



News digest 10
Q 2–3, 2006

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

- On June 20–21, MVP convened a pharmaceutical meeting at the PATH office in Ferney-Voltaire, France, to review and discuss the strategic plan for vaccine licensure and production.
- The Drugs Controller General of India (the Indian National Regulatory Authority) approved the start of the Phase 2 study in Africa.
- Ongoing stability studies conducted at Serum Institute of India Limited (SIIL) show that the MenA conjugate vaccine is stable for at least two years at temperatures between +2°C and +8°C.
- MVP established a formal collaboration with the Medical Research Council (MRC) in The Gambia and the Centre pour le Développement des Vaccins-Mali (CVD-Mali) in Mali to conduct the Phase 2 clinical study of the MenA conjugate vaccine.
- MVP established a formal collaboration with the University of Maryland. The University of Maryland's Center for Vaccine Development will assist in the performance of the Phase 2 clinical study in Mali.
- MVP established a formal collaboration with the Norwegian Institute of Public Health (NIPH). NIPH will perform assays to evaluate antibody responses induced by the MenA conjugate vaccine.

Clinical Activities

- The Phase 1 clinical study has been successfully completed. The study was designed to determine the safety and immunogenicity of the new MenA conjugate vaccine in 74 healthy volunteers enrolled at three clinical sites in India: B.Y.L. Nair Hospital (Mumbai), King Edward Memorial Hospital (Mumbai), and Nizam's Institute of Medical Sciences (Hyderabad). The vaccine was shown to be safe and immunogenic, and two posters describing the results were presented at the 15th International Pathogenic Neisseria Conference in Cairns, Australia, on September 10–15.

To view the Phase 1 poster, click on this link: <http://www.meningvax.org/files/MVP-poster-Australia2006-Borrow-phase%20I.pdf>.

To view the physicochemical analysis poster, click on this link:

http://www.meningvax.org/files/Physicochemical%20analysis%20poster_%20IPNC2006.PDF.

- All required ethical and regulatory clearances have been granted to begin the Phase 2 study.
- Two investigators meetings, including a workshop on good clinical practice in clinical trials, took place in Bamako, Mali, on July 12–14 and in Banjul, The Gambia, on July 17–19. The meetings were organized by the Agence Africaine de Recherche en Santé Humaine and SIIL and were attended by MVP staff and clinical staff from both study sites. Dr. Narcisse de

Medeiros participated in the Bamako meeting as a member of the MVP Project Advisory Group (PAG).

- The Phase 2 clinical study has started in Africa. Complete enrollment of the 600 children is planned to be achieved by mid-November.
- The MVP clinical team visited a potential site for the next clinical study of the MenA conjugate vaccine in Africa. Prof. Richard Adegbola participated in the field visit as a member of the MVP PAG. Meetings were held with local researchers, representatives of health authorities, and colleagues at the World Health Organization (WHO) country office.

Surveillance Activities

- With more than 33,000 cases and 3,000 deaths reported, 2005–2006 was an intense season across the meningitis belt. Eight countries reported epidemics, and 70 districts were affected. Considering the significant increase of meningitis outbreaks across the belt (5-fold increase since 2005) and the fact that four of the "big five" countries (Burkina Faso, Ethiopia, Niger, Nigeria, and Sudan) were affected after six to ten quiet years, WHO Epidemic and Pandemic Alert and Response fears that 2006 might be the beginning of a new epidemic wave in sub-Saharan Africa.
- The International Coordinating Group on vaccine provision for epidemic meningitis control—the group that coordinates the best use of the limited amount of vaccine available—responded to 19 vaccine requests during the 2005–2006 season. More than six million people were vaccinated with meningococcal polysaccharide bivalent or trivalent vaccines.
- Burkina Faso was the hardest-hit country in the meningitis belt with 18,517 cases and 1,587 deaths reported (34 districts affected out of 55). About 9,000 health workers were mobilized to vaccinate six million people in less than three months. The direct cost of these emergency mass vaccination campaigns is evaluated at US\$3.5 million (5 percent of the country's annual health expenditures).

Vaccine Introduction Strategy and Communication

- MVP worked in close collaboration with WHO's Health, Information, and Promotion office to organize two communicators' workshops in Mali (May 9–12) and The Gambia (September 26–29). About 60 professional health communicators and media representatives (audiovisual media, print media, and national languages) participated in the workshops that provided information on a variety of topics including meningococcal meningitis, disease epidemiology, vaccine development and clinical trials, strategies and challenges of the MVP, and the strategic plan for the introduction of the MenA conjugate vaccine. Workshop participants wrote communication plans aimed at facilitating the conduct of the clinical trials and were given the opportunity to visit CVD-Mali in Bamako and the MRC in Banjul.
- Dr. Narcisse de Medeiros, an expert on communication issues in Africa, is the fourth interviewee in a series of interviews with PAG members. To read about how the aviation world lost a potential pilot, and how MVP gained an experienced communication advisor, click on this link: <http://www.meningvax.org/files/PAG-interviews-Dr-de-Medeiros-July-2006.pdf>.
- Dr. Kader Kondé, the WHO/MVP focal point, has been transferred from the WHO Regional Office in Africa in Harare, Zimbabwe, to Ouagadougou, Burkina Faso, where he joins the MVP team.

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>.