



The Meningitis Vaccine Project is a partnership between PATH and WHO

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Mass Campaign With First Vaccine Allowed “Outside Cold Chain” in Africa Protects Remotest African Regions from Deadly Meningitis Epidemics

A second study by World Health Organization suggests keeping vaccines at ambient temperatures during campaigns could cut storage and transportation costs in half

GENEVA (19 February 2014) – The first mass vaccination campaign conducted in Africa with a vaccine that does not require constant refrigeration succeeded in providing complete coverage while ensuring the vaccine stayed viable even in ambient temperatures up to 39°C (102.2°F), according to a study published online today in the journal *Vaccine*.

Conducted as part of a ten-day meningitis A vaccination campaign in Benin in November 2012, the study represents a breakthrough not only for the vaccine, MenAfriVac®, but potentially for increasing the efficiency, coverage, and affordability of other lifesaving vaccines as well, especially in remote, hard-to-reach areas where keeping the vaccine cold is difficult. Researchers with Optimize, a now-completed collaboration between the World Health Organization (WHO) and the global health nonprofit PATH, cooperated with the government of Benin to implement the study.

If widely used, this approach could significantly reduce the workloads of health workers, who spend vast amounts of time maintaining the cold chain, and extend vaccines to areas that are so far removed from access to electricity they could never be reached by a cold chain system, the study found.

Additionally, a separate study published in the *Bulletin of the World Health Organization* on the economic benefits of this approach found that the costs of administering the MenAfriVac vaccine without keeping it cold could drop by 50 percent.

“The impressive coverage we saw in Benin when MenAfriVac was used outside of the cold chain paves the way for future campaigns in other regions with challenging geography, including countries where the vaccine will be administered later this year to

rural populations living in the desert,” said Dr. Marie-Pierre Preziosi, director of the Meningitis Vaccine Project, the collaboration between WHO and PATH that drove the development of MenAfriVac.

According to WHO, over 20 million children are under vaccinated and remain at risk of being infected by vaccine-preventable diseases. This is due, in part, to the difficulties faced in the “last mile” for effectively getting the vaccine from a health center to the vaccinee.

“Finding solutions to reducing the cost and logistical challenges of reaching people living in remote areas would remove a major constraint to achieving universal coverage with vaccines beyond MenAfriVac. Indeed, a similar approach is being explored with the manufacturers of other vaccines, such as the yellow fever or the oral cholera vaccines,” said Michel Zaffran, coordinator of WHO’s Expanded Programme on Immunization and former director of Optimize, the WHO-PATH collaboration aimed at improving immunization systems and technologies.

The pioneering MenAfriVac vaccine was developed through the PATH-WHO Meningitis Vaccine Project using a unique vaccine development model that aimed at providing an effective, affordable, and long-term solution to epidemic meningitis in the African meningitis belt, a large area that stretches across the continent from Senegal to Ethiopia. Over the past century, hundreds of thousands were killed or permanently disabled by the cyclical epidemics of meningitis A, many of them children or young adults.

“Findings from these new studies show that it is possible to deliver vaccines more conveniently and at a lower cost when refrigeration is not needed every step of the way,” said Dr. David C. Kaslow, vice president of product development at PATH. “MenAfriVac is helping to show a less expensive, simpler, and more convenient way for other current and future lifesaving vaccines to get to the hardest to reach people in need.”

In October 2012, MenAfriVac received approval from the Indian regulatory authorities and the WHO prequalification team to be kept outside of the cold chain for up to four days at up to 40°C, in a “Controlled Temperature Chain” (CTC). The vaccines had to be kept out of direct sunlight as well. This marked the first time a vaccine for developing countries was granted authorization to be used outside of the recommended 2°–8°C temperature range.

Results of Benin campaign using Controlled Temperature Chain

The Benin study published in *Vaccine* aimed to assess and demonstrate for the first time the feasibility and acceptability of using the CTC approach in a massive vaccination campaign, rather than keeping the vaccine within the traditional temperature range at all times.

The pilot targeted the rural Benin district of Banikoara, vaccinating 155,000 people across 150 villages and achieving a 106 percent administrative coverage rate. In 2013, no cases of meningitis A were reported across Benin, including the area where the vaccine wasn’t kept cold, and the enhanced pharmacovigilance field activities showed the vaccine was safe when administered following the new distribution approach.

During the campaign, only nine vaccine vials were discarded due to surpassing the four-day limit, and no vial was discarded because of exposure to a temperature higher than 40°C; a special card with a heat-sensitive sticker in the vaccine carriers showed if temperatures reached this level.

The study also showed that the vaccinators were enormously positive about using the CTC approach since it allowed them to vaccinate more people per day. It also meant that they didn't need to return from far-away villages to the health centers each night to continuously freeze ice packs. In addition, they appreciated the reduced weight of the vaccine carriers. Overall, 100 percent of vaccinators and 99 percent of supervisors said they preferred CTC to the traditional cold chain.

“This flexibility makes it easier for vaccinators to reach ‘the last mile,’ from the health center to the child, ensuring that we reach and protect all people at risk, even those in remote areas and not just those that can be accessed by a cold chain,” said study author Simona Zipursky, who spearheaded this approach within the WHO-PATH Optimize collaboration and led the study in Benin.

Vaccination campaign costs could be reduced by half

The related WHO study on the economic benefits showed that cutting out the cold chain beginning at the district-level storage point for vaccines could halve logistical costs. The study looked at the costs incurred during a ten-day meningitis A mass vaccination campaign in three regions of Chad in December 2011, where the cold chain was used throughout. If the vaccines were instead kept at or near ambient temperature for up to four days, the study found, the costs could potentially be halved from US\$0.24 to US\$0.12 per person vaccinated.

Vast resources are spent on the cold chain system, such as acquiring and transporting ice packs, refrigerators, and freezers, as well as kerosene to keep the refrigerators running. Additional transportation and human resources costs are also incurred when vaccines, cold boxes, and fresh ice packs need to be replenished—a particular challenge in “last mile” remote areas.

Other logistical challenges include unreliable electricity and poorly functioning or absent equipment. In 8 of the 12 districts targeted by the meningitis A vaccine in Chad, only 50 percent of the cold chain equipment was functioning; the rest was broken or too run down to store vaccines or produce frozen ice packs. In response, 52 additional refrigerators or ice pack freezers and 332 cold boxes were deployed, requiring a moving company to transport the equipment.

“The ability to use vaccines in a controlled temperature chain will certainly increase the cost-effectiveness of the Men-A strategy in settings where the cold chain infrastructure is fragile and will bring about significant savings on the operational costs of conducting a campaign in the meningitis belt countries,” said Patrick Lydon, a health economist at WHO and lead author of the study published in the WHO Bulletin.

For more than 100 years, sub-Saharan Africa has suffered from meningitis A epidemics that claim thousands of lives. In 1996 and 1997, an epidemic killed more than 25,000

people and sickened 250,000. Those who survive often suffer from deafness, epilepsy, loss of limb, and mental retardation.

Tailor-made to meet a major public health need in Africa, the MenAfriVac vaccine, which is manufactured by Serum Institute of India Ltd., is already saving lives along Africa's meningitis belt. Since 2010, more than 150 million people aged 1- to 29-years in 12 countries have received the vaccine with not a single group A meningitis case identified in the vaccinated populations. By the end of the 2013 epidemic season, the number of meningitis cases in the belt was the lowest in ten years, a decrease attributed to the introduction of MenAfriVac. By 2016, the vaccine initiative aims to have reached more than 250 million people across the 26 countries in the meningitis belt.

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The Meningitis Vaccine Project (MVP)

Established in 2001, the Meningitis Vaccine Project is a partnership between PATH and the World Health Organization. Its mission 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.