衞生防護中心
Centre for Health Protection

Centre for Health Protection
Scientific Committee on Vaccine Preventable Diseases

Use of Hepta-valent Pneumococcal Conjugate Vaccine in the Childhood Immunisation Programme

Background

Streptococcus pneumoniae is a common bacterial pathogen causing pneumonia, acute otitis media, and various forms of invasive pneumococcal diseases (IPD), namely, septicaemia, meningitis and bacteraemic pneumonia. In 2005, World Health Organization (WHO) estimated that IPD has been causing 1.6 million deaths annually, including 0.7–1 million children younger than 5 years of age mostly in developing countries. In developed economies such as Europe and United States (US), children younger than 2 years of age and elderly people carry the major burden of disease.

2. So far, more than 90 serotypes of the bacteria have been identified and a hepta-valent pneumococcal conjugate vaccine (PCV7), targeting seven of the most common serotypes have been marketed internationally. This vaccine has been licensed for use in children up to 9 years of age. Other pneumococcal conjugate vaccines with wider serotype coverage, including a 10-valent vaccine and a 13-valent vaccine, are in the late stages of development. For adults and children older than 2 years, an unconjugated polysaccharide vaccine targeting at 23 serotypes is available internationally.

3. The Scientific Committee on Vaccine Preventable Diseases (SCVPD) have reviewed the disease epidemiology in the past few years and developed recommendations on the use of the two vaccines in 2007. This paper focuses on issues related to incorporation of PCV7 to routine childhood immunisation programmes. For the use of pneumococcal vaccine in other at-risk groups, please refer to an earlier SCVPD paper entitled "Recommendations on the Use of Pneumococcal Vaccines".

Hepta-valent Pneumococcal Conjugate Vaccine

4. Clinical trials conducted in developed countries using a standard regimen of 3-dose primary series given at the age of 2 months, 4 months, and 6 months and an additional booster given at the age of 12 to 15 months demonstrated an efficacy of more than 90% against the serotypes contained in the vaccine. These seven vaccine serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, 23F) were responsible for 65-80% of IPD among young children before the vaccine was introduced in industrialised countries.

5. PCV7 has been marketed for over eight years and more than 20 million doses have been distributed in the US. Post-marketing surveillance showed that PCV7 is safe and adverse reactions are generally mild. Slight swelling and tenderness at the injection site may occur shortly following injection. Transient fever of >39ºC has been reported up in up to 4.7% of PCV7 vaccinees. Hypersensitivity or severe allergic reaction to a prior dose or any component of the vaccine, including diphtheria toxoid, is a contraindication to use of the vaccine. Persons with moderate or severe acute illness should not be vaccinated until their condition improves.

Considerations for introducing universal childhood pneumococcal vaccination

6. The US is the first country that has incorporated PCV7 in the universal childhood immunisation programme since 2000, followed by Canada in 2002. At least another 18 countries followed, mostly in the recent 3 years. These countries included United Kingdom, Australia, France, New Zealand, and other European countries. Catch-up programmes have been implemented to various extent in some countries.

7. The SCVPD has recommended use of pneumococcal vaccine for personal protection in 2007. Based on the latest available scientific evidence, the SCVPD recently examined the benefits and potential drawbacks to the Hong Kong community by introducing universal childhood pneumococcal vaccination. The main considerations are summarised below.

Additional benefits

8. Experience in industrialised countries has shown a decline in the incidence of IPD among children by up to 77%. Most countries have adopted a regimen in line with those used in clinical trials, consisting of a 3-dose primary series plus one booster dose at the age of 12 to 15 months.

9. Herd protection effect, that is, an indirect protection to the non-vaccinated population through reduction of nasopharyngeal carriage and the subsequent transmission of vaccine serotypes, have been demonstrated in the US. However, the unimmunised individuals themselves do not develop immunity and the coverage of PCV7 required for such indirect effect to occur is uncertain.

10. A reduction of IPD caused by antibiotic resistant *S. pneumoniae* by up to 59% has been demonstrated in studies.

11. From the economic perspective, incorporating PCV7 in universal childhood immunisation programme has been demonstrated beneficial in overseas studies using various assumptions. More importantly, a recently released local study commissioned by the Centre for Health Protection showed supportive findings. Inclusion of PCV7 in the local childhood immunisation programme is estimated to have a benefit to cost ratio of 1.8 in this local study, when assuming a certain market price per each PCV7 dose, and a herd protection effect of reducing pneumococcal pneumonia in adults aged 20 years or older. In addition, the net cost per life-year saved in the above model is estimated to be HK$55,000 and is about 25% per capita GDP of Hong Kong. (The GDP per capita of Hong Kong in 2006 was HK$215,006, at current market price.).

Potential drawbacks

12. Despite an overall decrease in incidence of IPD, significant increase in IPD caused by non-vaccine serotypes has been observed in places following the introduction of PCV7 in the routine childhood immunisation programme. One study in the US showed various serotypes have been reported and serotype 19A has been found to be the predominant cause of IPD in children in this study. Antibiotic resistance strains of these non-vaccine serotypes have also been reported.

13. Practical concerns about incorporating pneumococcal childhood immunisation include: acceptability among parents because of an additional injection at the age of 2, 4 and 6 months and the sustainability of vaccine supply as PCV7 is produced by only one pharmaceutical company.

Recommendation

14. This Committee has already recommended use of hepta-valent pneumococcal conjugate vaccine for personal protection among high risk groups of suitable age range, primarily children under 2 years of age. Balancing the additional benefits and potential drawbacks as revealed in updated scientific studies, this Committee recommends incorporation of PCV7 in the universal childhood immunisation programme.

15. The standard regimen includes a primary series consisting of three doses given at the age of 2 months, 4 months, and 6 months and a booster dose given at 12 to 15 months of age. The vaccine can be given simultaneously with DTaP-IPV, hepatitis B, and MMR vaccine, as indicated at different injection sites.

16. We also recommend the setting up of a comprehensive pneumococcal surveillance programme to monitor the impact of the vaccine use on herd protection, serotype replacement, and antibiotic resistance strains. We also recommend efforts in the Government to ensure vaccine sustainability, acceptability of parents as well as a high coverage rate.

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