

National Vaccine Plan (Plan) Status Update

Raymond A. Strikas, MD, FACP
CAPT, U.S. Public Health Service
National Vaccine Program Office
June 3, 2009



Presentation Overview

- Summary of sources for comments' on the draft Plan
- Approach to reviewing comments
 - Example: Goal 1 working group review
- Status of IOM expert committee review for priorities in the Plan
- Next steps

Overview

- Comments accepted through March 31, 2009
- Received 466 comments from:
 - Advocacy groups (e.g., consumer [6])
 - Global health advocates [2]
 - Individuals (e.g., general public [389], academics [29])
 - Industry (e.g., insurance, manufacturers [11])
 - International (e.g. representatives of governments, WHO [8])
 - Health care professional organizations [21]

Process

- Comments sorted by each goal (#1-5)
- Comments will be reviewed by working groups of staff across agencies and Departments (e.g., NVPO, CDC, FDA, NIH, HRSA, USAID, DoD, VA) for each goal
- Working groups will address each comment, provide rationale for inclusion or exclusion, make recommendations for revisions in the next draft of the Plan

Goal 1:

Develop new and improved vaccines

- Weekly meeting of Goal 1 working group (CDC, FDA, NIH, and NVPO staff)
- Goal 1 Review Process
 - Reviewed all comments
 - For each comment agreed on disposition and provided rationale
 - Provided alternative wording and formatting as agreed upon by working group

Goal 1 Template and Process

- Comments stratified by Plan sections:
 - General
 - Executive Summary
 - Indicator
 - Objective
 - Strategy
- Comments fell into 3 types of comments:
 - General, but not specific to Goal 1
 - (e.g., this plan is great; should be formatted in the way of a playbook)
 - Specific (e.g., add an indicator)
 - Clarification (e.g., clarify elements related to research and development)

Goal 1 Template and Process - 2

- Disposition/Rationale - 6 category codes:
 - Accept as suggested
 - Accept with modifications
 - Do not accept
 - Should be considered/addressed in implementation plan
 - General comment, no action needed
 - Comment related to another goal

Goal 1- Types of comments received

– General comments

- “...the priorities are well thought out- especially with regards to the need for development of a vaccine for TB, HIV, and a more robust vaccine for seasonal influenza”
- “The [Plan] should result in a comprehensive, high level ‘playbook’ complete with clear goals, objections, tactics, clear timelines, clear responsibilities and accountability, in a matrix format”
- “ The language in the [Plan] needs to be balanced to ensure that the plan includes the entire lifespan, as written, there is a bias towards pediatric vaccines”

Goal 1- Types of comments received

– Specific comments

- Reword objective 1.3 to “support research on novel & *improved* vaccine delivery methods”
- Add a new indicator to support the increase in basic [research] funding

Goal 1- Types of comments received

– Clarification comments

- “How will consensus be reached/tried with such a large group of stakeholders? (Indicator 1)
- Need to clarify the six month timeline used in Indicator 4
- Need to clarify “delivery systems’ throughout goal one

Goal 1 Working Group Discussion

- Comments deliberated and disposition agreed to by consensus
- Process transparent, posted for entire working group
- Revisions will inform next version and implementation plan

Next Steps

- Complete other Goals' comments' review
- Provide working groups' revisions to federal agencies, Departments, and NVAC, then to external stakeholders for review
- Revise draft strategic Plan
 - Strive for consensus from majority of government and external stakeholders
 - account for IOM committee recommendations

IOM Expert Committee Process and Timeline

- The IOM Committee will hold workshops with national expert stakeholders in medicine, public health, and vaccinology to review a publicly available, draft update of the National Vaccine Plan. The committee will prepare a report with conclusions and recommendations about priority actions within the major components of the draft Plan. :
 - July 24, 2008 (Vaccine supply, delivery, programs): Chicago, IL
 - December 1, 2008 (Research and development): Irvine, CA
 - February 2, 2009 (Communications and education): Washington, DC
 - April 14, 2009 (Vaccine Safety): Washington, DC
 - June 4, 2009 (Global Health): Seattle, WA
- Final report from IOM to NVPO expected in November, 2009

Questions or comments?

National Vaccine Plan: http://www.hhs.gov/nvpo/vacc_plan/