

The New Primary Childhood Immunisation Schedule

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www.immunisation.ie

Objectives

- To describe the new primary childhood immunisation (PCI) schedule
- To provide an overview of MenB disease, the MenB vaccine and common queries
- To provide an overview of rotavirus disease, the rotavirus vaccine and common queries
- To explain other changes to the PCI schedule.
- To discuss issues specific to vaccination of hospitalised babies
- To discuss the role out of the new changes and information materials available



The New PCI Schedule

All babies born on or after **1st October 2016** will be offered the new PCI schedule

New schedule to start on **1st December 2016**
(at 2 months of age)



The New PCI Schedule

Change	When
Addition of meningococcal B (MenB) vaccine	2, 4 and 12 months
Addition of rotavirus vaccine	2 and 4 months
Timing of MenC1	from 4 to 6 months
Timing of PCV3	from 12 to 13 months
Replacement of Hib and MenC with Hib/MenC (2 injections to 1 injection)	13 months



The New PCI Schedule

	Current Schedule		Babies born on or after 1 st October 2016	
Age (months)	Vaccine	No of injections	Vaccine	No of injections
2	6in1 + PCV	2	6in1 + PCV + MenB + Rotavirus	3 + oral vaccine
4	6in1 + MenC	2	6in1 + MenB + Rotavirus	2 + oral vaccine
6	6in1 + PCV	2	6in1 + PCV + MenC	3
12	MMR + PCV	2	MMR + MenB	2
13	MenC + Hib	2	Hib/MenC + PCV	2



The New PCI Schedule

From 1st October 2016 until at least November 2017

2 schedules in place

- the old (current) schedule
- the new schedule



Meningococcal B (MenB) disease

- Caused by *Neisseria meningitidis*.
- Most common and serious clinical presentations
 - meningitis and septicaemia
- An important clinical and public health problem
 - rare but serious
 - disease onset is sudden and often dramatic
- A significant case fatality rate ~10%
- 1 in 10 survivors have long term complications including
 - brain damage, deafness, epilepsy, limb/digit loss, cognitive deficit

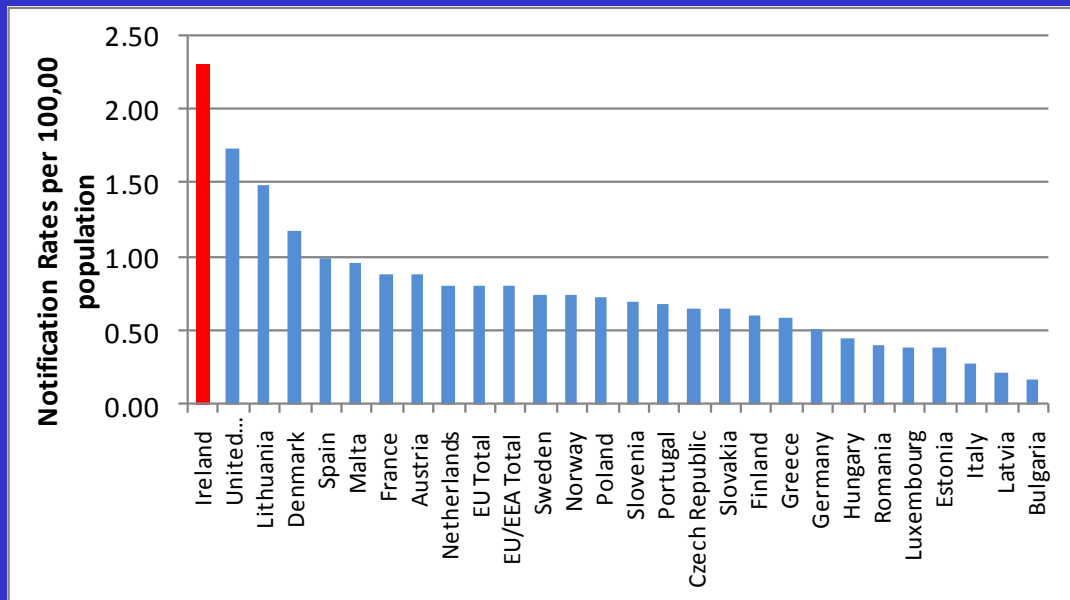


Meningococcal B (MenB) disease

- Most common in infancy and early childhood (0-4 years)
- A second smaller peak of incidence in adolescents and young adults
- Ireland has one of the highest notification rates of invasive meningococcal disease (IMD) in Europe

Confirmed cases in the EU/EEA, 2008-2012

Source: HPSC



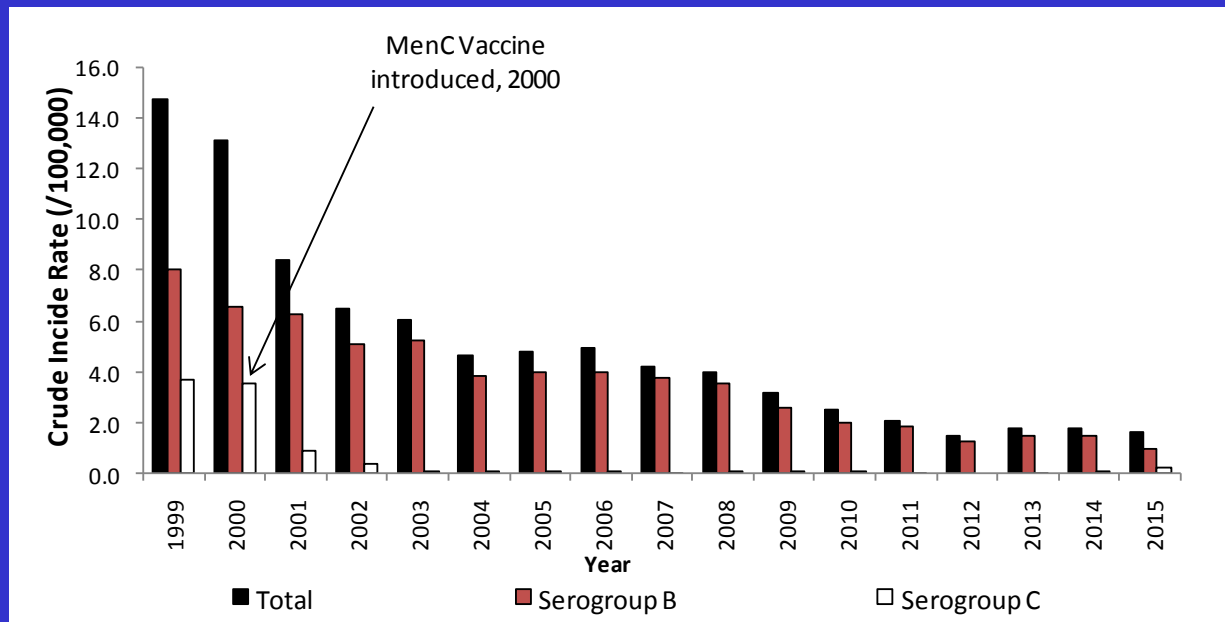
Meningococcal B (MenB) disease

In Ireland since MenC vaccine was introduced in 2000

- MenC disease incidence decreased
- MenB disease incidence also decreased
- MenB disease the main cause of invasive meningococcal disease

Crude incidence rate of IMD in Ireland, 1999-2015

Source HPSC



MenB Vaccine

- A recombinant multi-component vaccine
- **NOT** a live vaccine

- Shown to be very safe and effective
- ~88% strains covered
- Widely given across Europe
- Introduced into the UK immunisation schedule in 2015

- Schedule
 - 2 + 1 schedule (not 3 +1 as per SPC)

- Can be given with all other vaccines in PCI schedule



MenB Vaccine

- Bexsero (GSK)
- Single packaged pre-filled syringe
- IM use (anterolateral thigh)



MenB Vaccine

Contraindications/ Precautions

Contraindications

- Anaphylactic reaction to a previous dose of vaccine
- Anaphylactic reaction to any constituent of vaccine including kanamycin and latex

Precautions

- Acute severe febrile illness
 - defer until well
- Known coagulation defects
 - caution with administration and apply pressure to the vaccine site for 1-2 minutes after vaccination



MenB Vaccine

Side effects

Very Common (1 in 10)

- Fever ($>38^{\circ}\text{C}$)
- Tenderness / pain at injection site
- Skin rash
- Irritability
- Vomiting / diarrhoea
- Unusual crying

Uncommon (1 in 100 to 1 in 1000)

- High fever ($>40^{\circ}\text{C}$)
- Seizures (including febrile seizures)
- Eczema

Rare (1 in 1,000 to 1 in 10,000)

- Urticaria
- Kawasaki's disease



MenB Vaccine and Paracetamol

- Fever is a common side effect when MenB vaccine is given with the other PCI vaccines
- NIAC recommends **all babies** are given 3 doses of paracetamol at the 2 and 4 month MenB vaccines
- Babies < 4kg (8lb 8oz) should be given paracetamol at a dosage of 15mg/kg
- Babies born before 37 weeks should be given paracetamol at using a dose correct for their weight (15mg/kg)

Liquid Infant Paracetamol (120mgs/5ml)		2 months	4 months
Dose 1	2.5 mls (60mg)	At the time of injection	At the time of injection
Dose 2	2.5 mls (60mg)	4-6 hours after dose 1	4-6 hours after dose 1
Dose 3	2.5 mls (60mg)	4-6 hours after dose 2	4-6 hours after dose 2



MenB Vaccine and Paracetamol

- Will reduce the fever by ~ 50%
- If fever persists a further dose of paracetamol may be given i.e. 4 doses in 24 hours after vaccination
- If baby unwell or fever persists – parents should seek medical advice

Paracetamol

- Previously not recommended routinely
- Recent studies show **NO** evidence of a decrease in the immune response when paracetamol is given with the MenB vaccine and other PCI vaccines
- Recommendation supersedes PIL
- Not routinely given at the 12 month MenB vaccination (risk of fever is less)

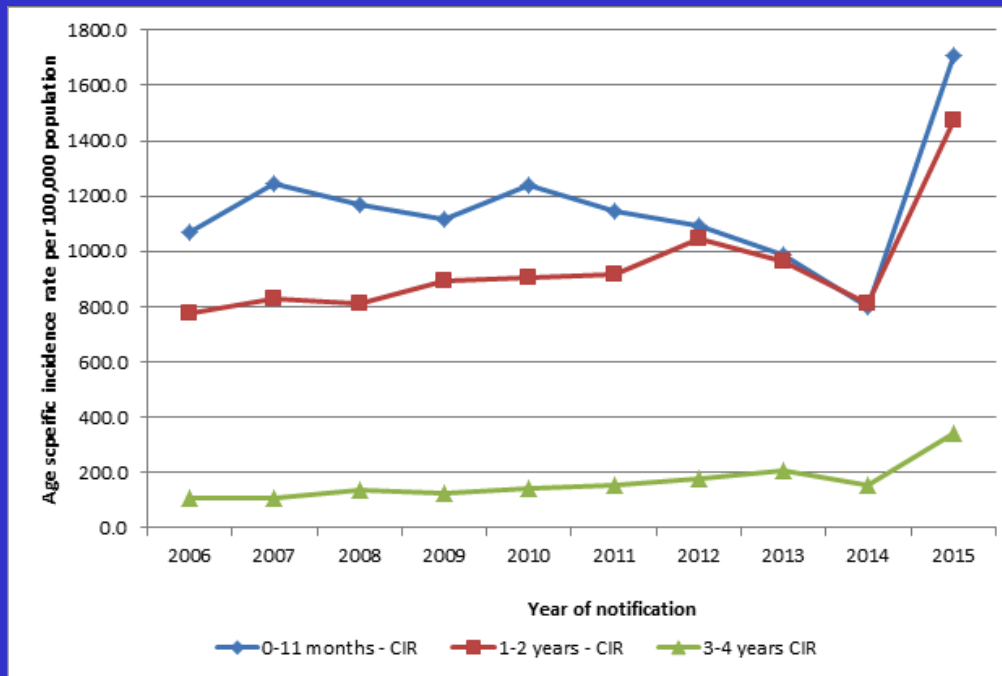


Rotavirus Disease

- Very common viral infection causing diarrhoea and vomiting
- ~ 2,400 cases notified in Ireland each year
- Most in under 1 year age group

Age specific incidence rate per 100,000 population of notified rotavirus cases

Source HPSC



Rotavirus Disease

- Estimated that all children infected with rotavirus by age 5
- Spreads very easily through hand to mouth contact and aerosol
- Symptoms
 - ~3-8 days
 - severe diarrhoea, stomach cramps, vomiting, dehydration a low-grade fever
- Most babies and children recover at home
- Every year
 - ~ 920 children aged 0-4 require hospital treatment
 - Average length of stay 5 days



Rotavirus Vaccine

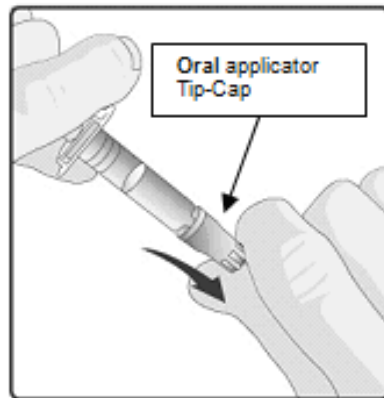
- A live attenuated vaccine
- 2 licensed vaccines (GSK and Sanofi)
- HSE procured Rotarix (GSK)
- 10 pack pre-filled oral applicator
- Oral vaccine



Rotavirus Vaccine

- Schedule
 - 2 doses at 2 and 4 months
- Give before injected vaccines

Instructions for administration of the vaccine:



1. Remove the protective tip cap from the oral applicator.



2. This vaccine is for oral administration only. The child should be seated in a reclining position. Administer orally (i.e. into the child's mouth, towards the inner cheek) the entire content of the oral applicator.

Rotavirus Vaccine

- Widely used routinely in Europe, UK, Australia and US
- Can be given with all other PCI vaccines
- Very effective (82-94%) in preventing rotavirus disease in young babies
- Reduces hospital admissions by ~ 70%
- Good safety profile and well tolerated in most babies



Rotavirus Vaccine

Contraindications/ Precautions

Contraindications

- Confirmed anaphylactic reaction to a previous dose of rotavirus vaccines or its constituents
- Severe Combined Immunodeficiency Disorder (SCID)
- Previous history of intussusception
- Malformation of the gastrointestinal tract (?lead to intussusception)
- Hereditary fructose intolerance, sucrose-isomaltase deficiency or glucose-galactose malabsorption

Precautions (defer until well)

- an acute febrile illness
- an acute vomiting or diarrhoea illness



Severe Combined Immunodeficiency Disorder (SCID)

- Rare inherited condition =>highly susceptible to infections
- More common in babies in some Traveller families (predominantly but not exclusively from the South East)
- About 1 case every year
- If diagnosed at or shortly after birth can be successfully treated with a bone marrow transplant (in the UK)

Need to ask parents

- Are there any diseases in the baby's family that affect the immune system?
- Did anyone in either family need a bone marrow transplant as a baby?



Severe Combined Immunodeficiency Disorder (SCID)

- “No” give rotavirus oral vaccine

- “Yes”

check if a FBC with differential white cell, including lymphocyte count was taken at birth and confirm the results

- lymphocyte count $<2.0/10^9$ litre referral to a Paediatric Immunologist should be made urgently
- Any baby at risk of SCID should **NOT** be given rotavirus oral vaccine.



Rotavirus Vaccine

Side Effects

Common (1 in 10)

- Diarrhoea
- Irritability

Uncommon (1 in 100)

- Abdominal pain / Flatulence
- Dermatitis (skin inflammation)

Very rare (1 in 50,000)

- Intussusception
- Blood in stools
- Gastroenteritis in babies with SCID



Rotavirus Vaccine Intussusception

- Very rare (approx 1 in 50,000 vaccinated babies)
- Intestinal prolapse leading to obstruction
- Most common in those aged 5 months – 1 year
- ~1 in 1000 babies will get this condition naturally

- Symptoms
 - severe abdominal pain
 - worsens with time, ‘draw’ legs up
 - may get blood in stools, vomiting
- Needs urgent hospital treatment



Rotavirus Vaccine Schedule

Two doses at 2 and 4 months of age

- Best protection if given on time
- Increased risk of intussusception with increased age
 - **No** doses after 8 months and 0 days
 - Minimum interval between dose 1 and 2 is 1 month
 - **Latest** time to start dose 1 is 7 months



Changes to Men C / PCV / Hib vaccines

- Men C vaccine
 - change from 4 and 13 months to 6 and 13 months.
 - to allow Men B vaccine at 2 and 4 months as greatest risk in this age group
- PCV
 - change from 2, 6 and 12 months to 2, 6 and 13 months.
 - to allow MenB booster at 12 months as greater risk in this age group
- Hib/MenC combination vaccine
 - replaces single Hib and MenC at 13 months
 - to keep the number of injections at 2 (Hib/MenC + PCV)



Hib/MenC vaccine

- Menitorix (GSK)
- Used in UK PCI schedule
- Single prefilled syringe and vial
- Requires reconstitution



Order and site of vaccines

At 2 & 4 months

Give rotavirus oral vaccine before injections

At 2 months

- Give MenB first in LEFT leg
- Give 6 in 1 followed by PCV in RIGHT leg

At 4 months

- Give MenB first in LEFT leg
- Give 6in1 in RIGHT leg

At 12 months

- Give MenB first in LEFT leg
- Give MMR in RIGHT leg

To monitor any local adverse reactions and to give most painful last PCV



Vaccines and Hospitalised Babies

- Babies born prematurely should still receive their vaccinations at the appropriate chronological age.
- For small babies who require 2 injections in one leg, 16mm needle may be required.
- If there is concern that there is insufficient muscle mass to allow injection of two vaccines 2.5 cms apart on the same occasion, vaccines can be separated by 1-2 days.

MenB Vaccine

- The minimum age a baby can receive MenB vaccine is 6 weeks.
- MenB vaccine is recommended for cases of meningococcal B who have not previously received MenB vaccine.
- No contraindication to MenB vaccine in immunosuppressed babies.



Rotavirus oral vaccine

- Minimum age a baby can receive rotavirus vaccine is 6 weeks.
- Vaccinated infants do not need to be isolated. Live attenuated vaccine virus can be excreted for at least 14 days =>standard infection control precautions should be followed to reduce the risk of transmission.
- Feeding tubes
 - NG feeding tube - give rotavirus oral vaccine orally, unless absolutely necessary to give via the tube. Can be given via gastrostomy.
- Recommended for babies with confirmed rotavirus infection to help protect against further episodes of infection.
- Benefits of rotavirus vaccination of preterm infants outweigh the risk of adverse events.
- ≤ 28 weeks gestation infants still in hospital:
Should have respiratory monitoring for 48-72 hours when given their first immunisations due to the risk of apnoea.
If apnoea, bradycardia or desaturations after the 1st routine immunisation, the 2nd immunisation should also be given in hospital, with respiratory monitoring for 48-72 hours.



Rotavirus oral vaccine

- There is some evidence to suggest that shedding may be more common and more persistent in preterm infants compared with term.
- The risk of transmission to other infants in the NICU, is low:
 1. Of the small proportion of immunised infants shedding live vaccine-derived rotavirus, the concentration of live vaccine-derived rotavirus in the stools is far below that in the vaccine itself. After Rotarix administration, rotavirus antigens can be detected in 50% of stools after the first dose and 4% after the second dose, but only 17% had live vaccine-derived virus.
 2. Standard NICU infection-control practices, should be sufficient to reduce the risk of transmission. Even if infection-control practices were to fail, the risk of horizontal transmission following exposure to a very low dose of viable, vaccine-derived rotavirus and subsequent vaccine-derived disease is likely to be minimal.
 3. In fact, the risk of wild type rotavirus infection is likely to be higher than the theoretical risk of vaccine-derived rotavirus infection in the NICU setting.

(Ladhani et al. Timely immunisation of premature infants against rotavirus in the neonatal intensive care unit. Arch Dis Child Fetal Neonatal Ed; 99(6), 445-447).



Information materials

- Information materials for parents
 - Updated
 - Maternity leaflet
 - ‘Your child's immunisation - A guide for parents’
 - Magnet
 - Immunisation passport
 - New tear pad at 6 weeks
 - Updated
 - Tear pad with after vaccine care
 - Information on website


Before NEXT APPOINTMENT

Immunisation Information

Babies born on or after 1 October 2016 are offered the vaccines in the table below.

Age	Vaccination
2 months	Visit 1 6 in 1+PCV+MenB+Rotavirus 3 Injections+Oral Drops
4 months	Visit 2 6 in 1+MenB+Rotavirus 2 Injections+Oral Drops
3 months	6 in 1+PCV+MenC 3 Injections
on or after 8 months 0 days	
4 months	MMR+MenB 2 Injections
5 months	Hib/MenC+PCV 2 Injections

> (doctor)



Your Child's Immunisation

A guide for parents

For children born on or after 1 October 2016



www.immunisation.ie

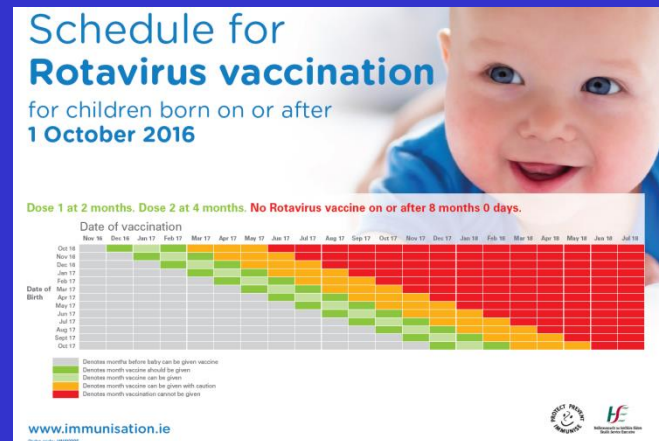


Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive



Information materials

- Train the trainers day 18th May, Dublin
- Local roll out of training programme
- Information materials for health care professionals
 - Frequently Asked Questions document
 - Wheel for rotavirus vaccine doses and ages
 - Posters - new schedule, rotavirus schedule and paracetamol dosage
 - Updated
 - Guidelines for Vaccinations in General Practice
 - FAQs for Health Professionals
 - Immunisation Guidelines for Ireland (NIAC)
 - Updated information on website



Paracetamol After MenB Vaccination

2 months Visit 1

- 6 in 1
- PCV
- MenB
- Rotavirus

3 injections
1 Oral drops

4 months Visit 2

- 6 in 1
- MenB
- Rotavirus

2 injections
1 Oral drops

Liquid Infants Paracetamol (1.50 mg/5 ml)	2 month visit	4 month visit
Dose 1	2.5 ml (50 mg) At the time of injection	At the time of injection
Dose 2	2.5 ml (50 mg) 4-6 hours after dose 1	4-6 hours after dose 1
Dose 3	2.5 ml (50 mg) 4-6 hours after dose 2	4-6 hours after dose 2

Paracetamol not recommended at 6, 12 and 18 month visits unless baby develops temperature over 39°C or appears distressed.

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Key points for new PCI schedule

- For babies born on or after October 1st 2016
- “Old” and new schedules in parallel for at least 1 year
- 3 doses of infant paracetamol at and after 2 and 4 month Men B vaccines to reduce fever
- No dose of rotavirus after 8 months and 0 days
- Additional information will be available
- Support from local Department of Public Health and the NIO

