

Teleconference: May 3, 2018 10:30 a.m. to 12:30 p.m. EST

Committee Members in Attendance

Kimberly M. Thompson, Sc.D., Chair Melody Anne Butler, B.Sc.N., RN Timothy Cooke, Ph.D. John Dunn, M.D., M.P.H. Leonard Friedland, M.D. Ann Ginsberg, M.D., Ph.D. Robert H. Hopkins Jr., M.D., MACP, FAAP Mary Anne Jackson, M.D., FAAP, FPIDS, FIDSA Melissa Martinez, M.D., FAAP Cody Meissner, M.D., FAAP Larry Pickering, M.D., FAAP, FIDSA Nathaniel Smith, M.D., M.P.H. Geeta Swamy, M.D., FACOG

NVAC Ex Officio Members

John Borrazzo, Ph.D., U.S. Agency for International Development

Ruben Donis, D.V.M., Ph.D. (for Rick Bright, Ph.D.), Biomedical Advanced Research and Development Authority

Laurie Hoffman-Hogg (for Troy Knighton, M.Ed., Ed.S., LPC), Department of Veterans Affairs

Donna Malloy, D.V.M., M.P.H., U.S. Department of Agriculture

Valerie Marshall, M.P.H., Food and Drug Administration

Jeffrey McCollum, D.V.M., M.P.H., Indian Health Service

Barbara Mulach, Ph.D., National Institutes of Health

Narayan Nair, M.D., CAPT, Division of Injury Compensation Programs, Health Resources and Services Administration (HRSA)

Kristin Pope (for Nancy Messonnier, M.D., CAPT), Centers for Disease Control and Prevention Judith Steinberg, M.D., M.P.H., Bureau of Primary Health Care, HRSA

NVAC Liaison Representatives

Gina Charos, Public Health Agency of Canada Rebecca Coyle, M.S.Ed., American Immunization Registry Association Kristen R. Ehresmann, RN, M.P.H., Association of Immunization Managers Nathalie El Omeiri, Pan American Health Organization Tiffany Tate, M.H.S., National Association of County and City Health Officials

Acting Director, National Vaccine Program Office (NVPO)

Melinda Wharton, M.D., M.P.H.

Acting Designated Federal Officer

Angela Shen, Sc.D., M.P.H., CAPT, Senior Advisor, NVPO, Department of Health and Human Services

Meeting Summary

Welcome—Kimberly M. Thompson, Sc.D., Chair, National Vaccine Advisory Committee (NVAC)

Dr. Thompson called the meeting to order at 10:32 a.m. She welcomed the participants to the virtual public meeting, which was intended to review the draft report of NVAC's Human Papillomavirus (HPV) Vaccine Implementation Working Group (WG). The minutes and presentations of past meetings are available online at http://www.hhs.gov/nvpo/nvac/index.html. The minutes from the February 2018 NVAC meeting were approved unanimously with one change: in the report from the Pan American Health Organization, the term "dysentery outbreaks" will be replaced with the correct term, "diphtheria outbreaks."

Dr. Thompson said time is allotted at the end of this meeting for public comments, which will be included in the public record. Written comments can be sent to NVAC for consideration by email (nvac@hhs.gov). NVAC hopes to post the draft report for public comment in late May via the *Federal Register*. The final report will be reviewed by the full NVAC during a public, virtual meeting on June 25, 2018.

Roll Call and Welcome— Angela Shen, Sc.D., M.P.H., CAPT, Senior Advisor, National Vaccine Program Office (NVPO), Department of Health and Human Services (HHS)

Dr. Shen outlined key parts of the Federal Advisory Committee Act, its conflict-of-interest rules, and standards of ethical conduct for NVAC members. Dr. Shen thanked the NVPO staff for their support in organizing the meeting and called the roll.

Opening Remarks—Melinda Wharton, M.D., M.P.H., Acting Director, NVPO

Dr. Wharton welcomed the participants, emphasizing that HHS relies on groups like NVAC to provide valuable perspectives from within and outside government. Over the past 10 years, there has been substantial progress in HPV vaccination in the United States. Advances in research have led to important policy and program changes. For example, the Advisory Committee for Immunization Practices (ACIP) recommended a two-dose regimen of HPV vaccine for boys and girls ages 11–12 years. In addition, HPV vaccination for males and females was incorporated into Healthcare Effectiveness Data and Information Set (HEDIS®) measures. However, HPV vaccine coverage rates are lower than rates for other adolescent vaccines. Dr. Wharton appreciated that the HHS Acting Secretary for Health (ASH) recognized the need for specific recommendations on implementation to boost vaccination rates. She thanked the staff and the WG for their efforts and looked forward to the discussion of the recommendations for implementation.

HPV Implementation WG Summary Presentation and Discussion—Nathaniel Smith, M.D., M.P.H., and Geeta Swamy, M.D., FACOG, Co-Chairs

Dr. Smith reiterated the ASH's charge to NVAC to develop implementation recommendations to improve HPV vaccine uptake, specifically around four questions:

1. Many national organizations are currently supporting HPV vaccination efforts. Are there additional national organizations that might contribute to increasing HPV vaccination coverage?

- 2. At the State level, many States have formed coalitions to support HPV vaccination efforts. Is there general guidance for States that do not yet have coalitions?
- 3. Integrated health care delivery networks can successfully integrate comprehensive quality improvement approaches to increase vaccination coverage rates. How can State immunization programs and coalitions engage with health systems to work together on improving HPV vaccination coverage?
- 4. Please specify recommendations on how to meet the needs of providers in rural areas.

Dr. Smith summarized the WG's timeline and process, noting that the goal is to finalize a document for full NVAC approval at the June 2018 NVAC meeting. He then summarized the introduction to the draft document. Dr. Smith and Dr. Swamy responded to comments from NVAC members.

Introduction and Charge to NVAC: Comments and Questions

Cody Meissner, M.D., FAAP, asked whether NVAC should recommend requiring HPV vaccination for school entry, noting that such a recommendation would be controversial. Dr. Smith said such a requirement would be "a hard sell" in some States. The rationale for requiring tetanus, diphtheria, and acellular pertussis (Tdap) and meningococcal vaccination in schools is that they protect against infections likely to occur in school settings, while HPV vaccine primarily aims to prevent cancer.

Dr. Meissner suggested that the recommended age range for the two-dose vaccine regimen be identified as 9–14 years. Dr. Smith said the text should stick to the specific ACIP recommendation of 11–12 years because it is a direct reference to the ACIP recommendation. In later discussion, Mary Anne Jackson, M.D., FAAP, FPIDS, FIDSA, suggested the WG discuss starting vaccination earlier as a way to facilitate conversation with parents that does not center entirely on the age of sexual debut. It was agreed that the WG would remain consistent with the current ACIP HPV recommendation of a 2-dose schedule for people aged 11 to 12.

Robert H. Hopkins Jr., M.D., MACP, FAAP, suggested adding to the end of the sentence "Bundling the recommendation and administration of vaccines for this age group is an effective strategy to implement the ACIP recommendations," the phrase "and increase uptake," and the group agreed.

There was brief discussion about the parenthetical reference to "presumptive" provider recommendations, as opposed to "participatory" recommendations. Dr. Smith summarized the difference as analogous to an opt-out (presumptive) or opt-in (participatory) approach to recommending HPV vaccine. The group decided to revise the introduction and ensure clarity of the text with appropriate references.

Rather than "Additionally, many adolescents are not visiting their primary care providers for a preventive visit," suggested beginning the sentence with "One potential cause for the low uptake rates is that...." Dr. Meissner raised the question of provider reluctance as a potential obstacle. The group agreed to Dr. Hopkins' suggestion to add to the paragraph that provider recommendations for HPV vaccine may not be as consistent as for other adolescent vaccines, along with a supporting reference¹.

Dr. Thompson asked whether the WG reviewed the 2015 NVAC report on HPV vaccine to assess what has been done since and what remains to be done. Dr. Smith said the WG did so but can

¹ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5145747/

review the 2015 report again. Specifically, Dr. Thompson said, the WG should assess whether the research recommended by NVAC in 2015 was conducted.

Section 3, Question 1

In written comments, Jean-Venable "Kelly" Goode, Pharm.D., BCPS, FAPhA, FCCP, indicated that the American Pharmacists Association would be a valuable partner among the national organizations because of the role that pharmacists play in initiating and completing the HPV vaccine series in various States and jurisdictions. Dr. Smith said the WG discussed the role of pharmacists but did not call them out specifically in the document. Dr. Smith asked Dr. Thompson if this could be discussed later in the open discussion. Dr. Thompson confirmed that it could be. Dr. Meissner asked that the American Academy of Pediatrics be named among the national organizations. Dr. Smith explained that the intention was not to name all organizations, but to mention the ones who created the roundtable.

Dr. Thompson suggested breaking Recommendation 1 into two recommendations of one sentence each, and the group agreed.

Dr. Jackson suggested the document discuss the importance of offering tailored communication strategies to different provider types. She proposed reaching out to the American Academy of Pediatrics and the American Academy of Family Physicians for insights.

Section 3, Question 2

Dr. Thompson suggested Recommendation 4 be cut down and that informational statements be moved into the text preceding the recommendation, and the group agreed.

Section 3, Question 3

In written comments, Jay C. Butler, M.D., CPE, FAAP, FACP, FIDSA, suggested the wording of Recommendation 5 be revised to recommend that the ASH take a more active role in engaging State health officials beyond "encouraging" collaboration. Dr. Smith suggested recommending the ASH work with State health officials to facilitate their engagement with the other stakeholders identified, and the group agreed.

Dr. Thompson said the 2015 NVAC HPV report made recommendations about immunization information systems (IIS), and she asked that the WG consider whether those recommendations should be referenced in this context or elsewhere in the report.

Dr. Hopkins suggested the ASH should work with the Office of the National Coordinator on Health Information Technology to encourage electronic medical record vendors to support evidence-based reminders and best practices on HPV vaccination. In 21st century medical practice, he said, clinicians should be using technology to facilitate care. Dr. Meissner also raised the issue of using IIS to identify vaccination opportunities. Dr. Smith said the WG would review the 2015 NVAC HPV report and draft a new, separate recommendation on the basis of these suggestions.

Dr. Thompson hoped the new draft recommendation would emphasize that working with the Office of the National Coordinator could encourage tracking and accountability. She also asked that NVAC liaison members with expertise in State IIS provide insight on how many jurisdictions are reporting HPV vaccination to their State IIS and to provide an update on progress related to the IIS-related recommendation in the 2015 NVAC HPV report. Rebecca Coyle, M.S.Ed., said all of the State IISs have the capacity to incorporate HPV vaccine reporting, but reporting varies

widely by jurisdiction. Dr. Thompson suggested that the 2015 recommendation(s) about IIS be updated on the basis of new information, if appropriate.

Action Item

Ms. Coyle will seek data on how many jurisdictions are reporting HPV vaccination to their State IIS.

John Dunn, M.D., M.P.H., said the document acknowledges the discrepancy between initiation rates and completion rates, which is more striking with this vaccine than others. He said Washington State has been looking at what works to improve completion rates. It may be appropriate to include a recommendation to that effect in this section regarding how State health departments can work with integrated delivery networks. Dr. Smith said the WG discussed this issue but recognized the limited resources of States. While it is necessary to improve both initiation and completion rates, Dr. Smith said, immunogenicity data suggests that if a choice must be made, it may be better to have more people who received one dose than fewer people who received two doses.

Section 3, Question 4

Where the background text for the recommendations gives examples of providers or settings that can facilitate access, Dr. Smith noted that Dr. Goode asked that pharmacists be included. Dr. Smith said the WG discussed the issue, but he was reluctant to raise a potentially controversial issue; he suggested the WG revisit the question. Dr. Shen added that the WG also discussed but did not reach a conclusion on whether to address the proportion of rural health clinics and Federally qualified health centers that provide HPV vaccine (in relation to access and uptake). Dr. Smith said there were not enough data to make a recommendation about such settings, but the topic could be raised in the context of background.

Also in the background, Dr. Meissner said provider reluctance to recommend HPV vaccine has been a major barrier to uptake; he suggested discussing the role of provider education. It was noted that low uptake may be related to access; it is not clear that provider education is a significant barrier unique to rural settings. Dr. Smith said the WG had discussed recommending the Project ECHO telehealth model for provider education.

Dr. Thompson suggested cutting Recommendation 6 down to the first sentence, then listing the specific topics for which more research is needed. The rest of the recommendation text can be incorporated into the background. Dr. Smith agreed, noting that the topic areas include rural health clinics and Federally qualified health centers, and the emerging role of pharmacists in vaccination.

Melody Anne Butler, B.Sc.N., RN, pointed out that the role of social media is not addressed in the discussion of technology. Dr. Smith said it is mentioned in the introduction, but he was not sure what NVAC could feasibly recommend to the ASH. Dr. Thompson said communication issues were raised in the 2015 NVAC HPV report. She suggested the WG rework this subsection of the report based on all of the group's comments.

Conclusion

Dr. Jackson pointed out that 40 percent of the adult population does not follow current cancer prevention recommendations. Early vaccination may be a way to counter that. Dr. Thompson suggested that the fact that the public does not fully embrace prevention is relevant and should be noted.

Other Issues

In response to a question about catch-up vaccinations, Dr. Smith said the WG focused on the four questions posed by the ASH. Dr. Thompson suggested the WG consider the issue and at least note it somewhere in the document. NVAC members were urged to send additional comments to NVPO staff by close of business on Friday, May 4.

Public Comment

Theresa Wrangham of the National Vaccine Information Center said she was cognizant of the charge to NVAC, but she felt it was important to acknowledge that HPV is a sexually transmitted disease that centers on lifestyle choices. There is no epidemic of HPV virus, she said, and for those who contract HPV, the Centers for Disease Control and Prevention has reported to Congress that over 90 percent of cases will resolve and those patients will have long-term immunity with no adverse outcomes. Ms. Wrangham emphasized the need to consider the fiscal feasibility of HPV vaccine recommendations, pointing out that the vaccine is very expensive. The National Vaccine Information Center advocates for informed consent and wants to ensure that all information is available to the public about HPV vaccine as an option for prevention. Everyone should be aware of it, Ms. Wrangham concluded.

Closing Remarks and Adjournment— Kimberly M. Thompson, Sc.D., Chair, NVAC Dr. Thompson thanked the co-chairs, the WG, the NVPO staff, and Dr. Wharton for their support of this effort. She adjourned the meeting at 12:05 p.m.