

National Vaccine Advisory Committee

2010 National Vaccine Plan

Mid-Course Review Work Group

Responses to Public Comments

Dr. Bonnie Maldonado

Dr. Nate Smith

7 February 2017

Agenda

- Review of the NVAC mid-course review process
- Discuss the public comments
- Solicit NVAC feedback and full approval

Work Group Members

NVAC Members

Bonnie Maldonado, Co-Chair

Nate Smith, Co-Chair

Tim Cooke

Sarah Despres

Ann Ginsberg

Phil Hosbach

Wayne Rawlins

NVAC Chair

Kimberly Thompson

NVPO Support Team

Bruce Gellin/ NVAC Designated Federal Officer
Anju Abraham, Jenny Gordon (former)/ NVPO Staff

Diane Epperson/ BAH/ Technical Advisor

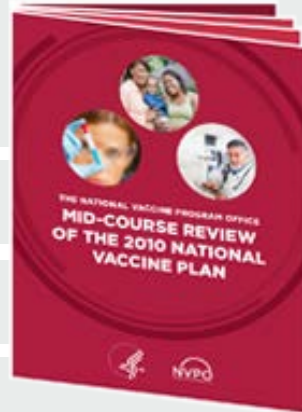
Kristin Baxter/BAH/ Technical Advisor

Timeline

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|----------------|--|
| September 2014 | <ul style="list-style-type: none">• NVAC Mid-Course Review work group formed |
| Winter 2014-5 | <ul style="list-style-type: none">• NVPO contacted representatives at each of the 16 partnering federal agencies and departments assigned responsibility under the National Vaccine Plan (NVP) to request a list of activities completed in support of the NVP• The 2013 and 2014 NVP Annual Reports were also reviewed for relevant activities and achievements from prior years and used to help generate the comprehensive list of achievements. |
| February 2015 | <ul style="list-style-type: none">• Working Group discussions put on hold pending formal solicitation of input from non-federal stakeholders |
| August 2015 | <ul style="list-style-type: none">• Engagement of consultant to develop NVPO mid-course review report |
| Fall 2015 | <ul style="list-style-type: none">• Request for information (using survey format) on significant achievements over the past five years (2010-2015), continuing gaps, and future priorities• Stakeholder interviews |
| February 2016 | <ul style="list-style-type: none">• Focus group sessions conducted to rank opportunity areas |

Timeline

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| March 2016 | <ul style="list-style-type: none">• Summary of NVPO Mid-Course analyses including outcomes of all focus group meetings, perform additional data collection from consumer representative groups |
| April 2016 | <ul style="list-style-type: none">• Frame possible end goals (e.g., success) and challenges to achieving success in identified Opportunity Areas• Propose indicators/metrics |
| May 2016 | <ul style="list-style-type: none">• Review of findings from federal partners• Identify key areas for NVAC discussion• Discussions with stakeholders |
| June 2016 | <ul style="list-style-type: none">• Solicit input from NVAC• Continue analyses based on NVAC input |
| September 2016 | <ul style="list-style-type: none">• Review draft report with NVAC• Revise draft for public comment |
| November 2016 | <ul style="list-style-type: none">• NVPO report released• Solicit public comment on NVAC draft report |
| January 2017 | <ul style="list-style-type: none">• Adjudicate and revise |
| February 2017 | <ul style="list-style-type: none">• Present final draft report for NVAC vote |



Objectives

- **Independent assessment of the NVPO Mid-course Review**
 - Review and verification of findings and prioritization of opportunity areas
 - Guidance for measurable, actionable, and time-bound considerations for development of the Implementation Plan
 - Characterizing end goals (i.e., defining what does success look like)
 - Proposing indicators (i.e., defining appropriate bench marks)
 - Noting possible challenges to success to steer future efforts
- **NVAC report and recommendations as a complement to NVPO analysis**
 - Underscore nuances in priorities among different stakeholder groups
 - Recommend activities for implementation to strengthen monitoring and evaluation of the National Vaccine Plan (e.g. development of new indicators)

Opportunity areas for the National Vaccine Plan Focus on top 5

Concurrence with NVPO analyses on ranking of opportunity areas

- 1) Strengthen health information and surveillance systems to track, analyze and visualize disease, immunization coverage, and safety data, both domestically and globally
- 2) Foster and facilitate efforts to strengthen confidence in vaccines and the immunization system to increase coverage rates across the lifespan
- 3) Eliminate financial and systems barriers for providers and consumers to facilitate access to routinely recommended vaccines
- 4) Strengthen the science base for the development and licensure of vaccines
- 5) Facilitate vaccine development
- 6) Increase coordination, collaboration and knowledge sharing among related parties and disciplines
- 7) Improve the transparency of the vaccine safety system and the entire vaccine enterprise to policymakers, the public and providers
- 8.a) Improve scientific knowledge about why and among whom vaccine adverse events occur
- 8.b) Support the strengthening of immunization systems globally through policies, practices and partnerships

Evaluation of opportunity areas for informing the development of the Implementation Plan

- What would successful implementation of the opportunity area look like in 2020?
- What existing indicators are available to track progress?
- What new indicators should be developed for the longer term?
- What are the possible challenges to making significant progress towards the indicators by 2020?
- Any other considerations to highlight for the Assistant Secretary for Health (ASH) when leading the development of the Implementation Plan?

Proposed NVAC Recommendations

- The ASH should charge the NVPO, in coordination with relevant departments and agencies, to adopt existing indicators (e.g., Healthy People 2020 indicators) to track progress on the National Vaccine Plan goals and to prepare an annual report to the ASH and the NVAC on progress. .
- The ASH should charge the NVPO, in coordination with departments and agencies, to develop and validate new indicators within each of the 5 opportunity areas to ensure improved tracking of goals. The new indicators should include one that will track and report on U.S. government annual financial investments in vaccine innovation that support the development of (i) vaccines for established pathogens that have no vaccines, (ii) vaccines for emerging pathogens, and (iii) improvements in existing vaccines. The new indicators should also consider investments in vaccine delivery technologies.

Proposed NVAC Recommendations

- The ASH should continue to strongly support U.S. contributions to global immunization efforts and the integration of global immunization efforts into the opportunity areas as appropriate.
- The NVPO should continue to implement the recommendations from previous NVAC reports, such as the 2015 NVAC report on *Assessing the State of Vaccine Confidence in the United States*. By doing so, the NVPO can highlight NVAC recommendations related to implementing the priorities outlined in the NVPO 2010 Mid-course Review. The NVPO should use the framework defined in this report to make further advancements under the existing 2010 National Vaccine Plan for both domestic and global immunization outcomes.

Proposed NVAC Recommendations

- The ASH should charge the NVPO to develop the 2020 National Vaccine Plan, which should incorporate the findings in this report, and consider the impact of health care disparities on implementation and achievement of the objectives of the 2020 Plan.
- The ASH should charge the NVPO, in coordination with other relevant departments and agencies, to begin developing strategies to (i) identify priorities for U.S. government investments in vaccine-related innovations and (ii) overcome barriers that inhibit innovation.

Summary of Public Comments Received As of December 27th, 2016

- Total of 3 public comments received representing organizations and industry

AAFP

PATH

Walgreens

- Majority of comments indicated public support of the recommendations
- The NVAC Mid-course Work Group reviewed all comments and made changes where appropriate

Commenter	Summary of comment(s)	Working Group Adjudication
PATH	<p>General comment in support of NVAC's emphasis that the US plays a critical role in global immunization as well as in vaccine innovation.</p> <p>General comment in support of the call to strengthen the science base and acknowledgement of innovation for vaccine delivery technologies emphasized throughout the evaluation.</p>	Thank you for this general support - No action needed
Walgreens	General comment in support of proactive research and effort	Thank you for this general support - No action needed
AAFP	Request inclusion in future focus groups like those that resulted in the mid-course review.	We thank the AAFP for taking the time to provide comments, and we regret that the NVPO did not include the AAFP in the focus group discussions. These focus groups unfortunately did not include all potentially interested parties but sought to capture the breadth of perspectives.

Commenter	Summary of comment(s)	Working Group Adjudication
AAFP	General comment in support of NVAC's recommendation to address the opportunity areas outside of the five selected, going forward	Thank you for noting this. While focusing on the five Opportunity Areas emphasized in the NVPO Mid-Course Review Report, the NVAC report specifically encourages work on all identified Opportunity Areas, as noted in the sentence, "Therefore, the NVAC emphasizes that implementation activities going forward should consider all opportunity areas and regularly assess the impact of these efforts on different stakeholder groups and particularly on populations at risk that may help to address overarching health care and access disparities that may prohibit achieving the objectives of the 2010 National Vaccine Plan."

Commenter	Summary of comment(s)	Working Group Adjudication
AAFP	Comment requesting use of adolescent and adult vaccine metrics and terminology	<p>Thank you. The report includes a significant amount of discussion about adolescent and adult vaccines in the text. In Box 6, the report used existing pediatric indicators while noting the limitations of these indicators. The report emphasizes the need for new indicators, and to be explicit about covering the entire lifespan, we have added “for all ages and for different vaccines” in Box 7.</p>

OA	Commenter	Summary of comment(s)	Working Group Adjudication
1	Walgreens	Agree that the standardization of data needs to continue to ensure seamless sharing to facilitate bi-directional communication.	We thank the commenter for underscoring the importance of standardization that supports bidirectional communication, which the report highlights in Box 2 as a challenge to achieving success in Opportunity Area 1.
1	AAFP	General support of interoperability and interstate data exchange of vaccination administration data.	Thank you for the general support and for underscoring the importance of interoperability - No action needed

OA	Commenter	Summary of comment(s)	Working Group Adjudication
2	AAFP	Comment encouraging NVAC to consult with the AAFP's policy on immunization exemptions	Thank you. We expect that subsequent efforts to implement the actions proposed by the report will consider all relevant policies and practices related to immunization exemptions, including the AAFP policy.
2	Walgreens	Comment seeking unification in pharmacist authority and regulations in administering vaccines across the states to support vaccine confidence. Comment calls for strengthening provider education.	Thank you. This comment underscores the discussion in the report about the vaccine neighborhood. We have added the following statement at the end of the discussion of the immunization neighborhood: "State-to-state variability in immunization policies and practices further increases complexity in the current system." The report includes an indicator to track the "Percentage of state and territories that allow pharmacists to administer all routinely recommended vaccines for adults > 19 without a patient-specific prescription." Finally, with respect to improving education, we added text to "Additionally, as vaccine science evolves, all stakeholders will need to incorporate new knowledge into education curricula to remain on the forefront of the immunization landscape."

OA	Commenter	Summary of comment(s)	Working Group Adjudication
2	AAFP	<p>Comment requests that the proposed metric for future development to create a "validated index... to measure vaccine confidence" acknowledge that vaccine confidence varies by vaccine. Comment strongly urges HHS to ensure the use of these measures does not add any undue burden on physicians as they administer vaccines.</p>	<p>Thank you for this comment. We added "and for different vaccines and vaccine formulations" to the associated text. In Box 7, related to the validated index, we added "for all ages and for different vaccines" to clarify what the indicator would measure. Finally, this report focused on using available indicators, which do not impose any additional burden. We expect that any new indicator development would consider burdens on the system.</p>

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2	Walgreens	<p>Comment requests that the proposed metric for future development to create a "validated index... to measure vaccine confidence" acknowledge that vaccine confidence varies by vaccine. Comment strongly urges HHS to ensure the use of these measures does not add any undue burden on physicians as they administer vaccines.</p>	<p>Thank you for this comment. We added "and for different vaccines and vaccine formulations" to the text. In Box 7, related to the validated index, we added "for all ages and for different vaccines" to clarify what the indicator would measure. Finally, this report focused on using available indicators, which do not impose any additional burden. We expect that any new indicator development would consider burdens on the system.</p>

OA	Commenter	Summary of comment(s)	Working Group Adjudication
3	Walgreens	<p>Comment highlights the potential of vaccine success when eliminating financial barriers and recommends adding to the proposed indicators for tracking success to include lessening cost sharing within Medicaid, Medicare, and the commercial market.</p> <p>Comment advocates for changes to broaden pharmacist authority.</p>	<p>Thank you for the comment and example. The report discusses the challenges associated with cost sharing and notes the changing landscape. “The NVAC acknowledges that changes to Medicare and Medicaid policies regarding costs to patients and providers may not resolve existing barriers in the remaining five years of the National Vaccine Plan” As discussed above, the report includes discussion about the immunization neighborhood and a indicator to track the “Percentage of state and territories that allow pharmacists to administer all routinely recommended vaccines for adults > 19 without a patient-specific prescription” that recognizes the role of pharmacists. Finally, we added text to emphasize prior calls from NVAC to develop a National Adult Immunization Program and to provide more funding for adult immunization.</p>

OA	Commenter	Summary of comment(s)	Working Group Adjudication
3	AAFP	<p>Comment addresses a proposed metric on Box 9, page 19, that suggests tracking the "percentage of state Medicaid programs that provide coverage of all ACIP/CDC-recommended vaccinations for adults...." and requests this metric expand to mention coverage through Medicare, and the significant co-payments required for some adult vaccinations under Medicare Part D.</p>	<p>Thank you, the report notes the "Mismatch in Medicare B/D payment for vaccines" explicitly as a challenge to achieving success for Opportunity Area 3.</p>

OA	Commenter	Summary of comment(s)	Working Group Adjudication
5	PATH	Comment supports the perspective that different incentives may impact large and small companies separately. And suggests one approach to sharing risk and costs is support for non-profit product development partnerships.	Thank you for this general support - No action needed
5	PATH	Comment supports recognition of the importance of incenting incremental improvements to products.	Thank you for this general support - No action needed
5	PATH	Comment encourages USG agencies to actively participate in the Coalition for Epidemic Preparedness Innovations (CEPI)	Thank you for providing information about this new coalition. To avoid naming specific entities, we removed mention of examples in Box 11.

OA	Commenter	Summary of comment(s)	Working Group Adjudication
5	PATH	Comment supports NVAC's recognition of sustaining vaccine supply and suggests this be shared in the context of the global dialogue about Access to Medicines. The comments calls for the relationship between price and supply to be examined on the global stage.	Thank you for this suggestion. The broader discussion of access to medicines falls outside of the NVAC purview, but as this comment highlights, the report discussed NVAC concerns about vaccine supply and incentives for innovation.
5	PATH	Comment supports the prioritization of regulatory harmonization in the NVAC recommendations. The comment suggests FDA's activities in providing technical guidance and support to national and regional regulatory bodies be highlighted in the implementation plan.	Thank you. As implementation occurs, the FDA will play a key role with respect to harmonization.

OA	Commenter	Summary of comment(s)	Working Group Adjudication
5	PATH	<p>Comment agrees with the proposed methods for developing a prioritized list for global vaccine development targets and recommends that there be periodic review of new evidence and data to ensure the list reflects the most recent science and remains up to date.</p> <p>Comment recommends comparing investments made to the priority targets, for the recommendation that NVPO develop a USG immunization-related funding tracking system.</p>	<p>Thank you. As noted in Box 13, the report proposes a new indicator that will offer “A mechanism to track the vaccine development pipeline that includes a specific number of target, priority pathogens.” As recognized in this comment, the creation of this indicator, once validated, should support efforts to evaluate the investments made for the priority targets.</p>
5	AAFP	<p>Comment supports reports emphasis on tracking the efforts to develop vaccines for pathogens for which there are no current vaccines.</p>	<p>Thank you for this general support - No action needed</p>

Discussion