Medical Xpress

Meningitis A vaccine breaks barrier: First to gain approval to travel outside cold chain

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Signaling a potential breakthrough for immunization programs in resource-poor countries, researchers today announced at the American Society of Tropical Medicine and Hygiene (ASTMH) conference that regulatory authorities—after conducting a rigorous review of stability data—will for the first time allow a vaccine in Africa to be transported and stored for as long as four days without refrigeration or even an icepack.

The meningitis A vaccine known as MenAfriVac, created to meet the needs of Africa's meningitis belt, can now be kept in a controlled temperature chain (CTC) at temperatures of up to 40°C for up to four days, a decision that could help increase campaign efficiency and coverage and save funds normally spent maintaining the challenging cold chain during the "last mile" of vaccine delivery.

The outcome of the review and decisions of the Drugs Controller General of India (DCGI), supported by a Health Canada analysis and confirmed by the World Health Organization (WHO) Vaccines Pre-qualification Programme, was revealed during a presentation this afternoon at the ASTMH conference in Atlanta by Godwin Enwere, MD, medical director for the Meningitis Vaccine Project. The regulatory approval has the effect of permitting the re-labeling of MenAfriVac, while ensuring that the vaccine remains effective and safe throughout its life cycle.

Costing less than US$0.50 per dose, the innovative vaccine that is

manufactured by Serum Institute of India Ltd. (SIIL) has dramatically reduced disease burden in the first countries to introduce it, according to recently-published findings. MenAfriVac® is the first vaccine designed specifically to help health workers eliminate meningococcal A epidemics from Africa's "meningitis belt," which includes 26 countries from Senegal to Ethiopia.

"The potential for some vaccines to remain safely outside the cold chain for short periods of time has been widely known for over 20 years," said Dr. Michel Zaffran, director of Optimize, the PATH-WHO collaboration aimed at improving immunization systems and technologies. "But this is the first time that a vaccine intended for use in Africa has been tested and submitted to regulatory review and approved for this type of use. And we expect this announcement to build momentum for applying the CTC concept to other vaccines and initiatives, allowing us to save more lives in low-income countries."

Evidence of the heat stability of MenAfriVac was validated by a team of experts from WHO, PATH, SIIL, and Health Canada. In collaboration with the government of Benin, the Meningitis Vaccine Project (MVP), Optimize, and the WHO regional office for Africa, a pilot use of the MenAfrivac® vaccine in a CTC will be conducted during the upcoming MenAfriVac® campaign in the northern part of the country, from November 15 through 25. Benin is the 10th country to introduce the vaccine, as well as the first country to work with the new CTC implementation guidelines, developed through WHO's Immunization Practices Advisory Committee.

"Vaccines save and improve lives wherever they are used, but reaching the millions of children in last mile communities like those in rural Africa continues to challenge us," said Dr. Orin Levine, director of Vaccine Delivery at the Bill & Melinda Gates Foundation. "Today's announcement marks a new milestone because it allows us to extend the

delivery of the MenAfriVac vaccine from the traditional cold chain and reach more people across Africa, safely and efficiently."

New evidence of vaccine's efficacy in combating meningitis A in Africa

Other research discussed at the conference in Atlanta suggests that MenAfriVac has already begun to do its job, eliminating meningitis A in the first countries where it was introduced. The authors of a recent paper in *Clinical Infectious Diseases* say they expect to see the impact repeated in all the countries that roll out the new vaccine.

The new article reports that swabs taken from the throats of thousands of Burkina Faso residents prior to and in the year that followed the introduction of MenAfriVac suggested that infection with the bacteria causing meningitis A had been eliminated in vaccinated and unvaccinated populations in Burkina Faso. According to one of the authors, Dr. Marie-Pierre Préziosi, director of the Meningitis Vaccine Project, "our findings show that the bacteria causing meningitis A have disappeared from the noses and throats of those too old or too young to have received the vaccine, resulting from a phenomenon known as 'herd immunity.'"

"From early evidence in the first introducing countries, based on public health surveillance combined with these hard data, we can say the signs are very promising," Préziosi said. "We have herd immunity, which we were expecting. And we can also show that after introduction in Burkina Faso, we saw the lowest level of epidemic meningitis in 15 years."

She noted that the experience of Chad is particularly dramatic because the country's limited cold chain capacity had led authorities to immunize target populations in four phases. The first was carried out in 2011, and

the other regions were set to receive the vaccine this year. The effect of the vaccine seemed evident almost immediately. In 2012, not a single group A meningitis case was identified in the three vaccinated areas, while the regions that had not yet received the vaccine suffered severe outbreaks caused by meningitis A.

For more than 100 years, sub-Saharan Africa has suffered from epidemics that exact a terrible and deadly toll. Across the meningitis belt, from Dakar to Addis Ababa, as many as 450 million people are at risk from the disease. Epidemics of meningitis A occur every 7 to 14 years and are particularly devastating to children and young adults.

"The introduction of MenAfriVac® in Burkina Faso in 2010 was the start of an exciting journey for the meningitis A vaccine. This revolutionary vaccine continues to break new ground as it rolls out across the meningitis belt," said Steve Davis, PATH president and CEO. "We are grateful for all the institutions and the individuals who have made this vision a reality. Our efforts won't stop here. Our next step will be to develop a thermostable multivalent meningitis vaccine that protects against the other causes of meningitis in the region. We will stay ahead of this disease that causes such destruction to health systems, economies, and Africa's most valuable resource—its children and young people."

MenAfriVac, first vaccine developed specifically for Africa

Developed by the MVP partnership between the WHO and PATH—with support from the Bill & Melinda Gates Foundation—the meningococcal A conjugate vaccine MenAfriVac provides African health authorities, for the first time, with an affordable, long-term solution that protects even young children against meningitis A (group A *Neisseria meningitidis*).

MenAfriVac was developed to meet the need in Africa for a safe, effective, and affordable vaccine. The vaccine is now being tested on children who are less than one year of age to ensure it can be included safely in the routine vaccination programs, according to Godwin Enwere.

"If we can immunize the infants, then we will be able to make exponential progress in preventing epidemics because all the age groups most at risk of disease will be protected for a significant period of time," said Enwere, who is the author of a paper being presented on the infant study at the ASTMH conference.

The rapid development of MenAfriVac® has happened thanks in large part to SIIL, which worked closely with partners to overcome the 20-year lag between the time a vaccine is approved for use in wealthy nations and when it is used in the nations that suffer from the greatest burden of disease.

"By going beyond that vision, and by asking ourselves what can be done to make this product even more useful in hard-to-reach areas, the PATH-WHO-SIIL team succeeded in getting more out of limited resources," said Dr. Cyrus Poonawalla, SIIL chairman. "We have opened a door that we can expect other vaccine manufacturers to walk through in the future."

Clinical trials, carried out in India, the Gambia, Ghana, Mali, and Senegal, beginning in 2005, showed the vaccine to be safe and highly effective. Indian regulatory authorities granted marketing authorization for export and use of MenAfriVac in December 2009. In June 2010, the vaccine was prequalified by WHO, which guarantees that the vaccine meets international standards of quality, safety, and efficacy. "The process of developing this vaccine and planning for its introduction helped strengthen systems in Africa for disease surveillance, clinical research, pharmacovigilance, vaccine regulation and vaccination

logistics," Préziosi said.

The GAVI Alliance has thus far contributed US$162 million to the effort to eliminate meningococcal A meningitis in Africa, and has committed to supporting its introduction across the remaining 15 or so nations.

Progress and impact of new meningitis vaccine

As of today, with the support of the GAVI Alliance, UNICEF, PATH, WHO, and their partners, along with the commitment of national governments, MenAfriVac vaccination campaigns have taken place in Burkina Faso, Cameroon, Chad, Ghana, Mali, Niger, Nigeria, Senegal, and Sudan. Benin is joining the group this week. It is estimated that by the end of 2012, more than 100 million people in Africa's meningitis belt will have received the lifesaving new vaccine that is already demonstrating significant impact on the course of the disease that has wreaked havoc for more than a century on the continent.

- In Burkina Faso—where the new group A conjugate vaccine was first introduced in December 2010—the number of meningitis cases was at its lowest in over a decade in 2011. In addition, there were no cases of meningitis A in individuals who received one dose of MenAfriVac during the 2010 nationwide mass campaigns.
- In 2012, about 85 percent of Burkina Faso patients suspected of having contracted meningitis were sampled, but none of those cases appear to have been caused by meningitis A.
- In Niger, no meningitis A cases have been identified in the 1- to 29-year-old target population that received the vaccine in 2010 or 2011, and the number of meningitis cases is at its lowest since 2003.

"The new flexibility in delivering this vaccine represents a huge step forward," said Zaffran, director of Optimize, the PATH-WHO collaboration. "It took the work of a dedicated team to break through political, operational, and regulatory barriers to get this vaccine re-labeled."

Provided by Burness Communications

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