Outline

• The current state of new vaccine introduction in Asia
• Cost issues
• Safety issues
• Concerns regarding burden of disease
• Concerns regarding vaccine effectiveness
• Advocacy and advertising
• The way forward
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## New vaccine introduction in Asia – by 2014 (thanks to WHO)

<table>
<thead>
<tr>
<th>Hepatitis B</th>
<th>Hib</th>
<th>PCV</th>
<th>Rotavirus</th>
<th>HPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indonesia</td>
<td>Bangladesh</td>
<td>Bangladesh</td>
<td>Thailand (one province only)</td>
<td>Bhutan</td>
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<td>Thailand</td>
<td>Nepal Sri Lanka</td>
<td>Nepal</td>
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<td>Maldives</td>
<td>North Korea</td>
<td>India</td>
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<tr>
<td>Bhutan</td>
<td>Indonesia (India)</td>
<td>Myanmar</td>
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<td>Bangladesh</td>
<td>Maldives</td>
<td>Myanmar</td>
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<td>Myanmar</td>
<td>Timor Leste</td>
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<td>Sri Lanka</td>
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<tr>
<td>Thailand</td>
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</tr>
<tr>
<td><strong>Malaysia, Mongolia</strong></td>
<td><strong>All</strong></td>
<td><strong>French/US states</strong></td>
<td><strong>French/US island states</strong></td>
<td><strong>French/US island states</strong></td>
</tr>
<tr>
<td><strong>All Pacific states</strong></td>
<td><strong>Cambodia, Lao, VN</strong></td>
<td><strong>Hong Kong, Macau</strong></td>
<td><strong>Fiji, Philippines (part)</strong></td>
<td><strong>Malaysia, Singapore (Medisave)</strong></td>
</tr>
<tr>
<td><strong>Japan, Korea, Sing.</strong></td>
<td><strong>Philippine, Vanuatu</strong></td>
<td><strong>Singapore (Medisave)</strong></td>
<td></td>
<td><strong>Japan, Brunei</strong></td>
</tr>
<tr>
<td><strong>All but China, HK</strong></td>
<td><strong>All but Thailand</strong></td>
<td><strong>Japan, Fiji, Kiribati, Laos, PNG, Philippines (two provinces)</strong></td>
<td></td>
<td><strong>Fiji, Vanuatu Cook Is, N Caledon</strong></td>
</tr>
</tbody>
</table>
Hib vaccine use - 2013

Data from Vaccine Information and Management System, IVAC, Johns Hopkins University
Partial introductions and demonstration projects

• Hib –
  • Partial introduction – India, Indonesia (complete in 2014)

• PCV –
  • Pilot evaluation – Mongolia (2016)
  • Partial introduction – Philippines (2014)

• Rotavirus –
  • Partial introduction – Philippines

• HPV –
  • Pilot introductions – Mongolia, Kiribati, Laos, Philippines

• All these vaccines are widely available in the private sector throughout Asia for very high prices
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Cost issues

• GAVI eligible countries
  • SEARO – Indonesia, Maldives, Bhutan, India, Bangladesh, Nepal, Sri Lanka, Myanmar, N Korea, Timor Leste
  • WPRO – Cambodia, Laos, Vietnam, PNG, Solomons, Kiribati

• LMI countries – Pacific states, Philippines
  • Increasing effort within GAVI to develop mechanisms for LMI countries to have access to new vaccines
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Safety issues

• Increasing awareness of vaccine safety issues
  • RV vaccine and intussusception
  • Sudden death following pentavalent – no proven association
  • Sudden death following HPV – no proven association

• Emerging data on the relative effectiveness of aP and wP vaccines
• The strange phenomenon of HANS in Japan
New neonatal rotavirus vaccine

RV3 vaccine manufactured by BioFarma Indonesia 0, 8, 15 weeks similar to 8, 15, 24 weeks in New Zealand Phase 2b trial underway in Yogjakarta, Indonesia
The strange public interpretations of AEFIs

• Consider the following:
  • “If the birth cohort of 25 million were immunised (with pentavalent vaccine), 1/8000-10,000 would die of AEFI, so 3125 children would die from AEFI. To save 350 lives from Hib disease, 3125 children would die from the adverse effects of the vaccine.”
    • Indian Journal of Medical Ethics, Vol X No. 3, July-September 2013
  • Grossly misleading – AEFI is not a diagnosis, or a cause of death
Pertussis vaccines – new developments

- Similar experience in Australia, UK, US
- Increased disease over past 15 years
- Young adults + young infants
- Now increased cases in 2-5 years group
Pertussis vaccines – new developments

• New studies show that immune response of aP is very different to that of wP
• Vaccine efficacy after 3 doses of aP vaccine:
  • 1st year – 83.5%
  • 2nd year – 70.7%
  • 3rd year – 59.2%

• Pertussis hospitalizations and deaths, Australia 2006-2013

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Hospitalizations</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6 mths</td>
<td>1832</td>
<td>10</td>
</tr>
<tr>
<td>6 mths-4 years</td>
<td>557</td>
<td>0</td>
</tr>
<tr>
<td>5-9 years</td>
<td>113</td>
<td>0</td>
</tr>
<tr>
<td>10-64 years</td>
<td>1,166</td>
<td>0</td>
</tr>
<tr>
<td>65 years+</td>
<td>740</td>
<td>1</td>
</tr>
</tbody>
</table>

Duration of Protection After First Dose of Acellular Pertussis Vaccine in Infants
Helen E. Quinn, Thomas L. Snelling, Kristine K. Macartney and Peter B. McIntyre
Pediatrics 2014;133;e513; originally published online February 10, 2014,
DOI: 10.1542/peds.2013-3181
Strategies to control infant pertussis mortality

- Cocoon strategy – successful in some settings where compliance is very good (eg. Chile)
- More boosters
  - Australia, US – 2m, 4m, 6m, 18m, 4y, adolescent
  - Effectiveness of boosters seems short
- Maternal immunization
  - Recommended in US, UK, Australia
  - Effectiveness in UK >90%
- Re-introduction of wP vaccines
  - Studies looking at wP for dose 1 under consideration
HPV in Japan - Human papillomavirus vaccination Associated with Neuropathic Syndrome (HANS)

Source – Dr Riko Nakamura
HPV vaccine in Japan - HANS

- Pain, fatigue, neuro-psychiatric symptoms
- Autonomic dysfunction
- Pseudo-seizures (normal EEG)
- Declining cognitive function
  - Eg. Inability to manage Chinese characters
The focus is the central nerve in the brain. Basically, adjuvants are the only possible cause. When they are highly active, they go beyond the blood-brain barrier like a tsunami. Microglia in the brain become active and the entire immune system goes wrong.”

“Professor from the Institute of Medical Science, Tokyo Medical University), President of the Japan College of Fibromyalgia Investigation (JCFI).”
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Hib in Asia

• No new developments
• China likely to introduce Hib soon
  • Private sector paradox – private sector market creates situation where powerful groups have a vested interest in status quo
Pneumonia burden in Asia

- General agreement that pneumonia is the top cause of post-neonatal child death in Asia
- Very few actual studies of causes of child death in Asia
- Models of pneumonia numbers by cause, etc, now lack credibility
- Gates Foundation now investing in studies to actually determine the causes of child death – SE Asia excluded
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MUSIC PROVIDED BY DJ KITT PROUDFOOT
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RESERVATIONS@VENDOMEMAYFAIR.COM | 0207 495 2595 | 85 PICCADILLY, MAYFAIR, LONDON W1J 7NB | WWW.VENDOMEMAYFAIR.COM
Will confusion about pneumonia and pneumococcal burden impede PCV use in Asia?

• Most major Asian countries have indicated their readiness to introduce PCVs
  • Pakistan, Bangladesh, Nepal, Laos have introduced
  • India, Sri Lanka, Philippines, Vietnam, PNG have plans
  • Indonesia involved in development of new pneumococcal vaccine
• Mongolia will undertake a PCV impact study in Ulaanbaatar
• Formal impact evaluation studies underway in Fiji, Laos, Nepal, Pakistan, Bangladesh
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Vaccine effectiveness

- Rotavirus
  - Slowness of rotavirus vaccine introduction hard to explain
  - Efficacy of vaccines ↓ in higher mortality settings

- PCV and Hib
  - Effectiveness tied up with disease burden and the fraction of pneumonia cases that can be affected by the vaccine
  - The potential for serotype replacement is a major threat to PCV effectiveness
    - Already signs of emerging serotype replacement with PCV13 in UK, US
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Advocacy and advertising

• Traditional role of UNICEF – very cautious about new vaccine advocacy
• Role of “champions” – can be overstated
• Advocacy groups have been perceived as tied to industry
• Wary of above, Asian countries are looking for “evidence” but unsure what evidence is needed
• Large scale private sector use in Asian countries appears to be a barrier to national introduction
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The way forward

- New vaccine introduction in Asia must be:
  - Evidence based, owned and wanted by countries
- Key role of WHO
  - Regional meetings and interaction
  - Promoting regional research as needed
  - Provide sober interpretation of published modelled data
- Role of research community
  - Undertake research that is needed
  - Minimize role of industry
  - Generate MUCH better data on mortality and causes of death
- Role of industry
  - Work as colleagues of the public sector
  - Move away from the notion of vaccines as products to be peddled
Thanks...

- Thanks to Dr Riko Nakamura for information on the HPV vaccine introduction in Japan
- Thanks to Dr Kim Fox, Dr Nyambat Batmunkh, Dr James Heffelfinger at WPRO/WHO