



The Meningitis Vaccine Project

Frequently asked questions

June 2011

The disease

What is meningococcal disease?

Meningococcal disease is an infection of the meninges, the thin lining that surrounds the brain and the spinal cord. It is usually caused by a virus or bacterium (meningococcus). It is transmitted through droplets of respiratory or throat secretions. Bacterial meningitis, such as meningococcal disease, can be very serious because it evolves rapidly and can kill in a few hours. Even with appropriate treatment, around 10 percent of patients die, and up to 20 percent of survivors have serious permanent health problems as a result of the disease (deafness, epilepsy, cerebral palsy, or mental retardation).

What is the extent of meningococcal meningitis in Africa?

Sub-Saharan Africa has been experiencing explosive and repeated meningococcal epidemics for more than a hundred years. Group A meningococcus is the main cause of meningitis epidemics and accounts for an estimated 80 to 85 percent of all cases. These deadly epidemics occur at intervals of 8–10 years in the 25 countries of the "meningitis belt," a strip of land that extends from Senegal in the west to Ethiopia in the east. Around 450 million people in this area are at risk of disease.

More than one million cases of meningitis have been reported in Africa since 1988. In 1996–1997, one of the largest epidemic waves ever recorded in history swept across Africa, causing more than 250,000 cases and 25,000 deaths.

The vaccine

What is the expected public health impact of this new vaccine?

If introduced in all 25 countries of the African meningitis belt, this vaccine is expected to eliminate the primary cause of epidemic meningitis, group A meningococcus, from the entire region, with an estimated 1 million cases of disease prevented and 150 000 young lives saved by 2020.

What advantages does MenAfriVac™ have over existing polysaccharide meningococcal vaccines currently used to combat epidemics in Africa?

Contrary to polysaccharide vaccines that are used currently to control epidemics after they have begun, the new conjugate vaccine will be offered to prevent epidemics. Key advantages of the new vaccine over existing polysaccharide vaccines are:

- It induces a higher and more sustainable immune response against the most prominent strain in the most affected age groups, from 1–29 years.
- It is expected to confer long-term protection not only for those who receive the vaccine, but on family members and others who would otherwise have been exposed to meningitis, given reduced transmission of the bacteria.

- It will be available at a lower price than other meningococcal vaccines, and significantly lower than other cutting-edge vaccines recently introduced in Africa.
- It is expected to be particularly effective in protecting children under two years of age, who do not respond to conventional polysaccharide vaccines.

Will this vaccine protect against all types of meningococcal meningitis?

No, MenAfriVac will only protect against disease caused by meningococcus A—the group that is responsible for about 80 to 85 percent of all meningitis epidemics in Africa. The vaccine will not protect against disease caused by other meningitis bacteria (pneumococcus, *Haemophilus influenzae*) or by other meningococcal groups, such as C, W135, X, and Y. Conjugate vaccines for these other groups are either not yet available (X) or far too expensive for African countries (A, C, W135, and Y). However, it is hoped that a combination of ongoing research and development efforts and tiered pricing will contribute to meningococcal polyvalent available to developing countries in the future.

How was the vaccine developed?

The new vaccine was developed through the Meningitis Vaccine Project (MVP), a product development partnership between PATH and WHO. The project included transfer of technology for manufacture of the vaccine from the Center for Biologics Evaluation and Research (CBER), a center of the US Food and Drug Administration, to the Serum Institute of India, Ltd. The project was set up in 2001 with core funding from the Bill & Melinda Gates Foundation. The overall mission of the MVP is to eliminate meningitis as a public health problem in sub-Saharan Africa through the development, testing, introduction, and widespread use of conjugate meningococcal vaccines.

Clinical trials, beginning in 2005, have been carried out in the Gambia, Ghana, India, Mali, and Senegal and have shown the vaccine to be safe and highly immunogenic.

How much does the vaccine cost?

The vaccine was developed at a cost of less than US\$0.50 per dose, a price low enough to promote widespread uptake throughout the affected region.

Introduction

What is the timeline for campaigns across the meningitis belt?

The vaccine was launched in three African countries in December 2010: Burkina Faso (completed), Mali, and Niger (to be completed in late 2011). The next three countries to introduce the vaccine are Cameroon, Chad, and Nigeria. Vaccine introduction in these three countries will also be phased, starting in fall 2011. It is hoped that all countries in the meningitis belt will be using the vaccine by 2016.

Why start with mass vaccination campaigns?

The goal of introducing the meningococcal A conjugate vaccine through mass vaccination campaigns of people ages 1 to 29 years (the age group most at risk) is to immediately and drastically reduce carriage and transmission of the bacteria in order to rapidly reduce rates of death and illness caused by the disease. Because large population groups will be vaccinated in a short period of time, the benefits of immunization should be quickly visible; the impact is expected to be considerable.

It is expected that future birth cohorts will be protected either through vaccination within the EPI schedule or through follow-up mass campaigns targeting 1–4 year-olds every five years.

What are the results thus far?

Nearly 20 million people in Burkina Faso, Mali, and Niger received MenAfriVac in 2010. Pharmacovigilance activities conducted thus far indicate that MenAfriVac is very safe and highly effective. Only four cases of meningococcal A disease have been laboratory-confirmed in Burkina Faso, the first and only country to have introduced MenAfriVac at national scale; three of the four cases occurred in individuals from neighboring Togo who crossed the border for medical care, and the fourth case was a citizen of Burkina Faso who had not received the new vaccine. This is the lowest number of meningitis A cases ever recorded during an epidemic season in the country. No confirmed cases were reported in Mali, while four cases were reported in Niger, all in unvaccinated individuals.

Is there commitment in Africa for the introduction of this vaccine?

Because of the prevalence of meningitis A in the population and the role it plays as a major cause of epidemics, controlling meningitis A has become an important public health priority in Africa. Countries in the meningitis belt have been eager to host the clinical trials of the vaccine and have contributed significantly to their success. Vaccine coverage during the December 2010 campaigns in Burkina Faso, Mali, and Niger was around 100 percent, and it is expected that populations throughout the meningitis belt will show the same enthusiasm for the vaccine when it is introduced in their region. Burkina Faso, Mali, and Niger contributed financially to MenAfriVac introduction as much as national budgets allowed, and it is expected that vaccine introduction in other African countries will also be at least partially supported by the countries themselves.

Funding shortfalls and cost-savings

How much money will be required to eliminate epidemic meningitis as a public health problem in sub-Saharan Africa?

It is estimated that introduction of the vaccine in 2011–2016 in all meningitis belt countries will require the mobilization from donor governments and others of US\$375 million in addition to the US\$100 million that the GAVI Alliance released earlier this year.

It is hoped that the international community will supplement the national budgets of introducing countries to ensure that this funding gap is met.

What are the expected cost savings due to introduction of this new vaccine?

Widespread introduction of MenAfriVac throughout sub-Saharan Africa could free up as much as US\$300 million over the next ten years that would otherwise be spent on medical costs for diagnosis and treatment, as well as repetitive vaccination campaigns with polysaccharide vaccine. This does not include the expected economic impact of saving lives and preventing disabilities caused by epidemic meningitis.

Next steps

What are the Meningitis Vaccine Project's next steps?

In addition to actively seeking funding that will guarantee vaccine introduction throughout the whole meningitis belt, MVP is working closely both with governments and institutions in the African region, and international partners, to monitor the effect of the new vaccine on the ground. The project is also conducting further clinical research to inform policy, in particular for infants, to determine how best to integrate the meningococcal A conjugate vaccine into existing routine immunization programs in Africa.