

Changes to the infant pneumococcal conjugate vaccine schedule

Information for healthcare practitioners



Summary

The UK pneumococcal conjugate vaccine (PCV) immunisation programme has successfully achieved high levels of population (herd) protection for all age groups. The Joint Committee for Vaccination/Immunisation (JCVI) have concluded that multiple doses of PCV13 are no longer required in the childhood immunisation programme. This is because there is very little carriage/disease due to PCV13 serotypes. The PCV13 immunisation schedule has therefore been changed as follows:

- January 2020 should be offered a single dose of PCV13 alongside their routine DTaP/IPV/Hib/HepB and rotavirus immunisations at 12 weeks of age, followed by a PCV13 booster at one year of age (on or after their first birthday). This will be referred to as the 1+1 PCV13 schedule.
- Infants born on or before 31

 December 2019 should continue
 to receive two doses of PCV13

 vaccine alongside their routine
 immunisations at 8 and 16 weeks
 of age, followed by a PCV13

 booster on or after their first
 birthday (referred to as the 2+1

 PCV13 schedule)

Background

The routine infant PCV programme was introduced in the UK in 2006, initially using a 7-valent vaccine (PCV7) which was replaced with the 13-valent vaccine (PCV13) in 2010. It has been highly successful, with large and sustained decreases in pneumococcal disease due to the 13 serotypes contained in the vaccine across the population and especially in young children. The PCV13 vaccine has proven to have very high effectiveness and there has been a high uptake of the vaccine for a number of years.

Given the success of the programme, both in those vaccinated, and in the wider population (through indirect population protection often referred to as 'herd immunity'), the Joint Committee of Vaccination and Immunisation (JCVI) reviewed the infant pneumococcal vaccination programme. They concluded that as the maximum direct and indirect benefit from the PCV13 programme has already been achieved, with very little carriage or disease due to the PCV13 serotypes, multiple doses of PCV13 should no longer be required in the childhood immunisation programme. Following detailed review and a stakeholder consultation, the JCVI agreed that a move from the 2+1 schedule to a 1+1 schedule was appropriate for the UK situation and that PCV13 should now be offered to infants at 12 weeks and one year of age.1

The 12-week dose will provide the infant with some protection against pneumococcal infection due to the vaccine serotypes and, importantly, will also prime their immune system to make a good response to the booster dose given at one year of age. The booster dose is particularly important, not only in providing individual protection, but also in preventing the vaccinated child from carrying pneumococcal bacteria in their nasopharynx and passing them on to others. This interruption of transmission is vital to sustaining the high levels of herd protection for unvaccinated susceptible individuals achieved to date in the UK.

The change in the UK pneumococcal recommendations has been carefully considered and is supported by several studies, including a clinical trial comparing the immunogenicity of the 2+1 and 1+1 schedules.² The 1+1 schedule should continue to provide individual protection and maintain population protection against pneumococcal disease. The epidemiology of pneumococcal disease will continue to be monitored very carefully and any changes in disease incidence in any age group can be detected, assessed and actioned quickly if needed.

The move to a 1+1 schedule provides the opportunity to reduce the number of vaccines administered at immunisation appointments and provides space in the vaccine schedule should any new vaccines need to be introduced in the future.

Scheduling for infants born on or before 31 December 2019

Infants on or before 31 December 2019 should be offered PCV13 alongside the other primary vaccines at 8 weeks and 16 weeks.

If infants born on or before 31 December 2019 are late in receiving their primary immunisations, they should be offered two doses of PCV13 eight weeks apart as per the previous 2+1 PCV13 schedule. For unimmunised or partially immunised children who present late for vaccination, the interval between doses may be reduced to four weeks if necessary to ensure that the immunisation schedule is completed.

Scheduling for infants born on or after 1 January 2020 (with the exception of those with asplenia, splenic dysfunction or those who are severely immunocompromised).

Infants born on or after 1 January 2020 should be offered PCV13 at 12 weeks of age at the same

time as their second set of primary immunisations. If an infant is late in starting their immunisation schedule (after 12 weeks of age), PCV13 can be given with the first set of primary immunisations or at any time from the age of 12 weeks and will still count as the single infant priming dose. If the first PCV13 dose is given very late (eg 11 months), then a minimum interval of four weeks should be observed before the booster dose to ensure appropriate boosting of the immune response.

As the immunogenicity of a single dose of PCV13 is lower when given at a younger age, any dose given before 12 weeks of age to infants born on or after 1 January 2020 will not be counted and another dose should be given once they reach 12 weeks of age, allowing at least four weeks between the two PCV13 doses.

Infants who have a reason to start their immunisations early (from six weeks) should receive their subsequent vaccines (which would include PCV13 vaccine) once they are 12 weeks old. Infants who have a reason to have their second set of primary immunisations administered earlier than 12 weeks should receive their PCV13 from 12 weeks of age, either with their third set of primary immunisations or on its own, if the third set of primary immunisations is likely to be given beyond 16 weeks.

Booster at one year of age

All infants (both born before and after 1 January 2020) should be offered a PCV13 booster dose at one year of age (on or after their first birthday) along with the other vaccines due at this age.

Children who start the immunisation schedule after their first birthday should be given a single PCV13 dose only, as has been previously recommended (with the exception of those who are asplenic, have splenic dysfunction or are severely immunocompromised – see relevant section below).

Infants given the incorrect schedule for their date of birth

Infants born on or before 31 December 2019 who are erroneously only offered a single dose of PCV13 with their second set of primary immunisations should be offered a second dose of PCV13 eight weeks after their first PCV13.

Infants born on or before 31 December 2019 who are inadvertently given PCV13 at 8 weeks and 12 weeks should receive another dose of PCV13 at 16 weeks.

Infants born on or after 1 January 2020 who are inadvertently given a dose of PCV13 before 12 weeks of age should be offered a second dose of PCV13 from 12 weeks of age allowing a minimum interval of 4 weeks between PCV13 doses.

Infants vaccinated abroad

The same date of birth rules apply for infants vaccinated abroad:

Infants born on or before 31 December 2019 who have not received any PCV13 in their country of origin should be offered two doses of PCV13 in the first year of life, allowing an eight week interval between doses. This should be followed by a booster at one year of age (on or after their first birthday), with a minimum of 4 weeks between the priming and booster dose. If they present on or after their first birthday, then they only require one PCV13 dose, irrespective of the number of previous PCV13 doses.

Infants born on or after 1 January 2020 who have not received any PCV13 in their country of origin should be offered a single dose of PCV13 when they present for immunisation at, or after 12 weeks of age, followed by a booster dose on or after their first birthday. If they have received a dose of PCV13 before 12 weeks of age, they should be offered PCV13 once they are 12 weeks old (allowing four weeks between doses),

followed by a booster dose once they reach their first birthday. Those that have received a dose of PCV13 in their country of origin over the age of 12 weeks do not require a further dose until the booster dose on/ after their first birthday.

Any infant who has received one or more doses of **PCV10** vaccine in another country should be offered a dose of PCV13 vaccine at least four weeks later, regardless of their date of birth. This ensures that infants coming into the UK are offered protection against the same pneumococcal serotypes as infants vaccinated according to the UK national immunisation schedule. These infants should receive one PCV13 dose from 12 weeks of age and a PCV13 booster at one year of age (on or after their first birthday, allowing an 8-week interval ideally or a minimum interval of 4 weeks between the two PCV13 doses.

Upper age limit for infant PCV

All unimmunised or partially immunised healthy children remain eligible for PCV13 up to their second birthday. Routine immunisation with PCV13 is not offered after the second birthday unless the individual is at increased risk of pneumococcal disease (see Green Book Pneumococcal chapter 25 (www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25) for risk groups).

Infants born prematurely

Additional doses of PCV13 are not recommended for premature infants unless they are asplenic, have splenic dysfunction or are severely immunosuppressed. Premature infants should follow the national schedule recommendations according to their date of birth as outlined above.

Infants and children in clinical risk groups

Additional doses of PCV13 are not recommended for infants/children in clinical risk groups unless they are asplenic, have splenic dysfunction or are severely immunosuppressed. Infants in other clinical risk groups should follow the national schedule recommendations according to their date of birth as outlined above.

Regardless of date of birth, all children who are asplenic, have splenic dysfunction or who are severely immunocompromised (includes children receiving a bone marrow transplant, with acute and chronic leukaemia, multiple myeloma or genetic disorders affecting the immune system (such as IRAK-4, NEMO), should receive the following:

Infants under 1 year of age: should receive two PCV13 doses 8 weeks apart in their first year of life followed by two doses 8 weeks apart in their second year of life.

Children between 1 year of age and second birthday: should receive two doses of PCV13, that is the PCV13 booster usually given at one year of age (on or after the first birthday) and an additional PCV13 booster dose 8 weeks later. The interval between doses may be reduced to 4 weeks if necessary, to ensure that the immunisation schedule is completed. Note: this is the schedule to follow regardless of how many primary doses of PCV13 were received in infancy.

Children aged two years and older who have one of the medical conditions listed in the paragraph above should follow the recommendations for PCV13 and PPV23 in the Green Book Pneumococcal chapter.

Interval between PCV doses

For infants born on or after 1 January 2020, in the rare circumstance where more than one PCV13 priming dose needs to be given in the first year of life (such as where an infant's only dose of PCV13 vaccine was given before 12 weeks of age or PCV10 was received abroad), a four-week interval should be observed between the first

PCV13 priming dose and the second. The routine primary immunisations should not be delayed to accommodate the PCV13 dose which can be given any time from 12 weeks of age, either alone or concomitantly with any of the primary immunisations.

Infants born on or before 31 December 2019 should continue to observe an eight-week interval between priming doses. For unimmunised or partially immunised children who present late for vaccination, the interval between doses may be reduced to four weeks if necessary, to ensure that the immunisation schedule is completed.

For all infants (born both before and after 1 January 2020), an eight-week interval between the priming dose(s) and the booster dose given at one year should be observed where possible in order to improve the response made to the booster. This interval can be shortened to a minimum four-week interval if the primary dose is not given until 11 months of age so that immunisations due on or after the first birthday are not delayed.

Prophylactic paracetamol

Prophylactic paracetamol is currently recommended when the MenB vaccine (Bexsero) is given with the other primary immunisations at 8 weeks and 16 weeks. There is no recommendation to give prophylactic paracetamol routinely at 12 weeks when PCV13 is given with DTaP/IPV/Hib/HepB and the oral rotavirus vaccine. However, no action needs to be taken if paracetamol is given prophylactically in error.

Paracetamol or ibuprofen can also be given to treat a fever or other symptoms following vaccination with PCV13 or any other vaccination if required. If an infant still has a fever 48 hours after vaccination or, if parents are concerned about their infant's health at any time following vaccination, advice should be sought from a GP or out-of-hours service.

Pneumococcal Polysaccharide Vaccine (PPV) given in error instead of Pneumococcal Conjugate Vaccine (PCV)

If PPV23 is inadvertently given to an infant in error where PCV13 should have been given, PCV13 should be given as soon possible after the error is realised. There is no need to observe any particular interval between the two vaccine doses in a child under two years of age.

Adapted from material produced by Public Health England.

References

- Joint Committee on Vaccination and Immunisation. Minutes of the meeting on 06 June 2018. Available at: app.box.com/s/ iddfb4ppwkmtjusir2tc/file/305779572165 www.gov.uk/government/groups/ joint-committee-on-vaccination-andimmunisation#minutes
- Goldblatt D, Southern J, Andrews N et al.
 Pneumococcal conjugate vaccine 13 delivered as one primary and one booster dose (1 + 1) compared with two primary doses and a booster (2 + 1) in UK infants: a multicentre, parallel group randomised controlled trial. The Lancet Infectious Diseases, February 2018; 18(2): 171-179.

For more information see pha.site/immunisationvaccine-preventable-diseases-hsc-public-health-agency



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