

Pentavalent and Hexavalent Vaccines

Cold Chain Equipment

Database ID 3_7

Year 2004

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.

Immunization in practice: a practical resource guide for Health workers – 2004 update _____ *Module 3: The cold chain*

WHO/IVB/04.06 Page 13

Vaccine Handling

Database ID 81_1

Year 2006

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 -15°C and -25°C . Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15°C to -25°C 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 $+2^{\circ}\text{C}$ and $+8^{\circ}\text{C}$. All other vaccines should be stored at between $+2^{\circ}\text{C}$ and $+8^{\circ}\text{C}$ 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.

Temperature sensitivity of vaccines

WHO/IVB/06.XX Page 2

Database ID 6_3

Year 2004

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.

Immunization in practice: a practical resource guide for Health workers – 2004 update _____ *Module 6: Holding an immunization session*

WHO/IVB/04.06 Page 4

Pentavalent and Hexavalent Vaccines

Database ID 21_4

Year 2001

The currently available pentavalent vaccine requires the reconstitution of lyophilized Hib conjugate vaccine with liquid DTP-hepatitis B vaccine. In this instance, the Hib vaccine should be reconstituted only with the DTP-hepatitis B vaccine produced by the same manufacturer.

Similarly, there is at least one DTP-Hib combination that requires the reconstitution of the lyophilized Hib conjugate vaccine with liquid DTP vaccine, and the Hib vaccine should be reconstituted only with the DTP vaccine produced by the same manufacturer.

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

WHO/V&B/01.29 Page 2

Database ID 15_15

Year 2000

The quadrivalent and pentavalent DTP+Hib and DTP-HepB+Hib formulations with lyophilized Hib are supplied in two separate vials (liquid DTP-HepB and lyophilized Hib) that are not packaged together. Lyophilized Hib vaccine can be stored either frozen at -20°C or refrigerated between 2°C and 8°C; however, liquid DTP or DTP-HepB vaccine **MUST NOT BE FROZEN**. To ensure that Hib is correctly reconstituted with DTP-HepB it is recommended that both vials of the pentavalent DTP-HepB+Hib formulation are stored together between 2°C and 8°C, and both vials should be shipped and distributed together.

Introduction of Haemophilus influenzae type b vaccine into immunization programmes

WHO/V&B/00.05 Page 15

Database ID 14_36

Year 1998

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.

Thermostability of vaccines

WHO/GPV/98.07 Page 47

Pentavalent and Hexavalent Vaccines

Multi-dose Open Vials

Database ID 15_13

Year 2000

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.

Introduction of Haemophilus influenzae type b vaccine into immunization programmes

WHO/V&B/00.05 Page 10

Database ID 26_18

Year 2000

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.

The use of opened multi-dose vials of vaccine in subsequent immunization sessions (WHO Policy Statement)

WHO/V&B/00.09 Page .

Schedule

Database ID 39_26

Year 2005

(Considerations for hepatitis B vaccine schedule:)

- A determination of the role of perinatal transmission (useful for birth dose considerations) can be made based on the overall seroprevalance of HBsAg, age-specific prevalence of HBsAg, and the prevalence of the HBeAg in pregnant women.
- Combination products may not be used at birth; therefore, programmes including the birth dose will need to include monovalent HepB vaccine in the supply.

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

WHO/IVB/05.18 Page 45

Pentavalent and Hexavalent Vaccines

Database ID 2_11

Year 2004

Only monovalent HepB vaccine should be used as a birth dose, the dose given within the first week of life. Combination vaccines should not be used at birth, but may be used in subsequent doses.

Do not use DTP-HepB+Hib as a birth dose. You may use the vaccine for subsequent doses.

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

WHO/IVB/04.06 Page 16 &
20

Database ID 55_7

Year 2004

When immunizing against HBV at birth, only monovalent hepatitis B vaccine should be used: the other antigens found in combination vaccines are currently not approved for use at birth (DTwP, DTaP, Hib, hepatitis A and IPV.)

Hepatitis B vaccines (WHO position paper)

Weekly Epid. Record (2004, 79: 255-263) Page 258

Database ID 20_4

Year 2001

Monovalent HepB vaccines must be used to give the birth dose of HepB vaccine.

Combination vaccines that include HepB vaccine must not be used to give the birth dose of HepB vaccine because DTP and Hib vaccines are not recommended to be given at birth.

Combination vaccines can be given whenever all of the antigens in the vaccine are indicated.

Introducing hepatitis B vaccine into national immunization services

WHO/V&B/01.28 Page 2

Database ID 21_5

Year 2001

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

WHO/V&B/01.29 Page 2

Pentavalent and Hexavalent Vaccines

Database ID 36_3

Year 2001

Monovalent hepatitis B vaccine MUST BE USED for the birth dose.

- Combination vaccines that include hepatitis B vaccine MUST NOT BE USED to give the birth dose of hepatitis B vaccine because DTP and Hib vaccines should not be administered at birth.
- Either monovalent hepatitis B vaccine or combination vaccines may be used for later doses in the hepatitis B vaccine schedule. Combination vaccines can be given whenever all the antigens in the vaccines are indicated.

Introduction of hepatitis B vaccine into childhood immunization services. Management guidelines, including information for health workers and parents

WHO/V&B/01.31 Page 9

Vaccine Administration

Database ID 2_12

Year 2004

Administration summary: HepB vaccine and Administration summary: DTP-HepB combination vaccine (see Appendix 2_12.)

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

WHO/IVB/04.06 Page 16

Database ID 2_13

Year 2004

Administration summary: Hib vaccine and DTP-HepB+Hib combination vaccines (see Appendix 2_13.)

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

WHO/IVB/04.06 Page 20

Database ID 36_6

Year 2001

- Hepatitis B vaccine SHOULD NOT be given in the buttock as this route of administration has been associated with decreased protective antibody levels, probably because of inadvertent subcutaneous injection or injection into deep fat tissue. In addition there may be a risk of injury to the sciatic nerve.
- Hepatitis B vaccine SHOULD NOT be administered intradermally because this route of administration does not produce an adequate antibody response in children.
- Hepatitis B vaccine SHOULD NOT be mixed in the same syringe with other vaccines unless specifically recommended by the manufacturer. (Note: pentavalent DTP-HepB+Hib vaccine is supplied in two separate vials, one containing DTP-HepB vaccine (liquid), the other containing Hib vaccine (lyophilized). The manufacturer recommends mixing the contents of the two vials and giving DTP-HepB+Hib vaccine in the same syringe.)

Introduction of hepatitis B vaccine into childhood immunization services. Management guidelines, including information for health workers and parents

WHO/V&B/01.31 Page 11

Pentavalent and Hexavalent Vaccines

Adverse Event

Database ID 76_6

Year 2005

GACVS concluded that (available) data are inconsistent with any association between hexavalent (diphtheria, tetanus, acellular pertussis, Haemophilus influenzae type b, poliovirus and hepatitis B (DTaP-Hib-IPV-HepB) combination)) vaccines and SID (sudden infant death) or SUD (sudden unexplained death.)

Global Advisory Committee on Vaccine Safety, 9–10 June 2005

Weekly Epid. Record (2005, 80: 242-247) Page 245

Database ID 77_3

Year 2005

On the basis of all the available data, GACVS concluded that there is no evidence to support a causal association between the administration of hexavalent (DTaP-Hib-IPV-HepB) vaccines and SUD (sudden unexplained death.) In response to the potential signal observed in the second year of life, the Committee encouraged studies to be conducted that are designed to provide more powerful evidence on the presence or absence of an association.

Global Advisory Committee on Vaccine Safety, 2–3 December 2004

Weekly Epid. Record (2005, 80: 3-7) Page 6

Research

Database ID 77_3

Year 2005

On the basis of all the available data, GACVS concluded that there is no evidence to support a causal association between the administration of hexavalent (DTaP-Hib-IPV-HepB) vaccines and SUD (sudden unexplained death.) In response to the potential signal observed in the second year of life, the Committee encouraged studies to be conducted that are designed to provide more powerful evidence on the presence or absence of an association.

Global Advisory Committee on Vaccine Safety, 2–3 December 2004

Weekly Epid. Record (2005, 80: 3-7) Page 6
