



News digest 25  
Q2, 2010

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](mailto: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**

- On June 23, the World Health Organization (WHO) prequalified MenAfriVac™, the meningococcal A conjugate vaccine developed through MVP and produced at Serum Institute of India Ltd (SIIL). Prequalification is a licensing process that guarantees that individual vaccines meet international standards of quality, safety, and efficacy. Read the [announcement](#) on the PATH website.

### **Vaccine Introduction and Communication Activities**

- A consultation took place on April 26 at the WHO Regional Office for Africa (WHO AFRO) in Brazzaville, Congo, to review the clinical development of MenAfriVac and the different strategies for its introduction in Africa. Several issues were debated, including vaccine availability, country-level preparedness, vaccine introduction scenarios in 2010 and beyond, and funding availability. Taking all these factors into consideration, it was decided that MenAfriVac will undergo a phased introduction in Burkina Faso, Mali, and Niger in the fall of 2010. The progressive introduction of MenAfriVac is scheduled to start in September in selected districts where an active system for pharmacovigilance is being set up.
- On June 24, WHO AFRO director Dr. Luis Gomes Sambo met with Blaise Compaoré, the President of Burkina Faso, to discuss the MenAfriVac introduction strategy in Burkina Faso and sub-Saharan Africa.
- Preparations for vaccine introduction in Burkina Faso continue to advance smoothly: the MenAfriVac introduction technical group consisting of the WHO Inter-country Support Team (IST) and representatives from the WHO country office continues to meet on a weekly basis to discuss planning and implementation of all MVP-related activities. Representatives from the UNICEF country office joined the technical group on June 15. Meetings are extended on an *ad hoc* basis to several departments at the Ministry of Health (MoH), including pharmacovigilance, disease control, and immunization. Teleconferences are also taking place twice a month between WHO/IST, the WHO country office, WHO AFRO, WHO HQ in Geneva, the UNICEF office in Burkina Faso, UNICEF New York, and the UNICEF West and Central Africa office in Dakar (UNICEF WCARO). From July onwards, these teleconferences will be extended to UNICEF country offices in Mali and Niger.
- UNICEF WCARO used GAVI funding to purchase the bulk of the vaccination cards that will be used during the mass campaign in Burkina Faso, and the cards have been delivered to the UNICEF country office in the country. PATH will purchase the remainder of the cards from the same manufacturer using Dell funds.
- The PATH procurement team in Seattle collaborated with WHO/IST and the UNICEF office in Copenhagen to purchase syringes, safety boxes, and cool boxes for vaccine introduction in Burkina Faso.

- From June 2–18, representatives from WHO HQ and WHO/IST made country visits to Burkina Faso, Mali, and Niger to meet with the national introduction committee in each country. The main purpose of the visits was to support vaccine introduction activities and to help national authorities in mobilizing resources for the cofinancing of MenAfriVac introduction.
- The first of a series of communication workshops took place in Bobo Dioulasso, Burkina Faso, on June 28–July 1. Organized by the MoH, the workshop gathered 40 communication and health professionals who finalized the Burkina Faso national communication plan for vaccine introduction in the country. Advocacy, social mobilization, and media activities have been planned at central, regional, and district levels, including resource mobilization activities to fill the estimated US\$3.7 million funding gap for country-wide introduction this year. A follow-up workshop focusing on the development of communication tools and messages has been planned.
- UNICEF WCARO provided technical support for the organization of two workshops in Niger (June 22–24) and Mali (June 28–29). Both workshops focused on communication issues around the introduction of new vaccines in Africa, including the introduction of MenAfriVac. A knowledge, attitude, and perception (KAP) survey is planned in selected districts in the next few weeks. Survey results will be used to sharpen communication strategies and messages surrounding the introduction of MenAfriVac.
- On June 30, Médecins sans Frontières issued a [statement](#) on the prequalification of MenAfriVac in which the humanitarian agency warned that widespread introduction of the vaccine in meningitis belt countries will depend on US\$475 million being mobilized internationally.

### **Clinical Activities**

- The Phase 1 [PsA-TT-001](#) clinical study in India has officially ended.
- The Phase 2 [PsA-TT-002](#) clinical study in Mali and the Gambia has officially ended.
- The Phase 2/3 [PsA-TT-003](#) clinical study in Mali, Senegal, and the Gambia, and the Phase 2/3 [PsA-TT-003a](#) clinical study in India have officially ended.
- The Phase 2 [PsA-TT-004](#) clinical study at the Navrongo Health Research Centre, Ghana, is going well and proceeding according to schedule. A total of 1,200 subjects have been enrolled for this Phase 2 study that evaluates the safety and immunogenicity of different dosages and schedules of the MenA conjugate vaccine in healthy infants when administered concomitantly with EPI vaccines.
- The Phase 3 clinical trial [PsA-TT-005](#) is proceeding within timelines. Enrollment was completed in May, and the last subject last visit has just been completed. Over the next few months study activities will be focused on the database lock. This trial is taking place at Vadu's Shirdi Sai Baba Rural Hospital, a rural division of the King Edward Memorial Hospital in Pune. The study evaluates the consistency of consecutive lots of MenA conjugate vaccine administered as a single dose to 830 healthy children ages 5 to 10 years.
- [PsA-TT-006](#), a Phase 3 trial, started on February 22 at the Center for Vaccine Development-Mali in Bamako. Well over half of the 6,000 subjects are now enrolled. The study looks at potential rare side effects related to the administration of one dose of the MenA conjugate vaccine in healthy subjects aged between 1 and 29 years. Like in all other MVP clinical studies conducted since 2005, no safety concerns have been identified thus far.

### **Surveillance and Epidemic Preparedness Activities**

- WHO/IST reports 25,595 suspected cases of meningitis so far this year in the 14 countries under enhanced meningitis surveillance. Burkina Faso is the hardest-hit country with 6,088 cases and 853 deaths (case-fatality rate: 14 %).
- WHO/IST made country visits to Benin (March 20–25), Mali (May 17–20), Niger (May 23–25), Togo (June 2–6), Côte d'Ivoire (June 7–12), and Liberia (June 8–20). The main purpose of the visits was to provide training on laboratory confirmation work and data management, analysis, and mapping. Special training on quality assurance and biosafety was also provided to laboratory staff in Mali and Niger.

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](mailto: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>.