



Editorial

Developing the next generation of vaccinologists

Vaccines are among the most effective public health interventions in decreasing infectious disease morbidity and mortality. In the United States and Western Europe, for example, most vaccine-preventable diseases have declined in excess of 95–99% compared to the pre-vaccine era. Even in some of the world's most economically disadvantaged developing countries the implementation of specific new vaccines (such as *Haemophilus influenzae* type b conjugate) has drastically diminished the burden of severe and fatal disease caused by the targeted pathogens [1]. Some previous scourges have been eradicated by vaccines (smallpox), while others have been dramatically curtailed (polio, measles, mumps, rubella, others) by the use of vaccines.

Such vaccines are conceived of, developed by, and vaccine policy developed by vaccinologists. Vaccinology is a medical discipline that synthesizes inputs from various basic sciences (e.g., microbiology, molecular biology, immunology, cell biology, genomics) clinical medicine (e.g., clinical trials expertise, pediatrics, internal medicine), public health (e.g., epidemiology and biostatistics) and social sciences (communications, public policy, anthropology). Vaccinologists typically have particular expertise in several of these areas, but what makes them vaccinologists is their knowledge of how all these components contribute collectively to the development, pre-licensure evaluation, implementation and public policy, and post-licensure measurement of the impact of vaccines and vaccination. The vaccinologist, whatever her/his sub-discipline(s), holds a clear overview of how the pieces come together to create a sum that exceeds the contribution of any single component. Indeed, a perusal of some of the giants of vaccinology of the past half century, identifies individuals with varying backgrounds and specific areas of expertise who nevertheless had broad knowledge of many areas. For example, Maurice Hilleman, a Ph.D. microbiologist had expertise in virology, immunology and the design of clinical trials. Albert B. Sabin and Jonas Salk were physicians who excelled in basic microbiologic research and were masters at translating their discoveries into disease prevention products for humans. Stanley Plotkin is an icon of pediatric infectious diseases, as well as an accomplished virologist. These examples of vaccinology leaders are offered to show the varied backgrounds yet the commonality of the breadth of knowledge of these giants of vaccinology. It is also notable that some of these individuals worked solely in the public sector, others spent their careers in vaccine industry and others bridged both.

Recognizing that vaccinologists may derive from varying backgrounds, it is fair to ask how young scientists, clinicians, epidemiologists and others can be formally trained to assure that there will exist a continuing pipeline of vaccinologists for the future. In our view, two critical pillars to such training are (1) an in-depth

exposure of trainees to the multi-disciplinary aspects of vaccinology; (2) academic preparation in basic and clinical sciences. Further, it is important to state that vaccinology training can be undertaken in both public sector and industry settings. This raises a dilemma however, as it is clear that future vaccine development is leveraged on the development of an adequate cohort of upcoming vaccinologists. An equally pressing matter in this regard is that the science supporting vaccine development efforts has become more complex, with ever increasingly sophisticated high throughput technologies requiring esoteric bioinformatic strategies to understand the massive amount of data that can now be generated. Combined with increasingly complex and hyper-variable organisms as vaccine targets (e.g., HIV, HCV, HSV, malaria, dengue, and other viral, bacterial and parasitic targets), it is apparent that the public health demands that a well-trained and technologically sophisticated cadre of future vaccinologists be developed. Unfortunately, such needs have not yet been adequately recognized or explicitly articulated, nor plans and funding put into place to achieve these desired results.

Within the United States for example, only one formally organized academic program in vaccine sciences exists. This program is an NIH-funded (T32) vaccinology training grant at the Center for Vaccine Development (CVD) at the University of Maryland. The program (which typically involves 3–4 years of post-doctoral training), includes three distinct tracks. One track provides training in basic research involving the stage of discovery and preparation of vaccine candidates through animal model evaluation and accumulation of the pre-clinical data necessary to support an Investigational New Drug application to the U.S. FDA to undertake “first in humans” clinical trials. A second track involves training in the design and performance of Phase 1 and 2 clinical trials, including intensive didactic and practical instruction in Good Clinical Practices, maintenance of INDs and strategies and options for paths to licensure. A third track involves the design and performance of large-scale Phase 3 pre-licensure efficacy trials and Phase 4 post-licensure studies to assess the impact and safety of vaccines when implemented in large populations; this track includes training in data management, analysis and biostatistics. The NIH-funded Vaccinology Training Program interacts with other activities within CVD, such as basic research projects supported by R01 and other grants, clinical trials of various vaccines supported by a NIH Vaccine and Treatment Evaluation Unit, N01 research contracts, various basic and translational projects supported by the Middle Atlantic Regional Center for Excellence in Biodefense and Emerging Infectious Diseases Research, and field epidemiologic and vaccine field trial studies supported by the Bill and Melinda Gates Foundation,

including at CVD's field units in Mali, Chile and Malawi. A limitation of the T32 grant is its restriction to U.S. citizens or permanent residents. Therefore, trainees from abroad are supported by other sources of training funds.

Another outstanding international example outside a formal university setting is the International Vaccine Institute (IVI) in Seoul, Korea. This organization was initiated by UNDP in the early 1990s with the vision of being the world's only legally constituted, international organization devoted exclusively to research and development of new generation vaccines for developing countries. Today, the IVI is a free-standing international organization established under treaty, with 40 countries and the WHO as signatories to its establishment agreement. Situated on the campus of Seoul National University, the IVI conducts research in vaccine discovery, vaccine development, vaccine production, and vaccine introduction, and leverages its location by collaborating with university faculty and students. In addition to its research mission, the IVI conducts didactic and hands-on training of vaccine professionals from developing countries, focusing on disciplines along the complete vaccine discovery–development–delivery continuum, including an annual International Advanced Courses on Vaccinology in the Asia-Pacific Region, now approaching its eleventh consecutive year.

A further example of post-graduate education is a unique course in Advanced Vaccinology that runs for several weeks each year, and offers an intensive overview of all aspects of vaccinology. Notable features of this course that is directed by Dr. Paul Henri Lambert of the University of Geneva are the extraordinary worldwide faculty that it gathers from public sector and industry each year to share their experience with the trainees.

An informal poll by one of us (GAP) of vaccine meetings, national and international vaccine advisory boards, vaccine manufacturing research departments, and vaccine clinical trialists suggests that the average age of vaccinologists in the US is somewhere in the late 40s to late 50s. Such demographics portend likely disruptions over the next 10–20 years and beyond, as the need for vaccines, both prophylactic and therapeutic, continues to grow. It is important to the field of vaccinology and the public health that well-trained physicians and scientists holistically informed about vaccine development and delivery be developed. How will these needs be met as the consequences of infectious and chronic diseases becomes more serious in an aging population and exacts larger and larger tolls on dwindling health care budgets? Clearly the answer begins with the workforce needed to meet these challenges. Other possible solutions we offer for discussion include the following:

1. Making federal funding available to increase the number of academic departments offering formal graduate tracks in vaccine sciences.
2. Giving visibility and acknowledging the need in federal planning and budget efforts for the next generation of vaccinologists. An example might be the unique program developed some years ago by the FDA and NIH in response to a perceived shortage of clinical pharmacologists. NIH provided funding jointly with the FDA to develop training programs for post-doctoral scientists to pursue clinical pharmacology training in the university setting, with rotations into FDA laboratories. The program was successful in providing visibility, interest, and opportunity to the field and successfully attracted a cadre of scientists and physicians who pursued this career path. Similar programs could and should be developed for vaccinologists.
3. Increasing programs that allow support for pre- and post-doctoral fellows to train on existing federally funded vaccine

grants and contracts. Similar to programs that already exist, specific programs and funding could be made available to attract students into laboratories of federally funded vaccine investigators, expose them to the field, and provide training and career pathway opportunities. In a similar vein, programs like the NIH K-award series could be developed with a specific focus on providing funding for those pursuing careers in vaccinology.

4. Partnering with Pharma to make training grants and laboratory rotations available to qualified students in order to raise visibility and interest in vaccinology as a career path. In this regard, it would be in industry's mid- and long-range advantage to fund such programs.
5. Requiring formal vaccine modules or course work in medical, nursing, pharmacy, and other health professions schools, in order to give visibility and exposure to students during the formative years of their academic development.

The public health needs, particularly in an era where the demographics of much of the world indicate an exponentially aging population structure, demands that an adequate workforce of vaccinologists be available. The increasing number of vaccine targets, important issues such as immunosenescence and the development of vaccines for non-infectious diseases (e.g., cancer, other chronic diseases such as atherosclerosis, diabetes, dental caries, addictions, Alzheimer's disease, and others), and the need to decrease health care expenditures while increasing quality and health care outcomes; requires that the nations of the world have an adequate supply of physicians and scientists willing to devote their professional careers to vaccinology. Meeting this need starts with providing the funding, faculty, and clear career pathways for bright and capable students. If not already too late, it is our hope that these needs can be anticipated in advance, and appropriate steps taken to insure that the professional workforce needed will be available. Like disease where it is better to prevent than to treat; by analogy it is better to anticipate the problem of an inadequate workforce and prevent calamity, than to wait until the problem is upon us and react, too late, out of necessity.

Reference

- [1] Sow SO, Tapia MD, Diallo S, Keita MM, Sylla M, Onwuchekwa U, et al. Haemophilus influenzae type B conjugate vaccine introduction in Mali: impact on disease burden and serologic correlate of protection. *Am J Trop Med Hyg* 2009;80(6 (June)):1033–8.

Gregory A. Poland*
Mayo Clinic, Rochester, MN, USA

Myron M. Levine
Maryland School of Medicine Center for Vaccine
Development, Baltimore, MD 21201, USA

John D. Clemens
International Vaccine Institute, Seoul,
Republic of Korea

* Corresponding author.

E-mail addresses: poland.gregory@mayo.edu
(G.A. Poland), mlevine@medicine.umaryland.edu
(M.M. Levine), jclemens@IVI.INT (J.D. Clemens)

22 October 2010