衞生防護中心
Centre for Health Protection

Scientific Committee on Vaccine Preventable Diseases

Recommendations on the Use of 13-valent Pneumococcal Conjugate Vaccine in Childhood Immunisation Programme

Note: These recommendations should be read in conjunction with SCVPD "Recommendations on the Use of Pneumococcal Vaccines"[1] *, "Use of Hepta-valent Pneumococcal Conjugate Vaccine in the Childhood Immunisation Programme"*[2] *and "Recommendations on the Interchangeability between 7-valent Pneumococcal Conjugate Vaccine and 10-valent Pneumococcal Conjugate Vaccine"*[3]

Background

I. Use of pneumococcal conjugate vaccine in Childhood Immunisation Programme

The Scientific Committee on Vaccine Preventable Diseases (SCVPD) recommended in 2008 the incorporation of 7-valent pneumococcal conjugate vaccine (PCV7) into the Childhood Immunisation Programme.

2. Since September 2009, PCV7 had been incorporated into the Childhood Immunisation Programme and it was subsequently replaced by 10-valent pneumococcal conjugate vaccine (PCV10) in October 2010.

II. Thirteen-valent pneumococcal conjugate vaccine

[1] SCVPD. March 2009. Recommendations on the Use of Pneumococcal Vaccines.
[2] SCVPD. October 2008. Use of Hepta-valent Pneumococcal Conjugate Vaccine in the Childhood Immunisation Programme.
[3] SCVPD. August 2010. Recommendations on the Interchangeability between 7-valent Pneumococcal Conjugate Vaccine and 10-valent Pneumococcal Conjugate Vaccine.

3. A 13-valent pneumococcal conjugate vaccine (PCV13) has been registered and available in Hong Kong since 2010. It is indicated for the prevention of invasive disease, pneumonia and acute otitis media caused by pneumococci in infants and children from 6 weeks to 5 years of age.

4. PCV13 contains capsular antigens of 13 serotypes of pneumococci (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F). The capsular antigens in the vaccine are individually conjugated to diphtheria toxoid CRM_{197}.

5. Available immunogenicity data shows that PCV13 generally met the non-inferior criteria predefined by the World Health Organization. Sub-optimal serological booster response to serotype 3 has been reported and its clinical significance is not clear at present.

6. Available safety data of PCV13 shows that it is comparable to that of PCV7. The most commonly reported adverse reactions are injection site reactions, fever, irritability, decreased appetite and sleep disturbances. No significant safety issue has been reported in countries which adopted PCV13 for their national immunisation programme.

III. Local epidemiology of invasive pneumococcal disease

7. Since the launching of the childhood PCV programme, the number of cases of invasive pneumococcal disease (IPD) showed considerable decline. The percentage reduction of IPD during 2008 – 2010 was 60% among children aged below 2 years, 21% among children aged below 5 years, and 11% among persons of all ages. These data lends support to the effectiveness of the PCV programme in reducing the incidence of IPD among children and other segments of the population via direct protection and possibly herd immunity effects.

8. On the other hand, the latest laboratory surveillance data in 2010 shows that the difference in coverage of local circulating serotypes of pneumococci between PCV13 and that of PCV7/PCV10 is gradually becoming greater. Among children below 5 years of age with IPD in 2009, the proportion caused by serotypes covered by PCV7*, PCV10* and PCV13 were 70%, 70% and 100%. In 2010, the corresponding proportions shifted to 47%, 47% and 93%. Notably, the number of childhood IPD caused by serotype 3 has increased from one case in 2009 to six cases in 2010. Similarly though to a lesser extent, among persons of all ages, the proportion of IPD caused by serotypes covered by PCV7*, PCV10* and PCV13 were 52%, 53% and 79% in 2009, and they changed to 47%, 49%, and 78% respectively in 2010. This phenomenon of serotype replacement has been observed in overseas countries

* assuming serotype 6B in PCV7 and PCV10 cross-protects serotype 6A

some time after initiation of childhood PCV programmes. The trend is expected to continue if the vaccine formulation in the childhood PCV programme is to remain unchanged.

Recommendations

9. Having reviewed the scientific data and safety data of PCV13, it is considered that PCV13 should confer an overall non-inferior protection against IPD serotypes covered by PCV7 and PCV10. Available immunogenicity data of PCV13 shows that the level of protection against serotype 3 may differ from other serotypes. The safety profiles of the three PCVs are comparable.

10. Based on local surveillance data of IPD, all three available PCVs provide substantial coverage to common pneumococcal serotypes that cause in Hong Kong, among which PCV13 provides the widest coverage against IPD whilst PCV10 provides additional protection against acute otitis media. According to the latest serotype distribution data in Hong Kong, serotype replacement has gradually progressed in recent years and the trend is expected to continue. As a result, there will be a larger proportion of childhood IPD cases potentially preventable by PCV13.

11. Taking into account the immunogenicity and safety profile of PCV13, overseas experience and recent trends in local surveillance data, it is considered that PCV13 is preferable over PCV7 and PCV10 for use in the Childhood Immunisation Programme of Hong Kong.

12. Regarding interchangeability between PCV10 and PCV13, there is currently no published immunogenicity data to address the interchangeability issue. From the antigenicity point of view, as the polysaccharide antigens in PCV10 and PCV13 are from the same bacteria, it is not likely that switching from one vaccine to another would cause undesirable reaction. Overseas experience also supported that PCV13 can be used safely as a direct replacement of PCV10 during the primary series. In this regard, SCVPD recommends that PCV13 be used as a direct replacement for PCV10 at any point during the course of immunisation. Such a schedule is expected to offer a non-inferior protection against IPD caused by the ten common pneumococcal serotypes contained in PCV10 and PCV13. The immunisation schedule for the remaining dose(s) should remain unchanged.

13. The standard regimen of pneumococcal vaccination in the Childhood Immunisation Programme of Hong Kong should remain unchanged at the moment (i.e. 3-dose primary series at 2nd, 4th and 6th months of age with a booster dose at 12-15 months). SCVPD will continue to review scientific data and overseas experience on the effectiveness of possible alternative primary schedules.

14. It should be noted that no PCV formulation can confer 100% protection to IPD as there are over 90 serotypes of pneumococci. Apart from vaccination, it is also important to observe personal hygiene measures such as: wash hands frequently; cover mouth and/or nose with tissue paper when coughing or sneezing; maintain good ventilation in indoor areas; avoid attending crowded or poorly ventilated public places if feeling unwell; and put on a surgical mask if having respiratory tract infection symptoms.

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