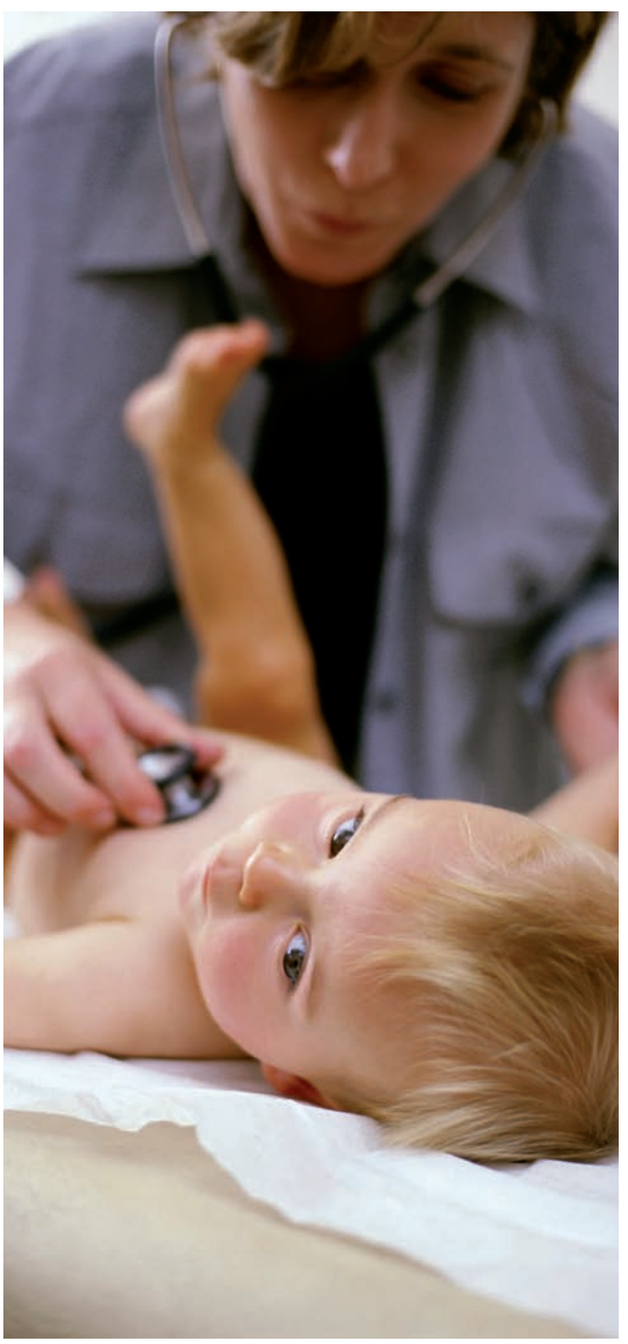
PROTECT HEALTH IMMUNISE

New programme, more protection

Frequently Asked Questions for Health Professionals



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

What are the changes to Primary Childhood Immunisation schedule?

The changes to the primary childhood immunisation schedule as recommended by the National Immunisation Advisory Committee (NIAC) in 2007 are

- replacing the 5 in 1 vaccine with a 6 in 1 vaccine to include Hepatitis B vaccine
- the addition of Pneumococcal conjugate vaccine (PCV)
- changes in the timing of Meningococcal C vaccine (Men C)
- changes in the timing of Haemophilus influenza vaccine (Hib)

When does the new schedule start?

All children born on or after July 1st 2008 will receive the new schedule.

The new schedule will start on September 1st 2008.

Change in Primary Childhood Immunisation schedule		
	By Age	
	Children born before 1/7/08	Children born on or after 1/7/08
Birth	BCG	BCG (1 injection)
2 months	5 in 1 + Men C	6 in 1 + PCV (2 injections)
4 months	5 in 1 + Men C	6 in 1 + Men C (2 injections)
6 months	5 in 1 + Men C	6 in 1 + PCV + Men C (3 injections)
12 months	MMR + Hib	MMR + PCV (2 injections)
13 months	-	Men C + Hib* (1/2 injections)
	By vaccine	
	Children born before 1/7/08	Children born on or after 1/7/08
Birth	BCG	BCG
5 in 1	2, 4, 6 months	-
6 in 1	-	2, 4, 6 months
Men C	2, 4, 6 months	4, 6, 13 months
MMR	12 months	12 months
Hib	12 months	13 months
PCV	-	2, 6, 12 months

5 in 1
Diphtheria
Tetanus
Pertussis (whooping cough)
Polio
Haemophilus influenza B (Hib)

6 in 1
Diphtheria
Tetanus
Pertussis (whooping cough)
Polio
Haemophilus influenza B (Hib)
Hepatitis B

* Men C + Hib combination may be available as a single vaccine

6 in 1 vaccine (includes Hepatitis B vaccine)

What vaccines are included in the 6 in 1 vaccine?

The 6 in 1, indicated for primary and booster immunisation of infants, contains vaccines against 6 diseases; diphtheria, tetanus, pertussis, Hepatitis B, poliomyelitis and disease caused by *Haemophilus influenzae* type b.

Why is Hepatitis B vaccine being introduced into the childhood schedule?

Hepatitis B is potentially a very serious disease (see below). In 2007, the National Immunisation Advisory Committee (NIAC) recommended the addition of the Hepatitis B vaccine to the primary childhood schedule because of the increasing incidence of Hepatitis B disease.

The introduction of Hepatitis B vaccine to the childhood programme in 2008 will provide protection for Irish children immediately and in the future. Introducing the vaccine at an early age has been found to be the most effective way to prevent Hepatitis B infection in populations.

When should the 6 in 1 vaccine be given?

At 2, 4 and 6 months of age.

6 in 1 is not licensed for use in children over 36 months of age. However, in accordance with NIAC guidelines 6 in 1 vaccine may be given to any late entrant under 5 years of age.

How long does the protection last after having the 6 in 1 vaccine?

Data from pre-licensure, post licensure and field studies indicates that this vaccine provides long-lasting protection against the six diseases.

Will a Hepatitis B booster be required?

No. Booster vaccination is not recommended. Current data show that vaccine-induced Hepatitis B surface antibody (anti-HBs) levels may decline over time; however, immune memory (anamnestic anti-HBs response) remains intact indefinitely following immunisation. Persons with declining antibody levels are still protected against clinical illness and chronic disease.

Are there side effects from the 6 in 1 vaccine?

Minor side effects are common and occur in approximately 1 in 10 recipients and include irritability, drowsiness, loss of appetite, fever $\geq$ 38°C, and pain, redness, and swelling at the injection site.

Any adverse vaccine reactions (ADRs) should be reported to the Irish Medicines Board via the yellow report card (available on www.imb.ie).

Are there any reasons why the 6 in 1 vaccine should not be given?

Contraindications:

- Previous anaphylactic reaction to any component of the vaccine.

Precautions

- Immunisation should be deferred in any child with acute severe febrile illness until the illness has resolved.

Does the 6 in 1 vaccine contain thiomersal (mercury)?

No. Thiomersal is not used in the 6 in 1 vaccine.

What about an at risk child who received Hepatitis B vaccine at birth?

This child should still have their routine 6 in 1 vaccines at 2, 4 and 6 months. This will provide a full course of Hepatitis B vaccine.

Is there a catch up programme for Hepatitis B vaccine?

No. NIAC did not recommend a catch up campaign for Hepatitis B vaccine. Other countries have introduced an universal adolescent Hepatitis B vaccination programme in addition to an universal infant programme but this is difficult to implement successfully. In view of this, in addition to universal infant vaccination, NIAC has recommended continued targeted vaccination of all those at risk.

What is Hepatitis B disease?

Hepatitis B is a vaccine preventable disease transmitted through contact with the blood or body fluids of an infected person. Hepatitis B virus can cause either acute hepatitis or chronic inflammation of the liver that can lead to serious liver disease such as cirrhosis and liver cancer. The World Health Organisation estimates that more than 350 million people worldwide are chronically infected with Hepatitis B virus. It is thought to be the second most common human carcinogen after tobacco smoke.

What are the symptoms of Hepatitis B?

The course and clinical symptoms of Hepatitis B infection depend on the patient's age and immune status.

Acute Hepatitis B is often asymptomatic. Only 10% of children and 30-50% of adults develop symptoms during the acute phase of Hepatitis B infection. The most common symptoms are: loss of appetite, nausea, vomiting, abdominal discomfort, and joint pain, often followed by jaundice.

Chronic Hepatitis B infection is more likely to develop in those infected early in life. About 70-90% of infected infants and young children and 1-10% of infected adults develop chronic (long term) Hepatitis B infection.

Chronic infection is associated with an increased risk of developing cirrhosis, liver failure and hepatocellular carcinoma. Premature death from chronic liver disease occurs in approximately 15-25% of chronically infected people.

How is Hepatitis B disease transmitted?

Hepatitis B virus (HBV) has been found in virtually all body secretions and excretions. However, only blood (and serum-derived fluids), saliva, semen and vaginal fluids have been shown to be infectious. People with chronic HBV infection are the primary reservoirs of infection.

Transmission mainly occurs by:

- Sexual intercourse
- Blood–to-blood contact
- Transmission from infected mother to child
- Transmission has rarely followed bites from infected individuals

Transmission by transfusion of contaminated blood or blood products is now rare because of routine screening of blood donors and viral inactivation of certain blood products.

Who are most at risk of Hepatitis B infection?

The following groups are at increased risk of HBV infection and should receive HBV vaccine if non-immune:

- Persons with occupational risk of exposure to blood or blood-contaminated environments
- Family and household contacts of individuals with Hepatitis B
- Injecting drug users (IDUs) and their contacts
- Individuals at high risk due to medical conditions
- Sexual contact risk groups
- Inmates of custodial institutions
- Tattoo and body piercing artists
- Immigrants from areas with a high or intermediate prevalence of HBV
- Travellers to areas with a high or intermediate prevalence of HBV
- Homeless people
- Children born to parents from high or intermediate endemicity countries

Does a child born before July 1st 2008 need Hepatitis B vaccine?

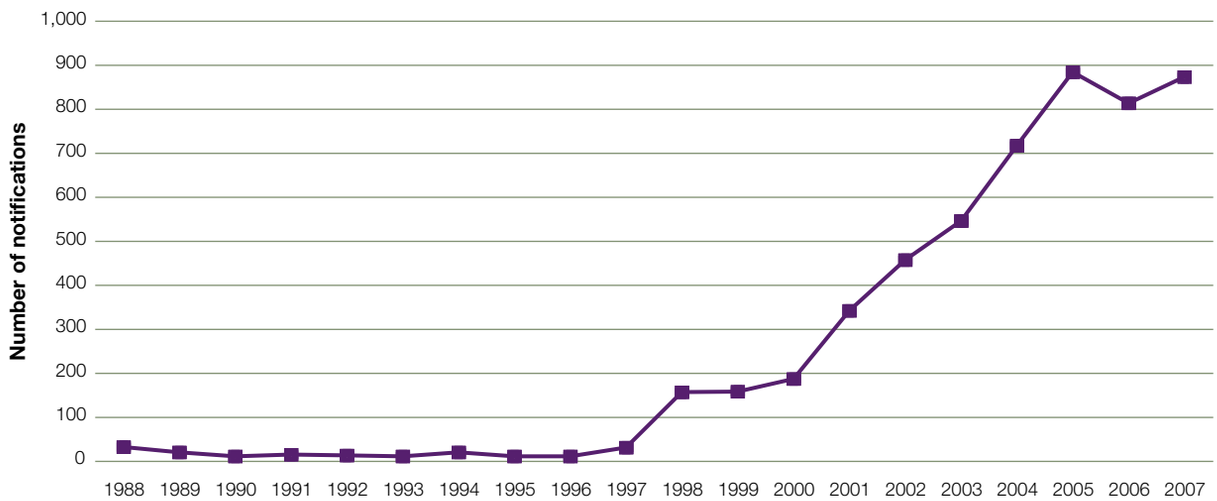
If a child is in an at risk group a full course of Hepatitis B vaccine should be given.

How many cases of Hepatitis B disease occur each year?

Ireland is generally considered to be a low prevalence country (<1% prevalence) but Hepatitis B is more common in certain high-risk populations such as injection drug users, prisoners and immigrants from high endemicity countries (see HPSC reports for more information at www.hpsc.ie).

In Ireland, notifications of Hepatitis B increased every year between 1996 and 2005. In recent years more than 800 cases have been reported annually (Figure 1).

Figure 1. Number of notifications of Hepatitis B by acute/chronic status, 1988-2007

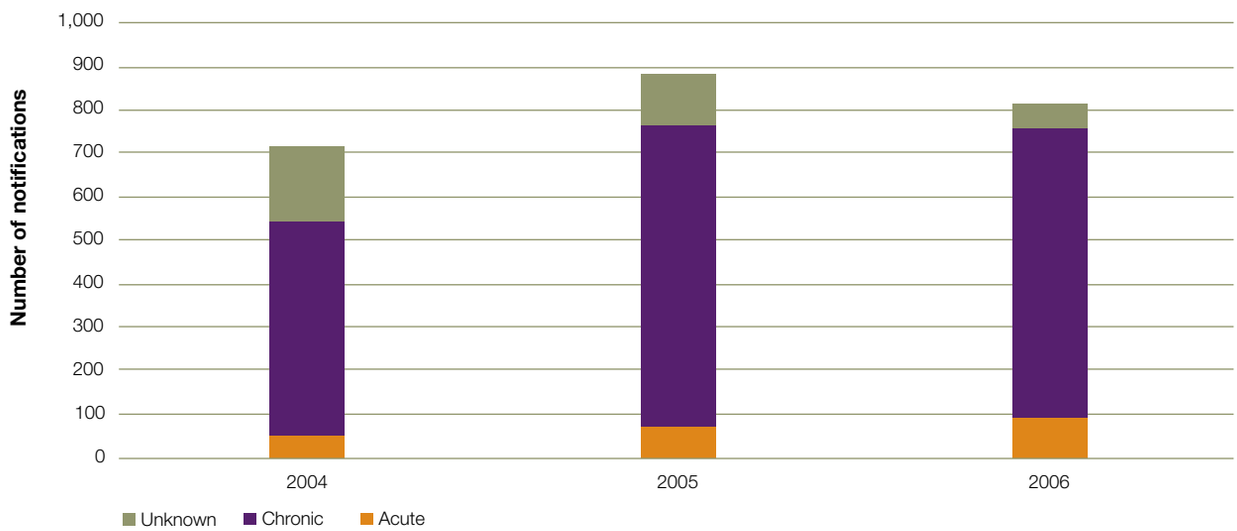


(2007 data is provisional) (Source: NVRL and CIDR, HPSC)

Note: In 2004, case definitions were introduced for Hepatitis B so that acute and chronic cases could be differentiated and it also became mandatory for laboratories to report all notifiable infectious diseases.

Data on type of Hepatitis B infection (acute or chronic) is only routinely available in recent years, since which time the majority of cases reported are chronic infections (Figure 2).

Figure 2. Number of Hepatitis B notifications by status, 2004-2006.



Source: CIDR. HPSC

Pneumococcal conjugate vaccine

What is pneumococcal conjugate vaccine?

Pneumococcal conjugate vaccine (7 Valent) PCV contains polysaccharide from seven of the most common capsular types. The polysaccharide is conjugated (bound) to a protein.

Approximately 90% of pneumococcal serotypes in circulation in Ireland are covered by PCV.

This vaccine has been recommended for high risk children under 5 years of age since 2002 and is now being included in the routine childhood immunisation schedule.

Is this the same as pneumococcal polysaccharide vaccine?

No. Pneumococcal polysaccharide vaccine (PPV23) contains purified polysaccharide from 23 of the most common capsular types of *S. pneumoniae*. This vaccine is recommended for elderly persons, and for at risk adults and children over 2 years of age.

PPV 23 is not recommended for children under 2 years of age due to an inadequate antibody response in young children.

Why is PCV being introduced into the childhood schedule?

Immunisation is the only available tool to prevent pneumococcal disease. PCV is being introduced into the childhood schedule due to the high incidence of the disease in young children.

A PCV catch-up programme is also being introduced for all children under 2 years of age as the incidence is highest in these children.

When should PCV vaccine be given?

At 2 and 6 months of age with a booster at 12 months of age.

How safe and effective is PCV?

PCV has demonstrated good safety records in both pre-licensure trials and post-licensure monitoring.

Clinical trials show that the vaccine is highly effective at preventing invasive disease due to serotypes included in the vaccine. The vaccine also has some efficacy against non-invasive disease and has led to a reduction in antibiotic resistant pneumococcal disease.

PCV is safe, effective and well tolerated when administered with other recommended childhood vaccines.

Studies from the US have shown that the introduction of PCV to the childhood schedule protects both vaccinated children (direct effect) and also unvaccinated groups especially those most at risk (the young and those over 65 years) (indirect effect) from pneumococcal disease. Protection of the unvaccinated groups occurs through decreased transmission of disease or herd immunity. In the US this has led to a significant decrease in pneumococcal disease morbidity and mortality in unvaccinated people.

How long does the protection last after having the PCV?

Studies from the United States where PCV has been used since 2000 show the vaccine provides long term protection against pneumococcal disease.

Are there side effects from PCV?

The most commonly reported adverse reactions are injection site tenderness (10-20%) and fever >38˚C which is more common in children receiving the 6 in 1 vaccine at the same time. No severe adverse events attributable to PCV have been reported.

Any adverse vaccine reactions (ADRs) should be reported to the Irish Medicines Board via the yellow report card (available on www.imb.ie).

Are there any reasons why the PCV should not be given?

Contraindications: Previous anaphylactic reaction to any component of this vaccine.

Precautions: Immunisation should be deferred in any child with an acute severe febrile illness until the illness has resolved.

Does the PCV contain thiomersal (mercury)?

No Thiomersal is not used in PCV.

What is pneumococcal disease?

Pneumococcal disease caused by the streptococcus pneumoniae bacteria leads to significant morbidity and mortality, particularly amongst the very young, the very old, those with impaired immunity and those with anatomic or functional asplenia. It is responsible for 50% of community acquired pneumonia with a case fatality rate between 20-60%

Streptococcus pneumoniae is a leading cause of meningitis in children under 5 years of age and bacteraemia where the overall mortality can be as high as 25%. It also causes a wide variety of other infections including otitis media, sinusitis, osteomyelitis, and bronchitis.

There are over 90 different serotypes of streptococcus pneumoniae but only a few produce serious pneumococcal infections.

Data on pneumococcal serotypes in circulation in Ireland suggests that PCV is likely to protect against approximately 85% of serotypes currently associated with invasive pneumococcal disease in children <2 years of age.

How is pneumococcal disease transmitted?

Transmission is from person to person, usually through respiratory droplet spread, but may be by direct oral contact or indirectly through articles contaminated with respiratory discharges. The incubation period varies by type of infection and can be as short as one to three days.

S. pneumoniae colonises the nasopharynx. On any single occasion between 5%-10% of healthy adults and 20-40% of young children will carry the organism. Carriage rates among toddlers and young children in day care are 40-60% and are higher in mid winter.

The pneumococcal serotypes most often responsible for causing infection are those most frequently found in carriers. The spread of the organism within a family or household is influenced by such factors as crowding, season, and the presence of upper respiratory infections or pneumococcal disease such as pneumonia or otitis media.

Who is most at risk of pneumococcal infection?

Those particularly at risk are young children, the elderly and persons with underlying immunocompromising medical conditions.

People with some chronic medical conditions are particularly vulnerable to infection. This includes those with no spleens or abnormally functioning spleens or other immunodeficiency conditions, chronic renal, lung, heart or liver disease, diabetes mellitus, sickle cell disease, patients with CSF leaks (congenital or acquired) and individuals with cochlear implants

How serious is pneumococcal disease in children?

S. pneumoniae is a common cause of otitis media, sinusitis, pneumonia, meningitis, and bacteraemia. It is a less frequent cause of endocarditis, septic arthritis and peritonitis and an uncommon cause of a variety of other infections.

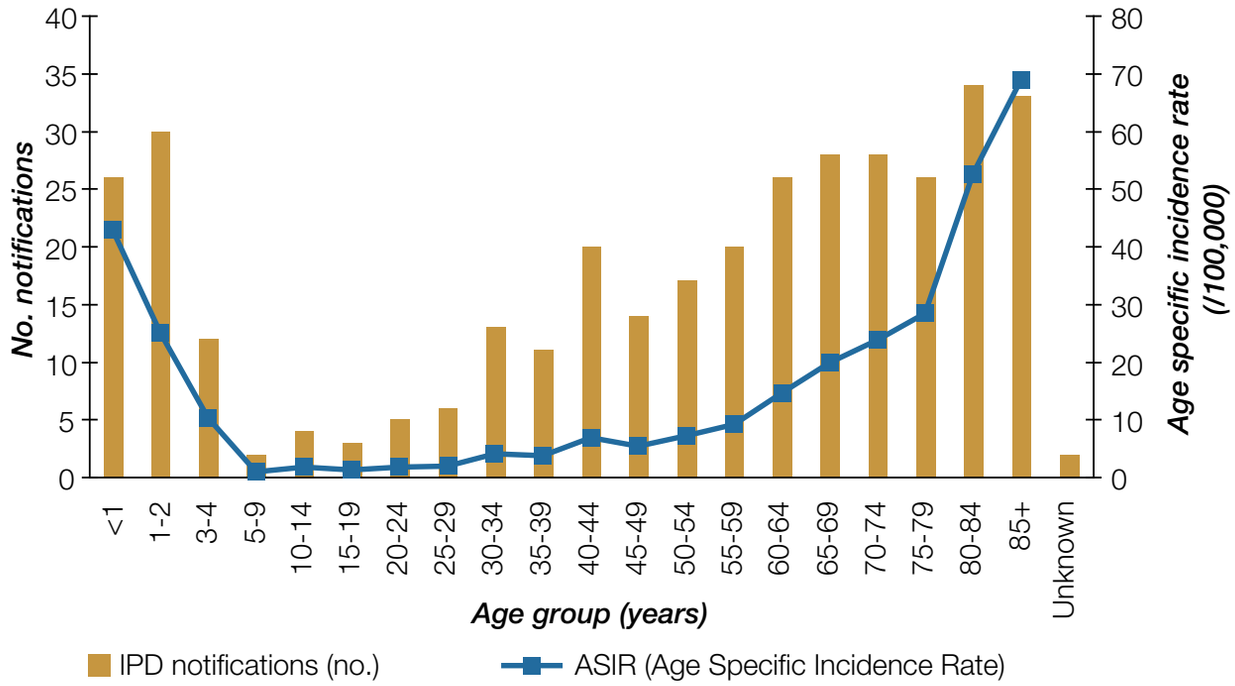
WHO estimates that between 700,000 and 1 million children under five years of age die from pneumococcal diseases each year. In high-income countries, elderly persons carry the major disease burden.

How many cases of childhood invasive pneumococcal disease (IPD) occur each year?

The epidemiology of IPD in Ireland is similar to that in other high-income countries. Invasive disease is relatively common in newborns and in infants up to 2 years of age, less common in teenagers and young adults, but increases in incidence in adults, particularly among those older than 65 years of age.

In 2007 (provisional data), there were 360 cases of IPD reported to the HSPC (crude incidence rate 6.5/100,000 population). This incidence rate is considered to be an underestimate of the true incidence of the disease in Ireland. The highest incidence rates are seen in young children less than five years of age and in older adults (age specific incidence rates 22.5/100,000 and 31.8/100,000 respectively).

Figure 3. Number and age specific incidence rates of IPD by age group, 2006.



Source: HPSC

Detailed analysis of the epidemiology of invasive pneumococcal disease is available on the HPSC website www.hpsc.ie

It is estimated that on average 1 in 5,000 children under 5 years old will be infected with IPD and of these:

1 in 3 will develop meningitis

1 in 3 will develop pneumonia

1 in 10 will die

Should any children over 2 years be given PCV?

If a child is in an "at risk" group they should be given PCV and PPV23 in accordance with NIAC guidelines.

Change in timing of Men C and Hib vaccines

The number of doses of Men C (3) and Hib (4) vaccines remains the same but the timing of these vaccines has changed.

What are the changes and why were they made?

Men C vaccine

A booster dose of Men C vaccine over a year of age is needed to provide further protection during the early childhood years and to maintain herd immunity.

Studies have shown that two doses of Men C vaccine under one year give as much protection as three doses under one year.

Men C vaccine now is recommended at 4, 6 and 13 months.

Timing of Men C vaccine		
	Children born before 1/7/08	Children born on or after 1/7/08
2 months	Men C	–
4 months	Men C	Men C
6 months	Men C	Men C
13 months	–	Men C

What about children who received 3 doses of Men C under 12 months of age – do they need a Men C booster?

No, these children do not need a Men C booster as, to date, there has been no evidence of vaccine failures in older children in Ireland.

Hib vaccine

- The booster dose of Hib has changed from 12 months to 13 months.
- NIAC has recommended that the PCV booster be given at 12 months.
- The combination vaccine Hib/Men C should not be given at the same time. This is a precautionary measure until more data is available to show these two particular vaccines can be given at the same time without any interference between them.

Hib vaccine is recommended at 2, 4, 6 (as part of the 6 in 1) and 13 months.

Timing of Hib vaccine		
	Children born before 1/7/08	Children born on or after 1/7/08
2 months	5 in 1	6 in 1
4 months	5 in 1	6 in 1
6 months	5 in 1	6 in1
12 months	Hib	–
13 months	–	Hib

General queries

Can three separate vaccines be given at one time at the 6 month visit?

Yes the 6 in 1, PCV and Men C can be given at the same time with no additional adverse effects. Three injections are given at the same time in the UK and US schedules.

Vaccines for children under one year of age should be given in the anterolateral aspect of the thigh.

The 6 in 1 and Men C should be given in one thigh and the PCV in the other.

Where two injections are given in the same limb they should be administered at least 2.5cm apart.

The site of each vaccination should be recorded accurately

Where do I get stocks of vaccine?

All vaccines for the Primary Childhood Immunisation schedule can be ordered through the National Cold Chain Delivery Service in the normal way.

How should the vaccines be stored?

All vaccines should be stored at 2-8˚C but not frozen.

Notes

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