



News digest 7
Q3, 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

- Analytical methods characterizing the meningococcal A conjugate (MenA conjugate) vaccine have been established and are in the process of being validated through the collaboration of Serum Institute of India Ltd. (SIIL), the National Institute for Biological Standards and Control (NIBSC), and the University of Capetown. SynCo BioPartners B.V. prepared a polysaccharide A reference standard from a GMP (good manufacturing practices) lot of polysaccharide that will be used for standardization between laboratories.
- Stability protocols have been developed and approved by all partners. These protocols will be used to study thermostability of the vaccine at 25°C, 37°C, and 45°C.
- Pharmaceutical documentation has been reviewed (standard operating procedures, batch protocol records, and flow diagrams of process and controls) and approved by all partners.
- MVP signed an agreement with the United Kingdom Health Protection Agency (HPA). HPA will develop serological assays that will be used to evaluate immune and functional antibody responses in trial participants immunized with the MenA conjugate vaccine.
- MVP signed clinical site contracts with the Seth G.S. Medical College & King Edward VII Memorial Hospital in Mumbai, India; the T.N. Medical College & B.Y.L. Nair Charitable Hospital in Mumbai, India; and Nizam's Institute of Medical Sciences in Hyderabad, India. These three institutions are doing the Phase I clinical trial of the MenA conjugate vaccine.

Clinical Activities

- Phase I study started in India where a total of 74 subjects aged 18 to 35 years were enrolled. A preliminary report on safety and immunogenicity of the MenA conjugate vaccine should be available by the end of the year.
- The clinical team prepared the synopsis for the first Phase II pivotal study in Africa and submitted the draft document to MVP partners for their review and contribution.
- The MVP team investigated the use of electronic data capture (eDC) for the Phase II clinical trials. eDC is a system that eliminates paper in the data collection process by capturing the data directly into custom-designed electronic databases. MVP anticipates running a pilot of eDC software at potential trial sites in Africa in late 2005.

Surveillance Activities

- The WHO teams and their national partners continued their detailed work on a retrospective analysis of meningitis data for the past two decades from three countries (Burkina Faso, Mali, and Niger).
- Surveillance data compiled at the WHO Multi-Disease Surveillance Center (MDSC) in Ouagadougou, Burkina Faso, between January 3 and July 17, 2005, showed 13,024 confirmed

cases of meningitis and 1,919 deaths in countries of the sub-Saharan meningitis belt that are under enhanced meningitis surveillance. Cumulative surveillance data from the same time period show 13 alert districts and 10 epidemic districts in the countries of the belt. Considering that during the same period in 2004 there were 34 alert districts and 17 epidemic districts, 2005 was a very quiet year in the meningitis belt.

Epidemiological Research

- On September 23, MVP, under the lead of the WHO Initiative for Vaccine Research, convened a group of experts in Geneva for the first of a series of meetings to be held on meningococcal carriage studies. The group of experts reviewed current knowledge on meningococcal carriage and provided recommendations on a research agenda for future studies to be conducted in Africa before, during, and after the introduction of the MenA conjugate vaccine, and for ways to take this initiative forward.
- The WHO *Weekly Epidemiological Record* devoted its September 16, 2005, issue entirely to enhanced surveillance of epidemic meningococcal meningitis in Africa, an activity that MVP has been supporting for several years. The report, which covers three years of enhanced surveillance, is available at <http://www.who.int/wer/2005/wer8037.pdf>.

Vaccine Introduction Strategy and Communication

- Dr. Kader Konde, MVP vaccine introduction manager and WHO focal point, moved from the WHO headquarters in Geneva to the WHO Regional Office in Africa in Harare, Zimbabwe, from where he will coordinate vaccine introduction activities for the MenA conjugate vaccine.
- Professor Francis Nkrumah, emeritus professor at the University of Ghana and former chairman of the Task Force on Immunization, is chairing the Project Advisory Group (PAG), a group of African public health officials from meningitis belt countries who advise MVP on its introduction strategy for conjugate vaccines. Despite a very busy schedule, Professor Nkrumah kindly agreed to be interviewed for the MVP quarterly newsletter. To see what he has to say about the PAG, MVP, and bringing a new conjugate meningococcal vaccine to Africa, click on this link: <http://www.meningvax.org/files/PAG-interviews-Prof-F-Nkrumah-May2005.pdf>.
- In addition, MVP participated in or made presentations at the following meetings: **Training Workshop for French-Speaking Journalists Writing on HIV/AIDS, Bamako, Mali, August 22–25.** Some 30 journalists, mostly from WHO, Mali, and Panapress (an international news and information service that provides news coverage of the African continent), participated in the workshop where Rodrigue Barry, MVP's advocacy and social mobilization officer, presented the project's strategic plan for advocacy activities in Africa. **Medicine and Health in the Tropics Congress, Marseille, France, September 11–15.** The WHO/MVP team and their national partners provided insights into the dynamics of epidemic meningitis in Burkina Faso, Mali, and Niger, where surveillance data have been gathered for the past two decades. The MVP team also presented recent progress on the clinical development of the MenA conjugate vaccine and vaccine introduction plans in Africa. **Health, Information, Promotion (HIP) Workshop in Cotonou, Benin, September 14–16, Cotonou, Benin.** This regional meeting, which brought together professional communicators from health ministries in francophone West Africa and Guinea Bissau, provided an opportunity for MVP to expand the project's communication network in Africa.

That's all for now from the MVP team. Stay tuned for our next news digest (January 2006). 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>.