

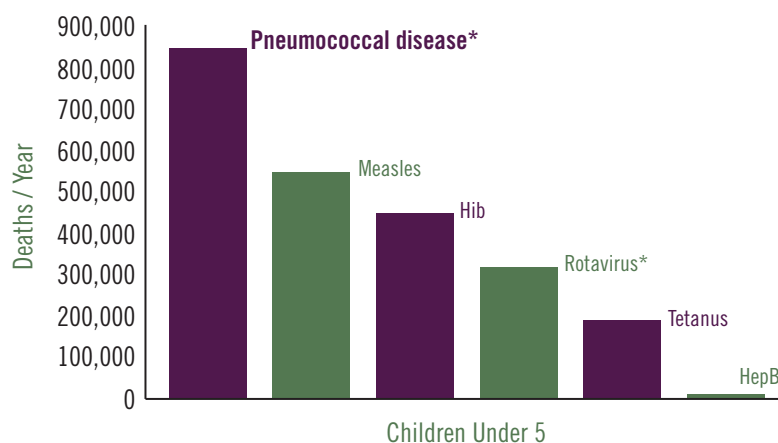
Why is the pilot AMC addressing pneumococcal diseases?

The decision about which disease to target was made by an independent expert committee chaired by Dr. Hetherwick Ntaba, former Minister of Health, Malawi. The committee included members from both developing and industrial countries with expertise in public health, epidemiology, industry economics, vaccine development and law. The committee came to the conclusion that of the six diseases they examined, pneumococcal vaccines were the best choice for a pilot AMC because of the potential to quickly demonstrate that the AMC concept works and because of the likely positive impact on the health of people in developing countries.

Pneumococcal vaccines are the right choice for the pilot AMC because:

- In the case of pneumococcal vaccines it is economics, not science, that currently stands in the way of new vaccines reaching developing countries. Various companies have suitable vaccines in the late stages of development and the AMC will provide the motivation for them to accelerate the process of making them available.
- Success can be easily measured – it will be defined by industry's willingness to build manufacturing capacity that would not otherwise have been developed. This is expected to happen quickly, yielding results in the near future that will drive decision-making about possible AMCs for other diseases.

Leading Causes of Vaccine-Preventable Death in Children <5 Years Old



Source: WHO official mortality rates — June 2003

* Provisional estimates

- This AMC represents good value for money. Because there is a large global market for pneumococcal vaccines, the pilot AMC will leverage the investments that industry has already made in research and development that were driven by the markets in high- and middle-income countries. This AMC will only pay for the incremental investment needed to supply developing countries.

AMCs allow developing countries to choose what vaccines they want.

As agreed by the donors, the objectives of the pneumococcal AMC are:

1. To accelerate the development of pneumococcal vaccines that meet developing country needs (e.g. serotype composition and vaccine presentation) as specified in the Target Product Profile.
2. To bring forward the availability of effective pneumococcal vaccines for developing countries by guaranteeing the initial purchase price, for a limited quantity of the new vaccines, that represents value for money and incentivises manufacturers to invest in scaling-up production capacity to meet developing country vaccine demand.

3. To accelerate vaccine uptake by ensuring predictable vaccine pricing for countries and manufacturers. This would include binding commitments by participating companies to supply the vaccines at low, long-term and sustainable prices after the AMC financing is depleted.
4. To pilot test the effectiveness of the AMC mechanism as an incentive for supplying needed vaccines and to learn lessons for possible future AMCs.

What are pneumococcal diseases and what is their impact?

Serious pneumococcal diseases – primarily pneumonia and meningitis – are the leading vaccine-preventable cause of death in children under five years old. The World Health Organization estimates more than 800,000 children in this age group die every year from pneumococcal infections. Although children everywhere are affected, more than 90% of these deaths occur in the developing world.

Further, interrelationships with other conditions are making pneumococcal disease a growing and urgent global health issue. Children infected with HIV are especially vulnerable to serious pneumococcal infections like pneumonia and meningitis. In fact, they are up to 40 times more likely to become ill than other children. And once they're sick, HIV-positive children are far more likely to die from pneumococcal disease, especially when, as is frequently the case in developing countries, they are not getting appropriate AIDS medication. Antibiotic-resistant infections are widespread and pneumococcal pneumonia frequently follows influenza infections.

Pneumococcal diseases hit poor families the hardest. Paying the hospital bills for a sick child may require them to use precious savings or to borrow money, and parents are deprived of income while they feed and care for their hospitalized children in countries where nursing care is limited.

In addition to the deaths caused, pneumococcal disease disables many survivors. For example, life-long disabilities that often occur after pneumococcal meningitis include hearing loss, learning delays, speech impediments and paralysis. These disabilities in turn can mean fewer educational opportunities and poor employment prospects, contributing to a vicious cycle of poverty and ill health.

Why is a pilot necessary?

A pilot AMC has been proposed to demonstrate both the feasibility of the AMC mechanism and its impact on accelerating vaccine development, investment in production capacity and introduction of the resulting vaccines in developing countries. Through this pilot AMC, practical concerns about how to establish appropriate legal and financial structures will also be addressed, streamlining similar ventures for other diseases.

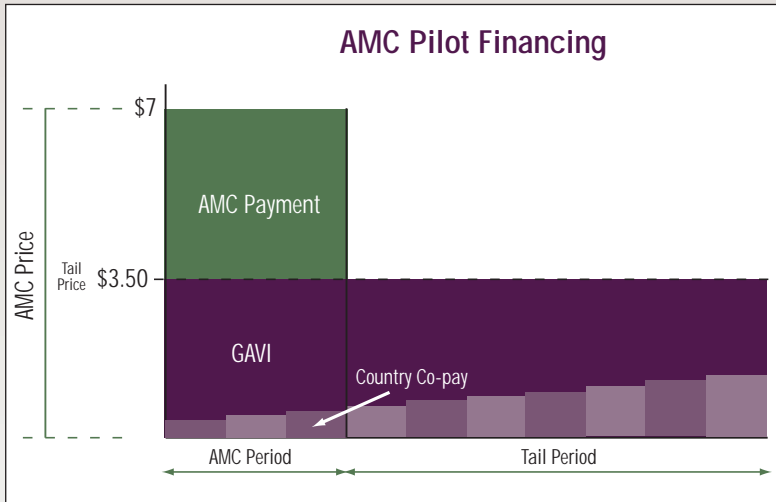
Why are new vaccines needed?

While a vaccine for pneumococcal disease exists, and is widely used in Europe and the United States, it is not optimal for developing countries. This is because there are many different strains of pneumococcal bacteria, known as serotypes. The current pneumococcal vaccine protects against seven serotypes (7-valent). In developing countries other serotypes, in addition to those covered by the 7-valent vaccine, are common, so a vaccine providing broader coverage, including these additional serotypes is needed.

The current vaccines are also too expensive, and not available in sufficient quantities to meet the potential global needs if all countries start immunising their children.

What new pneumococcal vaccines are currently in development?

Developing countries need a pneumococcal vaccine that is safe, effective against the prevalent disease strains, can be delivered as part of existing vaccine programmes and comes in a form that is easily adapted to local conditions.



More than twenty conjugate vaccines as well as common protein vaccine formulations are in the early stages of development. Several of these products may be licensed between 2015 and 2019. Potential emerging market suppliers for conjugate vaccines include producers in Brazil, Cuba, India and China who may manufacture their own vaccines or be licensed by a multinational to produce an existing vaccine. Several multinational companies have discontinued work on their pneumococcal vaccines but could potentially resume their efforts. A few “common protein” vaccines, which would protect against all serotypes, are in development.

Two late-stage vaccine candidates with adequate serotype coverage are currently in development: a 10-valent vaccine and a 13-valent vaccine. Both these vaccines may meet the needs of developing countries and are likely to be available by late 2009.

How much will the new vaccines cost?

The vaccines made available under this pilot AMC will cost only a fraction of the price currently paid in developed countries – probably a saving of around 90%, which is unprecedented.

Manufacturers that take part in an AMC will sign legally-binding commitments to supply their vaccine for 10 years at a price no higher than \$3.50 per dose. In return, companies will receive an additional payment averaging \$3.50 per dose for about 20% of the doses they provide.

Children in developing countries are the big winners from an AMC.

This additional payment is designed to provide sufficient incentives for manufacturers to make and recoup the initial investment in developing and manufacturing the vaccine.

The AMC price will also include a “co-pay” component to be paid by the government in the developing country that is using the vaccine, and by multilateral agencies such as GAVI and UNICEF, who traditionally assist with vaccine purchase. The country portion of this co-pay will gradually increase over the course of the AMC.