



News digest 19
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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

- The consistency lots of the new meningococcal A (MenA) conjugate vaccine for the Phase 3 clinical trials have been released by Serum Institute of India Limited (SIIL), India.
- Good progress continues to be made towards completing the regulatory file. The aim is to submit the file to the Drugs Controller General of India for Indian licensure and to the World Health Organization (WHO) for prequalification in the first quarter of 2009. Countries are only able to purchase a vaccine through UNICEF once a prequalification certificate has been granted by WHO.

Clinical Activities

- The PsA-TT-001 clinical study in India has officially ended. The official report on this Phase 1 study, which will be part of the regulatory file, is almost completed.
- The PsA-TT-002 clinical study in Mali and The Gambia is approaching closeout, with the last visit of the last subject being planned for the end of March 2009. This two-year-long pivotal Phase 2 study looks at safety and immunogenicity of the MenA conjugate vaccine in 600 12- to 23-month-olds (the younger age group targeted by the mass vaccination campaigns).
- The PsA-TT-003 clinical study in Mali, Senegal, and The Gambia, and the PsA-TT-003a clinical study in India are also approaching closeout. The last subject visit took place in December, and the database lock is planned for the first quarter of 2009. These Phase 2/3 studies look at safety and immunogenicity of the MenA conjugate vaccine in the age groups targeted by the mass vaccination campaigns (2–29 years).
- The PsA-TT-004 clinical study started at Navrongo Health Research Centre, Ghana, in November. The first infants have been immunized, and screening and enrollment will proceed until a total of 1,200 subjects are recruited. This Phase 2 study evaluates the safety and immunogenicity of three different schedules using the MenA conjugate vaccine in healthy infants.
- Preparations for the PsA-TT-005 clinical study in India are well under way. The MVP clinical team submitted the dossier in support of the study to all concerned ethical review boards, thereby completing the first step in the ethical and regulatory review of this Phase 3 study that will evaluate the safety and consistency of consecutive lots of the MenA conjugate vaccine administered as a single dose to healthy children ages 5 to 10 years.
- The MVP clinical team developed a draft protocol for PsA-TT-006, a large Phase 3 safety study that will take place in Africa. Both PsA-TT-005 and PsA-TT-006 are scheduled to start in 2009.
- A serology meeting took place in Dakar, Senegal, on October 28–30 to coordinate the publication of scientific results from MVP-related studies. The meeting was opened by

Dr. Antonio Filipe Jr., WHO representative in Senegal, and was attended by about 30 participants, including MVP partners.

Surveillance and Epidemic Preparedness Activities

- At the beginning of the epidemic season, the WHO Multi-Disease Surveillance Centre (MDSC) team in Ouagadougou, Burkina Faso, reports that the situation remains calm despite alerts in Burkina Faso (district of Sapouy, which already crossed the alert threshold last year) and in Mali (district of Ouelessebouyou). The MDSC team is also investigating rumors of meningococcal meningitis cases in Nigeria (state of Sokoto).
- On November 12–21, the MDSC team made a follow-up country visit to the Democratic Republic of the Congo (DRC) to provide a refresher training course on the standard operating procedures for enhanced surveillance of meningococcal meningitis. While DRC lies outside the official meningitis belt, the increasing number of cases reported in the country (6,125 suspected cases of meningitis from January 1 – December 28) is consistent with the suspicion that the African meningitis belt may be expanding southward and affecting regions that have been spared until now.
- The MDSC team organized workshops on standard operating procedures for enhanced surveillance of meningococcal meningitis in Benin (November 24–29) and in Chad (December 12–20). During these visits, the team revised the national work plan for meningitis activities and provided technical support to ministry of health surveillance units. Local surveillance staff were trained on data management and laboratory techniques to identify disease-causing serogroups.
- An advanced draft of the new guidelines for case-based surveillance of meningococcal meningitis in the African meningitis belt has been finalized. Under the old system suspected cases were reported. Under the new guidelines, confirmed cases are reported with complete epidemiological and laboratory data. The new system should improve understanding of epidemic patterns in Africa.
- The MDSC team in collaboration with the WHO office in Geneva has begun to enhance case-based meningitis surveillance capabilities in preparation for vaccine introduction in Burkina Faso in 2009 and the subsequent introductions in Mali and Niger.

Vaccine Introduction Strategy and Communication

- MVP worked in close collaboration with WHO's Health, Information, and Promotion office to organize a communicators' workshop in Accra on November 25–28. About 30 professional health communicators and media representatives participated in the workshop that provided information related to the launch of the Ghanaian infant study. Prof. Francis Nkrumah, chairman of the Project Advisory Group, spoke at the opening ceremony that was presided over by Dr. Daniel Kertesz, the new WHO representative in Ghana. Both reminded communicators about the crucial role they play in informing the community about the clinical study and the new vaccine. Mr. Jean-Marc Fleury, executive director of the Quebec-based World Federation of Science Journalists also attended the workshop to explore ways to develop health- and vaccine-related media coverage in Africa in the context of MVP.
- The MVP team developed a communication plan to support the carriage study in Burkina Faso.
- After approving US\$55 million for the immediate creation of a meningococcal A vaccine emergency stockpile, the GAVI Alliance Board approved US\$29 million for the introduction of the MenA conjugate vaccine in three meningitis belt countries (Burkina Faso, Mali, and Niger).
- MVP held its annual workshop in Mijoux, France, on October 15–17. During the workshop the achievements of the past year were reviewed, and the team developed its work plan for 2009. Key will be to put all elements in place to allow for vaccine introduction in Burkina Faso in the last quarter of 2009. This will require a major effort on all fronts—the regulatory file, clinical trials, surveillance, and communication—to achieve this goal.

That's all for now from the MVP team. Stay tuned for our next news digest in three months' time.

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>.