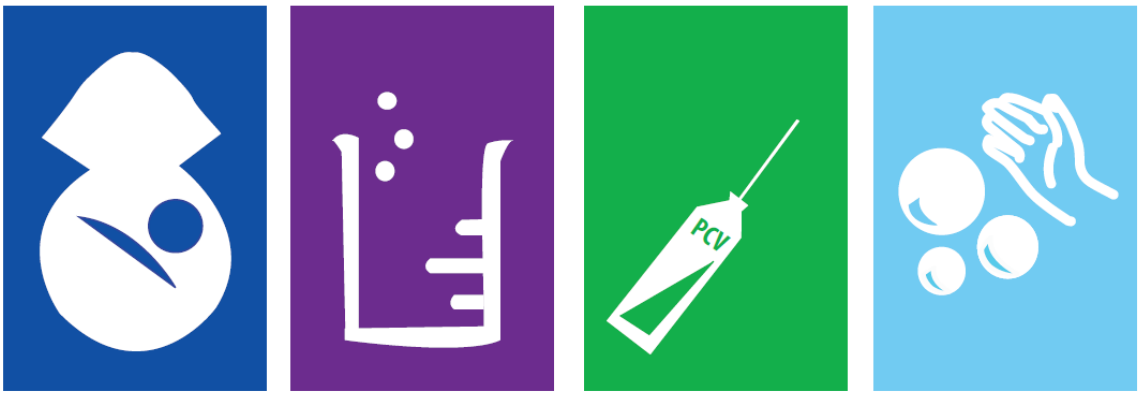
# Introduction of pneumococcal vaccine PCV13, A handbook for district and health facility staff

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## Introduction

**This handbook has been developed for countries introducing PCV13 Pneumococcal Vaccine.**

**Other presentations of pneumococcal vaccine are available, and materials for specific products have been developed.**

**This handbook is most useful for staff working at district and health facility levels. Some adaptations will need to be made at national level (by the National EPI Manager, in-country partners, and others) before its distribution, to ensure that certain aspects, such as national schedule, waste disposal or Adverse Events Following Immunization (AEFI) monitoring, are aligned with national policies.**

**Training materials and other resources related to Pneumococcal vaccines can be found at** http://www.who.int/nuvi/pneumococcus/resources/en/index.html

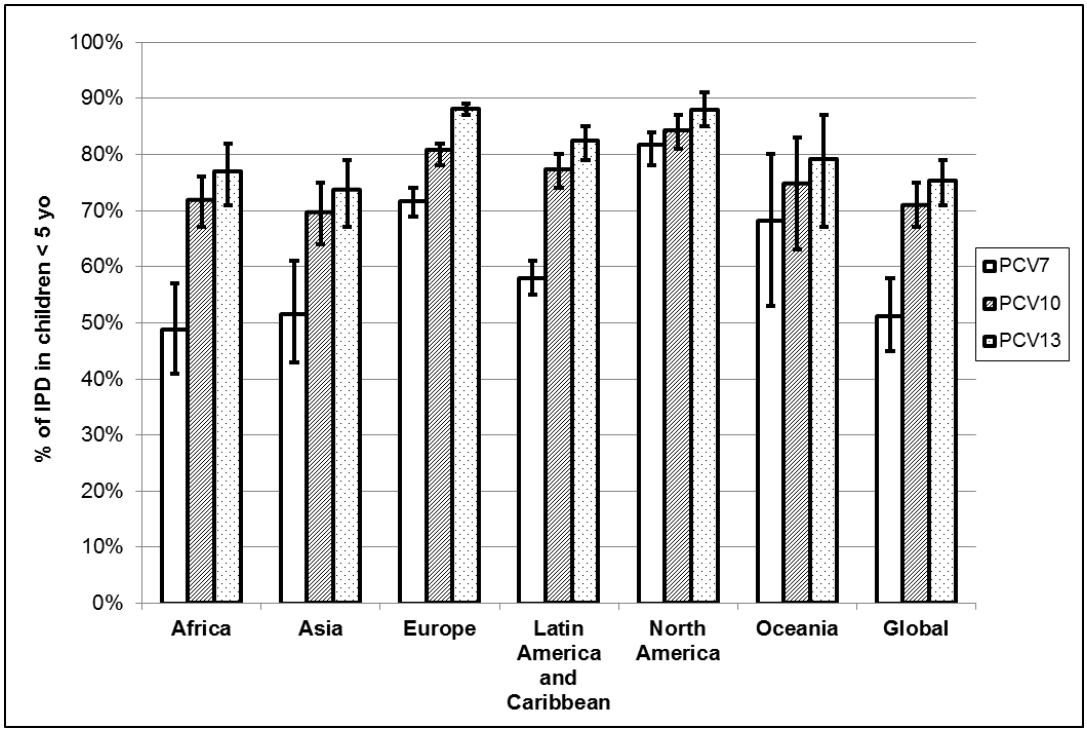
# 1. Pneumococcal Disease

### *1.1 What is pneumococcal disease?*

Pneumococcal disease is the name given to a group of diseases caused by a bacterium called *Streptococcus pneumoniae*, (also known as pneumococcus). Pneumococcal infection and disease can affect a variety of organ systems resulting in a number of disease syndromes. Diseases caused by pneumococcus include 1) severe diseases such as pneumonia, meningitis and bacteraemia (presence of bacteria in the blood), and 2) milder diseases such as middle ear infection (otitis media), sinusitis and bronchitis. In 2000, about 14.5 million episodes of serious pneumococcal disease were estimated to occur globally. Of the estimated 8.8 million global annual deaths amongst children <5 years of age in 2008, WHO estimated that 541,000 (uncertainty range: 376,000- 594,000) global child deaths due to pneumococcal(Streptococcus pneumoniae) infections among those under 5 years, of which 476,000 (uncertainty range: 333,000 – 529,000) occurred among HIV-negative children.

Pneumococcus is classified into a number of serotypes, based on the composition of its outer capsule. There are about 93 known serotypes whose prevalence varies by geographic region of the world, as well as by age. These different serotypes have varying potential to cause disease with relatively few serotypes associated with severe disease in children. Some serotypes also are more frequently associated with antibiotic resistance. The current 10-valent and 13-valent formulations of the pneumococcal conjugate vaccine include pneumococcal serotypes which cause over 70% of serious pneumococcal disease in children in all geographic regions. Below is a bar graph that shows the global distribution of pneumococcal serotypes and the different vaccine formulations currently available with the serotypes included in the vaccines.

**Figure 1: Proportion of regional Invasive Pneumococcal Disease represented by serotypes in vaccine formulations, 2008**



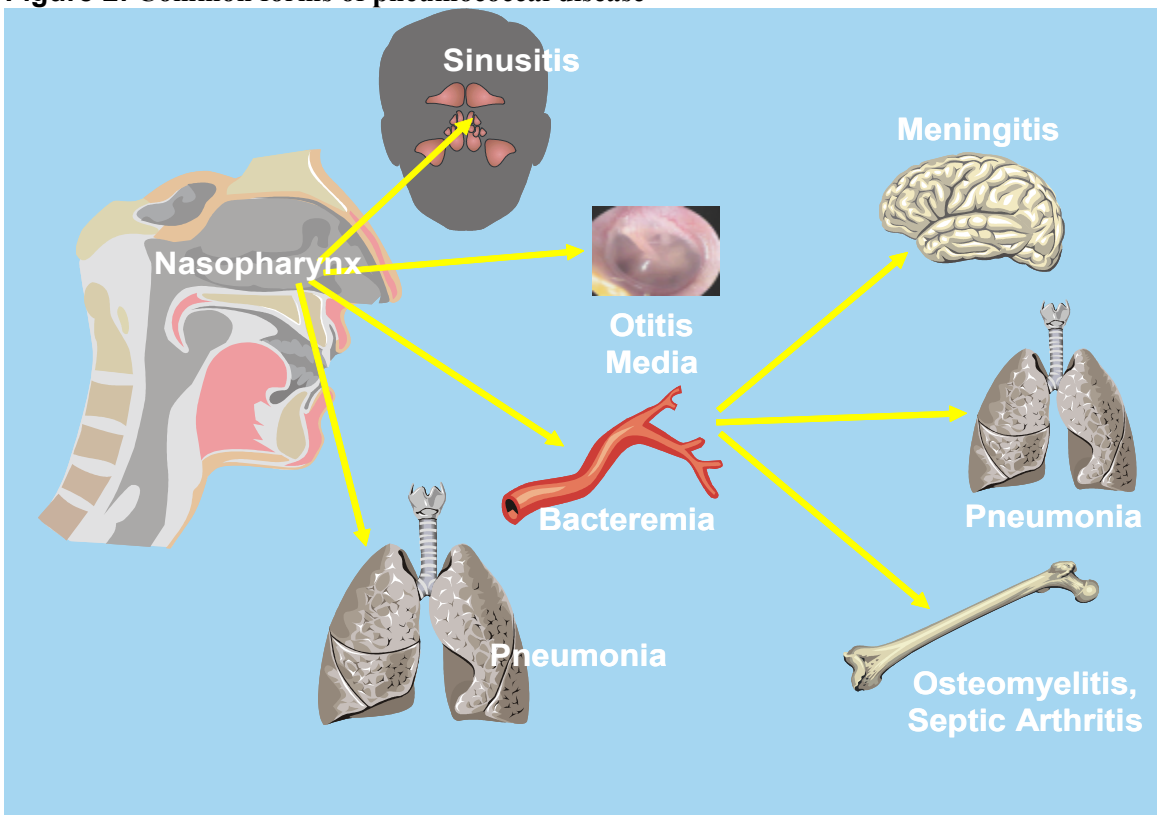

Source: Systematic Evaluation of Serotypes Causing Invasive Pneumococcal Disease among Children Under Five: The Pneumococcal Global Serotype Project

### *1.2 What are the common forms of pneumococcal disease?*

Pneumococcus causes both severe and non-severe disease. Pneumococci frequently colonize the nose and throat asymptomatically; a high proportion of children carry this bacteria in their nose or throat at any given time. Sometimes, within an individual pneumococcus can spread from the nose and throat to the blood stream causing bacteraemia and then infect sites such as the meninges (lining of the brain). Diseases caused by invasion of the blood stream and subsequent infection of other sites are collectively referred to as Invasive Pneumococcal Disease (IPD). Pneumococci can also be aspirated from the nose and throat into the lung resulting in pneumonia, or can spread to other adjoining sites such as the middle ear, causing otitis media, or to the sinuses, causing sinusitis. The most common severe form of pneumococcal disease is pneumonia. Less commonly, pneumococcus causes meningitis, which can be fatal or leave survivors with permanent disabilities. The less severe infections such as otitis media, sinusitis, and bronchitis all are much more common than pneumonia or meningitis, but not usually fatal.

In developing countries, deaths from pneumococcal disease are common in children under 5 years. In industrialized countries, pneumococcal disease is also a common cause of death in the elderly. In developing countries, the contribution of pneumococcal disease to death in the elderly is not well quantified.

**Figure 2:** Common forms of pneumococcal disease




### *1.3 How is pneumococcal disease transmitted?*

Pneumococcus is transmitted by respiratory secretions of people carrying pneumococcus in their nose or throat.

### *1.4 How is pneumococcal disease diagnosed?*

It can be difficult to establish whether pneumococcal infection is the cause of the patient's symptoms because even in true pneumococcal cases the specimens collected often do not yield the bacterium. This is particularly true of pneumococcal pneumonia because specimens from the actual site of infection (i.e. the lung) cannot be collected and in only a small fraction of pneumococcal pneumonia cases is the blood also infected. Nevertheless, pneumococcal infections are normally diagnosed through laboratory testing of the blood

(for bacteraemia and bacteraemic pneumonias) or in the case of suspected meningitis by performing a lumbar puncture, which involves inserting a needle into the epidural space to obtain a sample of cerebrospinal fluid (CSF). Pneumococcus is a difficult bacterium to grow in the laboratory and frequently goes undiagnosed even when blood or CSF samples are truly infected with the pneumococcus.

### *1.5 Who are most at risk for pneumococcal disease?*

Children under 5 years of age and especially those under 2 years of age are most at risk of developing and dying from pneumococcal disease. Case fatality rates may be up to 20% for pneumonia, and as high as 50% for meningitis in developing countries. Lack of exclusive breastfeeding, nutritional deficiencies, and indoor air pollution are risk factors for pneumonia, including pneumococcal pneumonia, in infants and young children. Apart from the high incidence in children <2 years of age, the risk for pneumococcal disease is increased in the elderly (>65 years of age), and in people who use tobacco or alcohol excessively. This risk is also increased in individuals who suffer from chronic medical conditions, such as heart disease, lung disease, diabetes, asplenia, chronic kidney disease or from other conditions that suppress the immune system, such as advanced HIV infection. Preceding infection with influenza virus is also a risk factor for pneumococcal pneumonia.

### *1.6 What is the treatment for pneumococcal disease?*

Pneumococcal disease, including pneumococcal pneumonia and pneumococcal meningitis, can be treated with antibiotics, usually amoxicillin. However, in many countries strains of pneumococcus are becoming resistant to some of the commonly used antibiotics. Pneumococcal infections which are resistant to these antibiotics require treatment using more expensive antibiotics

### *1.7 Why do we vaccinate against pneumococcal disease?*

The risk of serious pneumococcal disease remains high throughout the first 24 months of life. Pneumococcal disease is associated with high mortality, especially when timely antibiotic treatment is not available. Vaccination can prevent substantial mortality and morbidity, especially in the underserved populations of the poorer countries.

## 2. Pneumococcal Conjugate Vaccine

### *2.1 What is Pneumococcal Conjugate Vaccine (PCV)?*

Pneumococcal conjugate vaccine consists of sugars (polysaccharides) from the capsule of the bacterium *Streptococcus pneumoniae* that are conjugated to a carrier protein. Unlike the pneumococcal polysaccharide vaccine, the pneumococcal conjugate vaccine protects children younger than 2 years of age. It protects against severe forms of pneumococcal disease, such as pneumonia, meningitis and bacteraemia. It will not protect against these conditions if they are caused by agents other than pneumococcus or by pneumococcal serotypes not present in the vaccine. Two conjugate vaccines are available since 2009, one 13-valent (PCV13) the other 10-valent (PCV10). The first pneumococcal conjugate vaccine, a 7-valent product, is no longer in use.

### *2.2 What is the vaccination schedule for PCV?*

For PCV administration to infants, WHO recommends 3 primary doses (the 3p+0 schedule) or, as an alternative, 2 primary doses plus a booster (the 2p + 1 schedule). In choosing between the 3p+0 and 2p+1 schedules, countries should consider locally relevant factors including the age distribution of pneumococcal disease, the likely vaccine coverage, and the timeliness of the vaccine doses.

If the 3p+0 schedule is used, vaccination can be initiated as early as 6 weeks of age with an interval between doses of 4 - 8 weeks, for example at 6, 10, and 14 weeks or at 2, 4, and 6 months, along with Pentavalent (DTP-HepB-Hib) and Rotavirus vaccine.

If the 2p+1 schedule is selected, the 2 primary doses should ideally be completed by six months of age, starting as early as 6 weeks of age with a minimum interval of 8 weeks or more between the two doses (for infants aged ≥7 months a minimum of 4 weeks between doses is acceptable) but every effort should be made to start vaccinations in children as early as possible). One booster dose should be given between 9 - 15 months of age. In this schedule, the booster does of pneumococcal vaccine may be given along with measles vaccine and Vitamin A supplementation.

Previously unvaccinated or incompletely vaccinated children (including those who had laboratory confirmed invasive pneumococcal disease) should be vaccinated using the recommended age appropriate regimens. Interrupted schedules should be resumed without repeating the previous dose.

For unvaccinated older children aged 12 - 24 months and children aged 2 - 5 years to who are at high risk of pneumococcal infection, two catch-up dose(s) at an interval of at least 8 weeks may be given.