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Planning and priority setting for vaccine development and immunization[☆]

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ABSTRACT

We review a sequence of strategic planning efforts over time in the United States, all involving processes to prioritize new vaccine candidates. The Institute of Medicine of the National Academies of Sciences, Engineering, and Medicine has been involved in three priority setting processes, each using different metrics and methodologies: infant mortality equivalents (1985–1986), cost-effectiveness (2000), and more recently, the implementation of a software system based on a broader multi-criteria systems approach that can include either of the earlier metrics among other various considerations (2015). The systems approach offers users the flexibility to select, combine, rank, weigh and evaluate different attributes representing their perspectives, assumptions, and particular needs. This approach also overcomes concerns relating to the previous single-metric ranking approaches that yielded lists that, once published, were static, and could not readily accommodate new information about emerging pathogens, new scientific advances, or changes in the costs and performance features of interventions. We discuss the rationale and reasoning behind the design of this multi-criteria decision support approach, stakeholder feedback about the tool, and highlight the potential advantages from using this expanded approach to better inform and support vaccine policies.

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1. Plans and priorities

“Plans are worthless,” Dwight Eisenhower once said, “but planning is everything. There is a very great distinction because when you are planning for an emergency you must start with this one thing: the very definition of ‘emergency’ is that it is unexpected, therefore it is not going to happen the way you are planning” [1]. So it is with infectious diseases, especially when a virulent strain emerges or re-emerges to affect public health and policy.

The bubonic plague killed well over half of the populations in European nations between 1346 and 1353 [2]. In London and Newcastle, over 10,000 people died in 1853, the year before John Snow’s famous pump handle action quelled an 1854 cholera outbreak with only 600 dead [3]. In 1918–1919, a deadly influenza outbreak killed upwards of 50 million people [4]. Even in recent

years, the world has seen panic over potential pandemics. In 2002–2003, an outbreak of the SARS virus paralyzed international travel. The FIFA Women’s World Cup events were shifted from China to the United States. Beijing closed schools for weeks. Canada quarantined over 5000 people. Universities in the U.S. banned foreign student enrollment from affected areas [5]. Most recently, following a major Ebola outbreak in West Africa with a case fatality rate of 40%, the desire to develop and deploy an effective Ebola vaccine became stronger, only after previous efforts were shelved a decade earlier for various reasons, including lack of manufacturers’ interest. The recent Zika outbreak provides anew a demonstration of the suddenness with which new threats can emerge and the need for a way to analyze their importance against other infectious diseases.

Clearly—demonstrating Eisenhower’s perceptiveness—none of these outbreaks could have been predicted in time, location, or severity. What then can strategic planning and priority setting do for the world of infectious diseases and for vaccine development and deployment? Our review of these issues begins with the 2010 National Vaccine Plan issued by the Department of Health and Human Services (HHS; Table 1)—the most recent planning effort in the U.S. on these crucial issues that has five key elements [6]:

[☆] The views expressed in this article are those of the authors and not necessarily of the National Academies of Sciences, Engineering, and Medicine or the U.S. Department of Health and Human Services.

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Table 1

2010 national vaccine plan: U.S. department of health and human services. Source: National Vaccine Plan Priorities for Implementation [2].

Goals

1. Develop new and improved vaccines
2. Enhance the vaccine safety system
3. Support communications to enhance informed vaccine decision making
4. Ensure a stable supply of, access to, and better use of recommended vaccines in the United States
5. Increase global prevention of death and disease through safe and effective vaccination

Priorities

- A. Develop a catalog of priority vaccine targets of domestic and global health importance (**Goal 1**)
- B. Strengthen the science base for the development and licensure of new vaccines (**Goals 1 and 2**)
- C. Enhance timely detection and verification of vaccine safety signals and develop a vaccine safety scientific agenda (**Goal 2**)
- D. Increase awareness of vaccines, vaccine-preventable diseases, and the benefits/risks of immunization among the public, providers, and other stakeholders (**Goal 3**)
- E. Use evidence-based science to enhance vaccine-preventable disease surveillance, measurement of vaccine coverage, and measurement of vaccine effectiveness (**Goal 4**)
- F. Eliminate financial barriers for providers and consumers to facilitate access to routinely recommended vaccines (**Goal 4**)
- G. Create an adequate and stable supply of routinely recommended vaccines and vaccines for public health preparedness (**Goal 4**)
- H. Increase and improve the use of interoperable health information technology and electronic health records (**Goal 4**)
- I. Improve global surveillance for vaccine-preventable diseases and strengthen global health information systems to monitor vaccine coverage, effectiveness, and safety (**Goal 5**)
- J. Support global introduction and availability of new and under-utilized vaccines to prevent diseases of public health importance (**Goal 5**)

1. Develop new and improved vaccines.
2. Enhance the vaccine safety system.
3. Support communications to enhance informed vaccine decision-making.
4. Ensure a stable supply of, access to, and better use of recommended vaccines in the United States.
5. Increase global prevention of death and disease through safe and effective vaccination.

The 2010 plan emerged from discussions among many federal agencies led by the HHS National Vaccine Program Office, including input from the National Vaccine Advisory Committee and a study by the Institute of Medicine (IOM) [7]. Table 2 shows the goals and objectives from the precursor 1994 National Vaccine Plan [8]. Comparison of the 1994 and 2010 plans highlights several differences. The 1994 plan focused heavily on traditional health care systems and practices, and did not specifically mention financial incentives to any participants. Inclusion of the words “for priority diseases” in Goal 1.1 provided the only direction towards any strategic priority setting [8].

The 2010 plan, in comparison to earlier plans, has a much broader focus: for example, it includes both a catalog of priority vaccine targets and creation of a vaccine safety agenda [6]. Further, the 2010 plan elevated the importance of evidence-based surveillance of disease incidence, vaccine coverage and effectiveness. This specifically recognizes the importance of global surveillance and information gathering, in light of the increasingly rapid international transmission of disease seen in the late 20th and early 21st centuries. Finally, it raises the importance of interoperable health information technology and electronic health records, and urges increased support for vaccines for global health. By contrast, with the exception of two words (“and abroad”), the 1994 plan focuses on domestic interventions.

In summary, the 2010 plan has a much wider focus and greater understanding of the high inter-connectivity of the various moving parts in the world of infectious diseases and immunization than did the 1994 plan. To be fair, fifteen years of advanced research and new technologies helped to inform the 2010 plan, information that was not available earlier.

The National Vaccine Plan is not the only participant in this broad discussion. In the United States, the National Vaccine Advisory Committee (NVAC) regularly recommends ways to achieve optimal prevention of infectious diseases in humans through vaccine development and to prevent adverse vaccine reactions. Further, the Advisory Committee on Immunization Practices (ACIP)

of the Centers for Disease Control and Prevention (CDC) regularly publishes guidance about deployment of existing vaccines in the U.S., using processes that include disease burden, vaccine safety, cost-effectiveness analysis and other metrics [9].

The U.S. is not unique in considering these issues. Many other international groups also deal with issues involving various aspects of planning and prioritizing, including the Strategic Advisory Group of Experts (SAGE) [10] and the Product Development for Vaccines Advisory Committee (PD-VAC) [11], both within the World Health Organization. The Vaccine Investment Strategy of GAVI (updated every five years, most recently in 2013) is oriented towards determining which vaccines that are already available or likely to be available in the near future that GAVI would support [12]. Similar roles are played at the national level in many countries, e.g., the Joint Committee on Vaccination and Immunisation (JCVI) for the U.K. National Health Service that uses cost-effectiveness as a formal metric for its analysis [13]. The WHO PD-VAC focuses entirely on advising the development of vaccines in Phase 2 and beyond dealing with highly burdensome diseases in low and middle income countries, while the other groups generally focus on advising about uses of existing or nearly-available vaccines.

The 2010 National Vaccine Plan specifically called for a vaccine research and development prioritization effort, a request that followed two earlier prioritization efforts by the IOM. In the next section, we review the priority lists created by the IOM in 1984–1985, in 2000, and then the most recent—and novel—systems-based approach to this challenge developed between 2010 and 2015 at the request of the National Vaccine Program Office.

2. Planning and prioritization

Planning encompasses more than prioritizing, which is necessary but insufficient to create a functional strategic plan. Plans also include (among other things) consideration of how to reach the desired end points, the mechanisms to finance those operations, consideration of contingencies, and methods to measure progress against the plans. Priority setting typically comes early on, if not as the first step. The 2010 plan included a call for a prioritization catalog, for which NVPO commissioned the IOM to create and test ways to prioritize among new preventive vaccines. As we discuss later in this article, the approach that emerged—Strategic Multi-Attribute Ranking Tool for Vaccines (SMART Vaccines)—not only provides a unique way to set priorities, but also provides a tool

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