



Shortage of combination DTP-HepB and DTP-HepB+Hib vaccines supplied by the Vaccine Fund through UNICEF

Options for introduction of hepatitis B and *Haemophilus influenzae* type b vaccines into national immunization programmes:

1. The supply situation of combination vaccines

UNICEF Supply Division Copenhagen, is informing us that there is an acute global shortage of DTP-HepB (tetravalent) and DTP-HepB+Hib (pentavalent) vaccines, the supply of which will remain at current levels until at least early 2004. This has programmatic implications for several countries already approved for combination vaccines through the Vaccine Fund and those countries wishing to introduce hepatitis B and *Haemophilus influenzae* type b vaccines in the near future.

The following countries, which were previously approved by the Vaccine Fund for combination vaccines and have already initiated introduction, are assured of requested supplies of the vaccines for the years for which they were approved:

- (a) ***Countries approved for DTP-HepB***
Cambodia, Cote d'Ivoire, Eritrea, Laos PDR, Madagascar, Mozambique, Tanzania
- (b) ***Countries approved for DTP-HepB+Hib***
Ghana, Kenya, Malawi, Rwanda, Uganda

The remainder of countries introducing the new vaccines and not listed above will not receive either of the two combination vaccines before 2004. In the light of the current situation plans to introduce the vaccines will need to be adjusted for these countries.

We have summarised below options for these countries and the programmatic impact. Additional guidance for specific country programme can be obtained through WHO offices.

2. Options for countries wishing to introduce hepatitis B and *Haemophilus influenzae* type b vaccines

(A) Countries introducing only hepatitis B (HepB) vaccine.

Monovalent DNA recombinant HepB vaccine is abundantly available in the global market in 10 dose, 6 dose, 2 dose and single dose preparations. There are various programmatic implications to be considered while introducing HepB vaccine.

(i) Choice of vial size and implication on cold store space

Since monovalent HepB vaccine is available in several vial sizes, the consideration of the choice of vial size must include the impact on the national cold store capacity. Typical volume per dose requirements are shown in table 1.

Table 1. Hepatitis B vaccine storage volumes (in cm³ per dose)

Vaccine	1-dose vial	2-dose vial	6-dose vial	10-dose vial
DTP	-	-	-	3.0
HepB monovalent	9.7-14.9	4.8	3.2	3.0

A 10-dose monovalent HepB vaccine would require additional cold chain space equal to that required for 10-dose DTP alone. Choosing single-dose vials can increase your storage space requirement by 3 to 5 times over what would be required for 10-dose vials. For developing countries, the most pragmatic choice would be to use 10-dose vials, especially those countries opting to use a HepB vaccination schedule identical to that of the DTP schedule. Choosing a 6-dose vial, on the other hand, might help reduce vaccine wastage.

(ii) *Injection equipment and supplies*

The introduction of a monovalent HepB vaccine will require an additional injection. Therefore, the number of auto-disable syringes and safety boxes must be re-calculated to ensure adequate supplies are available. No reconstitution syringe is required.

(iii) *Programme management*

The introduction of monovalent HepB vaccine requires giving one additional injection, along with DTP, where the HepB schedule is identical to that of DTP. In those countries where a birth dose is given, the schedule need not necessarily follow that of DTP: for example, it can be administered at birth, 2 and 3 months of age. Regardless of the schedule, close supervision and monitoring are critical to prevent pilferage and administration of the vaccine out of the target group.

(B) Countries introducing both HepB and Hib vaccines

(i) Three options exist for the introduction of both antigens within the framework of the Vaccine Fund supplies:

Option 1. The most attractive option may be to introduce HepB as soon as is possible as an additional monovalent injection and delay the introduction of Hib until towards late 2002 or later when a combination DTP-Hib may be available. There is, however, uncertainty about the exact timing of availability and the quantity which will be available.

Option 2. Introduce HepB and Hib as separate monovalent injections. This will entail giving three injections to each child at the same time if the HepB schedule is the same as that of DTP and Hib.

Option 3. Delay introduction till 2004, when more pentavalent vaccine may be available. This is the least attractive option because it will mean that at least two birth cohorts will not be protected against either hepatitis B or Hib diseases.

(ii) *Choice of vial size, type of vaccine and implication on cold store space*
 Hib comes as either liquid or lyophilized forms. The liquid vaccine is available in single dose and 10-dose vials whereas lyophilized Hib is available only in single dose vials. The decision to use single dose preparations will have

significant implications on cold chain space requirements. For most countries, the optimal choice would be 10-dose liquid Hib until the combination DTP+Hib is available. Typical storage volume per dose of the various formulations of the monovalent Hib is presented in table 2.

Table 2. Hib preparations and their storage volume (cm³ per dose)

Vaccine	Liquid, single dose	Lyophilized, single dose	Liquid 10-dose
Hib monovalent	32.0	9.7	9.5-13.8

(iii) Injection equipment and supplies

If the liquid Hib monovalent is chosen, then there is no need for reconstitution syringes, but the number of auto-disable syringes and safety boxes must be correctly estimated. However, if monovalent lyophilized Hib is chosen reconstitution syringes will also be required.

(iv) Programme management

It is unlikely that a country would be interested in introducing both HepB and Hib as monovalent at the same time, particularly if the HepB schedule is the same as DTP and Hib, as it would mean giving three injections to the same child on the same visit. Such programmes will require more training and supervision to avoid programme errors.

(C) Countries choosing to introduce only Hib

Monovalent Hib vaccine is available in, either liquid or lyophilized form, and would require a separate injection, with similar impact as noted for introduction of hepatitis B alone (section 2.A above) on cold chain, injection equipment and programme management. The only difference from the considerations in 2.A would be, if a lyophilized monovalent Hib was selected, reconstitution syringes and needles would be required. However, use of a monovalent Hib should be unnecessary as combination DTP+Hib vaccine becomes available in late 2002. The liquid form requires no additional injections or reconstitution.

3. Financial Implications

While formulating the country programmes, financial implications of the choices must be weighed carefully. There are different prices for different formulations and vial sizes of the new vaccines. While smaller dose vials may reduce wastage to some extent, the demand on cold chain capacity would rise. If significant cold chain capacity expansion becomes necessary, there will be substantial financial implication on the programme. Additional injection will also contribute to increased injection waste management cost.

4. Availability of DTP-Hib

As the DTP-Hib combination vaccine is not currently available at large scale production levels, the vaccine is in limited supply. Therefore, if a country is interested to use this vaccine, prior to a final decision, the country should contact UNICEF Supply Division and intimate the Supply Division of their requested quantity, presentation and timing, in order to receive a quotation on availability.