Adding Hib conjugate vaccine to the national immunization programme will require:
• an assessment of cold chain storage capacity and cold chain procedures at all administrative levels; and,
• development and implementation of plans to modify cold chain storage capacity and cold chain procedures, if needed.

Monitoring (Hib vaccine wastage) increases ordering accuracy and reduces wastage by providing reliable data for estimating the number and size of vials to be ordered. It also serves as a tool for improving the practices of health centres when wastage rates are found to be unacceptably high. Strategies to reduce vaccine wastage include the following:
• careful planning of vaccine ordering and distribution;
• use of both single-dose and multidose vials;
• careful maintenance of the cold chain;
• implementation of WHO’s multidose vial policy, when appropriate.

Hib conjugate vaccine procured through The Vaccine Fund will be supplied with auto-disable syringes and safety boxes. Additional disposable syringes will be needed for lyophilized vaccines that require reconstitution. Managers at each level are responsible for ensuring that adequate supplies are available at all times. Attention should also be given to the proper use and disposal of the safety boxes used to collect these materials.
Hib

Cold Chain Equipment

The freeze indicator is used to warn of freezing and is packed with vaccines that are sensitive to freezing temperatures: DTP, TT, DT, Td (freezing point of -6.5°C), hepatitis B (-0.5°C), liquid Hib and their combinations (DTP-HepB, and DTP-HepB+Hib vaccines) and JE.

Every refrigerator storing vaccines should have a freeze indicator (Freeze Watch™). It is strongly recommended that one freeze indicator be placed in each cold box during vaccine transport and distribution. This is critical in places subject to low temperatures.

Vaccine Handling

The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81_1. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or province level, OPV must be kept frozen between -15oC and -25oC. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15oC to -25oC if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2oC and +8oC. All other vaccines should be stored at between +2oC and +8oC at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.
Hib

WHO recommends that a policy permitting the use of vaccine outside the cold chain can be implemented either generally for all routine immunization activities or on a limited basis in certain areas or under special circumstances, such as:
§ national immunization days;
§ hard-to-reach geographical areas;
§ immunizations provided in the home;
§ cool seasons;
§ storage and transportation of freeze-sensitive vaccines (DTP, TT, DT, Td, hepatitis B and Hib vaccines) where the risk of freezing is greater than the risk of heat exposure.

However, it should be noted that in most cases lyophilized (Hib) vaccine should not be maintained past six hours after reconstitution.

Liquid Hib should never be frozen, especially in combinations with DTP, as freezing may damage the immunogenicity of the product.
WHO recommended vaccine storage conditions (Appendix 17_3).

WHO no longer recommends that freezedried vaccines (measles, yellow fever, Hib and BCG) be shipped and stored at -20°C. Storing them at -20°C is not harmful but is unnecessary. Instead, these vaccines should be stored and transported at +2°C to +8°C.

Check the freeze indicator in the refrigerator. If it warns of freezing or you suspect that a freeze-sensitive vaccine (DTP, DT, TT, Td, HepB, DTP-HepB, liquid Hib and DTP-HepB+Hib vaccines) has been frozen, you should perform the shake test.

A policy permitting the use of vaccine outside the cold chain can be implemented either generally for all routine immunization activities or on a limited basis in certain areas or under special circumstances, such as:
- national immunization days;
- hard-to-reach geographical areas;
- immunizations provided in the home;
- cool seasons;
- storage and transportation of freeze-sensitive vaccines (DTP, TT, DT, Td, hepatitis B and Hib vaccines) where the risk of freezing is greater than the risk of heat exposure.
The storage temperature for Hib conjugate vaccines is the same as for DTP and hepatitis B vaccines, from 2°C to 8°C.

Introducing Haemophilus influenzae type b (Hib) conjugate vaccine into national immunization services

Hib vaccine should be stored between 2-8°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 avoid errors.

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

Introduction of Haemophilus influenzae type b vaccine into immunization programmes

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.

Introduction of Haemophilus influenzae type b vaccine into immunization programmes

Liquid Hib vaccine must never be frozen.

Introduction of Haemophilus influenzae type b vaccine into immunization programmes

WHO no longer recommends that freeze-dried vaccines (measles, yellow fever, Hib and BCG) be shipped and stored at –20°C. Storing them at –20°C is not harmful but is unnecessary and uses up valuable storage space in the deep-freeze. Instead, they should be kept in refrigeration and transported at +2° to +8°C.

Proper handling and reconstitution of vaccines avoids programme errors
Reconstituted monovalent Hib vaccine or reconstituted Hib vaccine combined with other vaccines (DTP, DTPHB, or DTP-IPV) should be destroyed after an immunization session or within six hours.

**Multi-dose Open Vials**

In multidose formulation, liquid Hib and DTP-Hib vaccines may be used at a subsequent session, even if they have been opened, according to the WHO Policy Statement on the use of opened vials of vaccine in subsequent immunization sessions.

Opened vials of measles, yellow fever, BCG and freeze-dried Hib vaccine cannot be used after an initial immunization session, (even if the VVM has not reached the discard point.). They must be discarded within six hours of reconstitution or at the end of the session, whichever comes first. The VVMs for these vaccines are attached to the vial caps and should be discarded when the vaccine is being reconstituted.

The WHO multi-dose vial policy applies to Hib vaccines as follows:
- All liquid formulations of Hib vaccine contain a preservative and can be used in subsequent immunization sessions.
- The freeze-dried formulation (lyophilized) contains no preservatives, and after being reconstituted with a diluent with no preservatives, must be discarded at the end of the session or within six hours, whichever comes first (the same as for BCG, measles, and yellow fever).
- Certain formulations of lyophilized Hib vaccine are supplied with DTP (or DTP/HepB) liquid vaccine or diluent containing preservatives. These reconstituted vaccines can be used safely over an extended period. However, the application of the multidose vial policy with DTP-HepB+Hib vaccine is recommended only if specific supervision and training activities are conducted in order to ensure appropriate implementation.
The revised (multi-dose vial) policy does not change recommended procedures for handling vaccines that must be reconstituted, that is, BCG, measles, yellow fever, and some formulations of Hib vaccines. Once they are reconstituted, vials of these vaccines must be discarded at the end of each immunization session or at the end of six hours, whichever comes first.

See "Multi-Dose Open Vial" section of the "General" chapter in this catalogue for policies relevant for DTP, DT, TT, DTP-hepB, DTP-hepB-Hib, hepatitis B, liquid formulations of Hib and OPV.

In accordance with the recommendations in the previous position paper on diphtheria, use of diphtheria–tetanus vaccine is preferable to single-antigen tetanus toxoid vaccine. In future, the inclusion of other antigens, e.g. pertussis or Haemophilus influenzae type b (Hib), in booster doses should be considered.
**Hib**

WHO recommends the following schedule for infants (Appendix 39_5).

*Vaccine introduction guidelines. Adding a vaccine to a national immunization programme: decision and implementation*

 wait at least four weeks between doses of OPV, DTP, Hib, and HepB vaccines.

*Immunization in practice: a practical resource guide for Health workers – 2004 update Module 2: The vaccines*

Combination vaccines that contain Hib conjugate vaccine:
- can be used anytime all of the antigens in the vaccine are indicated by the schedule;
- cannot be used before 6 weeks of age (e.g. for the birth dose of hepatitis B vaccine) because the immunogenicity of the DTP and Hib components will be reduced if given before this age.

*Introducing Haemophilus influenzae type b (Hib) conjugate vaccine into national immunization services*

Immunization of infants with Hib conjugate vaccine is usually accomplished by giving the vaccine at the same ages as DTP vaccine, either as a separate injection or in combination.

In general, infants should receive a primary dose schedule of 3 doses of Hib conjugate vaccine in the first year of life. Doses of Hib conjugate vaccine should be administered at least 4 weeks apart.

Children older than one year of age require only a single dose of Hib conjugate vaccine.

*Introducing Haemophilus influenzae type b (Hib) conjugate vaccine into national immunization services*
**Hib**

Booster doses of Hib conjugate vaccine may be given to children in the second year of life, but successful control of Hib disease does not require a booster dose.

*Introducing Haemophilus influenzae type b (Hib) conjugate vaccine into national immunization services*

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

*Introduction of Haemophilus influenzae type b vaccine into immunization programmes*

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In general, the scheduling practices below are followed for Hib immunization:
- The first dose 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 document, a three-dose primary series will be considered routine. One conjugate is licensed for a two-dose primary series, but is not marketed widely.

*Introduction of Haemophilus influenzae type b vaccine into immunization programmes*

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In most countries, the primary series of Hib immunizations protect children through their most susceptible period and thus, in general, a booster is not needed. Although boosters may be considered when Hib disease is a substantial problem for children older than 12 months, some countries do not use booster doses even under these circumstances because of the increased cost and administrative complexity.

*Introduction of Haemophilus influenzae type b vaccine into immunization programmes*
**Vaccine Administration**

**Database ID** 21_8  
**Year** 2001

Hib conjugate vaccine is administered by intramuscular or subcutaneous injection in the anterolateral aspect of the thigh (infants) or the deltoid muscle (older children). If given as a combination with DTP in the same syringe, it should be given intramuscularly.

*Introducing Haemophilus influenzae type b (Hib) conjugate vaccine into national immunization services*  
WHO/V&B/01.29 Page 2

**Database ID** 21_9  
**Year** 2001

Hib conjugate vaccine can be given safely at the same time as other vaccines such as DTP, polio, hepatitis B, measles, BCG, and yellow fever vaccines.

*Introducing Haemophilus influenzae type b (Hib) conjugate vaccine into national immunization services*  
WHO/V&B/01.29 Page 2

**Database ID** 21_10  
**Year** 2001

The injection equipment for Hib conjugate vaccine is the same type as that for DTP or hepatitis B:

- 0.5 ml (auto-disable), 1.0ml or 2.0ml syringe
- 25mm, 22 or 23 gauge needle
- Sterile auto-disable (AD) injection devices are recommended.
- The standard paediatric dose is 0.5 ml.

*Introducing Haemophilus influenzae type b (Hib) conjugate vaccine into national immunization services*  
WHO/V&B/01.29 Page 2
Hib vaccine is given by intramuscular injection in the anterolateral aspect of the thigh (infants) or deltoid muscle (older children).

- The interval between (Hib vaccine) doses is not less than one month.
- The size of a dose is 0.5 ml.

*Introduction of Haemophilus influenzae type b vaccine into immunization programmes*  
WHO/V&B/00.05  Page 6

The (Hib) vaccine may be given at the same time as DTP, OPV, and (if applicable) HepB vaccines. 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.

*Introduction of Haemophilus influenzae type b vaccine into immunization programmes*  
WHO/V&B/00.05  Page 6

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.

*Introduction of Haemophilus influenzae type b vaccine into immunization programmes*  
WHO/V&B/00.05  Page 4

Injection equipment for Hib vaccine and for reconstitution are indicated in Appendix 15_17.

*Introduction of Haemophilus influenzae type b vaccine into immunization programmes*  
WHO/V&B/00.05  Page 13
Contraindications

There are no contra-indications to Hib immunization, except a history of hypersensitivity to any of the components in the vaccine (for example, tetanus or diphtheria toxoids).

Immunization Safety

The injection equipment for Hib conjugate vaccine is the same type as that for DTP or hepatitis B:

• Sterile auto-disable (AD) injection devices are recommended.

Hib conjugate vaccine procured through The Vaccine Fund will be supplied with auto-disable syringes and safety boxes. Additional disposable syringes will be needed for lyophilized vaccines that require reconstitution. Managers at each level are responsible for ensuring that adequate supplies are available at all times. Attention should also be given to the proper use and disposal of the safety boxes used to collect these materials.
**Immunization Coverage**

At minimum, monitoring (of Hib vaccine coverage) should include the proportion of children who complete the Hib primary series of three doses by 12 months of age. It may also include:

- The proportion of the target population receiving 1, 2, and 3 doses of Hib vaccine.
- The number of fully immunized children (FIC), which will now be defined as including 3 doses of Hib, as well as the traditional EPI vaccines.
- The drop-out rate.

*Introduction of Haemophilus influenzae type b vaccine into immunization programmes*

**Surveillance of Vaccine Preventable Disease**

Recommended types of surveillance for bacterial meningitis (including Haemophilus influenzae type b (Hib), Neisseria meningitides, and Streptococcus pneumoniae):

1) Surveillance of suspected and confirmed cases:
   A. Epidemic season: routine weekly reporting of surveillance data is recommended from the peripheral level to the intermediate and central levels. Note: During the epidemic season, it is important to have a well-functioning system for reporting cases and deaths of suspected meningitis in all provinces and to have laboratory confirmation of initial cases in every epidemic district.
   B. Inter-epidemic season and throughout the year in countries without epidemic meningitis: routine monthly reporting of surveillance data is recommended from the peripheral level to the intermediate and central levels. Note: It is more important to have a well-functioning system in some areas than to have a national system that functions poorly.
   C. Designated sites at all levels should report even if there are zero cases (referred to as “zero reporting”).

2) Probable cases should also be reported if laboratory performance indicator are to be monitored.

*WHO–recommended standards for surveillance of selected vaccine-preventable diseases*
**Hib**

**Database ID** 15_19  **Year** 2000

After the introduction of the vaccine, hospitals and laboratories should be the focus of responsibility for case reporting since Hib disease can only be confirmed through laboratory testing. Difficulties in diagnosis of the many types of Hib disease have led to surveillance strategies focusing on meningitis alone, or meningitis and blood stream infection.

**Introduction of Haemophilus influenzae type b vaccine into immunization programmes**

**Database ID** 70_8  **Year** 2006

SAGE recognized that studies on surveillance and disease burden were needed to support evidence-based decision-making in countries that have not introduced routine Hib vaccination, bearing in mind issues such as vaccine supply and cost, and carefully exploring financing options. Cost-benefit studies would also be needed. Whether all countries need to undertake all of these activities has not been resolved. Limitations in laboratory capacity were identified as major impediments that needed to be properly addressed. New financing opportunities for the poorest countries, particularly through the Global Alliance for Vaccines and Immunization and the IFFIIm, will need to be encouraged.

SAGE strongly recommended that this new framework (GAVI Hib initiative) for Hib introduction should be expanded to the fullest extent possible to increase demand for the vaccine and accelerate the lowering of its price.

SAGE also recommended global implementation of Hib vaccination – unless robust epidemiological evidence exists of low disease burden, lack of benefit or overwhelming impediments to implementation.

**Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 9-11 November 2005**

**Database ID** 21_2  **Year** 2001

(Regarding Hib vaccine,) immunization of all infants through routine services is the highest priority for all countries.

**Introducing Haemophilus influenzae type b (Hib) conjugate vaccine into national immunization services**

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**27 June 2008**  **Page 14 of 17**
**Hib**

Catch-up vaccination of older children. (Note: The Vaccine Fund does not provide funding to purchase vaccine for catch-up vaccination):
Children aged greater than 12 months can be protected with just a single dose of Hib conjugate vaccine. At the time of introduction, some countries have chosen to conduct one-time national campaigns to vaccinate all children 1 to 5 years of age with a single dose of Hib conjugate vaccine. This approach may provide some protection to older children but should be undertaken only if it does not draw resources away from infant immunization. Because the risk of Hib disease falls sharply after age 5 years, vaccination of persons older than age 5 years should not be undertaken.

*Introducing Haemophilus influenzae type b (Hib) conjugate vaccine into national immunization services*

Adding Hib conjugate vaccine to the national immunization programme will require:
• an assessment of cold chain storage capacity and cold chain procedures at all administrative levels; and,
• development and implementation of plans to modify cold chain storage capacity and cold chain procedures, if needed.

Important elements of integrating Hib vaccination into national immunization services include:
- revising training and informational materials, forms used to monitor and evaluate the programme, and vaccination cards.
- information, education and communication (IEC) efforts are important from the beginning in order to generate support and commitment for the new vaccine and to assure that the vaccine is appropriately handled and administered. The primary target audiences for IEC efforts are decisionmakers/ opinion leaders, health care staff, and the general public (including parents).

Various tools are available from the WHO regional office which use existing local and regional data to estimate the burden of Hib disease. As a result, disease burden studies will not be needed in most countries (before introducing Hib vaccine.)
Hib

The easiest way to introduce Hib conjugate vaccine is to simply begin vaccinating each infant that comes for routine DTP vaccination. Some countries may wish to consider one-time catch-up vaccination of older children (<2 years or <5 years of age). This will lead to a more immediate reduction in Hib cases but will be more expensive and somewhat more complicated to achieve.

Introducing Haemophilus influenzae type b (Hib) conjugate vaccine into national immunization services

The introduction of Hib conjugate vaccine into the routine services should be used as an opportunity to strengthen the existing services. Programme elements that need particular attention for the introduction of Hib conjugate include stock management, reducing vaccine wastage, and injection safety. Also, the introduction of this new vaccine against serious childhood illness represents an opportunity to renew community interest in all routine vaccinations.

Introducing Haemophilus influenzae type b (Hib) conjugate vaccine into national immunization services

Capital and recurrent costs related to the introduction of Hib conjugate vaccine should be estimated and included in the annual EPI budget. Additional capital costs might include: investment in means of transport, cold chain equipment and sterilization equipment.
Investment in an information campaign targeted at the general public should also be included. Additional recurrent costs include: vaccines, auto-disable injection devices, salaries, transportation (petrol and maintenance), training, cold chain maintenance, safe disposal of waste, disease surveillance and other supplies, such as laboratory media and stationery.

Introducing Haemophilus influenzae type b (Hib) conjugate vaccine into national immunization services
Capital and recurrent costs related to the introduction of Hib conjugate vaccine should be estimated and included in the annual EPI budget. Additional capital costs might include: investment in means of transport, cold chain equipment and sterilization equipment. Investment in an information campaign targeted at the general public should also be included. Additional recurrent costs include: vaccines, auto-disable injection devices, salaries, transportation (petrol and maintenance), training, cold chain maintenance, safe disposal of waste, disease surveillance and other supplies, such as laboratory media and stationery.

Introducing Haemophilus influenzae type b (Hib) conjugate vaccine into national immunization services

WHO recommends that Hib vaccine now be included in routine infant immunization programmes for all children, as appropriate to national capacities and priorities.

In introducing Hib using a catch-up strategy, there will be multiple schedules in the first year for health workers and parents. For example, a schedule for catch-up dosing is outlined in Appendix 15_10.

For older children who have already received DTP immunizations, monovalent Hib vaccine will have to be used, not a combination vaccine such as Hib-DTP, thus resulting in two Hib vaccine formations at the health centre level.