National Vaccine Advisory Committee

2010 National Vaccine Plan
Mid-Course Review Working Group

Update and Preliminary Findings

Dr. Bonnie Maldonado and Dr. Nate Smith
8 June 2016

Goals of Today's Discussion

- Provide an overview of the WG process

- Share preliminary analysis and findings following completion of NVPO's mid-course review

- Solicit NVAC feedback and guidance on key questions encountered by the WG in their deliberations

NVAC Mid-course Review Working Group Objectives

- **To provide an independent assessment of NVPO's Mid-Course Review findings**
  - Independent review and verification of findings and prioritization of opportunity areas
  - Guidance for measurable, actionable, and time-bound considerations for development of (2016-2020) Implementation Plan
    - Characterizing end goals (i.e., defining what does success look like)
    - Proposing metrics (i.e., defining appropriate bench marks)
    - Noting possible challenges to success to steer future efforts

  - **NVAC report and recommendations will complement NVPO's 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 metrics)

Working Group (WG) Members

NVAC WG Members

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Nate Smith

Tim Cooke

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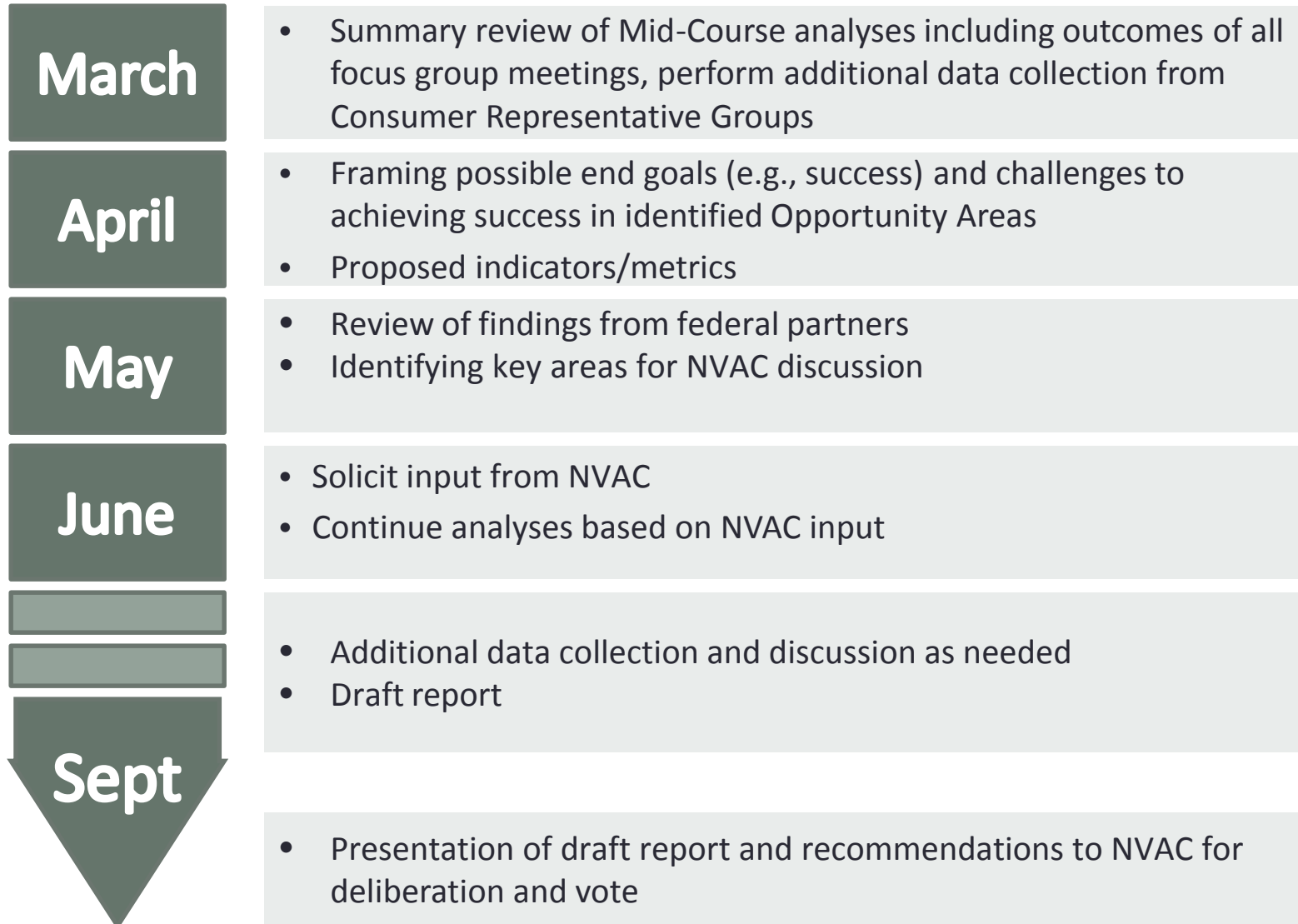Ann Ginsberg

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NVAC WG Support Team

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Methodology

March	• Summary review of Mid-Course analyses including outcomes of all focus group meetings, perform additional data collection from Consumer Representative Groups
April	• Framing possible end goals (e.g., success) and challenges to achieving success in identified Opportunity Areas • Proposed indicators/metrics
May	• Review of findings from federal partners • Identifying key areas for NVAC discussion
June	• Solicit input from NVAC • Continue analyses based on NVAC input
	• Additional data collection and discussion as needed • Draft report
Sept	• Presentation of draft report and recommendations to NVAC for deliberation and vote

Top Five Opportunity Areas for 2016-2020 of the National Vaccine Plan – General Findings by WG

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) Identify and implement solutions to overcome vaccine development barriers.

WG Evaluation of Opportunity Areas for Informing the Development of the 2016-2020 Implementation Plan

- For each Opportunity Area (OA) the WG discussed:
    - What would successful implementation of the opportunity area look like in 2020?

    - What existing metrics are available to track progress?
        - What new metrics should be developed for the longer term?

    - What are the possible challenges to making significant progress towards the metrics by 2020?

    - Were there any other considerations that the WG wanted to highlight for the ASH when leading the development of the 2016-2020 Implementation Plan?

#1 - Strengthen health information and surveillance systems to track, analyze and visualize disease, immunization coverage, and safety data, both domestically and globally.

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Successful implementation of this Opportunity Area would be defined by:

- Interoperable IISs across all US states and territories
- Bidirectional, real time exchange of data between all IISs and all EHRs used by vaccine providers in the US
- End-to-end tracking of vaccines across all sectors utilizing standardized, interoperable IT solutions (e.g. practice level utilization of 2D bar-coding)
- Post-market surveillance in all countries

#1 - Strengthen health information and surveillance systems to track, analyze and visualize disease, immunization coverage, and safety data, both domestically and globally.

Challenges to making significant progress towards those outcomes by 2020:

- Legal barriers to sharing IIS data among jurisdictions
- Lack of EHR standardization to facilitate bidirectional data sharing between EHRs and IISs
- Funding health IT applications, such as bar coding, across the immunization enterprise
- Absence of global case-based surveillance systems for many diseases (global)
- Lack of vaccine safety surveillance in many countries (global)

Other Considerations for Development of Implementation Plan?

- Potential for 2D barcodes in managing inventory and supply chain
- Strengthening global capacity for pharmacovigilance in tracking AEFIs

#1 - Strengthen health information and surveillance systems to track, analyze and visualize disease, immunization coverage, and safety data, both domestically and globally.

Existing *metrics that would be helpful for tracking progress in the Opportunity Area?*

Metric	Baseline	Target?
Percent of office-based physicians who are electronically sharing patient information with any providers outside their organization (domestic)	ONC 42% (2014)	TBD
The number of vaccines on CDC-contracted price list that include a 2D barcode on unit of use or primary vaccine products (e.g., vials, syringes) (domestic)		100%
Percent of healthcare providers who are electronically sharing patient information with their state IIS (e.g., as meaningful use requirement)	ONC 73% of eligible hospitals in U.S. able to report vaccination to their local IIS (2014)	TBD
Number of countries with case-based surveillance for vaccine-preventable diseases (global metric of surveillance)	GVAP SAGE 67% Member States IBD; 52% Member States rotavirus (2013)	75% of LMIC for hospital-based sentinel site surveillance for IBD and rotavirus

#1 - Strengthen health information and surveillance systems to track, analyze and visualize disease, immunization coverage, and safety data, both domestically and globally.

Proposed *metrics that would be helpful for tracking progress in the Opportunity Area?*

Metric Proposed for Future Development	As a Measure of?
Number of operational MOAs between state and territorial IISs	Progress toward interoperability of IIS
Percent of providers utilizing 2D barcodes to populate EHRs and IIS	More accurate data collection on immunization safety, efficacy, and coverage

#2 - Foster and facilitate efforts to strengthen confidence in vaccines and the immunization system to increase coverage rates across the lifespan.

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Successful implementation of this Opportunity Area would be defined by:

- Improved immunization coverage rates across all age groups
- Reduced number of personal belief exemptions for vaccination in all states
- Robust vaccine communication tools available for HCP and community advocates

#2 - Foster and facilitate efforts to strengthen confidence in vaccines and the immunization system to increase coverage rates across the lifespan.

Challenges to making significant progress towards those outcomes by 2020:

- Clear communication and understanding when changes are made to the immunization schedule (e.g., new vaccines, dosing schedule)
- Adults continue to be under-vaccinated and skeptical about the need to be up-to-date on their immunizations
- Need for consistent and reliable methods to communicate with the public about the importance of vaccines and other strategies to bolster vaccine confidence

Other Considerations for Development of Implementation Plan?

- NVAC Recommendations on Vaccine Confidence should strongly influence the development of the implementation plan for this priority area, especially around the development of targeted metrics for vaccine confidence

#2 - Foster and facilitate efforts to strengthen confidence in vaccines and the immunization system to increase coverage rates across the lifespan.

***Existing** metrics that would be helpful for tracking progress in the Opportunity Area?*

Metric	Baseline	Target?
Decrease the percentage of children in the United States who receive 0 doses of recommended vaccines by age 19 to 35 months	HP2020 0.8% (2012)	Target not set (informational)
Increase the percentage of adults aged 18 and older who are vaccinated annually against seasonal influenza	HP2020 38.1% (2010-2011)	70%
Percentage of pregnant women who report receiving influenza immunization during pregnancy (domestic)	CDC Internet Panel Survey 52% (CDC, 2013)	not set (developmental)
Track state legislation on personal belief exemptions	-	decreasing trend
The dropout rates between DPT3 and DPT1, globally (global metric of demand)	GVAP SAGE 18.6% Member States w/ dropout rates ≥10%	decreasing trend

For NVAC Discussion:
- *Should age groups each have individual metrics for coverage?*
- *Is HPV coverage the right metric for gauging confidence in adolescent vaccination?*
- *Should HPV coverage levels should match Tdap and Men vaccine coverage?*

#2 - Foster and facilitate efforts to strengthen confidence in vaccines and the immunization system to increase coverage rates across the lifespan.

Proposed *metrics that would be helpful for tracking progress in the Opportunity Area?*

Metric Proposed for Future Development	As a Measure of?
Standardized school-based data collection on PBEs across states and jurisdictions	More uniform information on state PBEs and their relation to vaccine confidence

#3 - Eliminate financial and systems barriers for providers and consumers to facilitate access to routinely recommended vaccines.

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Successful implementation of this Opportunity Area would be defined by:

- Increased vaccination rates and increased offering of vaccines by providers
- Increased number of providers that stock and administer vaccines
- Surveillance of vaccine provider perceptions about the profitability of delivering vaccines in their practices

#3 - Eliminate financial and systems barriers for providers and consumers to facilitate access to routinely recommended vaccines.

Challenges to making significant progress towards those outcomes by 2020:
- Mismatch in Medicare B/D payment for vaccines
- Payment methods, bundling, capitation
- ACIP recommended A/B ratings
- Alternate vaccinators (not in-network but part of the immunization neighborhood)
  - concerns from pediatricians regarding medical home for children
- Inventory costs of newer, more expensive vaccines

Other Considerations for Development of Implementation Plan?
- Consensus that federal programs need to align and the inconsistencies between Medicare and Medicaid need to be addressed in some way
- Need to ensure access to immunizations across the lifespan
- Need efforts to better understand the age restrictions by state for the administration of vaccines by pharmacists and other non-physician providers

#3 - Eliminate financial and systems barriers for providers and consumers to facilitate access to routinely recommended vaccines.

Metric	Baseline	Target?
Percentage of state Medicaid programs that provide coverage of all ACIP/CDC recommended vaccinations for adults and prohibit cost-sharing	20% (CMS, 2012)	100% (NAIP)
Percentage of states and territories that allow pharmacists to administer all routinely recommended vaccines for adults > 19 without a patient-specific prescription	85% (APhA, 2013)	100% (NAIP)
Number of providers who are stocking appropriate vaccines and providing full adult vaccination services for patients (YOY trend)	20% Internists and 31% FP (CDC, 2012)	60% (NAIP)
Number of WHO regions achieving measles elimination by 2020 (global metric of access)	GVAP, SAGE 0/5 WHO regions (2010)	5 WHO regions
Number and proportion of countries providing MCV2 through routine services with coverage levels of second dose MCV and RCV (global metric of access)	-	>90% nationally and >80% in all districts

#3 - Eliminate financial and systems barriers for providers and consumers to facilitate access to routinely recommended vaccines.

Proposed metrics that would be helpful for tracking progress in the Opportunity Area?

Metric Proposed for Future Development	As a Measure of?
Number of providers who are not providing immunization services for their patients (YOY trend)	Continuing barriers to providers to offer immunization services in their practice
Number of countries that have eliminated rubella	Global measure of access, equity, and strength of routine immunization systems

#4 - Strengthen the science base for the development and licensure of vaccines.

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Successful implementation of this Opportunity Area would be defined by:

- Clinical development for new vaccines moves more quickly through phase 3
- Harder targets can be tackled with better understanding of natural immunity and correlates of protection
- Projects characterizing the human immune response and those contributing to our understanding of vaccine science are well funded, staffed and supported

#4 - Strengthen the science base for the development and licensure of vaccines.

Challenges to making significant progress towards those outcomes by 2020:
- The size and cost of clinical trials has grown and efficacy studies are larger and more difficult to conduct
- Understanding of waning immunity and how to address it (e.g., pertussis)
- How to overcome poorer T cell induction by vaccines in infants to address better persistence of antibodies following booster doses in older children and adolescents
- Improve vaccines and immune responses for elderly

Other Considerations for Development of Implementation Plan?
- Need better correlates of protection and understand their roles and opportunities in clinical trials
  - Relieve the need to do large efficacy trials when disease burden is not high or unpredictable year to year (e.g., influenza vaccines)
  - Start with harnessing the available data and identification of data gaps

#4 - Strengthen the science base for the development and licensure of vaccines.

***Proposed** metrics that would be helpful for tracking progress in the Opportunity Area?*

Metric	Baseline	Target?
Track funding for vaccine research and development across the stakeholder community (both federal and non-federal) to understand the level of funding from different stakeholders and how this changes over time.		

For NVAC Discussion
- Indicators that measure the progress of science are very difficult and are not always informative about the health of the system
    - Funding
        - Increases need to be highly targeted to answer specific questions
        - Tracking should include how federal funds coordinate research to ensure optimal investments
    - Number of journal articles on vaccine science also not straightforward indicator
        - Research must be deemed as high quality in the peer-reviewed community and targeted for true advances to be made

#5 - Identify and implement solutions to overcome vaccine development barriers.

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Successful implementation of this Opportunity Area would be defined by:

- For priority targets, there are enough vaccine candidates in the pipeline to lead to at least one licensed vaccine taking into account the expected attrition rates
- New products addressing incremental improvements for priority targets are accepted and supported to encourage further incremental development
- Emerging pathogen threats can be addressed by vaccination before outbreak ends
- Year-to-year funding is tracked and increase for vaccine R&D
- An increasing number of regulatory authorities harmonize and upgrade their standards for vaccine licensure and distribution

#5 - Identify and implement solutions to overcome vaccine development barriers.

Challenges to making significant progress towards those outcomes by 2020:
- Building and maintaining a pipeline of vaccine candidates that is robust enough to be likely to lead to at least one licensed vaccine against priority targets
- Preparing in advance for developing vaccines against emerging pathogen threats so that responses to outbreaks can be more proactive
- Harmonizing global regulatory requirements for the development and distribution of vaccines

Other Considerations for Development of Implementation Plan?
- Drivers of innovation take into account incentives for smaller biotechs as well as large vaccine manufacturers
- Rewarding manufacturers for incremental improvements in vaccines
- Efforts to harmonize regulatory reviews globally

#5 - Identify and implement solutions to overcome vaccine development barriers.

Existing metrics that would be helpful for tracking progress in the Opportunity Area?

Metric	Baseline	Target?
Licensure and launch of at least one platform delivery technology and/or the number of vaccine deliver technologies (devices and equipment) that have received WHO pre-qualification against the 2010 baseline (global metric of innovation)	-	1 or more technologies

#5 - Identify and implement solutions to overcome vaccine development barriers.

Overall, the working group did not feel that any of the existing metrics adequately addressed this opportunity area

- WHO developed a pipeline tracker that is currently limited to clinical-stage vaccines HIV-1, malaria, TB, RSV and enteric pathogens
- Need to develop an expanded pipeline tracker is warranted

Proposed metrics that would be helpful for tracking progress in the Opportunity Area?

Metric Proposed for Future Development	As a Measure of?
Track the clinical stage vaccine development pipeline that includes a specific number of target, priority pathogens (prevalent, emerging, and improved) so that the number of candidates and length of time spent in each phase can be tracked over time	Overall robustness of the development pipeline
Agreements signed and acted upon by key regulatory agencies to perform joint reviews	Efforts to harmonize regulatory reviews globally

Next Steps

March	• Summary review of Mid-Course analyses including outcomes of all focus group meetings. Additional data collection from Consumer Representative Groups
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