

The New Primary Childhood Immunisation Schedule

Dr Brenda Corcoran
National Immunisation Office



www.immunisation.ie

Objectives

- To describe the new primary childhood immunisation (PCI) schedule
- To explain other changes to the PCI schedule
- To discuss the implementation plan for the role out of the new changes



The New PCI Schedule

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



The New PCI Schedule

Change	When
Addition of rotavirus vaccine	2 and 4 months
Addition of meningococcal B (MenB) vaccine	2, 4 and 12 months
Timing of 1 st MenC	from 4 to 6 months
Timing of 3 rd PCV	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 (since 1 st July 2015)		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

Schedule will start when babies reach

- 2 months of age
- on or after 1st December 2016

From 1st October 2016 until at least November 2017

2 schedules in place

- the old (current) schedule
- the new schedule



Rotavirus Vaccine

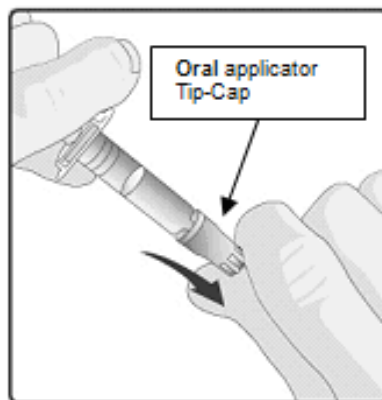
- A live attenuated vaccine
- 2 licensed vaccines (GSK 3 dose and Sanofi 2 dose)
- HSE procured Rotarix (GSK)
- Oral vaccine



Rotavirus Vaccine (Rotarix)

- Schedule
 - 2 doses at 2 and 4 months
- Give before injected vaccines
- Can be given with all other PCI vaccines
- No restriction on feeding before or after vaccine

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

Contraindications/ Precautions

Contraindications

- Confirmed anaphylactic reaction to a previous dose of rotavirus vaccine 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



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 on or after 8 months and 0 days**
 - Minimum interval between dose 1 and 2 is 4 weeks
 - **Latest time to start dose 1 is 7 months**
 - Differs from UK recommendations
 - 1st dose by 15 weeks of age
 - 2 doses by 24 weeks
 - Aligned to US recommendations



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
- Guidelines currently state MenB cannot be given at same time as MenC



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 and after 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

- Liquid infant paracetamol 120mg/ 5 ml
- Not ibuprofen
- Number of doses for babies < 3 months differs from SPC and PIL
- Ask parent to watch oral administration of rotavirus vaccine



MenB Vaccine

Paracetamol

- Will reduce the fever by ~ 50%
- If fever persists 1 more dose may be given
i.e. 4 doses in 24 hours after vaccination
(differs from UK advice)
- If baby unwell or fever persists – parents should seek medical advice
- 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
- Not to be routinely given at the 12 month MenB vaccination (risk of fever is less)



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)



Implementation plan

- Funding
- Vaccine procurement and distribution
- GP negotiations
- ICT changes
 - invitation letters, vaccine data, defaulter reports, payments
 - 8 systems
 - Careworks upgrade approved (E, NE, NW and MW)
- Surveillance and monitoring



Communications

- HSE staff
- ICGP – Summer Scientific Meeting/ ? elearning module
- IMO/ NAGP
- IPNA – Annual meeting
- Paediatric hospitals/ A/E departments
- Clinical lead paediatrics
- Faculty of Paediatrics
- Meningitis Research Foundation
- Creches/ Pre school inspectorate



Communications

- Press release to announce start date?
- Press release at time of change
 - October /December?
- Articles in press and media interviews
- Articles in parents/ maternity magazines
- No radio/ press advertising campaign



Information materials

- Train the trainers day 18th May, Dublin
- Local roll out of training programme
- Information materials for parents
 - Updated
 - Maternity leaflet
 - ‘Your child's immunisation - A guide for parents’
 - New tear pad at 6 weeks
 - Updated
 - Tear pad with after vaccine care
 - Information on website
- Information materials for health care professionals
 - Frequently Asked Questions document
 - Wheel for rotavirus vaccine doses and ages
 - Poster for rotavirus vaccine doses and ages and paracetamol dosage
 - Updated
 - Guidelines for Vaccinations in General Practice
 - Immunisation Guidelines for Ireland (NIAC)
 - Updated information on website



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 the NIO

