

The New Primary Childhood Immunisation Schedule

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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 the role out of the new changes and information materials available



The New PCI Schedule

All babies born on or after **1st October 2016**

- 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

| Age (months) | Old Schedule | | New Schedule Babies born on or after 1 st October 2016 | |
|-----------------|--------------|------------------|--|---------------------|
| | 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 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

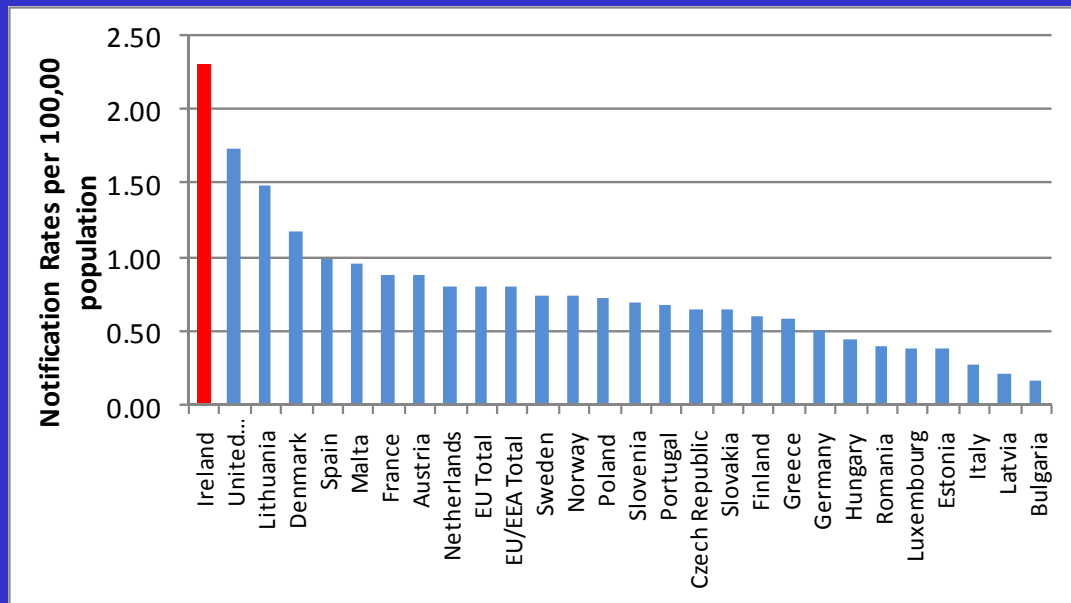


Meningococcal B (MenB) disease

- 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



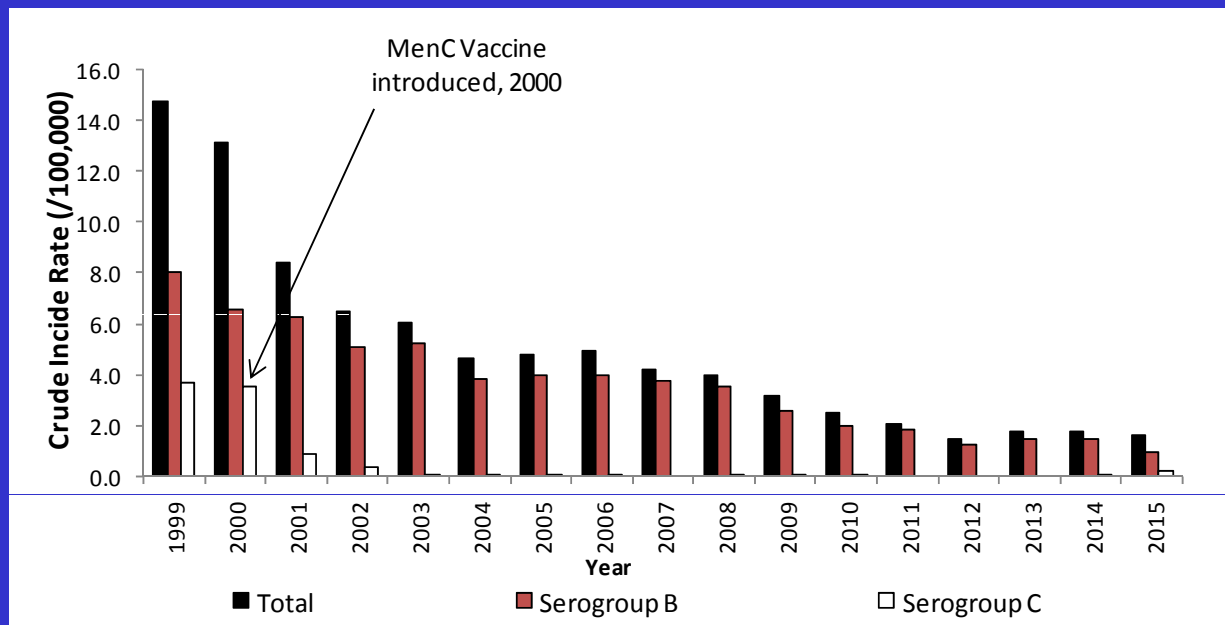
Meningococcal B (MenB) disease

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 Paracetamol

- Fever with MenB vaccine is a common side effect
- NIAC recommends **all babies** are given 3 doses of paracetamol at the 2 and 4 month MenB vaccines

| 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

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 (NOT Ibuprofen)

- 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
- No increase in parental attendance if informed beforehand
- Not routinely given at the 12 month MenB vaccination (risk of fever is less)

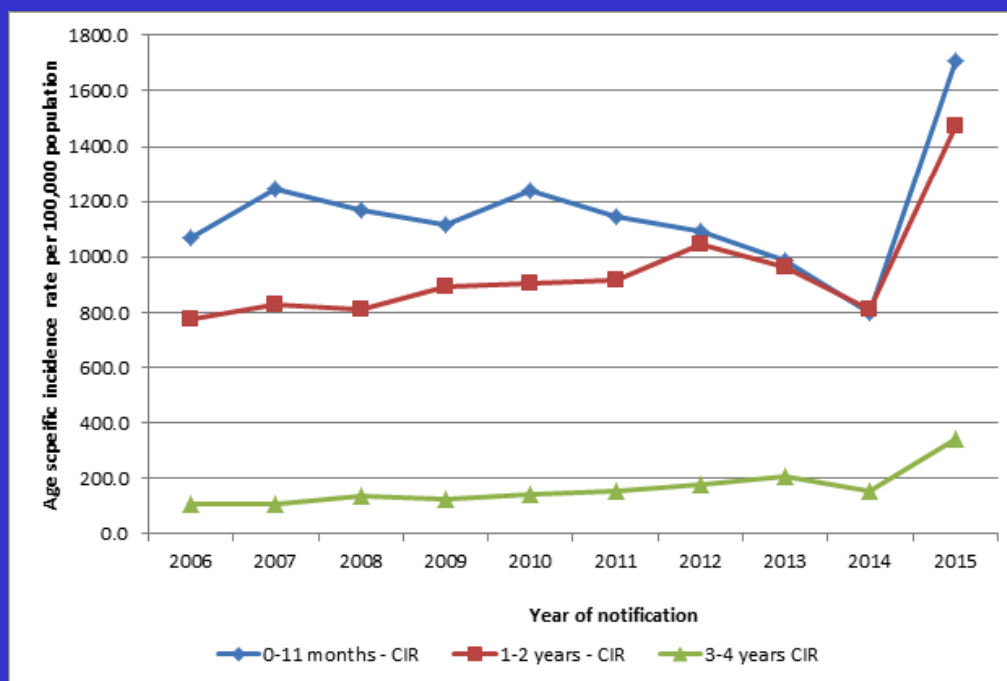


Rotavirus Disease

- 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

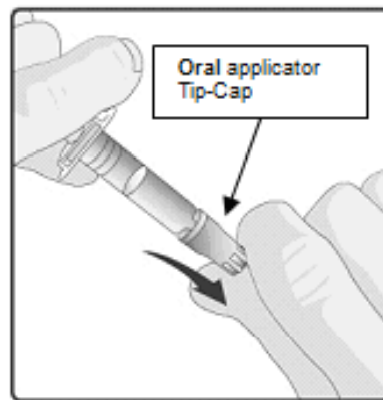
- A live attenuated vaccine
- 2 licensed vaccines (GSK and Sanofi)
- HSE procured Rotarix (GSK)
- 10 pack pre-filled syringe
- Oral vaccine



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?

If Yes => FBC required

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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 5months – 1year
- ~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
- Will be available to order October 2017



Order and site of vaccines

- Give MenB first in LEFT leg
- Give 6 in 1 followed by PCV in RIGHT leg
- To monitor any local adverse reactions
- To give most painful last (PCV)



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 <small>on or after 9 months 0 days</small> |
| 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

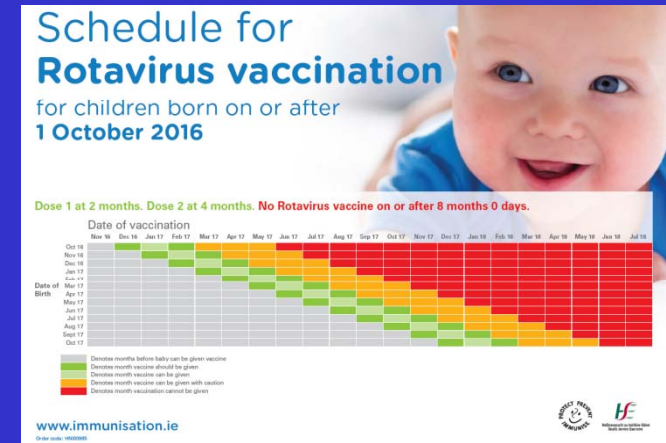


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Information materials

- 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
 - 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 Infant Paracetamol (120 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
- Additional information will be available
- Support from local Department of Public Health and the NIO

