



News digest 12
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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

- Serum Institute of India (SIIL) is developing the Phase 3 lots of the new meningococcal A (Men A) conjugate vaccine in their new facility in Pune.
- Stability studies are ongoing, and initial results are very promising.
- SIIL with support from the MVP team is assembling the regulatory file for licensure.

Clinical Activities

- The Phase 2 study is ongoing at the Center for Vaccine Development-Mali and at the Medical Research Council in The Gambia. The study is going well, and a press release describing the initial safety and immunogenicity data will be issued in early June.
- On March 12–14, 2007, Phase 2/3 investigators gathered in Bamako, Mali, for an intersite meeting. The meeting was organized by Agence Africaine de Recherche en Santé Humaine (AARSH) as part of preparatory activities for Phase 2/3 clinical studies that will start later this year in four African countries and in India. AARSH is one of the two contract research organizations (CROs) that perform clinical trial monitoring services for the MVP clinical studies. The meeting was an opportunity for all the investigators involved in MVP clinical studies to present clinical sites and harmonize their procedures, including development of study standard operating procedures (SOPs), community approach and consent process, clinical trial organization, monitoring, and laboratory procedures. The meeting also served as a team-building activity with the slogan "One mission, one team!"
- A CRO meeting took place on March 20–22 in Ferney-Voltaire, France. Staff from AARSH and iGATE CRI discussed a wide variety of issues related to trial monitoring and preparation of Phase 2/3 clinical studies. iGATE CRI is the second CRO performing data management services for MVP clinical studies.
- The MVP clinical team finalized the dossier in support of the Phase 2/3 studies and obtained clearance from Western Institutional Review Board (WIRB), thereby completing the first step in the clearance process for the Phase 2/3 studies. WIRB is the independent ethics committee that provides ethical review of vaccine clinical studies sponsored or supported by PATH.

Surveillance and Epidemic Preparedness Activities

- On March 5–13, the World Health Organization's (WHO's) Multi-Disease Surveillance Centre (MDSC) team in Ouagadougou, Burkina Faso, made a follow-up country visit to Nigeria. The team had fruitful discussions with Nigerian WHO staff, the federal ministry of health, and partners involved in epidemic preparedness and response, including Médecins sans Frontières (MSF), UNICEF, and the United States Agency for International Development (USAID). Key

points discussed included the status of implementation of SOPs for enhanced meningitis surveillance; the system of data collection, collation, and reporting; and data analysis and mapping at federal and state levels.

- Surveillance data compiled at the MDSC between January 1 and April 8, 2007, showed 27,357 suspected cases of meningitis and 2,149 deaths in sub-Saharan African countries that are under enhanced meningitis surveillance.
- Once again, the hardest-hit country is Burkina Faso where 22,255 suspected cases including 1,490 deaths were reported from January 1 to April 8, 2007 (41 districts out of 55 crossed the epidemic threshold). Cerebrospinal fluid specimens from all affected areas have tested positive for serogroup A *Neisseria meningitidis*. The increase in cases, both this and last year, confirms the fear that a new epidemic wave may have begun in sub-Saharan Africa.
- At the end of March, with the support of WHO, Burkina Faso's government launched an emergency US\$3 million appeal for international assistance. The appeal was positively received, and contributions from European Commission Humanitarian Aid Department (ECHO), Medicos del Mundo, MSF, Plan Burkina, the Swedish International Development Cooperation Agency (SIDA), UNICEF, the UN Central Emergency Response Fund, and USAID should enable Burkina Faso to finance all necessary vaccination campaigns.
- As of April 11, 2.7 million Burkinabè in 15 districts had been vaccinated with polysaccharide vaccines, with reactive emergency campaigns still on-going in six additional districts.

Vaccine Introduction Strategy and Communication

- In January, Dr. Ian Macdonald, founder and chairman of the Maryland-based Somerled Foundation, visited Burkina Faso. The Somerled Foundation, which is dedicated to “distributing meningococcal vaccines throughout the Third World in order to prevent the long-term disabilities which can result from meningitis” has committed US\$1 million in initial support to the demonstration study to be implemented in Burkina Faso at the end of 2008. The study will evaluate the impact of large-scale introduction of the Men A conjugate vaccine in Burkina Faso, where more than nine million 1 to 29 year olds will be vaccinated. The Somerled Foundation has launched fundraising efforts for the MVP demonstration study.
- MVP partnered with Rockhopper TV to develop a documentary on meningococcal meningitis for the BBC series *Kill or Cure?* Filming took place in Burkina Faso, in the midst of the epidemic, and in Mali where the Men A conjugate vaccine is being tested. The documentary offers a poignant and revealing account of the devastating impact meningitis epidemics have on individuals, families, and communities, and it explains how the new vaccine offers the hope of eliminating epidemic meningitis as a public health problem in sub-Saharan Africa. After being broadcast on BBC World June 8–13, 2007, the film will be made available on the MVP website (www.meningvax.org) and on DVD.
- On April 9–12 MVP convened a meeting at the MDSC to discuss the preparation of the demonstration study and funding issues related to vaccine introduction. The meeting was attended by representatives of the Burkina Faso Ministry of Health, local WHO staff, MVP staff, and international partners.
- Professor Rasmata Ouédraogo is the sixth interviewee in a series of interviews with Project Advisory Group members. To read how a little girl turned a simple hygiene advice—“Your hands are dirty, wash them so you don't get sick”—into a lifelong passion and career, click on this link: <http://www.meningvax.org/files/PAG-interviews-Pr-R-Ouedraogo-Jan-2007.pdf>.

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>.