



News digest 22
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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 Drugs Controller General of India (DCGI)—the Indian regulatory authorities—conducted an onsite inspection at Serum Institute of India Ltd (SIIL) in early July.
- SIIL submitted the regulatory dossier to the World Health Organization (WHO) for vaccine prequalification on 23 September. Once Indian market authorization has been granted the dossier will be evaluated according to WHO's fast-track procedure.

Clinical Activities

- The PsA-TT-001 clinical study in India has officially ended.
- The clinical team and partners are preparing the addendum to the clinical study report for the PsA-TT-002 study that was recently closed in Mali and the Gambia. The addendum will provide final data on safety and antibody persistence at one and two years postvaccination. This two-year-long pivotal Phase 2 study looked at safety and immunogenicity of the meningococcal A (MenA) conjugate vaccine in 600 12- to 23-month olds (the younger age-group targeted by the mass vaccination campaigns).
- The clinical team and partners are preparing the addenda to the clinical study reports for PsA-TT-003 in Mali, Senegal, and the Gambia, and for PsA-TT-003a in India. The addenda will provide final data on safety and antibody persistence at one year postvaccination. Both these Phase 2/3 studies looked 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 at the Navrongo Health Research Centre, Ghana, is going well. A total of 1,200 infants have been enrolled as per protocol, and some have received two doses of MenA conjugate vaccine. The independent Data Safety and Monitoring Board has reviewed preliminary safety data and concluded that there are no safety concerns to date. This Phase 2 study evaluates the safety and immunogenicity of three different schedules using the MenA conjugate vaccine in healthy infants.
- Preparations for PsA-TT-005 in India are complete. PsA-TT-005 is a 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 awaits the final study approval from the DCGI to begin the study.
- Preparations for PsA-TT-006, a large Phase 3 safety study in Africa, are at an advanced stage. The clinical team submitted the clinical documents to the local ethics committee, thereby completing the first step in the clearance process for the study.

Surveillance and Epidemic Preparedness Activities

- So far in 2009, a total of 81,283 suspected cases and 4,473 deaths from meningitis were reported in the 14 countries under enhanced surveillance. The countries hit hardest were Nigeria (55,747 suspected cases; 2,448 deaths) and Niger (13,387 suspected cases; 551 deaths). Group A *Neisseria meningitidis* was the principal cause of disease in epidemic districts.
- Preparations are underway for the 7th Annual Intercountry Review and Planning Meeting on Enhanced Meningococcal Surveillance and Response to Meningitis Epidemics in Africa. The meeting will be an opportunity to exchange on lessons learned, challenges, and constraints faced by countries that have experienced meningitis outbreaks, and to draw recommendations and plan for the upcoming meningitis season.
- On 23–29 July, the WHO Inter Country Support Team (IST) held a workshop in Bangui, Central African Republic, to train laboratory technicians in data management techniques for enhanced meningitis surveillance.
- On 24–29 August, the IST held a meeting in Bamako, Mali, to review and update the 2005 standard operating procedures (SOPs) for enhanced meningitis surveillance. The revised SOPs will be distributed to meningitis belt countries at the annual planning meeting.
- Surveillance personnel from two of the five pilot sites that received the new data management software for epidemiological surveillance and laboratory testing gathered at the Burkina Faso Ministry of Health on September 25–26 to follow a two-day training on data management for case-based surveillance.

Vaccine Introduction Strategy and Communication

- The IST in Ouagadougou, Burkina Faso, is developing plans with the government of Burkina Faso for the introduction campaign. In particular, needed vaccine delivery supplies and equipment (cold rooms, refrigerators, waste disposal systems, radios/cell phones, vehicles) have been identified, and a procurement process is underway to ensure that all supplies and equipment are repositioned in Burkina Faso before the vaccine is introduced.
- On 23–25 September the IST held a workshop in Ouagadougou to develop the microplanning tools template for introduction of the MenA conjugate vaccine. Health personnel will adapt the template as needed at local, provincial, and regional levels.
- Preparations are underway for a partners' meeting on the introduction of the MenA conjugate vaccine in Africa. The meeting will take place in Ouagadougou and will be attended by representatives from meningitis belt countries, the WHO office in Geneva, the WHO regional office for Africa, the WHO country office in Burkina Faso, UNICEF, and other stakeholders. Vaccine introduction was originally hoped to start in the last quarter of 2009, but regulatory issues were such that the introduction has been rescheduled for 2010.
- The London School of Hygiene and Tropical Medicine received US\$10.7 million to lead the African Meningococcal Carriage Consortium (MenAfriCar), the largest, most concerted effort to date to better understand how meningococcal meningitis is transmitted, and to document the impact of the new MenA conjugate vaccine on reducing transmission of the disease in Africa. MenAfriCar will work closely with MVP in the years to come.

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>.