

INTRODUCTION OF HAEMOPHILUS INFLUENZAE TYPE B VACCINE INTO IMMUNIZATION PROGRAMMES

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INTRODUCTION:

Haemophilus influenzae type b (Hib) is one of the six types of encapsulated strains of the bacteria. Infections due to this bacterium are a major cause of morbidity and mortality in young children globally. Out of the six serotypes (types a-f), type b is responsible for over 90% of the life threatening Haemophilus influenzae infections in children, including meningitis and pneumonia. About 300,000 to 500,000 children die each year due to these Haemophilus influenzae type b infection.

Researchers have developed the new "conjugate" vaccines by connecting certain proteins with part of the Hib bacterium. The proteins enhance the immune response to the Hib component, and the vaccines protect children from the age of two months on. Current Hib vaccine is safe and highly effective - 90 - 99% of children develop antibodies after three doses. It prevents meningitis, pneumonia, epiglottitis, and other serious infections caused by the Hib bacterium. In some developed countries like United States of America, there is a decline of about 99% of Hib cases from 1986 to 1995 in children under five, consequent to the use of Hib vaccines. WHO therefore recommends that Hib vaccine should now be included in routine infant immunization programmes for all children, as appropriate to national capacities and priorities.

THE EPIDEMIOLOGY OF Hib

The Hib Bacterium

Haemophilus influenzae type b is one of six types (a, b, c, d, e and f) of encapsulated strains of the bacteria. All the six are characterized by the following:

- i. They live in the nose and throat of people and usually do not cause serious illness;
- ii. When they do cause serious illness, they mostly affect children under five years of age; they may become systemic, i.e. spread by the blood throughout the body, and can be life-threatening.

Type b bacterium accounts for 90% of serious Haemophilus influenzae infections in children.

The Hib Diseases

i. Bacterial meningitis: This involves inflammation of the membranes that cover and protect the spinal cord and brain. Bacterial meningitis in children is usually caused by Hib. In industrialized countries, between 3 and 5% of these cases are fatal and in developing countries, as many as 40% result in death. 15-35% of children who survive Hib meningitis are left with permanent neurological disabilities such as mental retardation and hearing impairment.

ii. Pneumonia: This involves inflammation of the lungs. In developing countries, Hib is a major cause of pneumonia (or acute lower respiratory infection, ALRI) in children. One study in Africa showed that 20% of the bacterial pneumonia cases severe enough to be seen on chest X-ray, were caused by

Hib. Other Hib infections include:

- iii. Epiglottitis: Inflammation of the larynx and pharynx. In the absence of appropriate and immediate treatment, 50% of cases are fatal.
- iv. Septicaemia: Presence of pathogenic bacteria in the blood.
- v. Osteomyelitis: Inflammation of the bones.
- vi. Cellulitis: Inflammation of tissue under the skin
- vii. Pericarditis: Inflammation of the membrane around the heart.

MODE OF TRANSMISSION

Transmission of the Hib bacteria is effected through droplets of saliva expelled from an infected child to a healthy child when the infected child coughs or sneezes. Hib also spreads when children share toys and other things that they have put in their mouths. Transmission is increased when many children spend prolonged periods of time together in settings such a day-care or creches.

Age Distribution

Hib disease is most common in children under five years old, and children between the ages of four months and 12 months are mostly at risk. At birth, maternal antibodies are adequate to protect most infants. Between 2 and 3 months of age, the level of these antibodies falls and incidence of Hib infections increases. By 4 - 5 years of age, children develop their own immunity; thereafter, Hib disease occurs rarely.

THE Hib VACCINE: Formulations

Quite a number of Hib conjugate vaccines are available from different manufacturers. All manufacturers use the capsular polysaccharide material of the bacteria and link it to tetanus toxoid, diphtheria toxoid, a diphtheria toxoid-like protein, or a mix of proteins from another bacterium. Each of these has been proven effective in the prevention of Hib infections. New Hib vaccines are produced every year. The formulations available as of February 2000 include:

- Liquid Hib vaccine (monovalent)
- Liquid Hib and DTP vaccines in combination
- Liquid Hib and Hepatitis B (HepB) vaccines in combination
- Lyophilized i.e. freeze dried Hib vaccine that the user mixes with saline diluent (monovalent)
- Lyophilized Hib vaccines that the user mixes with liquid DTP, DTP/HepB, DTP/IPV, DTaP, or DTaP/IPV in combination.

All of these vaccines protect against *Haemophilus influenzae* type b but do not prevent diseases caused by other types, such as bronchitis, otitis and sinusitis. They do not prevent meningitis and pneumonia caused by other agents.

Interchangeability

Types and formulations of Hib vaccines can be interchanged, so vaccines from different manufacturers can be used for each dose that a child receives. Diluents, both in saline form and made from other

vaccines, are produced to go with specific Hib vaccines and are not interchangeable.

Presentation: Hib vaccines come in 10 dose and single-dose glass vials and in single-dose pre-filled syringes. A new two-dose formulation mixed with DTP/hepatitis B was available in 2001.

Storage Temperature: Hib vaccine should be stored between 2° and 8° C. Liquid Hib vaccine must never be frozen. Lyophilized vaccine may be frozen until reconstitution, but since the most commonly used diluent, DTP, cannot be frozen, it is recommended to also store lyophilized Hib at 2 - 8° C, to eschew errors.

Shelf Life : The shelf life of Hib vaccines is two years from the date of manufacture if stored between 2° and 8° C.

Indications: Hib vaccine is indicated in children from the age of 6 weeks up to 18 months.

Contraindications: Except for history of hypersensitivity to any of the components in the vaccine (e.g. tetanus or diphtheria toxoids), there are no known and documented contraindications to Hib immunizations.

Schedule of Hib Immunization: Hib immunization schedules differ from country to country depending on the type of Hib vaccine used and the schedule for other vaccines. Generally scheduling practice are as follows:

AGE	VACCINES
6 weeks	DTP ₁ , OPV ₁ , HepB ₁ , Hib ₁
10 weeks	DTP ₂ , OPV ₂ , HepB ₂ , Hib ₂
14 weeks	DTP ₃ , OPV ₃ , HepB ₃ , Hib ₃

- The first dose (size of a dose is 0.5ml) is given to children at six weeks of age or older.
- Three doses are given. Most Hib vaccines require three doses, and in the remainder of this presentation, a three-dose primary series will be considered routine.
- The interval between doses is not less than one month.
- The vaccine may be given at the same time as DTP, OPV and (if applicable) HepB vaccines as shown in the schedule above.

Administration: Liquid vaccine is used directly from the vial. Freeze-dried vaccine must be reconstituted before administration either with diluent or with another vaccine specifically identified and indicated for this purpose by the manufacturer, e.g. DTP.

Hib vaccine is given as intramuscular injection in the anterolateral aspect of the thigh (infants) or deltoid muscle (older children). It can be given at the same time as DTP, OPV, IPV and HepB vaccines without ill-effect. However, if used as a monovalent vaccine, it should

not be injected in the same limb at the same time as other vaccines.

Side Effects : Hib vaccine has not been associated with any serious side effects. However, redness, swelling, and pain where the injection is given may occur in about 25% of children receiving the vaccine. These usually start within one day after the immunization and last from 1 - 3 days. Less commonly,

children may develop fever or irritability for a short time after immunization. When given at the same time as DTP, the rate of fever and/or irritability is not higher than when DTP is given alone.

DTap - *Diphtheria Tetanus acellular pertussis vaccine*

DTP - *Diphtheria Tetanus pertussis vaccine*

HepB - *Hepatitis B vaccine*

IPV - *Injectable polio vaccine*

OPV - *Oral polio vaccine*

Hib - *Haemophilus influenzae type b*

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