



KOMITE PENASIHAT AHLI IMUNISASI NASIONAL (Indonesian Technical Advisory Group on Immunization)

SK. MENKES No. 904/MENKES/SK/VII/2010

SEKRETARIAT : JL. PERCETAKAN NEGARA 29 JAKARTA PUSAT

TLP/FAX. 424-9024 – 425-7044

Update Review of Hib (*Haemophilus influenzae* type b) vaccine integration in a pentavalent vaccine (DTP/HB/Hib) into national immunization program

This review is conducted as a follow up of The Indonesian Technical Advisory Group on Immunization (ITAGI) meeting on Oct 21, 2010 to provide the latest input for the decision makers regarding update from countries which have been successfully integrating Hib (*Haemophilus influenzae* type b) vaccine into their national immunization program.

Referring to the first meeting of the *Technical Advisory Group on immunization* on the 7th of June 2007 in Jakarta with invitees that includes foreign experts: from WHO-HQ, Department of Immunization, Vaccine and Biologicals/IVB; from John Hopkin University of Public Health/Hib Adip; from AMP/Association pour l'Aide a la Medicine Preventive), it was recommended to include Hib vaccine in Indonesian basic immunization program.

During the next meeting on the 10th of November 2008, the meeting recommended that the Hib vaccine that will be utilized in national immunization program should be a local product. To be cost, time storage efficient, the meeting also recommended to use a liquid form of Hib combined with DTP/HB (pentavalent).

In reference to the letter from Director of Immunization and Quarantine with number T.U.04.02/II.5/382/2010 dated Feb 23, 2010, regarding Hib vaccine recommendation; the Technical Advisory Group on immunization conducted a Hib vaccine evaluation during its meeting on March 4, 2010. The meeting was also attended by Supporting Independent Immunization and Vaccine Advisory Committees (SIVAC) team, Representative from WHO-EPI Indonesia, Indonesian Technical Advisory Group on Immunization, Bio Farma, National Institute of Health Research and Development (Badan Lit Bang Kes), Sub Directorate Immunization and Sub Directorate URTI from Indonesian CDC.

Therefore, Indonesian Technical Advisory Group on immunization highly encouraged the integration of Hib vaccine into the Indonesian national Immunization program.

Results of scientific review of experiences from other countries that have successfully integrated Hib vaccine into their national routine immunization program :

1. Based upon Indonesian Technical Advisory Group on immunization review for Hib vaccine on 4th of June 2010 and "Regional Review Meeting on Immunization, WHO/SEARO meeting in New Delhi, India in July 2010, there are **165** countries that have integrated Hib immunization into their national immunization program (EPI), 4 countries are in the process of integration (India, Cina, Indonesia and Nigeria), from these countries 75 of them are categorized as eligible countries to receive GAVI (*Global Alliance Vaccine and Immunization*)'s for the Hib vaccine introduction process period¹



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2. Other countries experiences :

a. Developing countries experiences

No	Country	Hib vaccine Introduction into national immunization program	Post routine immunization evaluation
1	<i>Gambia</i> ²	- Since 1997	<ul style="list-style-type: none"> o Reduction in Hib Meningitis incidence among children < 5 years of age from 60 cases (1990) to 0 cases (2002) o reduced the number of Hib meningitis in children <5 years from 200 cases (1990) to 0 cases (2002) o Decline in prevalence of Hib carriage rate from 12% to 0,25%
2	<i>South Africa</i> ³	- Since 1999	<ul style="list-style-type: none"> o reduced incidence rates of Hib in children < 1 year by 65%, from 55 cases (1999-2000) to 19 cases (2003-2004)
3	<i>Kenya</i> ⁴	- Since November 2001	<p>a. evaluation of post routine Hib immunization among children < 5 years from 2002 to 2005 :</p> <ul style="list-style-type: none"> o reduced incidence rates of Hib infection from 66 per 100,000 children to 47 per 100,000 children at 1 year after routine immunization and 7.6 per 100,000 children at 3 years after routine immunization. o Effectiveness of Hib vaccine (2004-2005) is 88% <p>b. evaluation of post routine Hib immunization among children < 2 years of age from 2002 to 2005 :</p> <ul style="list-style-type: none"> o reduced incidence rates of Hib infection from 119 per 100.000 children to 82 per 100.000 children at 1 year after routine immunization and 16 per 100.000 children at 3 years after routine immunizations. o effectiveness of Hib vaccine (2004 - 2005) is 87% rutin.
	<i>Malawi</i> ⁵	- Since 2002	<p>Post Hib immunization evaluation of children age 1 – 59 months who have been treated in hospital (1997-2005) :</p> <ul style="list-style-type: none"> o reduced annual Hib meningitis rates from 20 - 40/100.000 children to almost none o before vaccine introduction, there are as many as 10 children per year suffering from Hib meningitis and HIV. After Hib immunization the incidence rates dropped to 2 children/year during 2003-2004 and none in 2005



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b. Asian countries experiences

No	Country	Hib vaccine Introduction into national immunization program	Post routine immunization evaluation
1	<i>Bangladesh</i> ^{6,7}	<ul style="list-style-type: none"> - Since 2009 - Schedule: 6th, 10th and 14th weeks - Combined with DPT/HB vaccine (pentavalent) 	<ul style="list-style-type: none"> a. routine immunization of infants with Hib vaccine will assist in reduction of one third of serious pneumonia cases and more than 80% of bacterial meningitis cases in Bangladesh b. to estimate the effectiveness of Hib conjugate vaccine in children age < 2 years (N=68.000), a case control study has been conducted in community and hospitals: there are 2679 children who had a chest X Ray, with results as follow : <ul style="list-style-type: none"> o 343 children identified with pneumonia. Following Hib immunization, with protective degree in using community and hospitals were 34% and 44% respectively. o 15 confirmed meningitis cases has been identified. Following Hib immunization, the preventable fractions using community and hospitals controls are 89% and 93% respectively
2	<i>Western Pacific Region</i> ⁸	In 2006, 17 out of 37 countries included Hib vaccine in their routine immunization program, these are Brunei Darussalam, Malaysia, Mongolia, Australia, New Zealand, American Samoa, Guam, Marshall Islands, Mariana Islands, Micronesia, Palau, French Polynesia, Wallis, Futuna, Fiji, Niue	<ul style="list-style-type: none"> o Australia reduced incidence of invasive Hib disease from 30,9 to 6,3 per 100.000 children < 5 years within 2 years after commencing routine Hib vaccination. o Fiji : led to a 32% reduction in Hib meningitis morbidity and a 78% reduction in mortality due to Hib meningitis among children < 5 years. o New Zealand : led to a 92% reduction in morbidity due to Hib meningitis among children < 5 years of age from 27 per 100.000 children (1988-1993) to 2 per 100.000 children (1995-2003)

c. Developed countries experiences

No	Country	Hib vaccine Introduction into national immunization program	Evaluasi pasca imunisasi rutin
1	<i>England</i> ^{9,10}	<ul style="list-style-type: none"> - Since 1992 - Utilize DTPw-Hib - Schedule: 2,3,4 months, with booster - Catch up for age <4 years (1992-1993) 	<ul style="list-style-type: none"> o reduce the incidence of Hib infection among children < 5 years of age by 98% in 1998 o the incidence rates declined from 23,8 per 100.000 (1991) to 0,65 per 100.000 (1998) in Wales and England



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2	<i>Germany</i> ¹¹	Combined Hib vaccine, introduced in 1996	National monitoring involves about 2 million children from year 1998-2011. The effectiveness of the vaccine for children > 2 years: <ul style="list-style-type: none">○ 94.7% for primary vaccination○ 97.2% for booster vaccination
3	<i>American Region (PAHO)</i> ¹²	- USA and Canada: since 1991 - Uruguay : since 1994 - Chile : since 1994	Monitoring and evaluation through the surveillance of diseases caused by Hib

3. Cost benefit analysis

. Cost benefit analysis

- Health economic study shows that *Haemophilus influenzae* type b immunization inclusion in the national immunization program can significantly reduce morbidity and mortality in Indonesia, thus it is a cost-effective intervention¹⁴.
- A pentavalent (DPT/HB/Hib) is more cost-effective compared to a monovalent vaccine¹⁵. SAGE (*Strategic Advisory Group of Experts on Immunization*) recommends Hib vaccine to be combined with DPT/HB making it a pentavalent (DPT/HB/Hib) vaccine to reduce the number injection given to the infants.

4. Provision of vaccine from local production

Bio Farma is making the necessary preparation for production of the pentavalent DTP/HB/Hib vaccine in liquid form, at present it is in clinical trials, and will be completed in 2012. The BPOM will assist through the fast track in its registration process for marketing authorization.

Conclusion:

- There are 165 countries that have integrated Hib immunization into national immunization program (EPI), in addition to experiences from various developed and developing countries that have significantly reduce morbidity and mortality due to Hib infection.
- Integration of Hib vaccine into national immunization programs will contribute to reduce morbidity, mortality and disability due to pneumonia and meningitis caused by Hib and will help accelerate the achievement of Millennium Development Goal 4.
- *Indonesian Technical Advisory Group on immunization* is highly encourages that Hib vaccine (*Haemophilus influenzae* type b) can be integrated into the national immunization program.

Jakarta, 31 October 2010
Chairman, Indonesian Technical Advisory Group on Immunization

Prof. Dr. Sri Rezeki S Hadinegoro, dr., Sp.A(K)



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