



News digest 6
Q2, 2005

Dear partners, friends, and colleagues,

The following is a summary of recent, current, and upcoming activities at the Meningitis Vaccine Project (MVP). We welcome your comments and suggestions at info@meningvax.org and encourage you to forward this update to friends or colleagues who might be interested in learning about MVP's progress.

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Vaccine Development Activities

- MVP signed a contract with iGATE Clinical Research International (iCRI). iCRI is a contract research organization that will be performing data management and clinical trial monitoring services for MVP clinical studies.
- MVP signed a Cooperative Research and Development Agreement with the US Centers for Disease Control and Prevention (CDC). CDC will develop serological assays that will be used to evaluate immune and functional antibody responses induced by the immunization of clinical trial participants with the meningococcal A conjugate (MenA conjugate) vaccine.
- MVP signed grant agreements with the Navrongo Health Research Centre in Ghana and Swiss Tropical Institute to support research studying the carriage of *Neisseria meningitidis* in northern Ghana.

Clinical Activities

- An investigators meeting, including a workshop on Good Clinical Practice in clinical trials, took place in Mumbai, India, on April 1–2. The meeting was organized by iCRI and Serum Institute of India Limited (SIIL) and was attended by MVP staff and Indian investigators who will be conducting the Phase I study.
- The fourth meeting of the MVP Project Advisory Group (PAG) took place in Ouagadougou, Burkina Faso, on May 5–6. The PAG, chaired by Professor Francis N'Krumah, reviewed and provided recommendations to the MVP clinical plan to qualify the MenA conjugate vaccine. PAG members reviewed the results of several site visits and accepted the proposed selection of two sites (one in Mali, one in The Gambia) for the first Phase II study that is being planned for early 2006.
- After in-house and external review of the vaccine dossier, the Drugs Controller General of India (the Indian National Regulatory Authority) gave clearance to start the Phase I study.
- Ethical clearance was received from two of the three sites' institutional ethics committees and from the Ethical Research Committee at the World Health Organization (WHO).
- All study documents and operational steps were finalized for the Phase I study.
- On May 13, staff from iCRI, SIIL, and MVP attended a one-day workshop on serious adverse events management led by Dr. Katharina Hartmann, head of pharmacovigilance at Berna Biotech Ltd. at the PATH office in Ferney-Voltaire. Dr. Hartmann, who is also a senior lecturer in pharmaceutical sciences at the Institute for Pharmaceutical Sciences in Zurich, Switzerland, serves as a consultant for MVP.

Surveillance Activities

- The WHO Multi-Disease Surveillance Center (MDSC) team in Ouagadougou, Burkina Faso, made country visits to Ethiopia and the Democratic Republic of Congo to assess their preparedness and provide training for the upcoming epidemic season as needed.
- The MDSC team is conducting a retrospective analysis of meningitis data for the past two decades from three countries (Burkina Faso, Mali, and Niger).
- Surveillance data compiled at the MDSC between January 3 and May 15, 2005, show 9,876 confirmed cases of meningitis and 1,519 deaths in countries of the sub-Saharan meningitis belt that are under enhanced meningitis surveillance. Two new districts in Chad reached the epidemic threshold at week 19, bringing the number of epidemic districts for the year 2005 to 15 in the countries under enhanced surveillance.

Epidemiological Research

- Collaboration with a data manager from the WHO Global Atlas has allowed the redesign of the literature database for web posting. The system, once finalized, will enable automatic updates and automatic report generation.

Vaccine Introduction Strategy and Communication

- A workshop on the Introduction of the MenA conjugate vaccine took place in Ouagadougou on May 2–4. Participants discussed a wide variety of issues that are central to comprehensive introduction of a MenA conjugate vaccine in sub-Saharan countries. While participants recognized the strategic importance of large countries like Democratic Republic of Congo, Ethiopia, Nigeria, and Sudan, there was general agreement that introduction should focus on so-called hyperendemic countries such as Burkina Faso, Chad, Mali, and Niger. Recommendations were made as to vaccine formulation and the importance of comprehensive campaigns for 1 to 29 year olds.
- The communication and vaccine introduction team continued collaboration with PATH's Children's Vaccine Program and Stanford University's School of Medicine to develop an Advanced Immunization Management (AIM) e-Learning module on meningococcal meningitis. AIM e-Learning modules are educational tools designed to help national immunization managers and other decision-makers in developing countries make well-informed management and implementation decisions.
- In addition, MVP participated in or made presentations at the Workshop on Strengthening National Regulatory Authorities (NRAs), Ouagadougou, May 21–28; and at the Global Vaccine Research Forum, Salvador de Bahia, Brazil, June 12–16.

Recent Hires

- Mr. Rodrigue Barry joined MVP on May 1 to develop advocacy and social mobilization activities in Africa. A trained journalist with more than 15 years of experience in the field of health communication, Rodrigue Barry is based in Ouagadougou where he most recently served as health information and promotion officer at the country office of the WHO. For a short biography of Rodrigue Barry, please visit <http://www.meningvax.org/team.htm#major>.

That's all for now from the MVP team. Stay tuned for our next news digest (October 2005). We look forward to receiving your comments at info@meningvax.org.

Created in 2001, the Meningitis Vaccine Project is a partnership between WHO and PATH. The mission of MVP is to eliminate epidemic meningitis as a public health problem in sub-Saharan Africa through the development, testing, introduction, and widespread use of conjugate meningococcal vaccines.

For more information on MVP, please visit our website at <http://www.meningvax.org>.