

News digest 28 Q1, 2011

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 introduction and communication activities

- Burkina Faso, Mali, and Niger conducted in-depth evaluations of the December 2010 MenAfriVacTM vaccination campaigns. Assessed components included campaign preparation, coordination and planning; social mobilization and communication activities; training and supervision of health workers; logistics; cold chain; waste management; surveillance of adverse events; vaccine coverage surveys, and use of financial resources. Lessons learned will be useful for the next round of vaccinations in Mali and Niger later this year and will assist in the planning of future introduction of MenAfriVacTM in other meningitis-belt countries.
- More than 90% of the funding needed for the completion of the vaccination campaigns in Mali and Niger has been secured. Once the funding gap of US\$3.1 million is cleared up, Mali and Niger will be able to fully implement the last phase of their vaccination campaigns and immunize the rest of their 1- to 29-year-old population against group A meningococcal meningitis (some 6 million people in Mali and some 8 million people in Niger).
- In consultation with the World Health Organization Regional Office for Africa (WHO AFRO), Chad, Cameroon, and Nigeria have been selected as the next three countries to introduce MenAfriVacTM. As was the case in 2010, MenAfriVacTM will undergo a phased introduction based on vaccine availability (35 million new doses in 2011), country-level preparedness, epidemiology, and funding availability. The first vaccination phase is scheduled to take place in early fall. The GAVI Alliance has approved US\$100 million, which represents 82% of the total funding needed for full implementation of MenAfriVacTM campaigns in these three countries.
- The WHO Intercountry Support Team (IST) is conducting weekly teleconferences on MenAfriVacTM rollout. Participants include technical staff from Burkina Faso, Mali, Niger, Cameroon, Chad, and Nigeria; representatives from WHO HQ in Geneva and WHO AFRO; and introduction partners, including UNICEF, Doctors without Borders, the US Centers for Disease Control and Prevention, Agence de Médecine Préventive, and the Bill & Melinda Gates Foundation.
- The IST and partners completed advocacy visits for MenAfriVacTM introduction in Cameroon, Chad, and Nigeria.

Surveillance and epidemic preparedness activities

- Only two cases of meningococcal A meningitis have been confirmed in Burkina Faso so far this year. The two cases occurred in teenagers who had not been vaccinated with MenAfriVacTM. *Streptococcus pneumoniae* is now by far the leading cause of meningitis in the country. Postintroduction surveillance activities are being conducted to allow identification of potential additional meningococcal A cases and better evaluation of the safety profile of the vaccine.
- Chad pays the heaviest tribute to meningitis this year, with 2,789 suspected cases reported at week 12. The predominance of *Neisseria meningitidis* A has been confirmed.
- The IST made country visits to Cameroon and the Democratic Republic of the Congo. The main purpose of the visits was to provide training on standard operating procedures for enhanced surveillance of meningitis, data management, and laboratory confirmation work.
- The seventh round of meningococcal A carriage studies in Burkina Faso was completed in March. Studies' results will be presented at the May MenAfriCar meeting in Dakar, Senegal.

Clinical activities

- The following five clinical trials related to licensing and prequalification of MenAfriVacTM for use in 1- to 29-year olds have been successfully completed:
 - Phase 1 PsA-TT-001 study in India.
 - Phase 2 PsA-TT-002 study in Mali and the Gambia.
 - Phase 2/3 PsA-TT-003 study in Mali, Senegal, and the Gambia.
 - Phase 2/3 PsA-TT-003a study in India.
 - Phase 2/3 PsA-TT-005 study in India.
- Research to document an indication for MenAfriVacTM use in infancy (in under 1-year-olds) is progressing according to schedule. A monitoring visit took place in March, and no major issues were reported. PsA-TT-004 is a Phase 2 study that evaluates the safety and immunogenicity of different dosages and schedules of the meningococcal A (MenA) conjugate vaccine in 1,200 healthy infants when administered concomitantly with EPI vaccines. The study is conducted at the Navrongo Health Research Centre in Ghana and is scheduled for completion in early 2013.
- The Phase 3 <u>PsA-TT-006</u> study conducted at Center for Vaccine Development-Mali in Bamako has been completed and is now in the reporting phase. The study looked at potential rare adverse reactions following the administration of a single dose of the MenA conjugate vaccine in healthy subjects aged between 1 and 29 years. The last visit was completed for all 6,000 subjects in January 2011. Like in all other MVP clinical studies conducted since 2005, no safety concerns have been identified thus far.

MVP says thank you and goodbye to Indian clinical sites and trial participants



Research staff at Shirdi Sai Baba Hospital in Vadu, India, organized community meetings in the nine villages that participated in MVP's PsA-TT-003a and PsA-TT-005 clinical trials. The meetings provided an opportunity for villagers to learn about study results and vaccine introduction in Africa. MVP and Serum Institute of India, Ltd (SIIL) clinical staff participated in a meeting at the ZP primary school in Rautwadi (see photo) and in a meeting in the Temple of Skirapur. All the meetings drew impressive and highly participatory crowds, including children who had participated in the studies, their parents and/or guardians, and community leaders. A common feeling among those present was that even though they were slightly worried at the beginning of the trials, by the time the studies ended they were very impressed with the seriousness of the work and, as a result, they would be willing to participate in another study with the same investigators and sponsors. The MVP-SIIL team concluded its Indian trip with a scientific meeting at Shirdi Sai Baba Hospital. The team also toured the study site, including the hospital, the research facilities, the archival room, and the laboratories.

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 <u>info@meningvax.org</u>.

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.