INTRODUCTION AND ADOPTION OF NEW VACCINES FOR THE INDONESIAN EXPANDED PROGRAM ON IMMUNIZATION

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BACKGROUND

• National Immunization programs in many middle income countries, including Indonesia, struggle to secure sufficient budget to maintain quality of the program, including the need to fund new effective vaccines.

• The stages for the introduction of new vaccines in Indonesia, include among others: knowledge synthesis (retrieval and summary of individual studies on vaccine safety, efficacy, immunogenicity, effectiveness, ranking of the level and quality of evidence of each study); synthesis of body of evidence of benefits and harms, and considering the relevance, quality of the evidence and magnitude of effects observed.

• For Indonesia, incorporating new vaccines to the routine National Immunization Program needs careful consideration, since every year there are additional more than 4.6 million newborn babies.
BACKGROUND

• Estimation of the Burden of Disease and Causes of Death by age group, show current and future problems and challenges faced by Indonesian health development

• Immunization with effective vaccine may reduce the morbidity and mortality significantly

• Incorporation of new vaccines into National Immunization Program need careful consideration, including results of Health Technology Assessment and cost effectiveness analysis of the vaccines as well as their sustainability and impact to the national and health budget
LEADING UNDERLYING CAUSES OF DEATH AMONG CHILDREN AGED 1 – 4 YEARS, INDONESIAN SAMPLE REGISTRATION SYSTEM/SRS, 2014

<table>
<thead>
<tr>
<th>No</th>
<th>Cause of Death &amp; ICD Codes</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Diarrhoea and gastroenteritis of presumed infectious origin (A09)</td>
<td>17.2</td>
</tr>
<tr>
<td>2</td>
<td>Pneumonia (J12 - J18)</td>
<td>12.9</td>
</tr>
<tr>
<td>3</td>
<td>Meningitis (G03)</td>
<td>6.3</td>
</tr>
<tr>
<td>4</td>
<td>Diseases of the digestive system (K46, K56, K57, K63, K74-K76, K83, K92)</td>
<td>4.3</td>
</tr>
<tr>
<td>5</td>
<td>Accidental drowning and submersion (W65 - W74)</td>
<td>4.3</td>
</tr>
<tr>
<td>6</td>
<td>Transport accidents (V02, V03, V22, V23, V27-V29, V33, V99)</td>
<td>3.0</td>
</tr>
<tr>
<td>7</td>
<td>Malnutrition and other nutritional deficiencies (E40, E41, E44, E46)</td>
<td>2.6</td>
</tr>
<tr>
<td>8</td>
<td>Congenital malformations of the heart (Q21, Q23, Q24)</td>
<td>2.6</td>
</tr>
<tr>
<td>9</td>
<td>Leukaemia (C91 - C95)</td>
<td>2.0</td>
</tr>
<tr>
<td>10</td>
<td>Tuberculosis (A16)</td>
<td>1.3</td>
</tr>
</tbody>
</table>
LEGAL BASIS OF HTA IN INDONESIA

Law No. 36 /2009 on Health:
Chapter 42 - 45

Technology and health technology products are produced, researched, distributed, developed and used for the health of community

Health technology includes all methods and devices that are used to prevent diseases, to detect diseases, to reduce suffering, to cure diseases, to prevent complication and to rehabilitate after sickness
The National Immunization Technical Advisory Group (NITAG) in Indonesia is officially recognized as “The Indonesian Technical Advisory Group on Immunization” (ITAGI) - is established in 2007.

The current mandate of ITAGI is “to provide advice to MoH through the Director General of the Disease Control & Environmental Health with ongoing timely medical, scientific, and public health advice relating to vaccines”. ITAGI recommendation has not been published to the public until this time. Membership on ITAGI consists of recognized experts in the fields of pediatrics, infectious diseases, immunology, medical microbiology, internal medicine, Health Economics, and Epidemiology.

ITAGI Working Groups are established to address specific vaccine and immunization issues. These groups review evidence and draft Advisory Committee Statements on specific vaccines, including options for vaccine recommendations for the full committee to consider. Conduct policy analysis and determine the most optimal national immunization Policy.

Advise the national government on the formulation of strategies for the control of vaccine preventable diseases through immunization.
EXAMPLES OF INTRODUCTION OF NEW VACCINES INTO NATIONAL PROGRAM

• HiB Vaccine
• Typhoid Vaccine
• H1N1 Vaccine for Hajj Pilgrimage
• Rotavirus Vaccine
• IPV Vaccine
• Rubella Vaccine (MR)
• Pneumococcus (PCV 13) Vaccine
CASE STUDY: ECONOMIC EVALUATION OF ROTAVIRUS VACCINE IN PURWOREJO DISTRICT AND YOGYAKARTA CITY, INDONESIA

- Objective: to assess the possibility of incorporating the vaccine in the National Immunization Program

- The results show that for 4.2 million children, followed up to five years old, the routine immunization program will prevent 488,547 outpatient cases, 176,375 in-patient cases and 8,148 deaths due to diarrhea

- With the assumption of US $14.00 per dose, analysis cost-effectiveness shows US $120.46,- per Disability Adjusted Life Year (DALYs) Loss averted

- Compared with the Indonesian GDP per capita: very cost effective
# Cost-Effectiveness Results in Studies Conducted by the Hib Initiative

<table>
<thead>
<tr>
<th></th>
<th>Kenya</th>
<th>Indonesia</th>
<th>Tunisia</th>
<th>Moldova</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs per discounted death averted</td>
<td>US$ 1,197</td>
<td>US$ 1,649</td>
<td>US$ 2,942</td>
<td>US$ 4,672</td>
</tr>
<tr>
<td>Costs per discounted DALYs Loss averted</td>
<td>US$ 38</td>
<td>US$ 46</td>
<td>US$ 79</td>
<td>US$ 126</td>
</tr>
</tbody>
</table>


Griffiths et al: Cost-effectiveness of delivering Hib vaccine as part of routine childhood immunization services in Tunisia, Hib Init.9/07

### Table 4: COST EFFECTIVENESS ANALYSIS OF MEASLES - RUBELLA (MR) VACCINE

<table>
<thead>
<tr>
<th>Vaccination Costs (Billion Rupiah)</th>
<th>Disease Costs (med. expenditure + Educ) (in Billion Rupiah)</th>
<th>Disease Costs Averted compared with no vaccination (in Billion Rupiah)</th>
<th>Vaccination Costs – Averted Disease Costs (in Billion Rupiah)</th>
<th>DALYs Loss (years)</th>
<th>DALYs averted compared with no vaccination</th>
<th>Incremental CER (Rp/DALY averted), compared with no vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Vaccination Campaign w/ Measles- Rubella (MR) Vaccine Only</td>
<td>---</td>
<td>180.2</td>
<td>150.2</td>
<td>299.8</td>
<td>19,566</td>
<td>3,783</td>
</tr>
<tr>
<td>Vaccination Costs</td>
<td>450</td>
<td>30.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The incremental cost per DALY averted of vaccination with Rubella Vaccine Only, compared with no vaccination would be **Rp. 18,995,121**,--

Indonesian GDP per capita in 2015: US $ 3,587.00- or Rp. 46,631,000,-
CONSIDERATION OF COST EFFECTIVENESS:
WHO THRESHOLD RANGE

- GDP per health outcome gained
  - Between 1 – 3 times GDP per health outcome gained
  - More than 3 times GDP per health outcome gained

- Very cost-effective
- Cost-effective
- Cost-ineffective

Increasingly likely that the payer could lose more health than it gains by funding a new treatment

POLICY CONSIDERATIONS

• Although there is evidence on the cost-effectiveness of a new vaccine, other important considerations are requested by the Ministry of Health, Ministry of Finance, National Planning and Development Board and National Parliament; that is:
  * Potency to make significant impact in reducing morbidity & mortality
  * Technical efficiency: monovalent or multivalent
  * Sustainability of national health budget to fund the program (price of the vaccine)
  * Competing priorities with other public health programs: TB Control, HIV/AIDS, construction of new health care facilities, provision of essential drugs, etc.
• National and global interests as well as community concern (Avian Influenza)
• Acceptability by the community, e.g. IPV and rejection by certain religious group
• Impact on the overall national health budget
• Program sustainability: whether the new vaccine could be produced in country (BIO-PHARMA Manufacturing Co)
CONCLUSIONS

• Introduction and adoption of new vaccines in Indonesia have a thorough processes and considerations involving many agencies, including National Parliament and the relative power of stakeholders involved

• Considering how decisions are made and the use of evidence (disease burden, vaccine efficacy and effectiveness, financial consideration) may enhance vaccine adoption making

• However, these important and effective efforts need to be carried out consistently and systematically to improve the welfare of the community