WHO position paper on pneumococcal vaccines 2012

Summary

The current WHO position paper, which focuses mainly on the 10-valent and 13-valent pneumococcal conjugate vaccines (PCVs), replaces the 2007 position paper on 7-valent PCV. The position paper on 23-valent pneumococcal polysaccharide vaccine published in 2008 remains valid in the absence of any new evidence that would require a change in recommendations. (Some still valid key recommendations on the use of PPV23 are included in the current document).

Infections caused by *Streptococcus pneumoniae* (the pneumococcus) include serious diseases such as meningitis, bacteremia, and pneumonia as well as less severe conditions such as sinusitis and otitis media. Pneumococci are usually transmitted through respiratory droplets from the nasopharynx, particularly from infants and young children.

S. pneumoniae includes >90 serotypes. In the pre-vaccination era, 6 – 11 of these serotypes accounted for ≥70% of all invasive pneumococcal disease worldwide. The WHO estimates that in 2008, out of the about 8.8 million global annual deaths amongst children aged <5 years, 476 000 (333 000 – 529 000) were caused by pneumococcal infections. In developing countries case-fatality rates among younger infants may reach 20% for pneumococcal septicemia and 50% for meningitis.

Currently marketed pneumococcal vaccines include one polysaccharide vaccine (PPV23) and two conjugate vaccines (PCV10 and PCV13). The 7-valent conjugate vaccine (PCV7) is gradually being removed from the market.

Pneumococcal polysaccharide vaccines are safe, but poorly immunogenicity in infants <24 months of age and fail to induce an anamnestic antibody response. To enhance immune responses selected polysaccharide serotype-antigens are conjugated with various protein carriers; PCV10 includes serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F, whereas PCV13 in addition includes serotypes 3, 6A, and 19A. Licensure both of PCV10 and PCV13 was based on non-inferiority trials as compared to the well documented protective efficacy of PCV7 and a related PCV9-formulation.

PCV10 and PCV13 are licensed for the prevention of invasive disease, pneumonia and acute otitis media caused by the respective vaccine serotypes in children from 6 weeks to 5 years of age. In addition, PCV13 is licensed for the prevention of pneumococcal disease in adults aged ≥50 years.

Recent reviews of randomized, controlled trials of PCV7 and PCV9 have shown vaccine efficacies (VEs) against invasive pneumococcal disease of 71% and 93%, respectively, following 3 primary doses or 3 primary plus a booster dose. For radiologically confirmed pneumonia (first episode), the estimated VE for 3 primary doses was 24%. Based on the immunogenicity data, PCV10 and PCV13 show comparable VEs for serotypes contained in the vaccines. The immunogenicity and reactogenicity of the involved antigens are shown not

to be significantly altered when PCVs are given concomitantly with other childhood vaccines. VE with PCV9 remained significant (78%) against IPD 6 years after PCV immunization.

PCVs are considered safe in all target groups for vaccination, including immunocompromised individuals.

WHO recommends that inclusion of PCVs be given priority in childhood immunization programmes world-wide, especially in countries with under-5-mortality of >50/1000 live births. For administration to infants, 3 primary doses (3p+0 schedule) or, as an alternative, 2 primary doses plus a booster (2p+1 schedule) are recommended. Primary vaccination can be initiated as early as at 6 weeks of age. In choosing between the 3p+0 and 2p+1 schedules, countries should take into consideration local disease epidemiology, particularly the peak age of disease. If the 3p+0 schedule is used, the minimum interval between doses should be 4weeks, with vaccinations scheduled at 6, 10, and 14 weeks of age or at 2, 4, and 6 months of age, depending on programmatic convenience.

If the 2p+1 schedule is selected, the 2 primary doses should be given at an interval of 8 weeks or more for the youngest infants and 4–8 weeks or more for infants aged ≥7 months. One booster dose should be given between 9–15 months of age.

Catch-up vaccination as part of introduction will accelerate herd protection and therefore the PCV impact on disease and carriage.

The impact of PCV should be carefully monitored as part of routine sentinel surveillance. Available evidence does not suggest that serotype replacement should not be an impediment s.to PCV introduction. However, the occurrence and magnitude of serotype replacement should be monitored through carefully conducted surveillance studies also including low income settings.

PCVs for immunization of older populations and the potential use of such vaccines for immunization in pregnancy to protect newborn babies are currently not considered sufficient to make policy recommendations.