health technology assessment

EXECUTIVE SUMMARY

CHILD IMMUNISATION

HEALTH TECHNOLOGY ASSESSMENT UNIT
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH
MOH/PAK/47.02(TR)

EXECUTIVE SUMMARY

BCG

VACCINE EFFICACY

There is wide variation across studies, and also countries ranging from no protection (India- Anonymous, 1999; Malawi- Ponninghaus, 1992), to 38% (Israel - Zibler, 1984), 83% (Thailand - Sirinavin, 1991) and 92% for ages 5 and below (Takamatsu, 1995), with reports of efficacy of - 77% - 86% in meningeal & miliary TB (Thithammol, 1996; Hashimoto, 1997)

VACCINE SAFETY

Local adverse effects include axillary & cervical lymphadenopathy, induration & pustule formation at injection site, while serious complications can occur e.g. ulceration at vaccination site, and disseminated BCG infection is a rare complication.

RECOMMENDATION

To continue the current immunisation schedule

DPT – DIPHTHERIA

VACCINE EFFICACY

The efficacy is more than 87% (from outbreak investigations – Immunisation policy, WHO, 1995), while complete vaccination substantially reduces risk of developing diphtheria, and vaccinated persons have milder illness (MMWR, 1991; Chen, 1976)

DPT - TETANUS

VACCINE EFFICACY

The efficacy of 2 dose tetanus toxoid was 85-100%, with vaccine failures in few adults. In the use of tetanus toxoid in pregnancy, there was 80-100% efficacy in preventing neonatal tetanus. For primary immunisation (3 doses) the protection is for at least 5 years. After the 4th dose, protection is for at least 10 years, while after the 5th dose, protection is for at least 20 years (Galazka WHO, 1993)

DPT - ACCELERATED DPT

VACCINE EFFICACY

The accelerated DPT immunisation schedule has been used in 64% African, 19% American, 11% European, 23 % Western Pacific, 64% SE Asian centers, where the schedule is at 6, 10, 14 weeks or at 2,3,4 months, with booster doses @ 12-24 months & 4-6 years. There is sufficient evidence of efficacy except for acellular Pertussis where there is varying efficacy.

DPT

VACCINE SAFETY

Local reactions are common, while there are mild systemic reactions like fever, drowsiness, fretfulness, anorexia and the like that are self-limiting. Moderate to severe reactions are infrequent including high fever, persistent crying (>3hrs.), collapse and short-lived convulsions. Severe reaction are rare, and these include encephalitis/encephalopathy, prolonged convulsions, infantile spasms, Sudden Infant Death Syndrome, Reye's syndrome , with only anecdotal evidence available on these. The rates of local reactions and common systemic side-effects are lower with acellular Pertussis DPT.

COSTS

The whole cell Pertussis DPT is 0.78 sen /dose while the acellular Pertussis DPT is RM 28.00/dose

RECOMMENDATIONS

It is recommended that the accelerated immunisation schedule at 6 weeks, 3 months and 5 months with a booster at 12 – 24 months and another at 4-6 years

POLIO

VACCINE EFFICACY

For oral polio vaccine (OPV)efficacy is 90 - 95%, whereas for the inactivated polio vaccine (IPV) is 95-100%. Thus, a combination can be used – OPV at birth, OPV+IPV at 6, 10, 14 weeks. There is also increased efficacy when combined with other vaccines e.g. DPT-IPV given in same syringe.

VACCINE SAFETY

The complications associated with OPV are Vaccine associated paralytic poliomyelitis (VAPP), transverse myelitis and facial paralysis. However, IPV is not associated with VAPP.

VACCINE COST

There is fair evidence of cost effectiveness

RECOMMENDATIONS

The current schedule of OPV should be continued, while IPV can be given to immuno-compromised patients.

VACCINE EFFICACY

The vaccine is highly immunogenic as follows:

Measles – 96 -100%

Mumps – 90 – 100%

Rubella – 99 - 100%

However, there is conflicting evidence on efficacy in children > 12 years of age.

VACCINE SAFETY

There are minimal side effects with this vaccine.

COSTS

There is good evidence of cost effectiveness.

RECOMMENDATIONS

The first dose should be given at 12 months, except for Sabah, where it is proposed that it be given at 9 months. The second dose should be given at 6-7 years.

HEPATITIS B

VACCINE EFFICACY

This vaccine has high effectiveness of 95 – 100 %, the frequency of seroconversion increases from 35% after 1st dose to > 90% after 3rd dose. However, double doses are needed in poor responders e.g. chronic renal failure, HIV positive, other immunocompromised patients. An accelerated schedule is recommended for high risk patients

VACCINE SAFETY

There is transient minor soreness & redness at injection site, low grade fever, nausea, dizziness, malaise and rash that are less frequent in children & infants. Rarely, there can be anaphylaxis, which is more common in adults.

COSTS

While there are no local cost benefit studies, studies in other countries show cost savings & cost effectiveness.

RECOMMENDATIONS

It is recommended to continue the current universal immunisation schedule at 0, 1 & 6 months

HEMOPHILUS INFLUENZA B(HIB)

VACCINE EFFICACY

There is good evidence of effectiveness – 90-98% (Adegbola, 1998; Booy, 1997; Takala 9184; NHMRC, Green Book etc.)

VACCINE SAFETY

There a re a few adverse reactions like pain, redness and swelling while systemic reactions like fever, irritability etc. are infrequent

COSTS

There is fair evidence of cost effectiveness.

RECOMMENDATIONS

It is recommended that HiB conjugate vaccine be given at 3,4 5 months, with an additional dose at 12-15 months.

JAPANESE ENCEPHALITIS (JE)

VACCINE EFFICACY

The inactivated mouse-brain derived vaccine has an efficacy of 100% after 3 months. However, there is a decline in antibody levels after 1 year of primary immunisation with 2 doses. The inactivated primary hamster kidney derived vaccine has low efficacy. The live attenuated vaccine has 80% efficacy after the first dose and 98% efficacy after 2 doses.

PROGRAMME EFFICACY

The JE immunization programme has been found to be effective in Japan, Korea, Taiwan, and Thailand. Two primary doses are given 4 weeks apart, with a booster after 1 year, followed by boosters at 3 year intervals. However, the optimal schedule and duration of immunity has not been well established.

VACCINE SAFETY

The mouse brain derived vaccine produces local reactions like tenderness, redness and swelling, while the systemic reactions include fever, headache, malaise and rash. Severe reactions can result in death. On the other hand, for the live attenuated vaccine there is good evidence of safety in short term, although there is no long term data.

RECOMMENDATIONS

For high risk areas the following is recommended - JE vaccine with DPT booster at 18 months, followed by a second dose at 19 months, and a booster at 30 months.

HEPATITIS A

VACCINE EFFICACY

Both the live attenuated vaccine and the inactivated vaccine are highly immunogenic even after first dose with efficacy of 94 – 100%, but the duration of protection is not known

VACCINE SAFETY

There are no serious side effects, the most common being soreness, feeding problems, headache, and induration at the injection site

COSTS

The cost benefits are variable depending on the country. It is cost effective for immunisation of travellers from countries with low or intermediate endemicity to areas of high endemicity if more than once in 10 years

RECOMMENDATIONS

Universal vaccination is not recommended, and should be given only in specific groups e.g. travellers

PNEUMOCOCCAL VACCINE

VACCINE EFFICACY

The 23 valent pneumococcal polysaccharide vaccine has poor immunogeneity especially in infants and young children, while for the 9-11 valent conjugate pneumococcal vaccine there is insufficient evidence of effectiveness especially in developing countries

VACCINE SAFETY

It is generally a safe vaccine with mild local reactions at injection site. The rare complications include moderate effects like fever and myalgia, while severe effects include local induration and anaphylaxis

COSTS

The evidence is inconclusive. Since the vaccine is not available locally, the costs are expected to be exorbitant

RECOMMENDATIONS

Data on true burden of penumococcal infection in children locally is needed before a policy can be formulated.