

CENTER FOR VACCINE DEVELOPMENT MALI

Informing Decisions and Saving Lives through Research

In 2001, a formal agreement between the Ministry of Health of Mali and the Center for Vaccine Development (CVD) at the University of Maryland, established a unit in Mali. CVD-Mali is dedicated to quantifying the burden of vaccine-preventable diseases, testing the safety, immunogenicity, and efficacy of relevant new vaccines, and training Malian vaccinologists. As a part of the Ministry of Health, CVD-Mali has the opportunity to bring research results to the attention of decision-makers and directly impact public health policy.

Haemophilus Influenza B (Hib) Story

Located in Bamako, the Hôpital Gabriel Touré (HGT) is the single largest government hospital that admits

infants and children with acute medical problems. An admissions survey found approximately 70 percent of children had presumed infections and 21 percent of all children admitted, died.

Prior to 2000, there was no clinical microbiology laboratory to diagnose infections. Using funds from the Bill & Melinda Gates Foundation and Rockefeller Foundation grants, the CVD and CVD-Mali established a clinical microbiology laboratory within HGT and trained a team of Malians as microbiologists and technicians. The staff was trained in Baltimore, MD and on site in Bamako.

In February 2000, the clinical microbiology laboratory at HGT began systematic surveillance for invasive bacterial infections through collection and testing of blood cultures from hospitalized children with fever and sterile body fluid cultures from patients with suspected focal infections. The data revealed an enormous burden of invasive infections due to two vaccine-preventable infections, Hib and pneumococcus, as well as a major burden caused by nontyphoidal Salmonella and seasonal peaks

of meningococcal infections. The data were used by the Malian authorities to introduce Hib vaccine with GAVI financing. In July 2005, Mali introduced Hib conjugate vaccine into its Expanded Immunization Program (EPI).

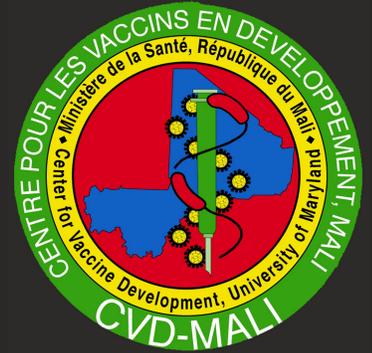
Following introduction,

CVD-Mali investigators monitored the vaccine program with continued surveillance. Three years after introduction, incidence of Hib disease had fallen by approximately 80 percent, which provided powerful feedback on the impact.

The Hib story is one example of how the surveillance activities at CVD-Mali are translated into public health actions that save the lives of Malian infants and children. CVD-Mali's work to quantify the burden of vaccine-preventable diseases has accelerated the introduction of many new vaccines into Mali, including pneumococcal conjugate, meningitis A, rotavirus, and human papillomavirus (HPV).



Dr. Samba Sow, Director General CVD-Mali and Adjunct Professor of Medicine at the University of Maryland School of Medicine



Mission: Prevent, control, and treat endemic and epidemic infectious diseases in Mali, in particular those that are vaccine-preventable, and in the course of doing so, train Malian specialists who will expand this work in the future.



CVD-Mali hosted the 10th African Rotavirus Symposium in June 2016. Hundreds of scientists and health officials from across the globe congregated to discuss "Reaching Every Child with Rotavirus Vaccines."



Arm measurement of child in GEMS study.

Experience and Capability

Research, training, field studies, and pivotal clinical trials for new vaccines

CVD-Mali's capacity for sophisticated, hypothesis-driven research increased with the establishment of research laboratories and enhanced training.

In the pivotal Global Enteric Multicenter Study (GEMS), CVD-Mali conducted population-based surveillance of moderate to severe diarrhea using multiplex polymerase chain reaction assays, immunoassays, and bacteriology. CVD-Mali continues to assess rotavirus vaccine introduction on the incidence and etiology of moderate-to-severe diarrhea in the Vaccine Impact on Diarrhea in Africa (VIDA) study.

From 2012 to 2014, CVD-Mali was a site in Pneumonia Etiology Research in Child Health (PERCH), a multi-country, case-control study to describe the etiology of severe and very severe pneumonia in children under five. Physicians perform lung aspirates and post-mortem biopsies to aid in identifying the cause of pneumonia.

CVD-Mali has a Demographic Surveillance System with a population of about 230,000 people, expanding capacity to perform studies requiring randomized samples or population-based estimates of disease burden. Experience includes monitoring the impact of rotavirus vaccine introduction on rotavirus gastroenteritis, as well as other etiologies of diarrheal disease and intussusception and field surveys, especially coverage surveys.

Training and education is an ongoing priority. CVD-Mali developed a vaccine delivery and management training program and for the past 10 years, has trained workers from the national to the peripheral level of EPI. Training in Good Clinical Practices, Good Clinical Laboratory Practices, and Human Subjects Training has enabled CVD-Mali to engage in high-level research to meet sponsor standards.

The CVD and CVD-Mali screened Malian women to characterize HPV epidemiology and cervical cancer. The results informed data-driven mathematical models for HPV vaccination. The vaccination of over 10,000 girls, ages 9 to 13, is expected to lead to a significant reduction in cervical cancer over the next 20 years.

Child Health and Mortality Surveillance Prevention (CHAMPS):

In June 2016, CVD-Mali was named an initial site in the CHAMPS network. The goal of CHAMPS is to understand and prevent the causes of child mortality.

Meningitis Vaccines: From 2004 to 2013, CVD-Mali conducted clinical trials of MenAfriVac, meningococcal A conjugate vaccine. Data from 8100 participants, infants to adults, contributed to the licensure and introduction of MenAfriVac in 2010. CVD-Mali's ongoing surveillance documented the disappearance of the disease in Mali.

Rotavirus Vaccine: CVD-Mali was one of three sites in sub-Saharan Africa in a multi-center, placebo-controlled Phase 3 trial of the Merck rotavirus vaccine (RotaTeq®). Data from the trial and GEMS supported successful application to GAVI for introduction in early 2014.

Trivalent Inactivated Influenza Vaccine (TIV, Vaxigrip®):

From 2011 to 2014, CVD-Mali performed a Phase IV, prospective, randomized, controlled trial to measure the efficacy, safety, and immunogenicity of TIV in pregnant women and infants. A total of 4193 pregnant women and infants were enrolled and followed for six months after delivery. Influenza vaccination in pregnancy resulted in a 68% reduction in influenza in infants less than four months of age.

Ebola Vaccine: In August 2014, CVD-Mali joined a consortium assembled by the World Health Organization in response to the Ebola epidemic. CVD-Mali conducted the first human trials of ChAd3-EBO-Z in Africa. The data generated informed decisions on the vaccine dose. CVD-Mali continues to conduct Ebola vaccine trials in children and adults.



Mali, a land-locked country in West Africa, is by United Nations criteria the world's 6th least developed country. The annual gross national income per capita is US \$720, the infant mortality rate is ~ 78 per 1000 live births, and the mean life expectancy is 54.6 years.

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Dr. Myron Levine consulting on a patient.