

The New Primary Childhood Immunisation Schedule

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www.immunisation.ie



Dates vaccines introduced into the Irish immunisation schedule

1937 - 1999	
Vaccine	Date introduced
1. BCG	1937
2. DT	1930s
3. DTP	1952
4. Oral Polio Vaccine (OPV)	1957
5. Rubella	1971
6. Measles	1985
7. MMR	1988
8. MMR2	1992
9. Hib	1992

2000 - 2016	
Vaccine	Date introduced
1. Men C	2000
2. DTaP-Hib-IPV (5 in1)	2001
3. Inactivated Polio (IPV)	2001
4. Hib Booster	2006
5. Hepatitis B (as part of 6 in 1)	2008
6. PCV7	2008
7. HPV	2010
8. PCV13	2010
9. Tdap	2012
10. Men C (adolescent booster)	2014
11. Rotavirus	2016
12. Men B	2016



The National Immunisation Advisory Committee (NIAC)

- Independent committee of the RCPI
- Variety of experts
- Advises the Department of Health
- Produces the National Immunisation Guidelines for Ireland

Based on

- best evidence regarding the safety and efficacy of vaccines
- the disease burden
- pharmacoeconomic analyses



The New PCI Schedule

For all babies born on or after 1st October 2016

New schedule started on 1st December 2016

(at 2 months of age)

From 1st October 2016 until at least November 2017

2 schedules in place

- the old schedule
- the new schedule



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



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

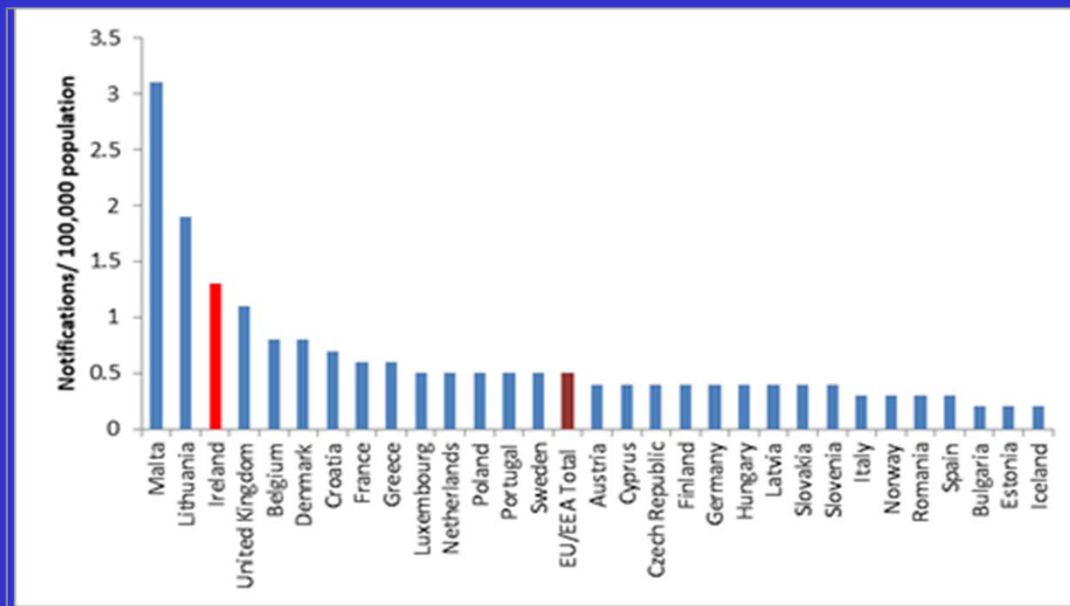


Meningococcal B (MenB) disease

- 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, 2008-2014

Source: HPSC



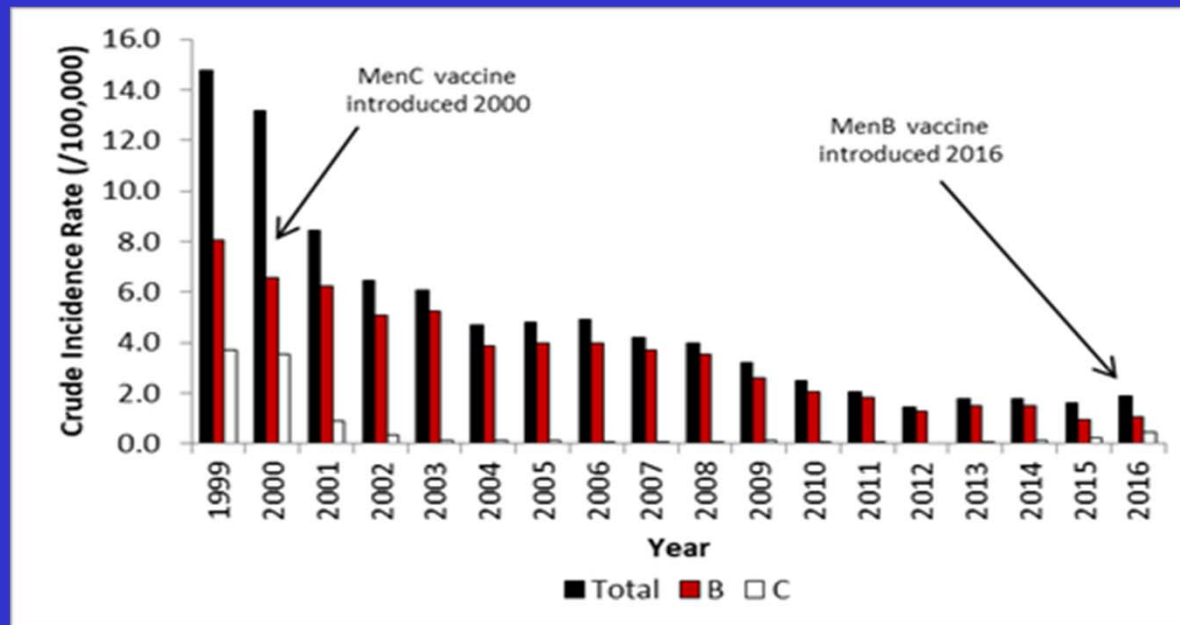
Meningococcal B (MenB) disease

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, 1999-2016

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 SmPC)
- Can be given with all other vaccines in PCI schedule



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 is a common side effect **when MenB vaccine is given with other PCI vaccines**
- 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 SmPC and PIL
- No increase in parental attendance if informed beforehand
- Not routinely given at the 12 month MenB vaccination (risk of fever is less)



Impact of MenB vaccine in the UK

- Significant reduction of 50% in MenB disease in vaccine eligible infants
- No safety concerns
- Ongoing surveillance continuing

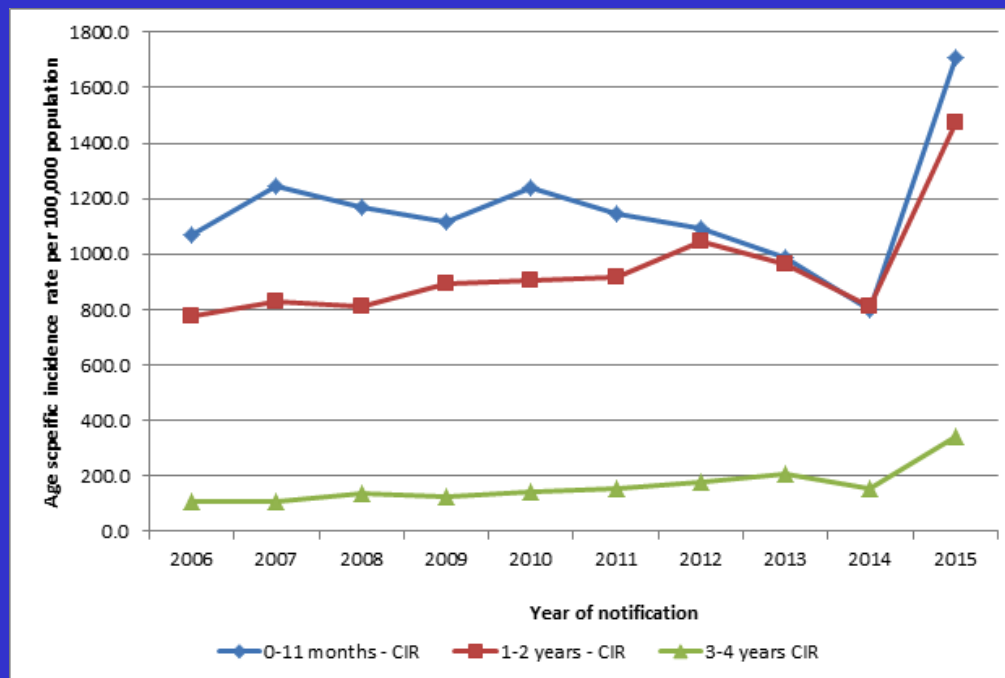


Rotavirus Disease

- 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

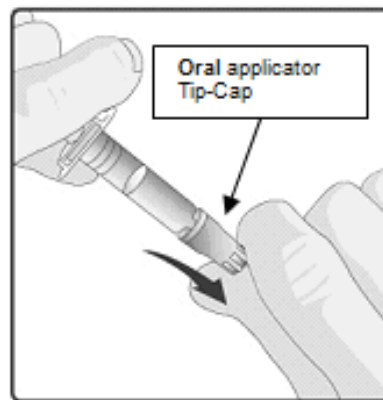
- Estimated that all children infected with rotavirus by age 5
- Spreads very easily through hand to mouth contact and aerosol
- Symptoms
 - ~3-8 days
 - severe diarrhoea, stomach cramps, vomiting, dehydration a low-grade fever
- Most babies and children recover at home
- Every year
 - ~ 920 children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



Rotavirus Vaccine

- 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**
- Recommendation supersedes SmPC and PIL



Impact of Rotavirus vaccine in the UK

- Rapid decline in rotavirus infection and acute gastroenteritis in vaccinated and unvaccinated within 1 year
- Protective association between full vaccine course and childhood seizures (~20% in the year following vaccination)
- No safety concerns
- Ongoing surveillance continuing



Changes to Men C / PCV / Hib vaccines

- Men C vaccine
 - changed 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
 - changed 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



Communications and information materials

- 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
 - Information for paediatric hospitals

Paracetamol After MenB Vaccination



2
months

Visit 1
 3 Injections
 1 Oral drops

- 6 in 1
- PCV
- MenB
- Rotavirus

4
months

Visit 2
 2 Injections
 1 Oral drops


- 6 in 1
- MenB
- Rotavirus

Liquid Inflix 1 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 38°C or appears distressed.

Schedule for Rotavirus vaccination

for children born on or after 1 October 2016



Dose 1 at 2 months. Dose 2 at 4 months. No Rotavirus vaccine on or after 8 months 0 days.

Date of Birth	Date of vaccination											
	Nov 16	Dec 16	Jan 17	Feb 17	Mar 17	Apr 17	May 17	Jun 17	Jul 17	Aug 17	Sep 17	Oct 17
Nov 16	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Dec 16	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Jan 17	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Feb 17	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Mar 17	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Apr 17	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
May 17	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Jun 17	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Jul 17	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Aug 17	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Sep 17	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Oct 17	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green

■ Doses months before baby can be given vaccine
■ Doses month vaccine should be given
■ Doses month vaccine can be given
■ Doses month vaccine can be given with caution
■ Doses month vaccination cannot be given

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Communications and information materials

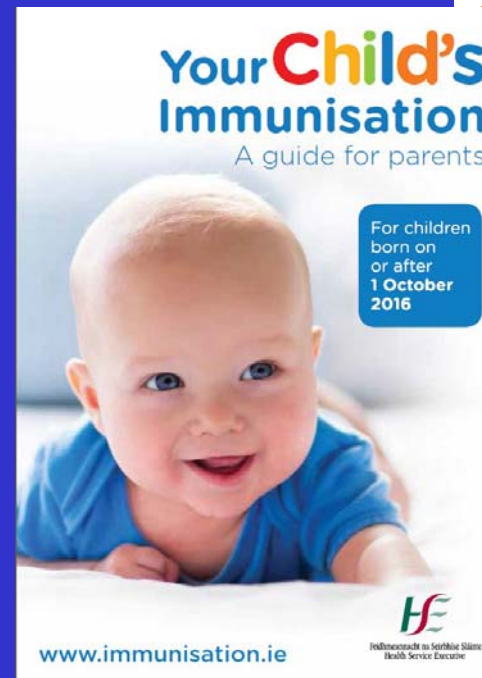
- Information materials for parents
 - Updated
 - Maternity leaflet
 - 'Your child's immunisation - A guide for parents'
 - Magnet
 - Immunisation passport
 - Tear pad at 6 weeks
 - Updated
 - Tear pad with after vaccine care
 - Information on website
 - Translated materials

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
6 months	Visit 3 6 In 1+PCV+MenC 3 Injections
No Rotavirus vaccine on or after 8 months 0 days	
12 months	Visit 4 MMR+MenB 2 Injections
3 months	Visit 5 Hib/MenC+PCV 2 Injections

Remember five visits to your GP (doctor)
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Further Information available at

www.immunisation.ie

