The New Primary Childhood Immunisation Schedule

Dr Brenda Corcoran
National Immunisation Office
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
<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(^{st}) MenC</td>
<td>from 4 to 6 months</td>
</tr>
<tr>
<td>Timing of 3(^{rd}) PCV</td>
<td>from 12 to 13 months</td>
</tr>
<tr>
<td>Replacement of Hib and MenC with Hib/MenC</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></th>
<th></th>
<th>Babies born on or after 1\textsuperscript{st} October 2016</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>6in1 + PCV</td>
<td>2</td>
<td></td>
<td>6in1 + PCV + MenB + Rotavirus</td>
<td>3 + oral vaccine</td>
</tr>
<tr>
<td>4</td>
<td>6in1 + MenC</td>
<td>2</td>
<td></td>
<td>6in1 + MenB + Rotavirus</td>
<td>2 + oral vaccine</td>
</tr>
<tr>
<td>6</td>
<td>6in1 + PCV</td>
<td>2</td>
<td></td>
<td>6in1 + PCV + MenC</td>
<td>3</td>
</tr>
<tr>
<td>12</td>
<td>MMR + PCV</td>
<td>2</td>
<td></td>
<td>MMR + MenB</td>
<td>2</td>
</tr>
<tr>
<td>13</td>
<td>MenC + Hib</td>
<td>2</td>
<td></td>
<td>Hib/MenC + PCV</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
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 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 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
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></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></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></td>
</tr>
</tbody>
</table>
MenB Vaccine
Paracetamol

- Liquid infant paracetamol 120mg/5ml

- 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
  – 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 1\textsuperscript{st} 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