective

antiviral when used alone in treating virus that has already settled in and caused acute respiratory distress syndrome or other complications. Remdesivir is given by IV administration.

A second drug currently in testing, EIDD-2801-NHC, has a slightly different mechanism of action but also meets the criteria that Dr. Denison's laboratory established for an effective antiviral. It is orally bioavailable, however, making it potentially more useful in practice. Dr. Denison pointed out that work continues on mAbs and host-directed therapies that, in theory, could be combined with direct-acting antivirals, particularly to extend the therapeutic window and further prevent infection.

Discussion

Dr. Denison noted that remdesivir has been deemed safe and is being used in Ebola virus trials, which is encouraging. It works against CoV in animal models, but more study is needed to understand the circumstances under which it would work for humans.

Dr. Denison speculated that CoV transmission from bats may occur by human contact or ingestion of meat. Dr. Baric said many people who work in or around bat caves are seropositive for CoV, presumably because of contact with bat guano or from eating bat meat. Bats can harbor multiple CoVs, and there are a number of mechanisms for transmission to humans, but how those translate into a human outbreak remains unclear.

Dr. Embry acknowledged some of the problems with SARS vaccine candidates and antibody enhancement in animal studies. The CoV vaccine in development that stabilizes the virus in its prefusion state should neutralize the virus before sustained infection and mitigate the possibility of antibody enhancement.

Dr. Denison pointed out that Dr. Baric's work in the 1990s predicted the potential for CoVs to cross species. He added that bats are a species at risk and should not be seen as enemies to humans. He also expressed optimism about the future of countermeasures, thanks to long-term research funding supporting the work that formed the basis for the promising vaccine and antiviral candidates described.

Dr. Schechter proposed the use of chloroquine or other protease inhibitors, and Dr. Denison agreed that both could be effective in preventing CoV replication. One protease inhibitor has been used successfully in cats in China against feline CoV. A combination of nucleoside analogues and protease inhibitors could potentially be very effective, Dr. Denison noted.

Novel CoV Medical Countermeasures (MCMs): U.S. Task Force Efforts—Robert Johnson, Ph.D., BARDA, Office of the Assistant Secretary for Preparedness and Response (ASPR), HHS

Dr. Johnson explained that BARDA forms public-private partnerships to move products toward licensure. It seeks to leverage existing products, platforms, and capabilities to develop MCMs, prioritizing development on the basis of public health impact and probability of success. COVID-19 represents the third CoV outbreak in less than two decades, yet no vaccines or therapeutics have been licensed for use. The ASPR established the COVID-19 MCM Task Force to align government agencies around an end-to-end solution and facilitate sharing of information and resources. Working groups on therapeutics, vaccines, diagnostics, and clinical trials will focus on their respective areas; subworking groups on animal models and sample sharing will address those needs across the development pipeline. The end-to-end approach requires partners to think through the process from discovery to licensure to large-scale production.

For COVID-19, BARDA aims to leverage proven vaccine platforms with large-scale capacity, rapidly, and using multiple approaches. Platform-based mAbs, if successful for treating COVID-19, can move forward quickly to licensing and manufacturing, as can other existing therapeutics that prove useful. New diagnostics are needed to enable earlier identification and treatment of the virus. Other efforts are addressing how current manufacturing facilities can be adapted to scale up production of COVID-19 products.

BARDA's market research portal is open for submissions related to COVID-19 from stakeholders. For COVID-19 diagnostics in particular, BARDA has opened the EZ Broad Agency Announcement and amended its own Broad Agency Announcement for abstracts and white papers.

Discussion

Dr. Johnson observed that the September Executive Order focuses on influenza vaccines, but many of the requirements and needs for that effort overlap with those of the COVID-19 efforts, so he anticipated mutually beneficial support for both.

NVAC Liaison Updates

VRBPAC—Hana El Sahly, M.D.

VRBPAC met on October 9, 2019, to hear a presentation of the research programs in the Laboratory of Hepatitis Viruses and the Laboratory of Vector-Borne Viral Diseases of FDA's Office of Vaccines Research and Review and to make recommendations on the strain selection for the trivalent and quadrivalent vaccines for the 2020 Southern Hemisphere influenza season. The Committee voted to include protection against influenza A and B in both formulations.

VRBPAC met again on November 8, 2019, to discuss recommendations for the development of chikungunya vaccine. Specifically, the committee reviewed the feasibility of randomized, controlled clinical disease endpoint efficacy trials, the role of seroepidemiologic data in identifying immune markers reasonably likely to predict vaccine effectiveness, and the role of animal models in predicting vaccine effectiveness. Members discussed the paucity of well-conducted chikungunya surveillance studies, which renders the conduct of a Phase III clinical trial challenging.

PAHO—Nathalie El Omeiri, Ph.D.

PAHO will celebrate Vaccination Week in the Americas from April 25 to May 2 with the slogan "Love, Trust, Protect, Get Vaccinated." The regional launch will take place in Dominica on April 25 with ministries of health from the Caribbean countries and territories and other key partners such as CDC, Public Health Agency of Canada, and other United Nations agencies.

PAHO is developing a regional adaptation of WHO's proposed 2030 immunization agenda, taking into account inputs from the countries in the region. PAHO continues to provide technical cooperation to countries in Latin America and the Caribbean to strengthen immunization programs and surveillance of vaccine-preventable diseases with a series of upcoming regional trainings and updates of guidelines. For instance, it is updating guidelines for surveillance of adverse events following immunization; guidance for evidence-based decision-making, specifically for national immunization technical advisory groups; and guidance for surveillance of tetanus, diphtheria, and pertussis.

In line with previous support to help countries evaluate the impact of vaccines after they are introduced, PAHO developed a guidance document for the evaluation of HPV vaccine impacts in Latin America and the Caribbean, and it will be validated by a group of experts in March 2020.

Considering the progress with maternal immunization and the success of hepatitis B vaccination programs in the Americas, which have resulted in significant progress towards the elimination of mother-to-child hepatitis B transmission, PAHO is working with CDC on country guidance for the verification of elimination in the Americas.

NACCHO—John Douglas, M.D.

With support from CDC, NACCHO implemented a local public health initiative to increase vaccine confidence and address vaccine misinformation within communities. The organization's annual conference will include immunization-related topics and recognize model practices, many of which fall into the category of immunization program work.

NACCHO submitted letters to Congress over the past 6 months on vaccination of detainees in Customs and Border Patrol custody, to HHS on the development of the 2020 National Vaccine Plan, to the U.S. House Oversight and Investigations Committee's about pandemic influenza, and to the Department of Homeland Security requesting implementation of an influenza vaccination program for asylum seekers and migrant workers.

NACCHO co-sponsored testimony by Jeff Duchin from the Seattle Public Health Department to Congress for a briefing in October titled Preventing Outbreaks: Working Together to Increase Vaccine Confidence. Taking advantage of its other broad communication platforms, the organization posted a variety of different materials for local health departments to use during HPV Prevention Week in January.

ASTHO—Kim Martin

ASTHO is working on several initiatives to address vaccine hesitancy, including a podcast and some videos to describe State health agency efforts during the recent measles outbreaks and an infographic showing the cost of an outbreak. It is tracking legislative changes and has developed blogs and resources about some of the vaccination policies to watch. ASTHO continues HPV Project Echo, through which nine States will share some of their challenges and promising practices and work together to develop solutions to increase HPV vaccination rates.

APhA—Jean-Venable “Kelly” Goode, Pharm.D.

APhA continues to focus on training, education, and information. It holds webinars after every ACIP meeting and had over 500 registrants for its November webinar. It also had a webinar on patient referral for vaccinations to and from pharmacies. On its website, APhA offers quizzes for members and nonmembers to test their vaccine knowledge. The organization uses the quizzes to identify topics for which it should provide education. More than 2,000 people have accessed the quizzes around vaccine storage and handling, HPV vaccine, adolescent immunizations, and immunization administration.

APhA conducted a pulse survey to get an idea of how pharmacists were interpreting shared clinical decision-making and how they were putting it into practice so it could address those issues with education. In March, APhA will hold its annual meeting in the Washington, D.C.

AIRA—Rebecca Coyle, M.S.Ed.,

AIRA'S measurement and improvement initiative is measuring immunization information systems performance in key content areas, most recently for clinical decision support features. After two cycles of measurement, AIRA is seeing improvement, as clinical decision support features become better aligned with national standards.

In addition to the measurement and improvement initiative, AIRA is hosting a 3-week webinar series with the University of Colorado on how to implement a centralized reminder recall system. The webinars provide a deep dive into a new toolkit developed in conjunction with AIRA. The webinars will be recorded and posted on the AIRA website.

AIRA will take part in the Healthcare Information and Management Systems Society meeting in March, where it will showcase some of the collaborative opportunities with the Society and CDC. It holds its national meeting in August in Portland, OR.

AIM— Claire Hannan, M.P.H.

AIM held its annual leadership training conference in December, where it celebrated its 20th anniversary. The organization continues to provide leadership and skill training and mentoring for new program managers. The turnover is still considerably high for people in state immunization director positions. AIM partnered with the University of Michigan to publish an article on improving fourth-dose diphtheria-tetanus-pertussis vaccine completion rates in the February 4, 2020, online journal, *Human Vaccines and Immunotherapeutics*. The information came from a roundtable conducted in June 2018 with nine city and State public health programs. AIM is working on two toolkits, one around lessons learned with engaging in policy work and another on improving vaccine confidence and vaccine hesitancy.

Advisory Commission on Childhood Vaccines (ACCV)—Cody Meissner, M.D., FAAP

ACCV conducted its 112th quarterly meeting on December 5, 2019. The meeting began with program updates from DICP and Chief Special Master Brian Corcoran of the U.S. Court of Federal Claims. Mr. Corcoran discussed the P100 Pilot and Pre-Assignment Review program, which aims to reduce the time needed to review and settle petitions and increase the number of petitions resolved annually by sending those petitions eligible for settlement to a neutral party for evaluation. In September 2019, the Office of the Special Master selected 25 petitions to test under the P100 program. The test group consisted of five petitions from each of the five law firms participating in a task force that was convened on November 7, 2018. If the pilot test is successful, the court anticipates referring 100 petitions to the P100 program for each round of neutral evaluations.

The P100 program seeks to increase the efficiency of processing petitions by defining case assignments to a Special Master until the record is substantially complete and ready for medical review. The initial review will result in either an activation order if the medical records and other evidence are substantially complete or a scheduling order, which sets forth the filings required to complete the process. The court will follow up scheduling orders as necessary until the record is substantially complete.

ACCV also reviewed program updates from CDC's Immunization Safety Office, NIAID, FDA's Center for Biologics Evaluation, and OI DP. ACCV is required by the National Childhood Vaccine Injury Act of 1986 to review new and modified vaccine information sheets. CDC revised eight vaccine information sheets to ensure that the language in certain sections is consistent

among them. During presentation of those information sheets, ACCV members made suggestions that CDC agreed to take under advisement.

VA—Troy Knighton, M.Ed., Ed.S., LPC

More than 2 million veterans have been vaccinated against influenza this season, including about 110,000 through VA's partnership with Walgreens. The Veterans Health Administration stood up a COVID-19 national workgroup with many subgroups to begin to plan a response and implement recommendations as they are developed by other federal agencies.

NIH—Barbara Mulach, Ph.D.

During his talk on CoV vaccine evaluation, Dr. Embry mentioned the Infectious Disease Clinical Research Consortium. Dr. Mulach explained that NIAID has modified the structure of its vaccine research entities and established a new, overarching leadership group, but the investigators associated with its longstanding Vaccine Treatment and Evaluation Units are still involved.

In December, NIAID issued an update to its 2014 report, *Antibacterial Resistance Program: Current Status and Future Directions*. It describes progress made since the original report and highlights innovative approaches to be pursued over the next 5 years to combat antimicrobial resistance. Over the summer, NIH made an award to the University of Alabama at Birmingham to begin an acute flaccid myelitis natural history study in collaboration with CDC and other partners. The international multisite study will reveal more about the incidence and distribution of acute flaccid myelitis and how it develops and progresses in children.

USDA—Geetha Srinivas, D.V.M., M.S.

Since May 2018, an outbreak of virulent Newcastle disease (VND) has had a devastating impact on backyard poultry populations in California. To eliminate the virus, a joint incident management team of the California Department of Food and Agriculture and USDA is humanely euthanizing infected and exposed birds, as well as conducting diagnostic testing to identify any new or potential sources of infection. On February 27, 2019, the state issued a regional quarantine for all of Los Angeles County and parts of San Bernardino and Riverside Counties to prohibit the movement of all poultry and poultry products as well as any poultry materials or equipment, including nonpoultry species that came in contact with the poultry.

VND is highly contagious and nearly always fatal among poultry, but it also affects other birds. The only way to stop the spread of the virus is to euthanize infected birds and all domestic birds within the infected areas. One way the disease spreads is by transporting infected birds and the equipment that comes in contact with them. More than 1.2 million birds have been euthanized in Los Angeles, Riverside, and San Bernardino counties to control the disease. The disease also spread to a few other isolated areas of California and some discrete areas of Utah and Arizona last year. All of the incidents outside the regional quarantine areas have been contained. The last positive detection was on January 7, 2020. The regional quarantine in Southern California is expected to extend until summer. Although VND can cause severe conjunctivitis in humans, to date, there has been only one case of conjunctivitis reported since 2018.

HRSA DICP—Mary Rubin, M.D.

Dr. Rubin said HRSA's Bureau of Primary Health Care had no update. The National Vaccine Injury Compensation Program (VICP) has continued to process an increased number of claims. In fiscal year 2019, 1,282 claims were filed, \$196.2 million was awarded to petitioners, and \$29.2 million was awarded in attorneys' fees and costs. As of January 1, 2020, a total of 289 claims had been filed with the program, and \$57.2 million had been awarded for petitioners and attorneys'

fees and costs. HRSA has a backlog of 913 claims alleging vaccine injury awaiting review. As of January 1, 2020, the Countermeasures Injury Compensation Program had compensated 39 claims totaling \$5.5 million.

FDA—Valerie Marshall, M.P.H.

In December 2019, FDA approved Ervebo, the first FDA-approved vaccine for the prevention of disease caused by the Ebola virus in individuals 18 years of age and older. In November 2019, FDA approved a supplement to the biologics license application for Fluzone vaccine to include the high-dose quadrivalent formulation for persons 65 years of age and older for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.

DoD—Limone Collins, M.D.

DOD completed its influenza vaccine program for 2019–2020, meeting its goal of vaccinating 90 percent of the forces by January 15. The program includes all active services and reserve components. DoD continues to maintain restricted distribution and rigorous control over the yellow fever vaccine, which is an ongoing issue within the Department. DoD anticipates the implementation of a new smallpox vaccine in September of this year that it hopes will have a greater safety profile. In regards to clinical studies, DoD is in the second year of its influenza vaccine effectiveness study. It is a collaborative study with the Immunization Healthcare Division and the Uniformed Services University’s Infectious Diseases Clinical Research Program. The study has enrolled almost 6,000 candidates. Dr. Collins said DoD is looking forward to getting some information about a more effective technology for influenza vaccine.

CMS—Mary Beth Hance

Regarding reporting of immunizations delivered through Medicaid, in September, CMS released its core set reporting for 2019, which describes data from 2018. For children, the core set includes two immunization measures that are also Healthcare Effectiveness Data and Information Set (HEDIS) measures: the childhood immunization status measure for children under 2, and the immunization for adolescents measure. The rate for the childhood immunization status measure was consistent in 2018, remaining flat since 2017. However, there was an increase in the immunization rate for adolescents from 74.5 percent to 77.4 percent, which CMS was happy to see. Details of the data are available on Medicaid.gov. For adults, the core set includes a measure for influenza vaccination, but the threshold of reporting by 25 States on that measure has not yet been met.

AHRQ and the U.S. Preventive Services Task Force (USPSTF)—Justin A. Mills, M.D., M.P.H.

USPSTF is updating its 2014 recommendation for hepatitis B screening in nonpregnant adolescents and adults at high risk. In 2014, USPSTF recommended screening for hepatitis B infection in persons at high risk for infection. USPSTF based this recommendation on adequate evidence that the screening is accurate for identifying persons with chronic hepatitis B infection, that the hepatitis B vaccination is effective at decreasing acquisition in persons who are negative for hepatitis B, and that there is antiviral treatment for chronic hepatitis B infection that is effective for improving intermediate and health outcomes.

USPSTF is also conducting a new systematic review on the safety of vaccines used for routine immunization in the United States. This review will provide an update to the 2014 AHRQ review for each of the following populations: adults, children, adolescents, and pregnant women. More information on both of these efforts should be available by the June 2020 NVAC meeting.

DISCUSSION

Mary Anne Jackson, M.D., FAAP, FPIDS, FIDSA, asked whether shoulder injury related to vaccine administration remains the most common VICP claim and whether any trends around those claims have been identified. Dr. Rubin said shoulder injury related to vaccine administration continues to be the most common claim, representing 54 percent of all claims filed in the past 2 years. VICP does not have data on the locations associated with claims.

AHIP, BARDA, CDC, and the Public Health Agency of Canada provided written reports only.

U.S. Influenza Vaccine Modernization Efforts

Modernizing the U.S. Influenza Vaccine Enterprise—Kristin DeBord, Ph.D., ASPR

Dr. DeBord outlined the threat of seasonal and pandemic influenza in economic terms and with an eye to national security. Most current influenza vaccines are derived from eggs and are effective but take a long time to prepare; half of the egg-based vaccine manufacturing occurs overseas, so the supply chain could be at risk in the face of a severe season or pandemic. Current vaccines are not designed to allow for incorporating new influenza strains rapidly. Further, U.S. vaccination rates are low—about 45 percent for adults and 62 percent for children in the 2018–2019 season.

The Executive Order on modernizing influenza vaccines highlighted the national security and public health implications. It established a National Influenza Vaccine Task Force to modernize the domestic influenza vaccine enterprise to be highly responsive, flexible, scalable, and more effective at preventing the spread of influenza viruses. The Task Force is jointly chaired by representatives of HHS and DoD and includes representatives from BARDA, NIH, CDC, CMS, USDA, VA, the Department of Homeland Security, and the Department of Justice. The Executive Order spells out four policy objectives:

- Reduce U.S. reliance on egg-based influenza vaccine production.
- Expand domestic capacity of alternative methods that allow more agile and rapid responses to emerging influenza viruses.
- Advance the development of new, broadly protective vaccine candidates that provide more effective and longer-lasting immunities.
- Support the promotion of increased influenza vaccine immunization across recommended populations.

The Task Force was charged with quickly creating a 5-year plan to achieve the objectives. The Task Force ultimately focused on a national strategy for modernization over 10 years to allow time for advanced development and licensure procedures. The resulting National Influenza Vaccine Modernization Strategy, 2020–2030, is aligned around three strategic objectives:

- Strengthen and diversify influenza vaccine development, manufacturing, and supply chain.
- Promote innovative approaches and use of new technologies to detect, prevent, and respond to influenza.
- Increase influenza vaccine access and coverage across all populations.

Other federal partners were consulted in the development of the new strategy. For example, Dr. DeBord said, the State Department contributed to the language on egg-based vaccine manufacturing, which can be a sensitive issue among international partners.

Implementing the NIAID Strategic Plan for a Universal Influenza Vaccine—Alan Embry, Ph.D., Division of Microbiology and Infectious Diseases, NIAID, NIH

Although the annual seasonal influenza vaccines are safe and effective, their overall effectiveness rates vary each year depending on how well the vaccine matches the circulating strains. The time required to develop or revise a vaccine is too long to address novel viruses in a timely manner. Taking into account these concerns, in 2017, NIAID convened experts in the field, who agreed that the ideal universal influenza vaccine would be at least 75 percent effective, protect against group I and II influenza A viruses, protect for at least 1 year, and be suitable for all age groups. NIAID developed its Universal Influenza Vaccine Strategic Plan with these goals in mind, outlining specific research goals and approaches to achieve them.

Under the strategy, NIAID's Centers for Excellence for Influenza Research and Surveillance (CEIRS) added longitudinal cohorts to better understand various factors, including preexisting immunity, which might affect response to vaccination and infection. A CEIRS study in Nicaragua determined that hemagglutinin stalk antibodies independently protect against infection and thus may be a target for vaccine development. Two studies are evaluating cohorts of infants longitudinally to understand the impact of first exposure to vaccine and the development of immunity after infection. NIAID is also expanding the capacity for human influenza challenge studies at Vaccine Treatment and Evaluation Units.

NIAID's Collaborative Influenza Vaccine Innovation Centers focus the efforts of three vaccine research centers around a comprehensive program for universal influenza vaccine development. The three centers represent national and international investigators at many sites. The Collaborative Influenza Vaccine Innovation Centers have proposed various novel approaches to vaccine delivery (including use of recombinant proteins, VLPs, nanoparticles, DNA, RNA, and microneedle patches) as well as novel antigen designs that they are testing in various animal models, including some nonhuman primates.

Among the seasonal influenza vaccine studies underway is a comparison of different combinations of two vaccines with and without one or two adjuvants, and more such studies are planned. NIAID is also considering adding "response" to the mission of the CEIRS program, focusing more on human studies and the animal interface, improving understanding of influenza transmission, and developing vaccines that address influenza B as well as influenza A (in the context of partnerships around universal influenza vaccine development).

Discussion

Larry Pickering, M.D., FAAP, FIDSA, noted the affordability and ease of access associated with influenza and other vaccinations delivered by retail pharmacists. Dr. Goode said about 30 percent of influenza vaccines are delivered through pharmacies, and she offered to provide more APhA data. Dr. DeBord said HHS hopes to expand how people get vaccines and health care in general. She believes pharmacies might be underutilized. Pharmacy-based vaccinations could be particularly helpful in a pandemic setting to avoid overwhelming emergency departments. Dr. Hopkins noted that the National Adult Immunization and Influenza Summit believes it will take a broad coalition of pharmacies, public health providers, visiting nurses, medical system providers, and others to vaccinate enough people to make a bigger impact on influenza.

Ms. Butler raised concerns about ensuring the nation has the resources to maintain its focus on influenza and also address emerging infections like COVID-19. Dr. Embry said influenza remains a top priority for NIAID, and its efforts to improve influenza vaccines are not affected by its work

on CoV. Dr. DeBord said HHS continues to have significant resources dedicated to influenza, even as some attention is temporarily diverted to COVID-19.

Dr. Dunn recommended that the National Influenza Vaccine Task Force include people with expertise in communication and public messaging. Despite the wide availability of free and low-cost influenza vaccine in multiple settings, uptake remains low, so addressing vaccine hesitancy and encouraging uptake are important.

Vaccine Confidence Subcommittee Update—John Dunn, M.D., M.P.H., Co-Chair

The Subcommittee was charged with updating NVAC's 2015 report on vaccine confidence to include determinants of vaccine confidence over the life span, recommendations on improving confidence in all vaccines, and guidance on applying evidence-based best practices from other social research fields to foster vaccine confidence. The subcommittee will provide a summary of research on vaccine confidence by age group and by vaccine that has emerged since 2015. It will make recommendations for new strategies and approaches that are concise, practical, and feasible. Draft recommendations will be presented at the June 2020 NVAC meeting, followed by publication for public comment, and the final report and recommendations will be submitted to the Council at the September 2020 NVAC meeting.

The subcommittee heard from experts on topics ranging from real-world approaches, the psychological underpinnings of vaccine hesitancy and confidence, the components of a resilient immunization system, the pros and cons of vaccine mandates, and the growing sophistication of the anti-vaccine movement. The subcommittee learned, for example, that effective approaches to build confidence vary by vaccine and by subgroup.

There has been some discussion about potential recommendations, such as the need for nuanced, balanced approach to mandates and nonmedical exemptions; increasing the role of state departments of education; increasing provider compensation for vaccine education; applying business concepts such as branding; and strengthening preparation at the local level for outbreaks. Future subcommittee meetings will focus on vaccine-specific confidence research, applicable findings from other social science fields, and evidence-based interventions.

Public Comments

No public comments were offered.

Adjournment

Dr. Hopkins adjourned the meeting for the day at 4:19 p.m.

Day Two—February 14, 2020

Chair's Welcome—Robert H. Hopkins Jr., M.D., MACP, FAAP, NVAC Chair

The meeting came to order at 9:02 a.m. Dr. Hopkins recapped the topics discussed on the first day of the meeting and outlined the agenda for day two.

Views on the Value of Vaccines—R. J. Reinhart, Gallup

Data from Gallup polls demonstrate that support for vaccination has declined since 2001. Mr. Reinhart compared findings from 2001, 2015, and 2019 Gallup surveys, the results of which highlighted differences among age groups and across educational ranges. The percentage of

people who believe that it is important for children to be vaccinated has declined across most subgroups, with the exception of those who have some graduate-level education. The overall percentage of people who have heard about the advantages of vaccines has increased across all subgroups, reaching 90 percent or higher for almost all age ranges. At the same time, a much larger percentage of people reported hearing about the disadvantages of vaccines when compared with 2001, which Mr. Reinhart attributed in part to the growing influence of the Internet.

The percentage of people who believe vaccines are more dangerous than the diseases they prevent increased from 6 percent in 2001 to 11 percent in 2019, with increases across most age ranges and levels of education. The percentage of people with children under the age of 18 who believe vaccines pose the greater danger rose from 6 percent in 2001 to 16 percent in 2019.

Asked whether certain vaccines cause autism in children, about half of respondents say they are unsure, and there is a correlation between being unsure and lower levels of education. Regarding government requirements that children be vaccinated, the overall percentage in favor has declined. People without children under 18 are more likely than those with children under 18 to favor vaccine mandates. People over 50 years and those with graduate-level education are also more likely to support mandates than others.

Other research finds that about 79 percent of people from 140 countries believe vaccines are safe, compared with 72 percent in the United States. Ukraine has the lowest percentage of people who believe vaccines are safe (29 percent).

Discussion

Mr. Reinhart said in the Gallup surveys, socioeconomic status tends to correlate with education level. He acknowledged the perception that the anti-vaccine movement is made up of mostly educated, middle-class people, but the data suggest that might not be the case.

Inoculating Misinformation on the Internet

(How) Should We Fight Misinformation on Social Media?—Niam Yaraghi, The Brookings Institution

Mr. Yaraghi said social media has evolved into something that looks similar to traditional media yet cannot be held to the same standard because of the sheer volume of content posted. While artificial intelligence has been proposed as a way to identify misinformation, it relies on old patterns and cannot adjust rapidly to changing tone and content and might not detect well-crafted misinformation.

Even if social media platforms could develop effective technology for filtering out misinformation, Mr. Yaraghi questioned whether that would be the best use of resources, given that there are so many different kinds of misinformation. He observed that the immediate consequences of vaccine misinformation and disinformation are more troublesome than those around flat-earth theories, for example. He proposed that companies convene experts to determine the topics for which it is most important to root out misinformation. Moreover, censorship can result in people becoming martyrs for their causes.

Social media provides good information as well as bad, and people should have sources of reliable information to combat the misinformation they might get from their social circles. Strategies include using disclaimers to notify users that certain claims have been debunked and promoting of links to other, credible resources (used by YouTube and Wikipedia). Mr. Yaraghi emphasized the need for having platforms people can trust.

Vaccine Safety Net (VSN)—Isabelle Sahinovi, WHO

The VSN, launched by WHO in 2003, is a network of websites verified by WHO that provide reliable, science-based information about vaccine safety. By linking to websites around the world, the VSN provides information in numerous languages, tailored to the local context, and taking into account an audience's health literacy. Through extensive criteria and review, WHO ensures that the websites in the VSN network demonstrate credibility, transparency, accountability, and accessibility. The VSN employs crosslinking strategies and recognition of good information practices with the goal of prioritizing VSN information in search engines.

The VSN portal provides access to the resources and information provided by network members. It also offers members a password-protected area for sharing information and best practices. The VSN gathers feedback from its social media efforts to inform VSN development. In 2019, Pinterest teamed up with WHO and the VSN to provide reliable information about immunization from leading public health organizations. In the future, the VSN plans to increase the reach of its social media, analyze patterns of successful interactions, and pursue collaborations with Facebook, Twitter, Google, and social media influencers around the world.

In 2017, WHO and VSN members agreed to share their individual website analytics to inform the entire network, which stimulated participating institutions to review their own online visibility. WHO is now planning to expand the scope of the VSN web analytics by integrating social media listening and audience analysis. This step is expected to inform VSN members about their respective strategies and enable the network to test and measure the impact of global information campaigns. The approach identifies audiences concerned about vaccine safety and segments them according to perceptions about vaccination, allowing analysts to understand how different communities talk about the same topic differently and enabling VSN members to tailor messages to key audiences.

The VSN portal currently includes a chat window, and WHO is planning to add a chat-bot to improve delivery of tailored messaging and address public concerns about vaccine safety. The chat-bot will allow the VSN to capture more user interactions and identify concerns. It will generate its own analytics, which could be used by the network to provide timely, tailored information. These data could also be paired with findings from the audience analysis project. The interactions will be evaluated by a team representing various social sciences. The VSN is also designing a data-driven digital vaccine safety information and communication strategy that can be implemented at the local, regional, and global levels and that will inform WHO's Global Vaccine Safety Initiative.

#ThereIsHelp—Lauren Culberson, Twitter

Ms. Culberson said Twitter excels at connecting people. As part of its effort to combat misinformation around vaccination, it launched a search prompt, Know the Facts, which links to reliable public health sources such as Vaccines.gov and HHS' Twitter account. Throughout the world, Twitter worked with health officials on the ground to direct users to credible sources of information for that market. Twitter now has 35 prompts running on the platform in 33 countries in 12 languages, representing 17 official sources of information.

Working with CDC and others, Twitter quickly established a search prompt for CoV that is running in several dozen markets. It is also working with HHS around the opioid crisis by supporting conversations about recovery and prevention. Another prompt addresses suicide and self-harm, linking people to a suicide prevention hotline. Ms. Culberson concluded that Twitter is committed to working with public health experts to address the challenge of misinformation.

Vaccine Misinformation: The Role of Social Media—Ana Santos Rutschman, S.J.D., Center for Health Law Studies, Saint Louis University School of Law

Dr. Rutschman prefaced her comments by observing that the topic of vaccine misinformation touches on broader issues of First Amendment rights around religion, which informs potential responses and regulation. She also distinguished misinformation, which is incorrect information, from disinformation, which is the purposeful spread of incorrect information, often to increase divisiveness, and said her presentation used the term “misinformation” to cover both. Dr. Rutschman said vaccine misinformation might present inaccurate or discredited science, including articles that were published in credible sources and later retracted; mischaracterize laws and policies to increase paranoia or bolster conspiracy theories; or make inaccurate claims about ownership of a vaccine (or even a virus) to support an argument about unnecessary or inappropriate use.

Although the majority of people in the United States and around the world support vaccination, a vocal minority does not, and that minority has taken advantage of social media to amplify its views disproportionately. Furthermore, evidence shows that bad actors generate anti-vaccine and pro-vaccine content for social media with the specific intent of generating divisiveness among the U.S. population, and such trends are likely to continue.

Among the approaches used by social media platforms to combat misinformation are suppression of content not deemed to stem from a credible source, downgrading of information so that it does not rise to the top of a search engine’s results, actively promoting accurate vaccine messages, and pairing with apps that provide vaccine reminders. Dr. Rutschman echoed reservations about the effectiveness of artificial intelligence approaches to identify misinformation online, which could fail to distinguish accurate from inaccurate information and raise issues about free speech rights.

There is a perspective that vaccines might be a public health good of such consequence that they are not subject to First Amendment constraints. Dr. Rutschman felt a better approach would be to bring together regulators, policy-makers, social media platforms, and content developers to address the problem. She did not believe stricter vaccine mandates would hold up in court or that such an approach would be in the government’s best interest. However, she suggested that government play a bigger role by working with social media to provide accurate, consistent public health messaging. Finally, Dr. Rutschman cautioned against using a broad brush to paint people as “anti-vaccine” when they might have valid concerns. Bringing all the voices to the table is important.

Discussion

Dr. Rutschman said she believes states, not the federal government, should determine which nonmedical exemptions to allow. She added that incentives and encouragement at the state level would be a better approach—such as apps that remind parents about the vaccine schedule or otherwise incentivize vaccination, tax breaks, or informal rewards (e.g., through online competitions).

Mr. Yaraghi said that the anti-vaccine movement sometimes uses false claims to support its arguments, while those in the pro-vaccine community rely on facts. Censoring those who promote misinformation—for example, banning them from Twitter—allows them to paint themselves as martyrs. He suggested continuing to counter misinformation with accurate information, online and in real life, pointing to credible information sources. Ms. Culberson added that overcoming

misperceptions requires an approach that provides correct information with a non-combative, neutral tone.

Dr. Rutschman said there are legal ways to tackle misinformation that she believes would be counterproductive, as the ideology would persist. She suggested the pro-vaccine community consider tapping a high-profile celebrity to promote its message, and Mr. Yaraghi agreed such a tactic is effective. He added that no amount of information or incentive would persuade someone who is already convinced. However, information or incentives might help those who are unsure or who have simply missed opportunities for vaccination. Dr. Hopkins added that establishing trust with patients is key, as is ensuring that the entire office staff presents a consistent message about vaccines. Dr. Rutschman pointed out that no major religious doctrine addresses vaccines; religious leaders might be worth pursuing as potential messengers.

Ms. Butler said that being open to dissenting views seems to conflict with the message of not responding to trolls and not creating martyrs. Dr. Rutschman responded that there are multiple layers to the types of misinformation being spread, and attempts to regulate free speech are unlikely to succeed. On social media, the only practical approach seems to be efforts to qualify or downgrade information, although it will never be sufficient. Ms. Culberson added that Twitter monitors the platform for spam and manipulation.

Mr. Yaraghi observed that concerns about the true impact of vaccine misinformation spread through social media may be overblown, as overall vaccination rates for children in America remain high. At the same time, trust in mainstream media sources is declining. If Twitter comes to be seen as mainstream, users might mistrust the credible sources of information that it promotes. It may be more effective to focus on disseminating accurate information through the offices of pediatricians and primary care providers, who are trusted by their patients.

Online Influence and Immunization Intentions

Vaccine Hesitancy and Networked Information—Rebekah Getman, M.A., M.Ed., Northeastern University

In-depth analysis of vaccine hesitancy online demonstrates that people crave good information, said Ms. Getman. Rather than rejecting science, vaccine-hesitant websites and social media users use the science to make their argument. In some cases, they cherry-pick information; in others, they exploit questions about efficacy in certain contexts. The media contributes to the murkiness by failing to accurately portray the slow, complicated scientific process. Vaccine-hesitant websites and users recognize the confusion and use it to their advantage, shaping the discourse to mobilize people to think more critically about vaccines.

Misinformation gets into the network by piggybacking off good science. It then travels across the network through the use of “social proof”—the fact that people trust those they know more than they trust experts they do not know. Within online communities, active users with lots of friends or followers act as hubs of information. Other users effectively link to other communities, and they are influencers, which are crucial for the spread of information.

Ms. Getman emphasized that although the vaccine-hesitant community feels like a loud, dominant group online, only about 20 percent of vaccine-related websites are vaccine-hesitant. The perception that the vaccine-hesitant community is rapidly gaining ground is driven by the messaging underlying both the vaccine-hesitant and pro-vaccine communities. Ms. Getman pointed to pro-vaccine discourse that is belittling and emphasizes selfishness or ignorance among vaccine-hesitant parents. However, the vaccine-hesitant websites use language that is community-

driven and talk about the reasons for their vaccine-hesitant or anti-vaccine approach, which has real impact for parents who are undecided. The point at which individuals enter the information network can determine what they think about each of these groups, where they feel comfortable asking questions, and whom they will trust for answers. Ms. Getman said these factors help people figure out where they belong within this movement, and the contrasting tone of messaging may be why the pro-vaccine community feels it is losing the battle.

The vaccine-hesitant community uses peer-reviewed science and collective identity to bring parents in, to make them feel comfortable, to answer their questions in a way that is challenging to combat. Ms. Getman proposed countering this movement through one-on-one conversations in doctors' offices and with public health providers—leveraging the relationships that people trust.

The Risks of Misinformation in the Age of Online Social Networks—Amelia Burke-Garcia, Ph.D., NORC at the University of Chicago

Dr. Burke-Garcia noted that within social media, “influencers,” or opinion leaders, can leapfrog over more traditional messengers and introduce new information because of the trust they have built in their networks and communities. Influencers can be celebrities, professionals, or even lay people. Lay influencers often have close relationships with a cohort of followers. Such strong ties can be beneficial for sharing reliable health information.

Dr. Burke-Garcia recruited 15 online influencers to talk about their beliefs, perceptions of vaccination, and communication via social media and blogs. Four themes emerged:

- **Traditional messengers are not as effective as they once were.** Influencers have access to information and feel they are more knowledgeable about vaccines and their own children's health than pediatricians are. They feel that pediatricians should support their decisions, and they network with other parents to find pediatricians whose practices align with their views.
- **The old communication and messaging are not working for this group.** The altruistic argument and the benefits of herd immunity do not resonate among those who feel their primary concern is their own child and family. They do not believe one size fits all for vaccines. They want “clean” vaccines. They express feelings of alienation, noting that their voices are not heard by the pro-vaccine community.
- **Technology supports and amplifies these beliefs.** In addition to social media, they use other technology, such as home genetic tests that purport to identify a predisposition for adverse reaction to vaccine and alternative search engines that do not downgrade anti-vaccine results as Google does.
- **The conversation about risk is multifaceted.** They weigh the perceived risks of vaccine against those of the disease, using the facts as they interpret them to protect their families and children.

Dr. Burke-Garcia called on the public health community to adapt communication strategies to incorporate influencers and overcome the barriers between so-called pro-vaccination and anti-vaccination movements. The public health community must devise new messages and use new messengers to bridge the gaps. It must recognize the importance of trusted online sources and work with them to provide reliable information and change behavior for the better.

Vaccine Information in a “Post-Fact” World—Rupali J. Limaye, Ph.D., M.P.H., M.A., Bloomberg School of Public Health, Johns Hopkins University

Dr. Limaye said more people are getting vaccine information online because they are losing trust in science and health care providers, are more swayed by emotional than personal framing, and are seeking information that speaks directly to their concerns. The concept of shared decision-making highlights that patients want a different type of interaction with their providers. User-generated information sharing is seen as more democratic than traditional top-down information dissemination, and at the same time, social media drives people into networks of like-minded people, creating an echo chamber. As a result, misinformation and disinformation are readily shared, with no fact checking or vetting. Shared stories tend to focus on negative experiences.

Dr. Limaye offered some concepts that providers can apply to communication with parents and patients who are vaccine-hesitant:

- Do not correct misperceptions.
- Tap into people's natural tendency to overestimate the importance of data that's available to them—such as personal experiences of family and friends.
- Focus on the susceptibility and severity of the disease.
- Use nudges and defaults—for example, framing vaccination as the default.
- Tailor information as needed (e.g., for pregnant women) in a way that is understandable and credible.

Dr. Limaye and colleagues used their research findings to develop an app for providers. For example, it helps providers give tailored information based on an individual's concerns (most often about vaccines, ingredients, side effects, or the schedule). It offers providers a framework for communication that begins with establishing trust and empathy by acknowledging that all parents want the best for their child. The provider is then guided to discuss the specific disease risk and make a call to action that highlights self-efficacy and incorporates a personal story or appeal.

***Social Media and the Health Professional—Austin Lee Chiang, M.D., M.P.H.,
Thomas Jefferson University Hospital***

Dr. Chiang recognized that his patients were getting a lot of information through traditional and social media. He began live Tweeting from medical conferences he attended, which led to him helping professional societies craft their social media strategies. As the Chief Medical Social Media Officer for Jefferson University's health enterprise, Dr. Chiang seeks to get more clinicians online, where they can counter misinformation. However, Dr. Chiang notes, as busy health professionals, clinicians need incentives to participate on social media. They also need guidance on using social media effectively to promote trust. Different social media platforms require different approaches—some support more academic conversations, while others can reach audiences not otherwise interested in health information. All social platforms have tools for engaging with audiences through, for example, live streaming, question-and-answer sessions, and polling.

Clinicians are usually not trained in marketing, public relations, broad communication, or storytelling. Learning to use social media effectively can be daunting. Social media has to be social—one cannot simply post something and expect it to go viral. Role models can help. Messages can be amplified through hashtag campaigns. Using platform analytics can help identify the audience and how best to engage. Using social media actively can help boost an institution's reputation and humanize the medical profession. A number of challenges and concerns have yet to be addressed, such as maintaining patient privacy, managing sponsorships

and endorsements, maintaining professionalism, and ensuring personal health and safety. Active social media users must be prepared to face backlash.

Dr. Chiang initiated the Verify Healthcare campaign to raise awareness that some of those providing medical information are misrepresenting themselves as physicians. He is also a founding member of the nonprofit Association for Healthcare Social Media. He hoped the whole medical community would use all available resources to talk about health.

Discussion

Dr. Burke-Garcia acknowledged the importance of understanding the demographics of social media users and taking a multigenerational approach to communication. Influencers know who their audiences are, and it is possible to gather data to learn about the demographics of a specific influencer. Dr. Burke-Garcia added that websites and influencers addressing specific racial/ethnic and cultural groups could be leveraged to reach more diverse audiences.

Dr. Schechter wondered whether herd immunity could be reframed in terms of personal risk, similar to emphasizing the need to protect oneself from environmental threats such as secondhand smoke and air pollution. Dr. Burke-Garcia said the influencers she studied felt strongly that their children's immune systems were adequate to protect against the risks of vaccine-preventable diseases. However, she said it would be interesting to pursue research to distinguish why they perceive vaccine-preventable diseases as different from, for example, secondhand smoke.

Experiences in the Field: Hawaii's New Vaccine Requirements for School Entry— Sarah Y. Park, M.D., FAAP, Hawaii Department of Health

Dr. Park explained that Hawaii statute requires that children be immunized to attend school but it also directs the state health department to establish the regulations and details. Those rules were last amended in 2001. The greatest barrier has been the need to go through full legal review by the attorney general for every change to the regulations, given how frequently the ACIP recommendations are updated. The state had to pass a new law to allow Hawaii to adopt the ACIP guidelines automatically, which it did in 2015.

The new school requirements, which go into effect in fall of 2020, include pneumococcal conjugate and hepatitis A vaccine for children in preschool or childcare facilities and hepatitis A vaccine for kindergarten through 6th grade students who are new to Hawaii schools. Notably, those in 7th grade must receive HPV vaccine; meningococcal conjugate vaccine; and tetanus, diphtheria, and pertussis vaccine. Students new to the Hawaii school system in grades 7–12 must have all of the vaccines required for 7th grade plus hepatitis A vaccine.

The health department sent providers a summary of the requirements and new rules along with ACIP guidelines and new medical exemption forms. In the past, parents needed only a letter from a licensed health care provider to gain exemption from vaccination requirements. The new form aligns with ACIP recommendations for allowable medical exemptions. The provider must describe the contraindication or precaution necessitating exemption and specify a period of time for which the exemption applies. A copy must be filed with the state health department.

Dr. Park noted that Hawaii allows parents to claim a religious exemption from vaccination, although they are not required to describe a specific religious belief. Some residents may claim the religious exemption as a stand-in for a philosophical exemption. Such exemptions have been rising steadily across Hawaii, which is concerning but still remains a small percentage overall. The state is mapping the exemption data by school district to determine where to target awareness

campaigns. Opponents of the school requirements are seeking legislation to establish a conscientious objector exemption. As that proposed legislation is revised over time, the intent changes, and it is now focused on how Hawaii would handle a mass vaccination campaign for an emerging infectious disease like CoV.

Discussion

Dr. Park reported that access to vaccines for children and adolescents is strong, thanks to the Vaccines for Children program and support from private insurance providers. Hawaii is the only state that still has a statewide school-based influenza vaccination program, even though influenza vaccination is not required. The program targets public schools on Oahu, the most urban island, and neighboring islands, particularly those with high rates of low-income families. Many health care providers in Hawaii already offer vaccinations in line with the ACIP recommendations, and Dr. Park said she has not heard any concerns about the need for catch-up campaigns.

Successful Sharing of Stories

Combatting Vaccine Hesitancy and Disinformation: Lessons from the Case of the HPV Vaccine in Ireland—David Robert Grimes, Ph.D.

Dr. Grimes summarized the history of anti-vaccination campaigns, which have advanced with the help of social media. People are susceptible to misinformation because of the power of stories and personal narratives to shape beliefs and the illusory truth effect—the tendency to believe information that is repeated. Moreover, content that provokes fear often grabs attention, and bad actors purposely sow disinformation. All of these factors combine to increase vaccine hesitancy and reduce vaccination rates, leading to resurgences in vaccine-preventable diseases.

The HPV vaccine has been widely available for about a decade and offers protection against the HPV strains that cause cervical and other cancers. Australia was the first country to invest in full HPV vaccination, and it is on track to eliminate cervical cancer by 2028. Yet false claims and conspiracy theories about the dangers of the vaccine persist. In Japan, in 2013, the rate of HPV vaccine uptake among young women was about 70 percent. Following a disinformation campaign that year, the government stopped recommending HPV vaccination. Uptake fell below 1 percent and has not yet recovered. The same dramatic decline occurred in Denmark following a so-called documentary that made fictitious claims about the HPV vaccine.

A similar crisis began in Ireland in 2015, with HPV vaccine rates dropping from 87 percent to 50 percent. But a group of medical professionals, scientists, parents, and public health officials allied to disseminate reliable information about the effects of HPV vaccine on preventing cancer. By 2017, the country began to see vaccination rates rise. The most effective component of the campaign was the compelling personal testimony of Laura Brennan, who was diagnosed with cervical cancer at age 24. Through a video and personal advocacy, Ms. Brennan gave a face to the real consequences of failing to vaccinate against HPV. She died at age 26, shortly after her video aired. Dr. Grimes concluded that to combat misinformation and fear, the public must be reminded of why vaccination matters through real and personal stories.

The Power of Patient Storytelling—Tamika Felder, Cervivor

Ms. Felder said that while she was working as a freelance journalist, she did not have health insurance and so did not get screened for cervical cancer. In 2001, she got a job with health benefits, and she was diagnosed with cervical cancer at age 25, following a routine screening. Although she survived, she lost her fertility, which remains a source of pain even decades later. And while she had not intended to become an advocate, she learned that cancer continues to affect her life every day, and she would never be the same person she was before the diagnosis.

Sharing her story was essential to healing, said Ms. Felder. She aimed to make her survivorship “count” by starting up Cervivor in 2003, an organization that helps people with cervical cancer share their stories. At the beginning, people were reluctant to talk about their cancer, but over time, more people came forward. The organization started Cervivor School, which is part educational retreat and part advocacy training, to inform and empower survivors and their allies. The Cervivor website now features personal stories uploaded by more than 100 women.

Cervical cancer is seen by some as easy to treat, and that thinking is used as rationale to delay HPV vaccination until adulthood. However, preventing cancer is far preferable to treating it, and even successful treatment can have long-term consequences, such as loss of fertility and radiation damage. Sharing personal stories is a powerful mechanism for raising awareness, but it can be difficult for the survivors, who still face shame and attacks from the anti-vaccine community.

Ms. Felder shared a video made by a young woman, Lisa, who had terminal stage cervical cancer when she attended Cervivor School. Lisa hoped that by describing her pain she could help others avoid suffering the same way. Ms. Felder concluded that she will continue to share her own story and others’ in the effort to end HPV-related cancers.

Addressing Vaccine Hesitancy with Storytelling—Serese Marotta, Families Fighting Flu

Ms. Marotta observed that a common theme across presenters has been that the patient voice is missing from the conversation. Families Fighting Flu is a nonprofit organization that gathers families’ stories and weaves them into its educational and advocacy initiatives. Ms. Marotta described, in detailed, emotionally wrenching terms, how her healthy, 5-year-old son, Joseph, was hospitalized with influenza in 2009, despite having been vaccinated. He initially improved with treatment, but then succumbed after 10 days. At the time, said Ms. Marotta, she did not know that healthy children or adults died from influenza or other vaccine-preventable diseases (although she had heard about the H1N1 influenza pandemic that circulated in 2009). Soon after Joseph’s death, Ms. Marotta committed to sharing his story so other families could be spared the same tragedy.

Ms. Marotta said the staggering figures of the number of deaths from influenza every year remind her that she gets vaccinated to protect herself, her family, and her community. She shares her story at every opportunity, and she has seen how it changes people’s minds about vaccination and motivated others to get vaccinated. She echoed that personal stories are powerful.

Families Fighting Flu uses social media through multiple channels to reach people on different platforms. Earned media can reach millions, and Families Fighting Flu connects media with families willing to share their experiences. The organization emphasizes that consumers and patients must seek out reputable sources of information. Ms. Marotta shared some other general advice, such as keeping communication consistent, timely, creative, and respectful, with the goal of educating people to make their own informed decisions.

Narrative communication—using storytelling to promote behavior change—relies on a number of theories about communication and relationships. For example, a person’s willingness to change behavior is based on perceived susceptibility, severity, benefits, and barriers. One psychologist determined that stories are 22 times more memorable than statistics. Ms. Marotta described some communication pitfalls to avoid, such as judgment, defensiveness, or an overly authoritative posture; audience fatigue; too much (or too little) information; technical language; fear mongering; and inconsistency with other reputable sources. She added that Families Fighting Flu offers narratives that reflect the experiences of families from diverse backgrounds. Despite all the

great science around vaccines, there is still a need to communicate directly with people so they get vaccinated, and personal stories can have a strong impact on behavior.

Vaccines Save Lives: Challenging Vaccine Hesitancy—Zahra Barnes, SELF Magazine

Ms. Barnes emphasized that SELF’s storytelling is guided by its core values of empathy, accuracy, inclusivity, and bodily autonomy. The role of vaccines in health is well established, but some remain unconvinced, primarily because of pervasive and compelling misinformation. As the magazine developed its Vaccines Save Lives campaign, Ms. Barnes said, editors had to keep in mind the challenge of combating misinformation without accidentally contributing to it. The campaign combines storytelling, reporting, and creative imagery to illustrate the importance of vaccines for individuals and for their communities.

SELF’s reporting aims to provide readers with trustworthy information they can act on and share. It tackled topics such as herd immunity, adult vaccinations, and parents’ questions about vaccinating their children. Through compelling personal essays, SELF brought forward the story of a woman whose child was immunocompromised and unable to be vaccinated. In another essay, a woman explained that she used to be anti-vaccine and why she changed her mind. Throughout the campaign, SELF sought to emphasize that everyone cares about the safety of their loved ones, and there are many reasons why individual philosophies on vaccination vary.

SELF partnered with the American Academy of Pediatrics and the primary care service One Medical to create a database of positive vaccine-related images, filling a void identified by the medical community. The images show health care providers and patients in real-life scenarios.

Recognizing that its campaign would open the magazine up to backlash, SELF worked closely with its social media partners to ensure brand fidelity and staff safety. It bolstered its website against cybersecurity attacks. In one instance, it closed the comments section of an Instagram post to ensure that it could not be used to disseminate misinformation. SELF spread the word about the campaign by reaching out to health care providers, their professional organizations, and health websites. The images it created are available to anyone and free to use. Ms. Barnes reported that news outlets and blogs picked up the images immediately, and she received a lot of positive feedback from medical professionals and people in the media about them. The campaign also garnered attention from national news outlets, and many people reached out to SELF’s staff to express gratitude for using its platform to spread the message.

Vaccine Counseling Coding Changes for 2021—Zach Hochstetler, American Medical Association (AMA)

Mr. Hochstetler explained the process behind changes to AMA’s reporting codes for evaluation and management office visits, effective January 1, 2021. Such visits represent about one fourth of Medicare spending. Providers will have the option of selecting codes according to the time required or the medical decision-making involved. The new 15-minute prolonged services code enables the provider to bill for a short period of counseling, which may be useful for counseling about vaccination. The new prolonged services code will not affect the current preventive counseling codes. As it rolls out the new codes, AMA will develop case studies to help users understand how to apply them. Mr. Hochstetler said AMA is developing case studies specific to vaccine counseling using the new codes, in partnership with the National Adult Immunization and Influenza Summit.

Public Comment

Theresa Wrangham of the National Vaccine Information Center (NVIC) said her organization embraced informed consent for vaccination and worked with Congress to draft and pass the National Childhood Vaccine Injury Act of 1986. Since that time, vaccine information requirements under federal law have been watered down. The physician committee reports from the National Academies of Science that inform the VICP have continued to grade the science as inadequate, which prevents them from making causality statements, with the result being that over 95 percent of injury compensation is for off-Table claims. This creates a heavy burden for the vaccine-injured to be compensated. In addition, the VICP continues to suffer from the public's lack of awareness.

Referring to parents as anti-vaccine is counterproductive. Many parents only opt out of one or a few vaccines and are not in favor of abolishing vaccines but rather ask that providers respect their right of informed consent, including the right to refuse vaccination. By comparison, parents' concerns about car seats that failed side impact safety tests are not referred to as "anti-car-seat," Ms. Wrangham noted. Demeaning parents who have vaccine concerns, many of which are legitimate, will not inspire trust or change minds. Implementing higher insurance premiums or taxes for not vaccinating could be viewed as sanctions and punitive measures that discriminate against the minority that choose not to use one or all vaccines.

Trust is in limited supply for doctors. Perhaps that is in part due to the many reports NVIC receives from families across the United States who are being refused health care because they ask questions about vaccination or they exercise their right to refuse vaccination. NVAC could assist in building trust by not encouraging state mandates that do not incorporate flexible exemptions for upholding informed consent rights. NVAC could also recommend independent research that would close the vaccine safety research deficits noted by the Institute of Medicine and be more inclusive of the hesitant and vaccine-injured community in their recommendation processes.

Public health would also be able to build trust by talking about vaccine failures when they occur rather than only vaccine successes. It should stop using rulemaking to force vaccination or require people to be tracked on registries. Registries should be opt-in, as there are privacy concerns held by many parents. Clear communications about disease and context of the United States versus Africa, for example, when talking about measles deaths would also be helpful, Ms. Wrangham concluded.

Wrap Up and Adjournment—Robert H. Hopkins Jr., M.D., MACP, FAAP, NVAC Chair

Dr. Hopkins thanked the participants and the NVPO staff and adjourned the meeting at 3:22 p.m.

APPENDIX: Abbreviations

ACCV	Advisory Commission on Childhood Vaccines
ACIP	Advisory Committee on Immunization Practices
AHIP	America’s Health Insurance Plans
AHRQ	Agency for Healthcare Research and Quality
AIM	Association of Immunization Managers
AIRA	American Immunization Registry Association
AMA	American Medical Association
APhA	American Pharmacists Association
ASPR	Office of the Assistant Secretary for Preparedness and Response
ASTHO	Association of State and Territorial Health Officials
BARDA	Biomedical Advanced Research and Development Authority
BCG	Bacille Calmette-Guérin (vaccine)
CDC	Centers for Disease Control and Prevention
CEIRS	Centers for Excellence for Influenza Research and Surveillance
CMS	Centers for Medicare and Medicaid Services
CoV	coronavirus
COVID-19	coronavirus disease (2019)
CRISPR-Cas9	clustered regularly interspaced short palindromic repeats (CRISPR)-CRISPR-associated protein 9
DICP	Division of Injury Compensation Programs
DoD	Department of Defense
DRC	Democratic Republic of Congo
FDA	Food and Drug Administration
HEDIS	Healthcare Effectiveness Data and Information Set
HHS	Department of Health and Human Services
HPV	human papillomavirus
HRSA	Health Resources and Services Administration
ID	intra-dermal
IM	intra-muscularly
IV	intra-venous
mAbs	mono-clonal antibodies
MCMs	medical countermeasures
MERS	Middle East respiratory syndrome
NACCHO	National Association of County and City Health Officials
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NVAC	National Vaccine Advisory Committee
NVIC	National Vaccine Information Center
NVPO	National Vaccine Program Office
OIDP	Office of Infectious Disease and HIV/AIDS Policy
PAHO	Pan American Health Organization
SARS	severe acute respiratory syndrome
TB	tuberculosis
USDA	U.S. Department of Agriculture
USPSTF	U.S. Preventive Services Task Force
VA	Department of Veterans Affairs
VICP	Vaccine Injury Compensation Program
VLPs	virus-like particles
VND	virulent Newcastle disease

VSN Vaccine Safety Net
WHO World Health Organization