Comments received by the National Vaccine Program Office from Individuals on the draft strategic National Vaccine Plan through January 30, 2009.

General Comments:

Dr. Reginald Finger, former member, Advisory Committee on Immunization Practices

Thanks for the opportunity to comment on the draft plan. All in all, it looks very comprehensive, well-written, and certainly builds on past successes. I'm gratified to be reminded at how far the whole immunization enterprise has come since I sat on the Grantee Working Group in 1994.

The action steps are very general in nature, and I think this must be by design. For instance, there is not a lot of detail about such things as specific vaccine safety research projects, specific enhancements to VPD surveillance, and specific plans to move the IIS system ahead from where it is now, including communication of information from the IISs between the states. I assume these kinds of specifics will come later in other documents.

Dr. Charles Helms, University of Iowa Medical Center

(1) ***Comments on priorities for the National Vaccine Plan for a ten year period:***

(a) What do you recommend be the top priorities for vaccines and the immunization enterprise in the United States and globally?

The five broad goals of the draft plan and their associated objectives and strategies reflect accurately, and in a balanced fashion, the top priorities for vaccines and the immunization enterprise in the US and globally.

The draft Plan puts forward in its five broad goals and associated objectives and strategies a road map that will stimulate innovation and safety in vaccine development and improve reliability and productivity in the immunization enterprise in the US. Enhanced vaccine innovation and safety, coupled with improved reliability and productivity of the US immunization enterprise will stimulate success and progress globally.

From my perspective as a physician and academic stakeholder, the goals, objectives and strategies that are important are included in the Plan and well presented.

(b) Why are those priorities most important to you?

See (1) (a) above.

I recognize that the five broad goals themselves are each individually important in achieving success and progress in the US and appear to have no particular relative priority. However, I believe the presentation of the broad goals of the Plan would better facilitate public understanding and support if the current order of goals were changed to the following order: 1) Support informed vaccine decision making, etc., 2) Ensure a stable supply, etc., 3) Enhance safety, etc., 4) Develop new and improved vaccines, and 5) Increase global prevention of disease, etc.

(a) Please identify which stakeholders you believe should have the responsibility for enacting the objectives and strategies listed in the draft Plan, as well as for any new objectives and strategies you suggest. Specifically identify roles your organization can play in the Plan.

The Plan identifies Federal and Non-federal stakeholders beneath each of the proposed objectives. This poses a potentially complex situation in assigning responsibility for Plan implementation and oversight.

A centralized oversight process should be developed to identify which and how Federal/Non-Federal stakeholders will take the operational lead to organize and oversee data collection for Goals. I think the NVPO/NVAC could be wisely used to oversee and assure progress. NVPO/NVAC could also develop a centralized process to assemble and present periodic Plan progress reports.

Julie Leask, National Centre for Immunisation Research & Surveillance, Australia

(2) *Comments on the goals, objectives, and strategies for the National Vaccine Plan for a ten-year period:* Please comment on the existing goals, objectives, and strategies in the draft Plan, and suggest specific goals, objectives, or strategies to be added to it, if the existing ones do not address your concerns. Are there any goals, objectives or strategies in the draft strategic Plan that should be discarded or revised? Which ones, and why?

Comment 1

There could be more linkage between the goals and objectives. At present it is not clear which objective relates to which goal or how they are related.

Comment 2

There are also multiple objectives. These could be thematically condensed to make the plan more manageable.

S. Michael Marcy, MD, UCLA Harbor Medical Center, and Member, Advisory Committee on Immunization Practices

The first 25+ pages were a lot of admin-speak, but the expanded discussion on the five goals was thoughtful, thorough and terrific!!

H. Cody Meissner, MD, Chief, Pediatric Infectious Disease, Tufts Medical Center Professor of Pediatrics, Tufts University School of Medicine

I have read through this document and found it to be thoughtful, timely and carefully written. It covers an enormous amount of information and provides an excellent overview of the critical areas relating to vaccines.

Julie Milstien, University of Maryland

This represents a lot of work and I congratulate you on your effort. I have a few comments that might improve it and make it easier to implement effectively:

1. Nowhere do I see any indication that the vaccine plan is going to be concerned with vaccine logistics, especially vaccine thermostability and the cold chain, which can affect vaccine safety, efficacy, and coverage. I have heard over the years, and most recently in December, statements from public health advisors that they are losing lots of vaccines by freezing, and that, in addition, they would welcome the use of Vaccine Vial Monitors to help assure that the vaccines are being distributed and stored properly. When was the last time there was a general cold chain review in the US? How will vaccines that are quite temperature sensitive, like rotavirus vaccines, be handled? How will vaccine administrators be able to handle new vaccines with differing characteristics? Why does the vaccine industry in the US place so little emphasis on basic thermostability characteristics?
2. It is not particularly clear from the plan, who will assure the monitoring of implementation of the plan? Is it to be done only by the individual stakeholders, and/or by NVP and/or by some outside body such as the IOM? How is this to be done? How frequently? This needs to be clearly understood and agreed, or in fact there is no need to have a plan.
3. Your plan suffers from the fact that what you are calling “Indicators” are not indicators. In most cases they are targets, although in some cases they are activities or strategies. An indicator would be, for example, “number of new candidate vaccines identified,” or the “existence of an updated Vaccine Table.” To be able to develop an implementation plan, the strategic plan needs to be clear, consistent, and able to be monitored.
4. I wonder about the objective 2.4 on improving causality assessments. Although this would be desirable, I wonder if it is possible by the strategies outlined, especially for a rare AEFI with one or only a few case reports. I believe the emphasis should be on good epidemiological methods, and the strategies should say this.

Walter Orenstein, MD, Gates Foundation

…the plan offered nothing to me in competing for resources within my agency. For example, an initiative to help meet Healthy People objectives could help in supporting the fact that we were attempting to achieve a national goal and gave some advantages against those with initiatives not mentioned in Healthy People. Thus, it would be important to get some language in the implementation phase that any vaccine-related initiative would be judged against the plan.

Finally, at some stage, the seriousness with which the plan is taken should be compatible with the budget devoted to each element. I recognize that budgeting by strategy or objective may be difficult. But if feasible, I think it could be helpful in determining what the real priorities are. At the moment, the plan is very comprehensive and it's difficult to see whether certain sections are more important than others. The plan implies everything is equally important.

George Rutherford, MD, University of California, San Francisco, Institute for Global Health

You asked me to comment on four areas. I have arranged my comments accordingly. I would, however, like to start with some general comments. I thought the report was very well done but noted that there were no numeric targets that appeared in Table 1 or elsewhere in the report. I assume these are currently being debated. Secondly, I applaud the use of the Institute of Medicine report to guide many of the goals, objectives and strategies of the report; I think it provides an extra layer of credibility. Thirdly, I also strongly applaud the inclusion of Goal 5 and think that internationally is where substantial benefits can be achieved in the relatively short term using products that are already on the shelf. Fourthly, while I realize prevention of infectious diseases in non-human animals is beyond the scope of this report, I would suggest including it somewhere near page 17 where other disclaimers appear.

I have also noted above the need to include professional societies in many of the stakeholder lists. While I recognize the dominance and role of the health insurance industry, I encourage you to seek out practitioners' voices. They are the ones, and not the health insurers, that are delivering immunizations and providing much of the front-line education to parents and patients.

Bonnie Sorenson, Director of Nursing, Southern Nevada Health District.

Vaccine Priorities

- The Cost of Vaccines has not kept pace with reimbursement
- Disease Surveillance (Adverse Event Monitoring)

- Education Strategies

Comments on Executive Summary and Introduction:

S. Michael Marcy, MD, UCLA Harbor Medical Center, and Member, Advisory Committee on Immunization Practices

Pg 4, paragraph 2, lines 4 and 5: Somebody cut-&-pasted" and forgot to erase one of the "and abroad"s

Walter Orenstein, MD, Gates Foundation

On page 17, last paragraph – I find the wording confusing. I think the plan should take into account infectious diseases and all of their outcomes including cancers. Would the prevention of post-infectious measles encephalitis not be considered a burden to prevented, even though it is an immunological reaction to the infectious agent? What I believe you are saying is that immunomodulators, including vaccines, which may be used to prevent and treat non-infectious diseases, will not be considered. This is a better way, in my opinion, of saying that.

<u>Goal 1 Comments:</u> Develop new and improved vaccines

Dr. Charles Helms, University of Iowa Medical Center

Goal 1 Indicators:

High priority evidence-based vaccine targets should be achieved within one year—okay.

Identify 4 candidate vaccines from those targets identified in the 1 year process above.

Advance the same 4 along the R&D and advanced clinical trials pathways.

Advance 4 delivery strategies to improve effectiveness, etc. of new or improved vaccines.

Dr. Alan Hinman, Task Force for Child Survival

Goal 1 – given the rapid development of genomic medicine, shouldn't there be an objective about assessing individual immunological characteristics and tailoring vaccines to match them?

Anna Johnson-Winegar, PhD, Consultant

1. Objective 1.2 Support research to develop new vaccine candidates and improve current vaccines to prevent infectious diseases, particularly those determined to be priorities.

Strategy 1.2.1 Advance research and development toward new and/or improved vaccines that prevent diseases, including those that protect against emerging, re-emerging, and important biodefense related pathogens.

Comment: What is the implementation plan for gaining additional resources for these research and development projects? How will advances in research be shared across Federal agencies and Departments?

2. Objective 1.4 Support development of vaccine candidates and the scientific tools needed to evaluate these candidates for licensure.

   Comment: The relevant DOD organization for this is the Chemical-Biological Medical Systems Office- a component of the Joint Program Executive Office for Chemical and Biological Defense. The Defense Threat Reduction Agency (DTRA) does not have authority for advanced development and licensure issues.

S. Michael Marcy, MD, UCLA Harbor Medical Center, and Member, Advisory Committee on Immunization Practices

Goal 1: I am delighted that there was mention of new adjuvants and new delivery systems. However, these goals are intended to cover 10 years of activities regarding immunization. It would seem appropriate to mention therapeutic vaccines vs infectious (e.g. Herpes group, hepatitis B, papillomavirus) and non- infectious (e.g.a variety of cancers) conditions. Perhaps, even prophylactic vaccines against non-infectious conditions (e.g. diabetes type 1, Alzheimer's, drug addiction, smoking).
By well before 2019 you can be sure that Objective 1.2 will be directed to "prevent and treat infectious and non-infectious diseases"

Walter Orenstein, MD, Gates Foundation

On page 25, bottom of the page are a set of goal indicators. As you can imagine, identifying X candidates and advance Y priority vaccines, will be quite difficult.

On page 26, last Goal 1 indicator – do you really think we will have candidates to be tested within 6 months of identification of the need for a vaccine – perhaps for influenza when we are using a technology we have, only changing the antigen slightly. I may be out of touch but to have a vaccine for human clinical trials within 6 months of identification of the pathogen and need for a vaccine does not seem realistic.

The figure on page 27 includes “vaccine research” and “vaccine development”. It seems somewhere in the text, those terms should be defined so people can understand how they are different. I wonder if it would be better to use the term “vaccine discovery” rather than “research” since the former is in greater and greater use. Regardless, I think it is important to list out what might be included in discovery, such as identification of the pathogen, understand pathogenesis, determination of the components of a protective immune response etc.

On page 28, you discuss a process for making priorities. It’s not until Goal 5, that I understood that the prioritization process not only included vaccines for domestic use but vaccines for use in developing countries as well. I think this should be clarified here. Should a regular review of priorities be undertaken (e.g., every 5 years or more frequently, if needed)?

George Rutherford, MD, University of California, San Francisco, Institute for Global Health

Vaccines for regional high-morbidity diseases. With regard to vaccine development, I would ask the Committee not to forget diseases that occur regionally, such as coccidioidomycosis, histoplamosis and Lyme disease that are not usually considered high-priority targets. Coccidioidomycosis, for instances, causes far more severe morbidity in the United States than other diseases that are considered high priorities.

Internationally, *Neisseria meningitidis* type b is an obvious target for new and improved vaccines and will have domestic use, as well.

NIH funding for vaccine development. While NIH has provided some funding for vaccine development, I would encourage it to be specifically included in the Clinical and Translational Sciences Initiatives.

Multiple-adjuvant vaccines. As a pediatrician, I would like to reinforce the need for continued development of multiple adjuvant vaccines that make office-based immunization so much easier. **Objective 1.1 or 1.2.** Explicitly add multiple-adjuvant vaccines that use existing vaccine antigens as a specific type of “new” vaccines.

Bonnie Sorenson, Director of Nursing, Southern Nevada Health District.

Comments:
-Ability to create more combination vaccines that allow fewer injections and compress the number of visits needed to complete a series.
-Delivery systems other than injection (Ex: Nasal).

Goal 2 Comments: Enhance the safety of vaccines and vaccination practices

Dr. Charles Helms, University of Iowa Medical Center

Goal 2 Indicators:
All indicators are appropriate, but I cannot personally suggest evidence-based targets.

Dr. Alan Hinman, Task Force for Child Survival

Goal 2 – shouldn't there be a specific objective about expanding the Vaccine Safety Datalink project to increase the proportion of the population included?

Julie Milstien, University of Maryland

I wonder about the objective 2.4 on improving causality assessments. Although this would be desirable, I wonder if it is possible by the strategies outlined, especially for a rare AEFI with one or only a few case reports. I believe the emphasis should be on good epidemiological methods, and the strategies should say this.

Walter Orenstein, MD, Gates Foundation

With regard to vaccine safety, one critical component of our old system was dismantled, the review by the Institute of Medicine (IOM). While not everyone was supportive of those reviews, I found them extremely helpful and I used the IOM reviews to argue that our policies with regard to safety were influenced by independent review by a group of experts. I would recommend that one of the strategies include: "Establish an independent group of experts to review major vaccine safety concerns including evaluation of the evidence that a vaccine or vaccines were causing particular adverse events and recommendations for future actions including further research".

Bonnie Sorenson, Director of Nursing, Southern Nevada Health District.

Comments:
-Improved Surveillance for Adverse Event Reporting especially as it relates to new vaccines.
-Expand the collaboration between providers, labs, etc.
-Who can report Adverse Events by use of an electronic reporting system.
-Better data collection system when new vaccines are introduced to monitor effectiveness and adverse event reporting in a timely manner.

Goal 3 Comments: Support informed vaccine decision-making by the public, providers, and policy-makers

Kelly Dang, International Community Health Service (ICHS)

In general, we support the goal of improving the accuracy and timeliness of communication and dissemination of information to the public, providers, and policy-makers. Specific to the proposed objective 3.1 of *improving communication and education efforts,* we would recommend that the proposed strategies include conducting research that is culturally appropriate and in the language of linguistically-isolated communities (proposed strategy 3.1.2). In addition, we would recommend that any development, testing of educational strategies to enable the public audiences about the risks and benefits when making immunization decisions, and assessment of the communication materials also be done in a culturally appropriate and in the language of linguistically-isolated communities (proposed strategy 3.1.3; 3.1.4; 3.1.5).

We believe that culturally appropriate and an in-language approach to research, development, and assessment of communication materials is important because language can be a barrier to participation and understanding. Studies have shown that those who live in linguistically-isolated communities have a low level of risk awareness and tends to under-utilize preventive care. For example, the Office of Minority Health reports that Asian Pacific Islander adults are 30 percent less likely to ever have received the pneumococcal vaccine as compared to non-Hispanic white adults. Also, Vietnamese immigrants have the highest prevalence for chronic infection with hepatitis B, but tend to have low levels of knowledge about HBV vaccines.

Specific to proposed objective 3.4, *Increase public awareness of vaccine preventable diseases and benefits and risks of vaccines and immunization, especially among populations at risk under immunization,* we would recommend that NPVO recognize and include the role of community health centers as the best resource to disseminate educational materials to parents and adolescents about the benefits and risks of vaccines (proposed strategy 3.4.1). For example, our community health center has dedicated staffs who speak Vietnamese, Chinese, Tagalog, Mien, and Korean, to perform outreach to the Asian Pacific Islander community about chronic disease and other health care issues. This approach has worked well as a way of keeping our patient population informed and healthy. We would recommend that NPVO consider exploring funding opportunities so that ICHS and other community health centers like ours can leverage existing community health outreach efforts to educate our patient population about the benefits and risks of vaccinations.

Also, we would recommend that NPVO and the Vaccine For Children Program work together to offer web-based information on vaccine preventable diseases and the benefits and risks of vaccines in multi-languages (proposed strategy 3.4.2). Currently, web-based information is only available in English. In order to reach as many audience groups as possible and to make dissemination of information as convenient as possible, NPVO

should present information in different languages - Vietnamese, Tagalog, Korean, Chinese, Spanish and Russian.

Dr. Charles Helms, University of Iowa Medical Center

Goal 3 Indicators

All indicators are appropriate, but I cannot personally suggest evidence-based targets.

For those indicators where it applies, I would suggest setting 5 years as a time to show evidence of at least some improvement (e.g., in stakeholder-public vaccine communication). I would require the final target % to be reached no later than the assigned target date. Previously measured baseline levels (%) will be required to show progress.

Dr. Alan Hinman, Task Force for Child Survival

Goal 3 – given the success of the United Kingdom in assessing public attitudes and perceptions about immunizations, shouldn't there be an objective about developing a comparable system in the United States?

Julie Leask, National Centre for Immunisation Research & Surveillance, Australia

(1) *Comments on priorities for the National Vaccine Plan for a ten-year period:* What do you recommend be the top priorities for vaccines and the immunization enterprise in the United States and globally? Why are those priorities most important to you?

Comment 1

Informing providers, rapidly and in a coordinated manner, is a priority. If good uptake of safe vaccines is one of the plan's (implicit) goals, providers need to be supported for two reasons: First is that providers are central to vaccine risk communication with the public. Much evidence points to the importance of providers as an information source and influence on public attitudes. Evidence from shifts in public attitudes to vaccines shows that media stories may abound but it is only once a controversy shifts the confidence of providers that we see a downturn in vaccination rates, presumable because we no longer have committed and confident providers. Second is evidence from surveys that show providers share the same general concerns about vaccines in similar proportions to the public. Hence, they are a key 'audience' in terms of effective communication. **Providers are the conduit for vaccine recommendations and their implementation. For every provider informed about vaccination and**

reassured, we inform a larger number of parents. Hence this strategy is also more cost effective.

(2) *Comments on the goals, objectives, and strategies for the National Vaccine Plan for a ten-year period:* Please comment on the existing goals, objectives, and strategies in the draft Plan, and suggest specific goals, objectives, or strategies to be added to it, if the existing ones do not address your concerns. Are there any goals, objectives or strategies in the draft strategic Plan that should be discarded or revised? Which ones, and why?

Comment 3

Tensions may arise between the explicit goal to support informed decision making and the implicit goal of maintaining high vaccination rates (as reflected in Objective 3.4 and the existence of mandates). Sometimes these can conflict, particularly when campaigns and persuasion are necessary to improve rates and no longer can claim a benign imparting of the evidence.

It is possible the plan assumes that the goal of supporting decision making leads to an informed decision that always results in vaccination, hence satisfying both goals. Two problems arise with this assumption. First is the assumption that those doubting or declining vaccination are merely wrong and if better educated and informed, will see the error of their ways and embrace immunisation. In fact, vaccine skepticism is often about deeply held values and wider tensions where science is either not trusted or used in ways to support one's existing views. More information and education is unlikely to work. Strategies need to be more sophisticated and informed by diverse fields. Persuasion may be necessary and if so, the goal of maintaining high immunisation rates should be explicit. Ethical guidelines exist in the health promotion literature on when appeals to threat (such as generating concern about a vaccine-preventable disease) are acceptable.

The second limitation of the informed decisions model is when a vaccine risk-benefit profile reverses for an individual (e.g., OPV and VAP during a time of country-wide elimination). Then, informed individuals seeking to maximise their own utility would rationally not vaccinate, leaving the population and future generations vulnerable to disease re-introduction – a Tragedy of the Commons. What happens if this occurs with another vaccine close to elimination and no safer alternative is available? The rhetoric of informed decision making is individualistic in its assumptions. **The plan, while embracing informed decision making, should make provisions for understanding and better communicating *population* benefit.**

To address these tensions in communication to the public, role distinction may help: to give the role of persuasion to government and vaccine advocacy groups and the role of giving risk/benefit information to providers and independent organisations funded by government.

Comment 4

The plan could be strengthened by an explicit strategy for engaging with vaccine-skeptical groups in the public arena – when, how and whom.

(3) *Comments on the indicators for the National Vaccine Plan for a ten-year period:* Please comment on the existing indicators in the draft Plan, and suggest target estimates for them. Please suggest new indicators to be added to it, if the existing ones do not address your concerns. Are there any indicators in the draft strategic Plan that should be discarded or revised? Which ones, and why?

Comment 1

Indicator 2 _X___ % of the public will report that they are satisfied with how their health care provider answers their questions about the benefits and risks of vaccines by Y (year).

The language of this goal depicts the public as passive recipients of information (see comment 3 above). It also assumes clinical communication fits easily into a question answer format. An alternative could be
X___ % of the public will report that they are satisfied with how their health care provider **communicates with them** about the benefits and risks of vaccines by Y (year).

Walter Orenstein, MD, Gates Foundation

On page 39, indicator 1, how do you measure "enhance communication"? Certainly, the time frames are easy to measure.

On page 40, last two indicators – "all" is tough to achieve. For example, are you saying that ophthalmologists and neurosurgeons should have immunization questions on their certifying examination? I agree that is a good goal, but should it be focused on primary care providers?

On page 42, strategy 3.1.7 only discusses collecting information on the direct and indirect costs of vaccination. Why not benefits and costs averted?

Page 45 – what is the difference between strategies 3.7.1 and 3.7.2?

George Rutherford, MD, University of California, San Francisco, Institute for Global Health

Goal 3 indicators seemed overly defensive to me. I would suggest that the indicators focus on public's knowledge of the benefits of vaccination rather than leaning so heavily on adverse events and risks. Moreover, I think under objective 3.3 making Important Information Forms shorter, more readable and less intimidating could be an important strategy.

Objective 3.1. Simplify Important Information Forms (see below)

Objective 3.2 et seq and 4.2. The list of non-federal stakeholders should include professional societies, such as the American Academy of Pediatrics, the American Academy of Family Physicians and the American College of Physicians.

Bonnie Sorenson, Director of Nursing, Southern Nevada Health District.

Comments:
-Agree with all educational outreach.
- Improve exemption laws. Too easy to "opt out." What does religious exemption or personal conviction mean?
-More research on evidence based practice on reaching targeted populations.
-Better marketing and implementation strategies with new vaccines.

Lynn Trefren, Nurse Manager, Tri-County Health Department, Aurora, Colorado

Goal 3: Support informed vaccine decision-making by the public, providers, and policy-makers	• Enhance communication with stakeholders and the public to more rapidly inform them (within _X_ days) about urgent and high-priority vaccine and vaccine preventable disease issues (e.g., outbreaks, supply shortages, vaccine safety concerns).	Too fast is as much of a problem is too slow and in the past trying to get information out fast has resulted in confusion – as part of a local public health agency we have at times heard things on the news or at the same time as the public announcement which gives us no time to prepare for questions.
Comments in column three from: Lynn Trefren, RN, MSN Nurse Manager Immunization Program Tri-County Health Department 303-363-3042	• __X__ % of the public will report that they are satisfied with how their health care provider answers their questions about the benefits and risks of vaccines by Y (year).	If providers were compensated adequately for the cost of vaccines and administration they would be more able to spend time answering questions – initial evaluation should be setting a baseline unless one exists
	• __X__% of the public will report they have access to information which allows them to make informed vaccination decisions for themselves or their children by Y (year).	Good quality information needs to be available by Google search or on YouTube – take advantage of information sources people are using and this will be successful.
	• __X__% of health care providers will report that they have access to accurate and complete information	No specific comment

	about vaccine benefits and risks and are able to adequately answer questions of parents and patients by Y (year).	
	• __X__ % of key decision- and policy-makers will report they have access to vaccine benefits, risks, and costs to make informed decisions about vaccine policy by Y (year).	An important goal, but not my area of expertise
	• By Y (year) all health professional schools and training programs will include vaccine and vaccine-preventable disease content in their curricula, and assess students' and trainees' knowledge.	This is critical – I hope it will be within five years.
	• By Y (year) all relevant health professional certifying examinations will include vaccine and vaccine preventable disease questions.	Again, within five years is my vote.

Amy Wishner, MSN, RN, Director, EPIC - Immunization; Curriculum Development, EPIC - Developmental Screening, PA Chapter, American Academy of Pediatrics (PA AAP)

Education – providers need to be educated based on the complexity of vaccine issues, the schedule, medical assistants immunizing, disease epidemiology, and always emerging "hot topics." Education is also needed for the public to address the increasing number of vaccine-hesitant or refusing families.

Goal 4 Comments: Ensure a stable supply of recommended vaccines, and achieve better use of existing vaccines to prevent disease, disability, and death in the United States

Dr. Jon Abramson, Wake Forest University, former member, Advisory Committee on Immunization Practices, former chair, Committee on Infectious Diseases, American Academy of Pediatrics

1) Page 12- goal 4, 2nd bullet: I think that we should specifically state that 100% of infants and children should report no barriers to immunization (if the 100% is not agreed to by the group writing the National Vaccine Plan then we should at least note that a very high minimum percentage that should be achieved in every state [>90% in every state]). This issue also related to the item to the last suggestion I have made (see 3 below)

3) Page 50- objective 4.2. Below is the last 2 paragraphs of a commentary I am currently in the process of writing for the AAP in response to NVAC's recent recommendations about vaccine financing. The basic issue is that I do not believe that we can achieve many of the goals that are outlined in this plan if we continue the present system that results in vaccines being prioritized on a state by state basis.

"The AAP shares the NVAC's stated goal that every child and adolescent should receive all ACIP-recommended vaccines without financial barriers. The AAP believes that the best way to accomplish this goal is to develop a national vaccine program that does not depend on our current incremental approach. Many of the recommendations that are contained in the 2008 NVAC Finance Working Group document have been made by previous NVAC and IOM committees, but have not been implemented or have not had a major impact on eliminating existing financial barriers in the nation's vaccine financing system. The current immunization program, even with the inclusion of all of the new NVAC recommendations, would continue to be implemented on a state-by-state basis. The efforts to improve the vaccine program would therefore need to continue to be advocated for state-by state. While these efforts could result in an increased number of children that get all ACIP-recommended vaccines in some states, in other states it is likely that little progress towards reaching the above stated goal would occur.

An immunization program that is national in scope is needed to ensure that all children get all ACIP-recommended vaccines. This immunization program could be part of a comprehensive national healthcare program for all children (e.g., Medikids). Alternatively, if a Medikids type program does not become reality than a national immunization program could be developed that is a partnership between the federal and private sector. At the time that NVAC passed its new recommendations the idea of a national immunization program was not felt to be feasible by some on the working group. However, NVAC voted on these recommendations prior to the most recent elections and given the makeup of the new Executive and Legislative Branch the possibility of a national immunization program needs to be reconsidered."

I hope that the group that is drafting the National Plan will consider the idea of supporting a national vaccine plan as a way of achieving the many worthy goals that are noted in the plan.

Kelly Dang, International Community Health Service (ICHS)

Specific to proposed objective 4.2, *Reduce financial and non financial barriers to vaccination, we* recommend that the NPVO strengthen Washington State's ability to purchase and expand access to recommended vaccines (proposed strategy 4.2.4). Currently, Washington State's Universal Childhood Vaccine Program is under threat of elimination due to projected budget deficit of $6 billion. Without the Universal Childhood Vaccine Program, children who are uninsured, underinsured, or who do not qualify under the federal Vaccine for Children program may not receive the recommended vaccinations. We would recommend that the NPVO consider adopting a universal childhood vaccination policy as a long-term goal.

Removing financial barriers to immunization, either by ensuring that out of pocket expenses are not cost prohibitive or by improving the supplies of vaccines so that shortages do not occur, will go a long way in promoting the benefits of immunizations. Moreover, because nearly 70 percent of our patient populations are limited English speakers, we hope that more development and outreach strategies are culturally and linguistically appropriate. These are our top priorities for vaccines and immunization activities.

Dr. Charles Helms, University of Iowa Medical Center

Goal 4 Indicators

All indicators are appropriate, but I cannot personally suggest evidence-based targets.

For those indicators where it applies, I would suggest setting 5 years as a time to show evidence of at least some improvement (e.g., in financial and non-financial barriers). I would require the final target % to be reached no later than the assigned target date. Previously measured baseline levels (%) will be required to demonstrate changes.

Dr. Alan Hinman, Task Force for Child Survival

"…the Plan does not go into any specifics about financing immunizations in this country, which is probably the biggest single issue yet to be resolved. Specific comments are:

Goal 4 – a major deficiency of the draft Plan is that it does not address the need for adequate reimbursement of practitioners for purchase and administration of vaccines or the need to enhance Federal support for immunizations through Section 317 and VFC (or some as-yet-unidentified mechanism). These must be addressed if the Plan is to be really useful."

Anna Johnson-Winegar, PhD, Consultant

Objective 4.1 Ensure consistent and adequate availability of vaccines for the United States.

Comment: Add DOD as a participating agency since they have primary responsibility for the contract for production of anthrax vaccine, which is then subsequently made available for the national stockpile.

Strategy 4.1.1 Increase U.S. licensed vaccine manufacturers to have at least two suppliers of each vaccine antigen recommended for routine use by infants, children, adolescents, and adults.

Comment: What incentives will be made available to commercial manufacturers to achieve this objective?

Comment: Suggest reconsideration of a government owned vaccine production facility. It could operate as a GOCO (government owned- contractor operated entity. Some efforts have been researched along these lines in the past.

Objective 4.9 Enhance immunization coverage of international travelers who are at risk of acquiring vaccine preventable diseases.

Comment: Add DOD and DOS as participating federal agencies since they have employees who are often in international areas and should maintain responsibility for their employees.

S. Michael Marcy, MD, UCLA Harbor Medical Center, and Member, Advisory Committee on Immunization Practices

Goal 4: In a recent survey of pediatricians and family physicians, barriers to HPV vaccination were primarily financial, including lack of insurance coverage (47%-64%); lack of adequate reimbursement (38%-52%), up- front costs for purchase of vaccine (3%-44%). There should be a sentence: "__X__% of providers report no barrier to immunization"

Julie Milstien, University of Maryland

Goal 4 seems to be several separate goals which are not necessarily conducive to being combined. Because of this, there are some strategies that are already put forward in earlier goals (communication, for example).

Objective 4.1 on vaccine availability relies on a number of strategies including vaccine stockpiles. It seems to me that stockpiles are not the best way to address this issue, and the other strategies should be promoted to the exclusion of this one. In addition, the best way to reduce vaccine shortages would be to lower the barriers to licensure of fully safe and effective vaccines that are manufactured in other countries including those outside of the US and Europe. This could be a major focus that could also greatly improve the global vaccine supply situation.

Objective 4.6 is very important, and I wonder, given US experience with this, if it would not be useful to add a strategy to help other countries with this objective as well – the NVP could learn and it could help the supply situation as new vaccine uptake increases.

George Rutherford, MD, University of California, San Francisco, Institute for Global Health

Objective 3.2 et seq and 4.2. The list of non-federal stakeholders should include professional societies, such as the American Academy of Pediatrics, the American Academy of Family Physicians and the American College of Physicians.

Objective 4.1. The lack of market-based solutions to improving the number of vaccine manufacturers is pretty glaring. I do not have a specific recommendation other than it should be considered by the Committee. If there is no way to incentivize private-sector manufacturers and make this market more attractive for investment, should we be moving toward a government-base manufacturing system, as other countries have done (e.g., Mexico and Brazil)?

Objective 4.4. This is an important objective and one that rests fairly squarely on the shoulders of state and local health departments. I would encourage that a new strategy be added that discusses improved federal funding for state and local surveillance and outbreak response.

Objective 4.8. I would specifically include local health agencies in the wording of the objective, i.e., "Enhance the effectiveness of *local,* state and federal immunization programs."

As a former state health officer, I thought the report gave somewhat short shrift to state and local health departments and their roles in surveillance, outbreak response, and vaccine financing and delivery (see comments re: Objective 4.4 above).

Bonnie Sorenson, Director of Nursing, Southern Nevada Health District.

Comments:
-We have had too many shortages of vaccine and interruptions in the Vaccination Schedule.

-Mandated Insurance coverage for all vaccines not subject to any Deductible (Include ERISA Plans)
-More and better development of Immunization Registries
-Allow large metropolitan areas to be directly funded or address "earmarks" to give them more direct access to vaccine and operational support. Their needs are often very different than other small communities in a State.
-Pay for education and counseling about vaccine and not just the cost of vaccines.

Amy Wishner, MSN, RN, Director, EPIC - Immunization; Curriculum Development, EPIC - Developmental Screening, PA Chapter, American Academy of Pediatrics (PA AAP)

U.S. – Simplify the process of ordering and obtaining reimbursement for vaccines. To me, this implies universal purchase for all recommended vaccines for all ages. Work with the pharmas to get them to give better pricing given the increase in quantity purchased. Currently, the process is cumbersome, time-consuming, and financially extremely challenging for individual practices. It would also make a level playing field for all vaccine recipients and not distinguish by insurance status.

Influenza vaccine – the current system does not facilitate or even allow implementation of the current recommendations. The VFC influenza vaccine distribution needs drastic improvement!!! Alternate methods of administration, such as school-based clinics and administration by specialists, needs to be facilitated, encouraged, and funded. Work with school nurses – public health nurses can not do it all - and provide vaccine.
Smaller, regional conferences – fund small, regional immunization education conferences. Even statewide conferences are not accessible by many front-line staff. Physicians and practice staff appreciate non-pharmaceutical educational opportunities in an evening format.

Immunization registries – hold states and other project areas accountable for immunization registry performance, i.e., Pennsylvania. I see how useful the Philadelphia KIDS registry is and do not understand how the PA state SIIS registry remains so dysfunctional.

Goal 5 Comments: Increase global prevention of death and disease through safe and effective vaccination

Dr. Jon Abramson, Wake Forest University, former member, Advisory Committee on Immunization Practices, former chair, Committee on Infectious Diseases, American Academy of Pediatrics

Page 13- goal 5, 4th bullet: I think that influenza vaccine should be added (I was recently appointed as a member of the WHO Strategic Advisory Group of Experts and have now become aware that the topic of influenza vaccine has moved up on the list of vaccines to be considered for global introduction). It is less clear to me that HPV vaccine can be introduced within the time frame of this plan, but I wanted to make sure that the decision not to include it in this bullet was made after careful consideration.

Nicole Bates, Gates Foundation

First, It is encouraging to see a full goal dedicated to global immunization efforts. The objectives are thoughtful. For example, I appreciate Objective 5.2 which encourages the link between immunization delivery and other priority health interventions. I do wonder, however, how so many activities – e.g., surveillance, laboratory networks, economic studies – will be resourced given the U.S.' limited immunization-specific bilateral and multilateral funding. I assume those details will be addressed in the implementation plan that follows this strategic plan.

Second, one could argue that Activity 5.6.7 (develop a global advocacy agenda) could be an explicit objective, since many of the activities that would emerge from the agenda – resource mobilization, political will, public awareness – will be critical to the success of the other Goal 5 objectives and activities. Assuming that the global agenda will remain an activity rather than a full objective, you may make the point that this component is a significant undertaking whose resource requirement does not convey as written. I would encourage the later implementation plan to provide some sense of priority among these many important activities.

Third, the plan references GAVI's role and importance. However, GAVI is not listed as a "non-federal stakeholder" under any of the specific objectives or in Appendix 3 (p.71) that lists stakeholders. This may be because GAVI is a partnership and not an agency. However, it is a primary vaccine delivery platform on which the U.S. relies and specifically funds through an embedded earmark in the State/Foreign Ops appropriations bill. It is likely that GAVI will play a central role in the implementation of the U.S.' global immunization strategy.

Dr. Reginald Finger, former member, Advisory Committee on Immunization Practices

There is an error on page 56. Currently the language reads:

Achieving the United Nations Millennium Development Goals of reducing the under-five mortality rate and the proportion of 1 year-old children immunized against measles by two-thirds will require addressing these challenges.

I think you meant to say we were supposed to reduce the proportion of 1 year-old children UNIMMUNIZED against measles by two thirds.

Dr. Charles Helms, University of Iowa Medical Center

Goal 5 Indicators

All indicators are appropriate, but I cannot personally suggest evidence-based targets. Development of practical indicators will require international consultation, cooperation and data.

Dr. Alan Hinman, Task Force for Child Survival

Goal 5 – although adding a goal on global immunizations is a great thing, why isn't HPV vaccine listed as a specific vaccine to be addressed? Also, why isn't GAVI listed as an important stakeholder?

S. Michael Marcy, MD, UCLA Harbor Medical Center, and Member, Advisory Committee on Immunization Practices

Goal 5: Any discussion of international vaccine development should at least mention Tb and malaria vaccine development, even if the major financial support seems to come from Bill and Melinda Gates.

Julie Milstien, University of Maryland

Although it is understood that this is a plan that involves stakeholders, and their actions are to be held accountable, the NVP is going a little far to consider that the activities of all countries can be included and monitored in the plan. For example, the target "Transmission of wild polio virus will be eradicated by Y year" -- even WHO has difficulty with that one, and they have a little bit more jurisdiction over national vaccine programs around the world than NVP does. It would be more useful to include targets that indicate the work that HHS can do that would assist polio eradication, such as training, laboratory support, epidemiological support, defining standards, etc. This fact is

noted on p56, so why is this difficulty then ignored? Strategies 5.5.1 and 5.5.2 are the kind of strategies that do belong in this plan.

Walter Orenstein, MD, Gates Foundation

On page 39, indicator 1, how do you measure "enhance communication"? Certainly, the time frames are easy to measure.

On page 40, last two indicators – "all" is tough to achieve. For example, are you saying that ophthalmologists and neurosurgeons should have immunization questions on their certifying examination? I agree that is a good goal, but should it be focused on primary care providers?

On page 42, strategy 3.1.7 only discusses collecting information on the direct and indirect costs of vaccination. Why not benefits and costs averted?

Page 45 – what is the difference between strategies 3.7.1 and 3.7.2?

Page 57 – I understand the desire to have a year by which polio will be eradicated. But that is running counter to what is now going on with the effort, which is basically saying it may take longer than expected but we need to achieve the goal. The problem is we have failed to meet a number of milestones including the original year 2000 and Rotary's 2005. Can we just say polio will be eradicated and then one can look at any given timeframe as to whether the goal has been achieved or not? In the absence of a global date, I think it is problematic for a date to appear in a US plan.

A major issue I did not see addressed was better measurement of immunization coverage. This is a hot issue in Global Immunization, especially with the recent paper by Chris Murray from the Institute for Health Metrics Evaluation at the University of Washington, charging that reported estimates were inflated and that GAVI had overpaid many countries for their performance. I think what is needed is to evaluate current tools to assess coverage, validate them (e.g., serosurveys for tetanus antitoxin to compare with maternal histories or records, hepatitis B surface antibody with negative tests for antigen and core antibody, etc). Further, should we be doing surveys in a different way? Thus I would recommend either a strategy or objective such as: "Improve the measurement of immunization coverage to assure it accurately reflects population immunity levels induced by vaccination".

One thing that surprised me in looking over some GAVI documents is the apparent lack of a standard metric for evaluating whether different vaccines are "good buys". How about under objective 5.3, adding in a strategy: "Evaluate standard metrics to be used in assessing whether new and improved vaccines represent a cost-effective investment"? In this way, one might look at cost/DALY averted as a potential standard or years of potential life lost. I'm no economist and this should be run by someone more familiar than me. But just like we use cost/QALY gained in the US to judge cost-effectiveness, I

think some similar process would be helpful globally. Obviously, a big problem is having the critical data to calculate such metrics. But that could be another strategy – to collect those data.

George Rutherford, MD, University of California, San Francisco, Institute for Global Health

Goal 5 is missing a sure thing. I would strongly encourage the inclusion of *Haemophilus influenzae* type b vaccine, a vaccine that we know works and has virtually eliminated this disease in the United States, to the list of indicators under the fourth bullet.

Bonnie Sorenson, Director of Nursing, Southern Nevada Health District.

Comments:
-Provide more assistance to large urban areas that have a regular influx of transient and foreign born individuals into their communities.
-Outreach to these populations is costly.
-Better delivery systems and vaccine marketing implementation in high risk areas.

Comments on Appendices:

Walter Orenstein, MD, Gates Foundation

I would urge you to include in an appendix, the legislation establishing the National Vaccine Program (NVP). When I think about how little I referred to the plan, while I was at the Centers for Disease Control and Prevention (CDC), what strikes me is the plan had nothing to do with any benefits to our program. No resources were associated with it. The original legislation had certain amounts that were authorized to be appropriated but never were. It would be interesting to adjust those amounts for today's dollars and look at the gap between authorization and appropriation.

On page 64, is that a 68% reduction in measles cases or in estimated measles deaths? It's not clear whether that is from 1994 or some other period. In fact for a number of the items in this appendix, it is not clear what time frame, both beginning and ending, the data refer to.

Complete Comments by Stakeholder Sector – Individuals

Dr. Jon Abramson, Wake Forest University, former member, Advisory Committee on Immunization Practices, former chair, Committee on Infectious Diseases, American Academy of Pediatrics

Overall I think the plan is very good. The following comments are for your group's consideration:

1) Page 12- goal 4, 2nd bullet: I think that we should specifically state that 100% of infants and children should report no barriers to immunization (if the 100% is not agreed to by the group writing the National Vaccine Plan then we should at least note that a very high minimum percentage that should be achieved in every state [>90% in every state]). This issue also related to the item to the last suggestion I have made (see 3 below)

2) Page 13- goal 5, 4th bullet: I think that influenza vaccine should be added (I was recently appointed as a member of the WHO Strategic Advisory Group of Experts and have now become aware that the topic of influenza vaccine has moved up on the list of vaccines to be considered for global introduction). It is less clear to me that HPV vaccine can be introduced within the time frame of this plan, but I wanted to make sure that the decision not to include it in this bullet was made after careful consideration.

3) Page 50- objective 4.2. Below is the last 2 paragraphs of a commentary I am currently in the process of writing for the AAP in response to NVAC's recent recommendations about vaccine financing. The basic issue is that I do not believe that we can achieve many of the goals that are outlined in this plan if we continue the present system that results in vaccines being prioritized on a state by state basis.

"The AAP shares the NVAC's stated goal that every child and adolescent should receive all ACIP-recommended vaccines without financial barriers. The AAP believes that the best way to accomplish this goal is to develop a national vaccine program that does not depend on our current incremental approach. Many of the recommendations that are contained in the 2008 NVAC Finance Working Group document have been made by previous NVAC and IOM committees, but have not been implemented or have not had a major impact on eliminating existing financial barriers in the nation's vaccine financing system. The current immunization program, even with the inclusion of all of the new NVAC recommendations, would continue to be implemented on a state-by-state basis. The efforts to improve the vaccine program would therefore need to continue to be advocated for state-by state. While these efforts could result in an increased number of children that get all ACIP-recommended vaccines in some states, in other states it is likely that little progress towards reaching the above stated goal would occur.

An immunization program that is national in scope is needed to ensure that all children get all ACIP-recommended vaccines. This immunization program could be part of a comprehensive national healthcare program for all children (e.g., Medikids). Alternatively, if a Medikids type program does not become reality than a national

immunization program could be developed that is a partnership between the federal and private sector. At the time that NVAC passed its new recommendations the idea of a national immunization program was not felt to be feasible by some on the working group. However, NVAC voted on these recommendations prior to the most recent elections and given the makeup of the new Executive and Legislative Branch the possibility of a national immunization program needs to be reconsidered.”

I hope that the group that is drafting the National Plan will consider the idea of supporting a national vaccine plan as a way of achieving the many worthy goals that are noted in the plan.

Jon [Abramson, MD]

Nicole Bates, Gates Foundation

Thanks for the opportunity to review the draft Strategic National Vaccine Plan. Three specific comments follow.

First, It is encouraging to see a full goal dedicated to global immunization efforts. The objectives are thoughtful. For example, I appreciate Objective 5.2 which encourages the link between immunization delivery and other priority health interventions. I do wonder, however, how so many activities – e.g., surveillance, laboratory networks, economic studies – will be resourced given the U.S.’ limited immunization-specific bilateral and multilateral funding. I assume those details will be addressed in the implementation plan that follows this strategic plan.

Second, one could argue that Activity 5.6.7 (develop a global advocacy agenda) could be an explicit objective, since many of the activities that would emerge from the agenda – resource mobilization, political will, public awareness – will be critical to the success of the other Goal 5 objectives and activities. Assuming that the global agenda will remain an activity rather than a full objective, you may make the point that this component is a significant undertaking whose resource requirement does not convey as written. I would encourage the later implementation plan to provide some sense of priority among these many important activities.

Third, the plan references GAVI’s role and importance. However, GAVI is not listed as a “non-federal stakeholder” under any of the specific objectives or in Appendix 3 (p.71) that lists stakeholders. This may be because GAVI is a partnership and not an agency. However, it is a primary vaccine delivery platform on which the U.S. relies and specifically funds through an embedded earmark in the State/Foreign Ops appropriations bill. It is likely that GAVI will play a central role in the implementation of the U.S.’ global immunization strategy.

Kelly Dang, International Community Health Service (ICHS)

On behalf of International Community Health Service (ICHS), I am writing to submit comments on the draft National Vaccine Plan that was released in 2008. Thank you for the opportunity to submit comments to the National Vaccine Advisory Committee in advance of the Committee's meeting on February 6, 2009. I understand that there will be another opportunity for ICHS to submit additional public comments through a Federal Register notice that will be published soon. ICHS is a community health center committed to providing culturally relevant, accessible and affordable primary care services to the Asian Pacific Islanders (API) and other members of our community. In 2007 ICHS served nearly 16,000 unduplicated patients. As a federally qualified community health center, our clinic staff serves patients who are limited-English speakers and often are unfamiliar with the health benefits and risks of vaccinations.

Below are our comments to the draft National Vaccine Plan (2008):
• Goal 3: Supporting informed vaccine decision-making by the public, providers, and policymakers.

In general, we support the goal of improving the accuracy and timeliness of communication and dissemination of information to the public, providers, and policy-makers. Specific to the proposed objective 3.1 of *improving communication and education efforts,* we would recommend that the proposed strategies include conducting research that is culturally appropriate and in the language of linguistically-isolated communities (proposed strategy 3.1.2). In addition, we would recommend that any development, testing of educational strategies to enable the public audiences about the risks and benefits when making immunization decisions, and assessment of the communication materials also be done in a culturally appropriate and in the language of linguistically-isolated communities (proposed strategy 3.1.3; 3.1.4; 3.1.5).

We believe that culturally appropriate and an in-language approach to research, development, and assessment of communication materials is important because language can be a barrier to participation and understanding. Studies have shown that those who live in linguistically-isolated communities have a low level of risk awareness and tends to under-utilize preventive care. For example, the Office of Minority Health reports that Asian Pacific Islander adults are 30 percent less likely to ever have received the pneumococcal vaccine as compared to non-Hispanic white adults. Also, Vietnamese immigrants have the highest prevalence for chronic infection with hepatitis B, but tend to have low levels of knowledge about HBV vaccines.

Specific to proposed objective 3.4, *Increase public awareness of vaccine preventable diseases and benefits and risks of vaccines and immunization, especially among populations at risk under immunization,* we would recommend that NPVO recognize and include the role of community health centers as the best resource to disseminate educational materials to parents and adolescents about the benefits and risks of vaccines (proposed strategy 3.4.1). For example, our community health center has dedicated staffs who speak Vietnamese, Chinese, Tagalog, Mien, and Korean, to perform outreach to the

Asian Pacific Islander community about chronic disease and other health care issues. This approach has worked well as a way of keeping our patient population informed and healthy. We would recommend that NPVO consider exploring funding opportunities so that ICHS and other community health centers like ours can leverage existing community health outreach efforts to educate our patient population about the benefits and risks of vaccinations.

Also, we would recommend that NPVO and the Vaccine For Children Program work together to offer web-based information on vaccine preventable diseases and the benefits and risks of vaccines in multi-languages (proposed strategy 3.4.2). Currently, web-based information is only available in English. In order to reach as many audience groups as possible and to make dissemination of information as convenient as possible, NPVO should present information in different languages - Vietnamese, Tagalog, Korean, Chinese, Spanish and Russian.

• Goal 4: Ensure a stable supply of recommended vaccines, and achieve better use of existing vaccines
Specific to proposed objective 4.2, *Reduce financial and non financial barriers to vaccination, we* recommend that the NPVO strengthen Washington State's ability to purchase and expand access to recommended vaccines (proposed strategy 4.2.4). Currently, Washington State's Universal Childhood Vaccine Program is under threat of elimination due to projected budget deficit of $6 billion. Without the Universal Childhood Vaccine Program, children who are uninsured, underinsured, or who do not qualify under the federal Vaccine for Children program may not receive the recommended vaccinations. We would recommend that the NPVO consider adopting a universal childhood vaccination policy as a long-term goal.

Removing financial barriers to immunization, either by ensuring that out of pocket expenses are not cost prohibitive or by improving the supplies of vaccines so that shortages do not occur, will go a long way in promoting the benefits of immunizations. Moreover, because nearly 70 percent of our patient populations are limited English speakers, we hope that more development and outreach strategies are culturally and linguistically appropriate. These are our top priorities for vaccines and immunization activities.

Please do not hesitate to contact me at kellyd@ichs.com should you have additional questions or concerns regarding this letter.

Sincerely,
Kelly Dang
Policy Analyst

Dr. Reginald Finger, former member, Advisory Committee on Immunization Practices

Thanks for the opportunity to comment on the draft plan. All in all, it looks very comprehensive, well-written, and certainly builds on past successes. I'm gratified to be reminded at how far the whole immunization enterprise has come since I sat on the Grantee Working Group in 1994.

The action steps are very general in nature, and I think this must be by design. For instance, there is not a lot of detail about such things as specific vaccine safety research projects, specific enhancements to VPD surveillance, and specific plans to move the IIS system ahead from where it is now, including communication of information from the IISs between the states. I assume these kinds of specifics will come later in other documents.

There is an error on page 56. Currently the language reads:

Achieving the United Nations Millennium Development Goals of reducing the under-five mortality rate and the proportion of 1 year-old children immunized against measles by two-thirds will require addressing these challenges.

I think you meant to say we were supposed to reduce the proportion of 1 year-old children UNIMMUNIZED against measles by two thirds. :=)

Thanks!

[Dr.] Reg[inald Finger]

Dr. Charles Helms, University of Iowa Medical Center

Input on Draft Strategic National Vaccine Plan

(1) ***Comments on priorities for the National Vaccine Plan for a ten year period:***

(a) What do you recommend be the top priorities for vaccines and the immunization enterprise in the United States and globally?

The five broad goals of the draft plan and their associated objectives and strategies reflect accurately, and in a balanced fashion, the top priorities for vaccines and the immunization enterprise in the US and globally.

The draft Plan puts forward in its five broad goals and associated objectives and strategies a road map that will stimulate innovation and safety in vaccine development and improve reliability and productivity in the immunization enterprise in the US. Enhanced vaccine innovation and safety, coupled with improved reliability and productivity of the US immunization enterprise will stimulate success and progress globally.

(b) Why are those priorities most important to you?

See (1) (a) above.

I recognize that the five broad goals themselves are each individually important in achieving success and progress in the US and appear to have no particular relative priority. However, I believe the presentation of the broad goals of the Plan would better facilitate public understanding and support if the current order of goals were changed to the following order: 1) Support informed vaccine decision making, etc., 2) Ensure a stable supply, etc., 3) Enhance safety, etc., 4) Develop new and improved vaccines, and 5) Increase global prevention of disease, etc.

(2) ***Comments on the goals, objectives and strategies for the National Vaccine Plan for the ten year period:***

(a) Please comment on the existing goals, objectives, and strategies in the draft Plan and suggest specific goals, objectives and strategies to be added to it, if the existing ones do not address your concerns.

From my perspective as a physician and academic stakeholder, the goals, objectives and strategies that are important are included in the Plan and well presented.

(b) Are there any goals, objectives or strategies in the draft Plan that should be discarded or revised? Which ones and why?

See (1) (b) above. I believe public understanding and support of the Plan would be facilitated by revision as suggested above.

(3) ***Comment on the indicators for the National Vaccine Plan for the ten year period:***

(a) Please comment on the existing indicators in the draft Plan, and suggest target estimates for them.

Goal 1 Indicators:

High priority evidence-based vaccine targets should be achieved within one year—okay.

Identify 4 candidate vaccines from those targets identified in the 1 year process above.

Advance the same 4 along the R&D and advanced clinical trials pathways.

Advance 4 delivery strategies to improve effectiveness, etc. of new or improved vaccines.

Goal 2 Indicators:

All indicators are appropriate, but I cannot personally suggest evidence-based targets.

Goal 3 Indicators

All indicators are appropriate, but I cannot personally suggest evidence-based targets.

For those indicators where it applies, I would suggest setting 5 years as a time to show evidence of at least some improvement (e.g., in stakeholder-public vaccine communication). I would require the final target % to be reached no later than the assigned target date. Previously measured baseline levels (%) will be required to show progress.

Goal 4 Indicators

All indicators are appropriate, but I cannot personally suggest evidence-based targets.

For those indicators where it applies, I would suggest setting 5 years as a time to show evidence of at least some improvement (e.g., in financial and non-financial barriers). I would require the final target % to be reached no later than the assigned target date. Previously measured baseline levels (%) will be required to demonstrate changes.

Goal 5 Indicators

All indicators are appropriate, but I cannot personally suggest evidence-based targets. Development of practical indicators will require international consultation, cooperation and data.

(b) Please suggest new indicators to be added to it, if the existing ones do not address your concerns. Are there any indicators in the draft Plan that should be discarded or revised? Which ones and why?

None to suggest.

(4) ***Comments on stakeholders' roles in the National Vaccine Plan:***

(a) Please identify which stakeholders you believe should have the responsibility for enacting the objectives and strategies listed in the draft Plan, as well as for any new objectives and strategies you suggest. Specifically identify roles your organization can play in the Plan.

The Plan identifies Federal and Non-federal stakeholders beneath each of the proposed objectives. This poses a potentially complex situation in assigning responsibility for Plan implementation and oversight.

A centralized oversight process should be developed to identify which and how Federal/Non-Federal stakeholders will take the operational lead to organize and oversee data collection for Goals. I think the NVPO/NVAC could be wisely used to oversee and assure progress. NVPO/NVAC could also develop a centralized process to assemble and present periodic Plan progress reports.

Dr. Alan Hinman, Task Force for Child Survival

I've reviewed the draft National Vaccine Plan and have the following "high level" comments. I'm copying my colleagues on the IDSA National and Global Public Health committee for their information (and possible agreement). I looked primarily at the goals and objectives, rather than the strategies and indicators. Overall, I think this is a very good start on the Plan and I'm particularly gratified that you've added a specific goal related to global immunizations, a topic that was not addressed in the first Plan. None of the objectives seem inappropriate and I think you've identified most of the important objectives. That said, I do have some comments, the main one of which is that the Plan does not go into any specifics about financing immunizations in this country, which is probably the biggest single issue yet to be resolved. Specific comments are:

Goal 1 – given the rapid development of genomic medicine, shouldn't there be an objective about assessing individual immunological characteristics and tailoring vaccines to match them?

Goal 2 – shouldn't there be a specific objective about expanding the Vaccine Safety Datalink project to increase the proportion of the population included?

Goal 3 – given the success of the United Kingdom in assessing public attitudes and perceptions about immunizations, shouldn't there be an objective about developing a comparable system in the United States?

Goal 4 – a major deficiency of the draft Plan is that it does not address the need for adequate reimbursement of practitioners for purchase and administration of vaccines or the need to enhance Federal support for immunizations through Section 317 and VFC (or some as-yet-unidentified mechanism). These must be addressed if the Plan is to be really useful.

Goal 5 – although adding a goal on global immunizations is a great thing, why isn't HPV vaccine listed as a specific vaccine to be addressed? Also, why isn't GAVI listed as an important stakeholder?

I hope these comments are helpful. Please let me know if you have questions.

Cheers,
Alan [Hinman, MD, MPH]

Anna Johnson-Winegar, PhD, Consultant

1. Objective 1.2 Support research to develop new vaccine candidates and improve current vaccines to prevent infectious diseases, particularly those determined to be priorities.

Strategy 1.2.1 Advance research and development toward new and/or improved vaccines that prevent diseases, including those that protect against emerging, re-emerging, and important biodefense related pathogens.

Comment: What is the implementation plan for gaining additional resources for these research and development projects? How will advances in research be shared across Federal agencies and Departments?

3. Objective 1.4 Support development of vaccine candidates and the scientific tools needed to evaluate these candidates for licensure.

   Comment: The relevant DOD organization for this is the Chemical-Biological Medical Systems Office- a component of the Joint Program Executive Office for Chemical and Biological Defense. The Defense Threat Reduction Agency (DTRA) does not have authority for advanced development and licensure issues.

4. Objective 4.1 Ensure consistent and adequate availability of vaccines for the United States.

   Comment: Add DOD as a participating agency since they have primary responsibility for the contract for production of anthrax vaccine, which is then subsequently made available for the national stockpile.

5. Strategy 4.1.1 Increase U.S. licensed vaccine manufacturers to have at least two suppliers of each vaccine antigen recommended for routine use by infants, children, adolescents, and adults.

   Comment: What incentives will be made available to commercial manufacturers to achieve this objective?
   Comment: Suggest reconsideration of a government owned vaccine production facility. It could operate as a GOCO (government owned- contractor operated entity. Some efforts have been researched along these lines in the past.

6. Objective 4.9 Enhance immunization coverage of international travelers who are at risk of acquiring vaccine preventable diseases.

   Comment: Add DOD and DOS as participating federal agencies since they have employees who are often in international areas and should maintain responsibility for their employees.

Julie Leask, National Centre for Immunisation Research & Surveillance, Australia

(2) *Comments on priorities for the National Vaccine Plan for a ten-year period:* What do you recommend be the top priorities for vaccines and the immunization enterprise in the United States and globally? Why are those priorities most important to you?

Comment 1
Informing providers, rapidly and in a coordinated manner, is a priority. If good uptake of safe vaccines is one of the plan's (implicit) goals, providers need to be supported for two reasons: First is that providers are central to vaccine risk communication with the public. Much evidence points to the importance of providers as an information source and influence on public attitudes. Evidence from shifts in public attitudes to vaccines shows that media stories may abound but it is only once a controversy shifts the confidence of providers that we see a downturn in vaccination rates, presumable because we no longer have committed and confident providers. Second is evidence from surveys that show providers share the same general concerns about vaccines in similar proportions to the public. Hence, they are a key 'audience' in terms of effective communication. **Providers are the conduit for vaccine recommendations and their implementation. For every provider informed about vaccination and reassured, we inform a larger number of parents.** Hence this strategy is also more cost effective.

(2) *Comments on the goals, objectives, and strategies for the National Vaccine Plan for a ten-year period:* Please comment on the existing goals, objectives, and strategies in the draft Plan, and suggest specific goals, objectives, or strategies to be added to it, if the existing ones do not address your concerns. Are there any goals, objectives or strategies in the draft strategic Plan that should be discarded or revised? Which ones, and why?

Comment 1
There could be more linkage between the goals and objectives. At present it is not clear which objective relates to which goal or how they are related.

Comment 2
There are also multiple objectives. These could be thematically condensed to make the plan more manageable.

Comment 3
Tensions may arise between the explicit goal to support informed decision making and the implicit goal of maintaining high vaccination rates (as reflected in Objective 3.4 and the existence of mandates). Sometimes these can conflict, particularly when campaigns and persuasion are necessary to improve rates and no longer can claim a benign imparting of the evidence.

It is possible the plan assumes that the goal of supporting decision making leads to an informed decision that always results in vaccination, hence satisfying both goals. Two problems arise with this assumption. First is the assumption that those doubting or declining vaccination are merely wrong and if better educated and informed, will see the error of their ways and embrace immunisation. In fact, vaccine skepticism is often about deeply held values and wider tensions where science is either not trusted or used in ways to support one's existing views. More information and education is unlikely to work. Strategies need to be more sophisticated and informed by diverse fields. Persuasion may be necessary and if so, the goal of maintaining high immunisation rates should be explicit. Ethical guidelines exist in the health promotion literature on when appeals to threat (such as generating concern about a vaccine-preventable disease) are acceptable.

The second limitation of the informed decisions model is when a vaccine risk-benefit profile reverses for an individual (e.g., OPV and VAP during a time of country-wide elimination). Then, informed individuals seeking to maximise their own utility would rationally not vaccinate, leaving the population and future generations vulnerable to disease re-introduction – a Tragedy of the Commons. What happens if this occurs with another vaccine close to elimination and no safer alternative is available? The rhetoric of informed decision making is individualistic in its assumptions. **The plan, while embracing informed decision making, should make provisions for understanding and better communicating *population* benefit.**

To address these tensions in communication to the public, role distinction may help: to give the role of persuasion to government and vaccine advocacy groups and the role of giving risk/benefit information to providers and independent organisations funded by government.

Comment 4

The plan could be strengthened by an explicit strategy for engaging with vaccine-skeptical groups in the public arena – when, how and whom.

(3) *Comments on the indicators for the National Vaccine Plan for a ten-year period:* Please comment on the existing indicators in the draft Plan, and suggest target estimates for them. Please suggest new indicators to be added to it, if the existing ones do not address your concerns. Are there any indicators in the draft strategic Plan that should be discarded or revised? Which ones, and why?

Comment 1

Indicator 2 _X___ % of the public will report that they are satisfied with how their health care provider answers their questions about the benefits and risks of vaccines by Y (year).

The language of this goal depicts the public as passive recipients of information (see comment 3 above). It also assumes clinical communication fits easily into a question answer format. An alternative could be
X___ % of the public will report that they are satisfied with how their health care provider **communicates with them** about the benefits and risks of vaccines by Y (year).

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S. Michael Marcy, MD, UCLA Harbor Medical Center, and Member, Advisory Committee on Immunization Practices

Pg 4, paragraph 2, lines 4 and 5: Somebody cut-&-pasted" and forgot to erase one of the "and abroad"s

The first 25+ pages were a lot of admin-speak, but the expanded discussion on the five goals was thoughtful, thorough and terrific!! Just a couple of thoughts:

Goal 1: I am delighted that there was mention of new adjuvants and new delivery systems. However, these goals are intended to cover 10 years of activities regarding immunization. It would seem appropriate to mention therapeutic vaccines vs infectious (e.g. Herpes group, hepatitis B, papillomavirus) and non- infectious (e.g.a variety of cancers) conditions. Perhaps, even prophylactic vaccines against non-infectious conditions (e.g. diabetes type 1, Alzheimer's, drug addiction, smoking).
By well before 2019 you can be sure that Objective 1.2 will be directed to "prevent and treat infectious and non-infectious diseases"

Goal 4: In a recent survey of pediatricians and family physicians, barriers to HPV vaccination were primarily financial, including lack of insurance coverage (47%-64%); lack of adequate reimbursement (38%-52%), up- front costs for purchase of vaccine (3%-44%). There should be a sentence: "__X__% of providers report no barrier to immunization"

Goal 5: Any discussion of international vaccine development should at least mention Tb and malaria vaccine development, even if the major financial support seems to come from Bill and Melinda Gates.

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H. Cody Meissner, MD, Chief, Pediatric Infectious Disease, Tufts Medical Center

Professor of Pediatrics, Tufts University School of Medicine

I have read through this document and found it to be thoughtful, timely and carefully written. It covers an enormous amount of information and provides an excellent overview of the critical areas relating to vaccines.

Cody

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Julie Milstien, University of Maryland

This represents a lot of work and I congratulate you on your effort. I have a few comments that might improve it and make it easier to implement effectively:

1. Nowhere do I see any indication that the vaccine plan is going to be concerned with vaccine logistics, especially vaccine thermostability and the cold chain, which can affect vaccine safety, efficacy, and coverage. I have heard over the years, and most recently in December, statements from public health advisors that they are losing lots of vaccines by freezing, and that, in addition, they would welcome the use of Vaccine Vial Monitors to help assure that the vaccines are being distributed and stored properly. When was the last time there was a general cold chain review in the US? How will vaccines that are quite temperature sensitive, like rotavirus vaccines, be handled? How will vaccine administrators be able to handle new vaccines with differing characteristics? Why does the vaccine industry in the US place so little emphasis on basic thermostability characteristics?
2. It is not particularly clear from the plan, who will assure the monitoring of implementation of the plan? Is it to be done only by the individual stakeholders, and/or by NVP and/or by some outside body such as the IOM? How is this to be done? How frequently? This needs to be clearly understood and agreed, or in fact there is no need to have a plan.
3. Your plan suffers from the fact that what you are calling “Indicators” are not indicators. In most cases they are targets, although in some cases they are activities or strategies. An indicator would be, for example, “number of new

candidate vaccines identified," or the "existence of an updated Vaccine Table." To be able to develop an implementation plan, the strategic plan needs to be clear, consistent, and able to be monitored.

4. I wonder about the objective 2.4 on improving causality assessments. Although this would be desirable, I wonder if it is possible by the strategies outlined, especially for a rare AEFI with one or only a few case reports. I believe the emphasis should be on good epidemiological methods, and the strategies should say this.
5. Goal 4 seems to be several separate goals which are not necessarily conducive to being combined. Because of this, there are some strategies that are already put forward in earlier goals (communication, for example).
6. Objective 4.1 on vaccine availability relies on a number of strategies including vaccine stockpiles. It seems to me that stockpiles are not the best way to address this issue, and the other strategies should be promoted to the exclusion of this one. In addition, the best way to reduce vaccine shortages would be to lower the barriers to licensure of fully safe and effective vaccines that are manufactured in other countries including those outside of the US and Europe. This could be a major focus that could also greatly improve the global vaccine supply situation.
7. Objective 4.6 is very important, and I wonder, given US experience with this, if it would not be useful to add a strategy to help other countries with this objective as well – the NVP could learn and it could help the supply situation as new vaccine uptake increases.
8. Although it is understood that this is a plan that involves stakeholders, and their actions are to be held accountable, the NVP is going a little far to consider that the activities of all countries can be included and monitored in the plan. For example, the target "Transmission of wild polio virus will be eradicated by Y year" -- even WHO has difficulty with that one, and they have a little bit more jurisdiction over national vaccine programs around the world than NVP does. It would be more useful to include targets that indicate the work that HHS can do that would assist polio eradication, such as training, laboratory support, epidemiological support, defining standards, etc. This fact is noted on p56, so why is this difficulty then ignored? Strategies 5.5.1 and 5.5.2 are the kind of strategies that do belong in this plan.

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Walter Orenstein, MD, Gates Foundation

The remarks below are my own and do not necessarily represent those of the Bill & Melinda Gates Foundation (BMGF).

I really like this version and the five goals. Given my current job, I appreciate especially having a separate Global Immunization Role.

I would urge you to include in an appendix, the legislation establishing the National Vaccine Program (NVP). When I think about how little I referred to the plan, while I was at the Centers for Disease Control and Prevention (CDC), what strikes me is the plan had nothing to do with any benefits to our program. No resources were associated with it. The original legislation had certain amounts that were authorized to be appropriated but never were. It would be interesting to adjust those amounts for today's dollars and look at the gap between authorization and appropriation.

Second, the plan offered nothing to me in competing for resources within my agency. For example, an initiative to help meet Healthy People objectives could help in supporting the fact that we were attempting to achieve a national goal and gave some advantages against those with initiatives not mentioned in Healthy People. Thus, it would be important to get some language in the implementation phase that any vaccine-related initiative would be judged against the plan.

Finally, at some stage, the seriousness with which the plan is taken should be compatible with the budget devoted to each element. I recognize that budgeting by strategy or objective may be difficult. But if feasible, I think it could be helpful in determining what the real priorities are. At the moment, the plan is very comprehensive and it's difficult to see whether certain sections are more important than others. The plan implies everything is equally important.

On page 17, last paragraph – I find the wording confusing. I think the plan should take into account infectious diseases and all of their outcomes including cancers. Would the prevention of post-infectious measles encephalitis not be considered a burden to prevented, even though it is an immunological reaction to the infectious agent? What I believe you are saying is that immunomodulators, including vaccines, which may be used to prevent and treat non-infectious diseases, will not be considered. This is a better way, in my opinion, of saying that.

On page 25, bottom of the page are a set of goal indicators. As you can imagine, identifying X candidates and advance Y priority vaccines, will be quite difficult.

On page 26, last Goal 1 indicator – do you really think we will have candidates to be tested within 6 months of identification of the need for a vaccine – perhaps for influenza when we are using a technology we have, only changing the antigen slightly. I may be out of touch but to have a vaccine for human clinical trials within 6 months of identification of the pathogen and need for a vaccine does not seem realistic.

The figure on page 27 includes “vaccine research” and “vaccine development”. It seems somewhere in the text, those terms should be defined so people can understand how they are different. I wonder if it would be better to use the term “vaccine discovery” rather than “research” since the former is in greater and greater use. Regardless, I think it is important to list out what might be included in discovery, such as identification of the pathogen, understand pathogenesis, determination of the components of a protective immune response etc.

On page 28, you discuss a process for making priorities. It’s not until Goal 5, that I understood that the prioritization process not only included vaccines for domestic use but vaccines for use in developing countries as well. I think this should be clarified here. Should a regular review of priorities be undertaken (e.g., every 5 years or more frequently, if needed)?

With regard to vaccine safety, one critical component of our old system was dismantled, the review by the Institute of Medicine (IOM). While not everyone was supportive of those reviews, I found them extremely helpful and I used the IOM reviews to argue that our policies with regard to safety were influenced by independent review by a group of experts. I would recommend that one of the strategies include: “Establish an independent group of experts to review major vaccine safety concerns including evaluation of the evidence that a vaccine or vaccines were causing particular adverse events and recommendations for future actions including further research”.

On page 39, indicator 1, how do you measure “enhance communication”? Certainly, the time frames are easy to measure.

On page 40, last two indicators – “all” is tough to achieve. For example, are you saying that ophthalmologists and neurosurgeons should have immunization questions on their certifying examination? I agree that is a good goal, but should it be focused on primary care providers?

On page 42, strategy 3.1.7 only discusses collecting information on the direct and indirect costs of vaccination. Why not benefits and costs averted?

Page 45 – what is the difference between strategies 3.7.1 and 3.7.2?

Page 57 – I understand the desire to have a year by which polio will be eradicated. But that is running counter to what is now going on with the effort, which is basically saying it may take longer than expected but we need to achieve the goal. The problem is we have failed to meet a number of milestones including the original year 2000 and Rotary’s 2005. Can we just say polio will be eradicated and then one can look at any given timeframe as to whether the goal has been achieved or not? In the absence of a global date, I think it is problematic for a date to appear in a US plan.

A major issue I did not see addressed was better measurement of immunization coverage. This is a hot issue in Global Immunization, especially with the recent paper by Chris Murray from the Institute for Health Metrics Evaluation at the University of Washington, charging that reported estimates were inflated and that GAVI had overpaid many countries for their performance. I think what is needed is to evaluate current tools to assess coverage, validate them (e.g., serosurveys for tetanus antitoxin to compare with maternal histories or records, hepatitis B surface antibody with negative tests for antigen and core antibody, etc). Further, should we be doing surveys in a different way? Thus I would recommend either a strategy or objective such as: "Improve the measurement of immunization coverage to assure it accurately reflects population immunity levels induced by vaccination".

One thing that surprised me in looking over some GAVI documents is the apparent lack of a standard metric for evaluating whether different vaccines are "good buys". How about under objective 5.3, adding in a strategy: "Evaluate standard metrics to be used in assessing whether new and improved vaccines represent a cost-effective investment"? In this way, one might look at cost/DALY averted as a potential standard or years of potential life lost. I'm no economist and this should be run by someone more familiar than me. But just like we use cost/QALY gained in the US to judge cost-effectiveness, I think some similar process would be helpful globally. Obviously, a big problem is having the critical data to calculate such metrics. But that could be another strategy – to collect those data.

On page 64, is that a 68% reduction in measles cases or in estimated measles deaths? It's not clear whether that is from 1994 or some other period. In fact for a number of the items in this appendix, it is not clear what time frame, both beginning and ending, the data refer to.

George Rutherford, MD, University of California, San Francisco, Institute for Global Health

Thank you for your e-mail of January 13, 2009, requesting my review and suggestions for the recently released U.S. National Vaccine Plan. In the interest of full disclosure, I am responding to this as an individual and not as Chair of the American Academy of Pediatrics' Section on Epidemiology, a position from which I stepped down last October. I have copied the current chair in case she wants to weigh in, as well.

You asked me to comment on four areas. I have arranged my comments accordingly. I would, however, like to start with some general comments. I thought the report was very well done but noted that there were no numeric targets that appeared in Table 1 or elsewhere in the report. I assume these are currently being debated. Secondly, I applaud the use of the Institute of Medicine report to guide many of the goals, objectives and strategies of the report; I think it provides an extra layer of credibility. Thirdly, I also strongly applaud the inclusion of Goal 5 and think that internationally is where substantial benefits can be achieved in the relatively short term using products that are

already on the shelf. Fourthly, while I realize prevention of infectious diseases in non-human animals is beyond the scope of this report, I would suggest including it somewhere near page 17 where other disclaimers appear.

(1) Comments on priorities for the National Vaccine Plan for a ten-year period: What do you recommend be the top priorities for vaccines and the immunization enterprise in the United States and globally? Why are those priorities most important to you?

I think the plan captures major priorities well, and I have only a few suggestions.

- **Vaccines for regional high-morbidity diseases**. With regard to vaccine development, I would ask the Committee not to forget diseases that occur regionally, such as coccidioidomycosis, histoplamosis and Lyme disease that are not usually considered high-priority targets. Coccidioidomycosis, for instances, causes far more severe morbidity in the United States than other diseases that are considered high priorities. Internationally, *Neisseria meningitidis* type b is an obvious target for new and improved vaccines and will have domestic use, as well.

- **NIH funding for vaccine development.** While NIH has provided some funding for vaccine development, I would encourage it to be specifically included in the Clinical and Translational Sciences Initiatives.

- **Multiple-adjuvant vaccines.** As a pediatrician, I would like to reinforce the need for continued development of multiple adjuvant vaccines that make office-based immunization so much easier.

(2) Comments on the goals, objectives, and strategies for the National Vaccine Plan for a ten-year period: Please comment on the existing goals, objectives, and strategies in the draft Plan, and suggest specific goals, objectives, or strategies to be added to it, if the existing ones do not address your concerns. Are there any goals, objectives or strategies in the draft strategic Plan that should be discarded or revised? Which ones, and why?

- **Objective 1.1 or 1.2.** Explicitly add multiple-adjuvant vaccines that use existing vaccine antigens as a specific type of “new” vaccines.

- **Objective 3.1.** Simplify Important Information Forms (see below)

- **Objective 3.2 et seq and 4.2.** The list of non-federal stakeholders should include professional societies, such as the American Academy of Pediatrics, the American Academy of Family Physicians and the American College of Physicians.

- **Objective 4.1.** The lack of market-based solutions to improving the number of vaccine manufacturers is pretty glaring. I do not have a specific recommendation other than it should be considered by the Committee. If there is no way to incentivize private-sector manufacturers and make this market more attractive for

investment, should we be moving toward a government-base manufacturing system, as other countries have done (e.g., Mexico and Brazil)?

- **Objective 4.4.** This is an important objective and one that rests fairly squarely on the shoulders of state and local health departments. I would encourage that a new strategy be added that discusses improved federal funding for state and local surveillance and outbreak response.

- **Objective 4.8.** I would specifically include local health agencies in the wording of the objective, i.e., "Enhance the effectiveness of *local,* state and federal immunization programs."

(3) Comments on the indicators for the National Vaccine Plan for a ten-year period: Please comment on the existing indicators in the draft Plan, and suggest target estimates for them. Please suggest new indicators to be added to it, if the existing ones do not address your concerns. Are there any indicators in the draft strategic Plan that should be discarded or revised? Which ones, and why?

- Goal 3 indicators seemed overly defensive to me. I would suggest that the indicators focus on public's knowledge of the benefits of vaccination rather than leaning so heavily on adverse events and risks. Moreover, I think under objective 3.3 making Important Information Forms shorter, more readable and less intimidating could be an important strategy.

- Goal 5 is missing a sure thing. I would strongly encourage the inclusion of *Haemophilus influenzae* type b vaccine, a vaccine that we know works and has virtually eliminated this disease in the United States, to the list of indicators under the fourth bullet.

(4) Comments on stakeholders roles in the National Vaccine Plan: Please identify which stakeholders you believe should have responsibility for enacting the objectives and strategies listed in the draft Plan, as well as for any new objectives and strategies you suggest. Specifically identify roles your organization can play in the Plan.

- As a former state health officer, I thought the report gave somewhat short shrift to state and local health departments and their roles in surveillance, outbreak response, and vaccine financing and delivery (see comments re: Objective 4.4 above).

- I have also noted above the need to include professional societies in many of the stakeholder lists. While I recognize the dominance and role of the health insurance industry, I encourage you to seek out practitioners' voices. They are the ones, and not the health insurers, that are delivering immunizations and providing much of the front-line education to parents and patients.

I hope these comments are helpful. I was delighted to get your note and would be happy to discuss any of these points with you or your staff if additional clarification is needed.

Best wishes,

George W. Rutherford, M.D., A.M., FAAP, FACPM
Salvatore Pablo Lucia Professor of Epidemiology, Preventive Medicine and Pediatrics
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Director, Institute for Global Health

Bonnie Sorenson, Director of Nursing, Southern Nevada Health District.

Vaccine Priorities

- The Cost of Vaccines has not kept pace with reimbursement
- Disease Surveillance (Adverse Event Monitoring)
- Education Strategies

Response to the Goals

Goal 1: Develop new and improved vaccines.
Comments:
-Ability to create more combination vaccines that allow fewer injections and compress the number of visits needed to complete a series.
-Delivery systems other than injection (Ex: Nasal).

Goal 2: Enhance the safety of vaccines and vaccination practices.
Comments:
-Improved Surveillance for Adverse Event Reporting especially as it relates to new vaccines.
-Expand the collaboration between providers, labs, etc.
-Who can report Adverse Events by use of an electronic reporting system.
-Better data collection system when new vaccines are introduced to monitor effectiveness and adverse event reporting in a timely manner.

Goal 3: Support informed vaccine decision-making by the public, providers, and policy-makers.
Comments:
-Agree with all educational outreach.
- Improve exemption laws. Too easy to “opt out.” What does religious exemption or personal conviction mean?
-More research on evidence based practice on reaching targeted populations.
-Better marketing and implementation strategies with new vaccines.

Goal 4: Ensure a stable supply of recommended vaccines and achieve

better use of existing vaccines to prevent disease, disability and death in the United States.

Comments:
-We have had too many shortages of vaccine and interruptions in the Vaccination Schedule.
-Mandated Insurance coverage for all vaccines not subject to any Deductible (Include ERISA Plans)
-More and better development of Immunization Registries
-Allow large metropolitan areas to be directly funded or address "earmarks" to give them more direct access to vaccine and operational support. Their needs are often very different than other small communities in a State.
-Pay for education and counseling about vaccine and not just the cost of vaccines.

Goal 5: Increase global prevention of death and disease through safe And effective vaccination.

Comments:
-Provide more assistance to large urban areas that have a regular influx of transient and foreign born individuals into their communities.
-Outreach to these populations is costly.
-Better delivery systems and vaccine marketing implementation in high risk areas.

Lynn Trefren, Nurse Manager, Tri-County Health Department, Aurora, Colorado

Goal 3: Support informed vaccine decision-making by the public, providers, and policy-makers Comments in column three from: Lynn Trefren, RN, MSN Nurse Manager Immunization Program Tri-County Health Department 303-363-3042	• Enhance communication with stakeholders and the public to more rapidly inform them (within _X_ days) about urgent and high-priority vaccine and vaccine preventable disease issues (e.g., outbreaks, supply shortages, vaccine safety concerns).	Too fast is as much of a problem is too slow and in the past trying to get information out fast has resulted in confusion – as part of a local public health agency we have at times heard things on the news or at the same time as the public announcement which gives us no time to prepare for questions.
	• __X__ % of the public will report that they are satisfied with how their health care provider answers their questions about the benefits and risks of vaccines by Y (year).	If providers were compensated adequately for the cost of vaccines and administration they would be more able to spend time answering questions – initial evaluation should be setting a baseline unless one exists
	• __X__% of the public will report they have access to information which allows them to make informed vaccination decisions for themselves or their children by Y (year).	Good quality information needs to be available by Google search or on YouTube – take advantage of information sources people are using and this will be successful.

	• __X__% of health care providers will report that they have access to accurate and complete information about vaccine benefits and risks and are able to adequately answer questions of parents and patients by Y (year). • __X__ % of key decision- and policy-makers will report they have access to vaccine benefits, risks, and costs to make informed decisions about vaccine policy by Y (year). • By Y (year) all health professional schools and training programs will include vaccine and vaccine-preventable disease content in their curricula, and assess students' and trainees' knowledge. • By Y (year) all relevant health professional certifying examinations will include vaccine and vaccine preventable disease questions.	No specific comment An important goal, but not my area of expertise This is critical – I hope it will be within five years. Again, within five years is my vote.

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(1) Comments on priorities for the National Vaccine Plan for a ten-year period: What do you recommend be the top priorities for vaccines and the immunization enterprise in the United States and globally? Why are those priorities most important to you?

U.S. – Simplify the process of ordering and obtaining reimbursement for vaccines. To me, this implies universal purchase for all recommended vaccines for all ages. Work with the pharmas to get them to give better pricing given the increase in quantity purchased. Currently, the process is cumbersome, time-consuming, and financially extremely challenging for individual practices. It would also make a level playing field for all vaccine recipients and not distinguish by insurance status.

Education – providers need to be educated based on the complexity of vaccine issues, the schedule, medical assistants immunizing, disease epidemiology, and always emerging "hot topics." Education is also needed for the public to address the increasing number of vaccine-hesitant or refusing families.

Influenza vaccine – the current system does not facilitate or even allow implementation of the current recommendations. The VFC influenza vaccine distribution needs drastic improvement!!! Alternate methods of administration, such as school-based clinics and administration by specialists, needs to be facilitated, encouraged, and funded. Work with school nurses – public health nurses can not do it all - and provide vaccine.
Smaller, regional conferences – fund small, regional immunization education conferences. Even statewide conferences are not accessible by many front-line staff. Physicians and practice staff appreciate non-pharmaceutical educational opportunities in an evening format.

Immunization registries – hold states and other project areas accountable for immunization registry performance, i.e., Pennsylvania. I see how useful the Philadelphia KIDS registry is and do not understand how the PA state SIIS registry remains so dysfunctional.

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