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 1\textsuperscript{st} October 2016 will be offered the new PCI schedule
The New PCI Schedule

<table>
<thead>
<tr>
<th>Change</th>
<th>When</th>
</tr>
</thead>
<tbody>
<tr>
<td>Addition of rotavirus vaccine</td>
<td>2 and 4 months</td>
</tr>
<tr>
<td>Addition of meningococcal B (MenB) vaccine</td>
<td>2, 4 and 12 months</td>
</tr>
<tr>
<td>Timing of 1\textsuperscript{st} MenC</td>
<td>from 4 to 6 months</td>
</tr>
<tr>
<td>Timing of 3\textsuperscript{rd} PCV</td>
<td>from 12 to 13 months</td>
</tr>
<tr>
<td>Replacement of Hib and MenC with Hib/MenC (2 injections to 1 injection)</td>
<td>13 months</td>
</tr>
</tbody>
</table>
## The New PCI Schedule

<table>
<thead>
<tr>
<th>Age (months)</th>
<th>Current Schedule (since 1\textsuperscript{st} July 2015)</th>
<th>Babies born on or after 1\textsuperscript{st} October 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vaccine</td>
<td>No of injections</td>
</tr>
<tr>
<td>2</td>
<td>6in1 + PCV</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>6in1 + MenC</td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>6in1 + PCV</td>
<td>2</td>
</tr>
<tr>
<td>12</td>
<td>MMR + PCV</td>
<td>2</td>
</tr>
<tr>
<td>13</td>
<td>MenC + Hib</td>
<td>2</td>
</tr>
</tbody>
</table>
The New PCI Schedule

Schedule will start when babies reach
– 2 months of age
– on or after 1\textsuperscript{st} December 2016

From 1\textsuperscript{st} 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 – 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 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°C)
- Tenderness / pain at injection site
- Skin rash
- Irritability
- Vomiting / diarrhoea
- Unusual crying

Uncommon (1 in 100 to 1 in 1000)
- High fever (>40°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

<table>
<thead>
<tr>
<th>Liquid Infant Paracetamol (120mgs/5ml)</th>
<th>2 months</th>
<th>4 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose 1</td>
<td>2.5 mls</td>
<td>At the time of injection</td>
</tr>
<tr>
<td></td>
<td>(60mg)</td>
<td>(60mg)</td>
</tr>
<tr>
<td>Dose 2</td>
<td>2.5 mls</td>
<td>4-6 hours after dose 1</td>
</tr>
<tr>
<td></td>
<td>(60mg)</td>
<td>(60mg)</td>
</tr>
<tr>
<td>Dose 3</td>
<td>2.5 mls</td>
<td>4-6 hours after dose 2</td>
</tr>
<tr>
<td></td>
<td>(60mg)</td>
<td>(60mg)</td>
</tr>
</tbody>
</table>
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 18\textsuperscript{th} 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