

Developing new vaccines against pneumonia and other pneumococcal diseases

Pneumonia is the leading cause of death among children less than five years of age worldwide. More than 900,000 of these children die each year—constituting 15 percent of all child deaths globally.¹ The most common cause of severe pneumonia is the bacterium *Streptococcus pneumoniae* (pneumococcus). Pneumococcus also causes sepsis (blood infection) and meningitis (brain infection), which kill and disable children worldwide, and is one of the leading causes of bacterial otitis media (inner ear infection). Vaccines are a critical strategy for protecting children from these diseases, particularly in Africa and Asia, where the vast majority of all pneumococcal deaths occur.

More than 90 kinds (or serotypes) of pneumococcus exist, which vary by region. The vaccines in current use for infants—pneumococcal conjugate vaccines (PCVs)—are effective against the serotypes contained in the vaccines, but do not protect against all pneumococcal serotypes. Furthermore, they are complicated and relatively expensive to produce, which makes them difficult for low-income countries to afford without considerable assistance. With the help of Gavi, the Vaccine Alliance; the Advance Market Commitment funding mechanism; and other international donors, PCVs are being rolled out in low-resource countries around the world.

New vaccines are needed, however, that are inherently more affordable and that provide either focused protection for children against serotypes prevalent in the developing world or broad protection across all pneumococcal serotypes. To meet this need, PATH is pursuing multiple approaches to developing safe, affordable, and effective pneumococcal vaccines for infants and children in low-income settings. We work from initial antigen discovery through clinical trials and licensure to shorten the vaccine development timeline—partnering with scientists and manufacturers along the way.

BROADLY PROTECTIVE PROTEIN VACCINE DEVELOPMENT

Vaccines that contain proteins common to essentially all pneumococcal serotypes could potentially offer broad,



Pneumonia kills more children before their fifth birthdays than any other infectious disease, but many of these deaths are preventable with existing and incoming vaccines. Photo: PATH/Evelyn Hockstein.

affordable protection to children worldwide. PATH and Boston Children's Hospital are collaborating with other partners to advance the development of an inactivated, pneumococcal whole cell vaccine candidate (wSP), which is protein-based and could provide broad and inexpensive protection.

To date, wSP has demonstrated good safety and immunogenicity in early-stage clinical evaluation among healthy adults in the United States. Currently, the vaccine candidate is being evaluated in early-stage clinical studies in Kenya, which will provide valuable information about the vaccine's suitability for target populations in Africa and other low-resource settings.

PATH is partnering with PT Bio Farma, a state-owned vaccine manufacturer in Indonesia, to produce wSP. We are also studying the epidemiology of pneumococcal disease and carriage in Indonesia in collaboration with Murdoch Childrens Research Institute and Universitas Padjadjaran, Bandung. These activities are supporting long-term goals of achieving licensure in Indonesia and World Health Organization prequalification so that the vaccine can be made available to low-income populations at an affordable price.

DEVELOPMENT OF NEW, AFFORDABLE PCVS

We are also advancing new PCVs, which attach polysaccharide antigens—the protective component—to “carrier proteins” to make the polysaccharides elicit immune responses in infants and young children. PATH is collaborating with the Serum Institute of India, Private, Limited (SIPL), to speed the development of a 10-valent PCV candidate that focuses on serotypes prevalent in Africa and Asia. The approach combines proven conjugation methods with new innovations for rapid and cost-effective vaccine development to make these vaccines affordable for low-income countries. PATH is currently evaluating the vaccine candidate in a Phase 3 clinical trial in The Gambia in collaboration with the Medical Research Council, The Gambia (MRCG). In parallel, the vaccine candidate is also being evaluated in India in clinical studies sponsored by SIPL.



Current pneumococcal vaccines are saving lives around the world, but additional, low-cost vaccines are needed to broaden protection and ensure sustainable access for all. Photo: PATH/Doune Porter.

REFERENCE

1. Liu L, Oza S, Hogan D, et al. Global, regional, and national causes of under-5 mortality in 2000-15: an updated systematic analysis with implications for the Sustainable Development Goals. *Lancet*. 2016;388:3027-3035.



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