UNIVERSITY of MARYLAND
SCHOOL OF MEDICINE
INSTITUTE FOR GLOBAL HEALTH

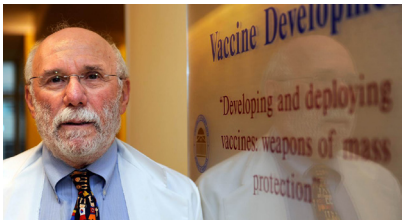
Center for Vaccine Development (CVD)

Harnessing the Power of Vaccines

The CVD at the University of Maryland School of Medicine (UM SOM) in Baltimore, MD has worked nationally and internationally for 40 years to develop, test, and deploy vaccines against infectious diseases to aid the world's underserved populations. The CVD is an academic enterprise engaged in the full range of vaccinology, including basic science research, vaccine development, pre-clinical and clinical evaluation, and post-marketing field studies. Since its inception in 1974, the CVD has created and tested vaccines against cholera, typhoid fever, paratyphoid fever, non-typhoidal salmonella disease, shigellosis (bacillary dysentery), Escherichia coli diarrhea, nosocomial pathogens, tularemia, influenza, and other infectious diseases. Our faculty and global staff includes molecular biologists, microbiologists, immunologists, internists, pediatricians, epidemiologists, malariologists, and biostatisticians.

Kathy Neuzil, MD, MPH
CVD Director

Our Capabilities and their Contribution to our Mission:



Myron Levine, MD, DTPH
Founding Director

- Disease burden/epidemiology: To prioritize the most needed vaccines
- Molecular pathogenesis: To understand the infections causing these diseases
- Antigen discovery: To design optimally-effective vaccines
- Pre-clinical vaccine development: To create safe and effective vaccines
- Phase I, II, III, IV vaccine trials: To evaluate safety and efficacy in humans
- Human challenge trials: To understand infectious process and measure efficacy
- Immune correlates of protection: To understand how best to stimulate immunity
- Vaccine policy: To introduce effective vaccines into underserved populations
- Training: To train the next generation of vaccine developers

Locations: The CVD has research, outpatient, and in-patient challenge facilities in Baltimore, MD and field sites in Mali, Malawi, Myanmar, and Chile. In addition, we pursue time-limited field studies in Africa, Asia, and Latin America. Examples of countries where we work include Pakistan, India, Thailand, Kenya, The Gambia, Mozambique, Bangladesh, Ethiopia, Peru, Indonesia, Costa Rica, Honduras, Panama, and Venezuela.

Dr. Karen Kotloff preparing for sample collection.

Mission: The mission of the CVD is to prevent disease and save lives through the development and delivery of vaccines against infectious diseases of global importance, including enteric diseases, influenza, Zika, and Ebola.

Dr. Sztein and a CyTOF mass cytometer[1].

[1]State-of-the-art instrument used at the CVD to advance understanding of immunological mechanisms of protection from infectious diseases.

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Success Stories: Some Examples

Vaccine Development: On June 10, 2016, the U.S. Food and Drug Administration (FDA) approved an oral cholera vaccine invented and developed by researchers at the CVD. The vaccine, Vaxchora, is a single-dose oral, live attenuated cholera vaccine for use in adults 18 to 64 years of age traveling to cholera-affected areas. Vaxchora is the only vaccine available in the U.S. for protection against cholera and the only single-dose vaccine for cholera currently licensed anywhere in the world. The Center for Disease Control and Prevention's Advisory Committee on Immunization Practices voted unanimously on June 22, 2016 to recommend the newly FDA-approved cholera vaccine for use in adult travelers to areas with active cholera transmission.

Vaccine Evaluation: In 2014, when the devastating Ebola epidemic struck West Africa, the CVD, at the behest of the World Health Organization, responded. The CVD faculty assisted in the planning and execution of a historic Phase 3 efficacy field trial in Guinea and evaluated two different dosage levels of two experimental Ebola vaccines at CVD-Mali. Data from the Mali trials found the vaccines to be well-tolerated and stimulated strong immune responses in adults in Mali, West Africa and the U.S. Larger trials are underway in adults and children in Mali.

Human Challenge Trials: For certain human-restricted bacterial enteropathogens, animal models were lacking or misleading. In the 1970s/1980s, researchers at the CVD pioneered the development of several human experimental challenge models in community volunteers. These models confirmed pathogenicity, elucidated virulence attributes, characterized immune responses, and identified protective antigens. The models also assessed efficacy of candidate vaccines to guide vaccine development. The recent cholera vaccine licensure was based on efficacy established through a human challenge model.

Diarrheal Disease Etiology

The Global Enterics Multicenter Study (GEMS): GEMS was the largest, most comprehensive study of childhood diarrheal diseases ever conducted in developing countries, occuring in four sites in sub-Saharan Africa and three in South Asia where collectively 80 percent of diarrheal disease deaths occur globally in "under-fives." Despite testing for about 40 pathogens, GEMS showed that four pathogens (rotavirus, Cryptosporidium, heat stable enterotoxin-producing *Escherichia coli*, and *Shigella*) were responsible for almost 50 percent of moderate-to-severe diarrhea. GEMS data have been critical to priority-setting for diarrheal disease control and intervention. A follow-on study, Vaccine Impact on Diarrhea in Africa (VIDA), is on-going at sites in Mali, The Gambia, and Kenya to understand the influence of rotavirus vaccine introduction on diarrheal disease incidence and etiology.

Training: The CVD has trained leading vaccinologists for four decades and holds a T-32 training grant in Vaccinology. Please see our website for further information.

A cholera ward in Bangladesh.

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Dr. Samba Sow consulting on a patient.