

Understanding influenza vaccine performance among children in Senegal

By today's estimates, annual influenza causes 250,000 to 500,000 deaths and three to five million cases of severe illness each year.¹ Public health leaders worry that a highly virulent pandemic strain could lead to more than 60 million deaths in today's highly interconnected world, mostly in the developing world.² While influenza's disease burden is believed to be considerable, it is largely overlooked in many countries.

In temperate regions of the world, influenza occurs in seasonal patterns, but less is known about the disease in developing, tropical countries, except that it can circulate year-round, with one or more peaks occurring per year. In Senegal, for example, influenza surveillance data indicate that the disease's peak tends to coincide with the warm rainy season.³ Throughout the tropical world, available data suggest that influenza-related morbidity may be underappreciated and substantial. Although effective influenza vaccines have been available for decades, they have not been well-studied or used extensively in tropical developing countries, including most African countries.

Since children are the suspected main transmitters of influenza and are particularly susceptible to influenza infection, determining the best prevention options for them is critical to controlling the spread and severity of influenza outbreaks, especially in low-resource populations where disease often takes the greatest toll. Knowing more about how influenza vaccines work in developing, tropical Africa is critical so that national, regional, and global public health officials can develop optimal control strategies more easily and effectively against the disease.

INFLUENZA VACCINE STUDY IN TROPICAL AFRICA

PATH and the Institut de Recherche pour le Développement (IRD) are partnering to gain a better understanding of the performance of seasonal influenza vaccines among children in a tropical, low-resource region of Senegal. Through a cooperative agreement with



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the US Centers for Disease Control and Prevention and with authorization from Senegal's Ministry of Health and Medical Prevention, we are conducting a Phase 2, placebo-controlled clinical study separately assessing the safety of and immune responses elicited by two different seasonal influenza vaccines among 300 children six months through five years of age in Niakhar, Senegal. Both vaccines are trivalent influenza vaccines (TIVs), meaning they include three influenza virus strains. The strains are inactivated, or killed, so they cannot cause influenza. One of the vaccines contains an adjuvant—an additive that enhances the immune response to a vaccine—and the other does not.

The adjuvanted TIV (adjTIV) is licensed for use in adults 65 years of age and older and has been tested safely in previous pediatric clinical studies, but is currently undergoing clinical development to gain regulatory

approval for use in children. While not currently licensed in Senegal, the vaccine is approved for adults in over 24 countries worldwide, including France. The adjuvant, MF59™, has been licensed and used safely in influenza vaccines for both children and adults around the world since the 1990s. Further research is needed to understand how this vaccine works in children living in tropical, low-resource settings.

The TIV without adjuvant is approved for use in adults and children six months of age and older in Senegal, France, and dozens of other countries worldwide. It is in wide use around the world for children three years of age and older at a standard full dose of 0.5 mL. For children six months to three years of age, some countries opt for the standard dose and other countries use a half dose. Continued research is required to determine which dose is best for young children in tropical Africa.

This Phase 2 study focuses on two research purposes. The first is to answer questions about adjTIV's feasibility as an influenza prevention tool that can meet the specific needs of children in tropical, low-resource African countries like Senegal. We are observing the vaccine's safety in participating children and measuring whether or not the adjuvanted vaccine improves immune responses—potentially decreasing the amount of vaccine needed for protection and stretching vaccine supplies further. Study results will ultimately inform future effectiveness studies that will assess adjTIV's ability to prevent influenza disease in children and their communities in tropical settings.

The second research purpose is to better understand how the full dose of TIV without adjuvant performs in children six months to three years of age in Senegal. We are measuring the immune responses of participating children at the standard full dose and observing the vaccine's safety in this age group. Data from this study will contribute to a larger effort to determine the best dosage level for this population.

Overall, results from this study will provide evidence to support larger research efforts to determine the most feasible and efficient ways of protecting populations in tropical, developing Africa from influenza through the use of vaccines. Furthermore, the information generated will help inform future influenza vaccination policy for young children in Senegal and the African region.

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References

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