
Adverse Event

Surveillance of Adverse Events Following Immunization

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A case investigation is usually the first major action to be taken when an AEFI is reported and should begin without delay.

On the other hand, in some programmes for certain AEFIs no further action is taken after they are reported. Illnesses known to have no causal relation to immunizations, such as pneumonia after a DPT injection, are often treated this way. However, even in these cases, if parents or other members of the community are convinced that a medical event was caused by an immunization, they must be given the opportunity to discuss their concerns with health authorities.

Global Advisory Committee on Vaccine Safety, 1011 June 2004

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At its December 2003 meeting, GACVS commissioned a special task force, independent of the Committee, to review the evidence for a deleterious effect (if any) of DTP vaccination on child survival.

Advised by the report of the task force, GACVS decided to regard the issue of a deleterious effect on childhood survival of DTP vaccination as not supported by the evidence and to set the matter aside unless new and persuasive evidence were to emerge in the future.

Diphtheria vaccine (WHO position paper)

[WER 2006, vol. 81, 3, pp
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In most cases, diphtheria toxoid is administered in fixed combination with other vaccines. For childhood vaccination, DTwP or DTaP is generally used, often in combination with other antigens administered at the same time, such as Haemophilus influenzae type b, poliomyelitis, and hepatitis B vaccines, in order to reduce the number of injections. This is a positive development as long as adverse events remain infrequent and the immunogenicity of the individual components is ensured.

BCG

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Typical immunization schedule for children (see Appendix 2_19.)

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

[WHO/IVB/04.16-20](#)
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WHO recommended vaccine storage conditions (Appendix 17_3).

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 6: Holding an immunization session

See Appendix 6_19 for chart entitled, "Administering vaccines to infants"

BCG, DTP, DTP-HepB, HepB, measles, yellow fever, OPV"

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

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

Temperature sensitivity of vaccines

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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.

Cold Chain Equipment

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

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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 -6.5C), hepatitis B (-0.5C), 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.

Diphtheria

Thermostability of vaccines

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If it is suspected that adsorbed DTP, DT, TT or hepatitis B vaccines have been frozen they should be examined for physical changes. Where these are found the vaccines should be discarded.

Getting started with vaccine vial monitors[WHO/V&B/02.35](#)

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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.

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Immunizing infants and children with DTP or DT and adults with Td prevents tetanus.

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 6: Holding an immunization session[WHO/IVB/04.06](#)

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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.

Diphtheria vaccine (WHO position paper)[WER 2006, vol. 81, 3, pp 24-32](#)

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The recommended schedule for vaccination against diphtheria varies considerably between countries. According to the WHO/EPI schedule, the primary series of DTwP- or DTaP-containing vaccines should be administered in 3 doses, starting as early as 6 weeks of age and given with a minimum interval of 4 weeks. Where resources permit, additional doses can be given after the completion of the primary series. Many national immunization programmes offer 1-2 booster doses, for example one at 2 years of age and a second at age 4-7 years.

Diphtheria vaccine (WHO position paper)[WER 2006, vol. 81, 3, pp 24-32](#)

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For previously un-immunized children aged 1-7 years, the recommended schedule (for diphtheria vaccine) is 2 doses 2 months apart, and a third dose after 6-12 months using DTwP or DTaP. The recommended schedule for primary immunizations of older children, adolescents and adults using the dT combination is 2 doses -months apart and a third dose after 6-12 months. People living in low-endemic or non-endemic areas should receive booster doses of DT approximately 10 years after completing the primary series and subsequently every 10 years throughout life. Special attention should be paid to immunizing health-care workers who may have occupational exposure to *C. diphtheriae*. Booster responses can still be elicited after intervals of 25-30 years, so repeat primary immunization is not required when boosters are delayed.

Diphtheria vaccine (WHO position paper)

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In most cases, diphtheria toxoid is administered in fixed combination with other vaccines. For childhood vaccination, DTwP or DTaP is generally used, often in combination with other antigens administered at the same time, such as Haemophilus influenzae type b, poliomyelitis, and hepatitis B vaccines, in order to reduce the number of injections. This is a positive development as long as adverse events remain infrequent and the immunogenicity of the individual components is ensured.

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 3: The cold chain

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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 -6.5C), hepatitis B (-0.5C), 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.

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The shake test can help give an idea whether adsorbed vaccines (DTP, DT, Td, TT or hepatitis B) have been subjected to freezing temperatures likely to have damaged them. The test should be conducted for all boxes where freeze indicators are found to be activated or temperature recordings show negative temperatures.

Identify and separate all vaccines that may have been frozen and ensure that none are distributed or used.

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

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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.

Temperature sensitivity of vaccines

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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.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

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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.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

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If it is suspected that adsorbed DTP, DT, or TT have been frozen they should be examined for physical changes. Where these are found the vaccines should be discarded. The amount of antigen in a non-homogeneous vaccine can vary greatly, and the administration of such a vaccine may be associated with a reduced immune response or an increased incidence of local reactions.

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 2: The vaccines[WHO/IVB/04.06](#)

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Vaccines containing tetanus toxoid :
TT/DT/Td/DTP vaccines should never be frozen. The shake test will determine if the vaccine has been damaged by freezing. If the vaccine fails the shake test you must discard it.

Tetanus vaccine (WHO position paper)[WER 2006, vol. 81, 20, pp 198-208](#)

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See Appendix 83_18 for a summary table of immunizations with diphtheriatetanuspertussis (DTP) and diphtheria toxoid (Td) vaccines required to obtain long-term protection against tetanus

GACVS

Global Advisory Committee on Vaccine Safety, 1011 June 2004[WER 2004, vol. 79, 29, pp 269-272](#)

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At its December 2003 meeting, GACVS commissioned a special task force, independent of the Committee, to review the evidence for a deleterious effect (if any) of DTP vaccination on child survival.

Advised by the report of the task force, GACVS decided to regard the issue of a deleterious effect on childhood survival of DTP vaccination as not supported by the evidence and to set the matter aside unless new and persuasive evidence were to emerge in the future.

General

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

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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.

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 2: The vaccines

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Administration summary: DTP vaccine (see Appendix 2_1)

Surveillance of Adverse Events Following Immunization

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A case investigation is usually the first major action to be taken when an AEFI is reported and should begin without delay.

On the other hand, in some programmes for certain AEFIs no further action is taken after they are reported. Illnesses known to have no causal relation to immunizations, such as pneumonia after a DTP injection, are often treated this way. However, even in these cases, if parents or other members of the community are convinced that a medical event was caused by an immunization, they must be given the opportunity to discuss their concerns with health authorities.

Thermostability of vaccines

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If it is suspected that adsorbed DTP, DT, TT or hepatitis B vaccines have been frozen they should be examined for physical changes. Where these are found the vaccines should be discarded.

Getting started with vaccine vial monitors

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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;
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Immunizing infants and children with DTP or DT and adults with Td prevents tetanus.

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Typical immunization schedule for children (see Appendix 2_19.)

Introduction of Haemophilus influenzae type b vaccine into immunization programmes[WHO/V&B/00.05](#)
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If more than one type of DTP is being stored, DTP that is not approved for reconstitution should not be stored where there is any chance of confusion with the DTP that is approved for reconstitution.

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4[WHO/IVB/04.16-20](#)
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WHO recommended vaccine storage conditions (Appendix 17_3).

Global Advisory Committee on Vaccine Safety, 1011 June 2004[WER 2004, vol. 79, 29, pp 269-272](#)
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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.

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See Appendix 6_19 for chart entitled, "Administering vaccines to infants" BCG, DTP, DTP-HepB, HepB, measles, yellow fever, OPV"

Diphtheria vaccine (WHO position paper)

[WER 2006, vol. 81, 3, pp 24-32](#)
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The recommended schedule for vaccination against diphtheria varies considerably between countries. According to the WHO/EPI schedule, the primary series of DTwP- or DTaP-containing vaccines should be administered in 3 doses, starting as early as 6 weeks of age and given with a minimum interval of 4 weeks. Where resources permit, additional doses can be given after the completion of the primary series. Many national immunization programmes offer 1-2 booster doses, for example one at 2 years of age and a second at age 4-7 years.

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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 -6.5C), hepatitis B (-0.5C), 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.

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The shake test can help give an idea whether adsorbed vaccines (DTP, DT, Td, TT or hepatitis B) have been subjected to freezing temperatures likely to have damaged them. The test should be conducted for all boxes where freeze indicators are found to be activated or temperature recordings show negative temperatures.

Identify and separate all vaccines that may have been frozen and ensure that none are distributed or used.

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

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

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

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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.

Temperature sensitivity of vaccines

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Temperature sensitivity of vaccines

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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:

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- 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.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

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The shake test should NOT be conducted under following circumstances and vials should be discarded immediately, without the need for any confirmatory test:

1. When a solid frozen vaccine vial(s) has been found
2. With a vial for which a homogeneous solution CANNOT be obtained after vigorous shaking. In such cases, the white lump/sediment cannot be separated from the walls of the glass vial. This happens only with DTP vials that are exposed to subzero temperatures without freezing.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

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If it is suspected that adsorbed DTP, DT, or TT have been frozen they should be examined for physical changes. Where these are found the vaccines should be discarded. The amount of antigen in a non-homogeneous vaccine can vary greatly, and the administration of such a vaccine may be associated with a reduced immune response or an increased incidence of local reactions.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

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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.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

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Liquid Hib should never be frozen, especially in combinations with DTP, as freezing may damage the immunogenicity of the product

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

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Vaccines containing tetanus toxoid :
TT/DT/Td/DTP vaccines should never be frozen. The shake test will determine if the vaccine has been damaged by freezing. If the vaccine fails the shake test you must discard it.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

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Liquid Hib should never be frozen, especially in combinations with DTP, as freezing may damage the immunogenicity of the product

Tetanus vaccine (WHO position paper)

[WER 2006, vol. 81, 20, pp 198-208](#)
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See Appendix 83_18 for a summary table of immunizations with diphtheriatetanuspertussis (DTP) and diphtheria toxoid (Td) vaccines required to obtain long-term protection against tetanus

Hepatitis B**Thermostability of vaccines**

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If it is suspected that adsorbed DTP, DT, TT or hepatitis B vaccines have been frozen they should be examined for physical changes. Where these are found the vaccines should be discarded.

Getting started with vaccine vial monitors

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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:

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Typical immunization schedule for children (see Appendix 2_19.)

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

[WHO/IVB/04.16-20](#)
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WHO recommended vaccine storage conditions (Appendix 17_3).

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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.

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See Appendix 6_19 for chart entitled, "Administering vaccines to infants" BCG, DTP, DTP-HepB, HepB, measles, yellow fever, OPV"

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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 -6.5C), hepatitis B (-0.5C), 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.

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The shake test can help give an idea whether adsorbed vaccines (DTP, DT, Td, TT or hepatitis B) have been subjected to freezing temperatures likely to have damaged them. The test should be conducted for all boxes where freeze indicators are found to be activated or temperature recordings show negative temperatures.

Identify and separate all vaccines that may have been frozen and ensure that none are distributed or used.

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

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

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

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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.

Temperature sensitivity of vaccines

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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.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

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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;
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- 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.

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

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

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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.

Getting started with vaccine vial monitors[WHO/V&B/02.35](#)

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Typical immunization schedule for children (see Appendix 2_19.)

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4[WHO/IVB/04.16-20](#)

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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.

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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 -6.5C), hepatitis B (-0.5C), 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 introduction guidelines. Adding a vaccine to a national immunization programme: decision and implementation

[WHO/IVB/05.18](#)
page 32

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

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

[WHO/V&B/00.09](#)
page 0

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.

Temperature sensitivity of vaccines

[WHO/IVB/06.10](#)
page 2

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.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 6

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.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

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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.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 21

Liquid Hib should never be frozen, especially in combinations with DTP, as freezing may damage the immunogenicity of the product

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 2: The vaccines[WHO/IVB/04.06](#)

page 25

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

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 21

Liquid Hib should never be frozen, especially in combinations with DTP, as freezing may damage the immunogenicity of the product

JE

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 3: The cold chain[WHO/IVB/04.06](#)

page 13

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 -6.5C), hepatitis B (-0.5C), 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.

MMR

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

[WHO/IVB/04.16-20](#)
page 1

WHO recommended vaccine storage conditions (Appendix 17_3).

Temperature sensitivity of vaccines

[WHO/IVB/06.10](#)
page 2

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.

Measles

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 2: The vaccines

[WHO/IVB/04.06](#)
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Typical immunization schedule for children (see Appendix 2_19.)

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

[WHO/IVB/04.16-20](#)
page 1

WHO recommended vaccine storage conditions (Appendix 17_3).

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See Appendix 6_19 for chart entitled, "Administering vaccines to infants" BCG, DTP, DTP-HepB, HepB, measles, yellow fever, OPV"

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

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

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 2

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.

Meningococcal

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 2

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.

Mumps

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 2

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.

Open Vials

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

[WHO/V&B/00.09](#)
page 0

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.

Temperature sensitivity of vaccines

[WHO/IVB/06.10](#)
page 21

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.

Pentavalent

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 6: Holding an immunization session

[WHO/IVB/04.06](#)
page 4

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 3: The cold chain

[WHO/IVB/04.06](#)
page 13

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 -6.5C), hepatitis B (-0.5C), 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.

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

[WHO/V&B/00.09](#)
page 0

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.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 2

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.

Policy

Introducing Haemophilus influenzae type b (Hib) conjugate vaccine into national immunization services[WHO/V&B/01.29](#)

page 2

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.

Immunization in practice: a practical resource guide for Health workers 2004 update _____ Module 2: The vaccines[WHO/IVB/04.06](#)

page 4

Administration summary: DTP vaccine (see Appendix 2_1)

Surveillance of Adverse Events Following Immunization[WHO/EPI/TRAM/93.02.](#)[Rev 1](#)

page 12

A case investigation is usually the first major action to be taken when an AEFI is reported and should begin without delay.

On the other hand, in some programmes for certain AEFIs no further action is taken after they are reported. Illnesses known to have no causal relation to immunizations, such as pneumonia after a DPT injection, are often treated this way. However, even in these cases, if parents or other members of the community are convinced that a medical event was caused by an immunization, they must be given the opportunity to discuss their concerns with health authorities.

Thermostability of vaccines[WHO/GPV/98.07](#)

page 12

If it is suspected that adsorbed DTP, DT, TT or hepatitis B vaccines have been frozen they should be examined for physical changes. Where these are found the vaccines should be discarded.

Getting started with vaccine vial monitors[WHO/V&B/02.35](#)

page 9

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.

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 1: Target diseases[WHO/IVB/04.06](#)

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Immunizing infants and children with DTP or DT and adults with Td prevents tetanus.

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 2: The vaccines[WHO/IVB/04.06](#)

page 24

Typical immunization schedule for children (see Appendix 2_19.)

Introduction of Haemophilus influenzae type b vaccine into immunization programmes[WHO/V&B/00.05](#)

page 12

If more than one type of DTP is being stored, DTP that is not approved for reconstitution should not be stored where there is any chance of confusion with the DTP that is approved for reconstitution.

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4[WHO/IVB/04.16-20](#)

page 1

WHO recommended vaccine storage conditions (Appendix 17_3).

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 6: Holding an immunization session[WHO/IVB/04.06](#)

page 4

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](#)

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See Appendix 6_19 for chart entitled, "Administering vaccines to infants" BCG, DTP, DTP-HepB, HepB, measles, yellow fever, OPV"

Diphtheria vaccine (WHO position paper)

[WER 2006, vol. 81, 3, pp 24-32](#)
page 29

The recommended schedule for vaccination against diphtheria varies considerably between countries. According to the WHO/EPI schedule, the primary series of DTwP- or DTaP-containing vaccines should be administered in 3 doses, starting as early as 6 weeks of age and given with a minimum interval of 4 weeks. Where resources permit, additional doses can be given after the completion of the primary series. Many national immunization programmes offer 1-2 booster doses, for example one at 2 years of age and a second at age 4-7 years.

Diphtheria vaccine (WHO position paper)

[WER 2006, vol. 81, 3, pp 24-32](#)
page 29

For previously un-immunized children aged 1-7 years, the recommended schedule (for diphtheria vaccine) is 2 doses 2 months apart, and a third dose after 6-12 months using DTwP or DTaP. The recommended schedule for primary immunizations of older children, adolescents and adults using the dT combination is 2 doses -months apart and a third dose after 6-12 months. People living in low-endemic or non-endemic areas should receive booster doses of DT approximately 10 years after completing the primary series and subsequently every 10 years throughout life. Special attention should be paid to immunizing health-care workers who may have occupational exposure to *C. diphtheriae*. Booster responses can still be elicited after intervals of 25-30 years, so repeat primary immunization is not required when boosters are delayed.

Diphtheria vaccine (WHO position paper)

[WER 2006, vol. 81, 3, pp 24-32](#)
page 31

In most cases, diphtheria toxoid is administered in fixed combination with other vaccines. For childhood vaccination, DTwP or DTaP is generally used, often in combination with other antigens administered at the same time, such as *Haemophilus influenzae* type b, poliomyelitis, and hepatitis B vaccines, in order to reduce the number of injections. This is a positive development as long as adverse events remain infrequent and the immunogenicity of the individual components is ensured.

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

[WHO/IVB/04.06](#)
page 13

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 -6.5C), hepatitis B (-0.5C), 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 26

The shake test can help give an idea whether adsorbed vaccines (DTP, DT, Td, TT or hepatitis B) have been subjected to freezing temperatures likely to have damaged them. The test should be conducted for all boxes where freeze indicators are found to be activated or temperature recordings show negative temperatures.

Identify and separate all vaccines that may have been frozen and ensure that none are distributed or used.

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

[WHO/IVB/05.18](#)

page 32

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

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

[WHO/V&B/00.09](#)

page 0

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.

Temperature sensitivity of vaccines

[WHO/IVB/06.10](#)

page 2

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.

Temperature sensitivity of vaccines

[WHO/IVB/06.10](#)

page 6

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.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 8

The shake test should NOT be conducted under following circumstances and vials should be discarded immediately, without the need for any confirmatory test:

1. When a solid frozen vaccine vial(s) has been found
2. With a vial for which a homogeneous solution CANNOT be obtained after vigorous shaking. In such cases, the white lump/sediment cannot be separated from the walls of the glass vial. This happens only with DTP vials that are exposed to subzero temperatures without freezing.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 13

If it is suspected that adsorbed DTP, DT, or TT have been frozen they should be examined for physical changes. Where these are found the vaccines should be discarded. The amount of antigen in a non-homogeneous vaccine can vary greatly, and the administration of such a vaccine may be associated with a reduced immune response or an increased incidence of local reactions.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 21

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.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 21

Liquid Hib should never be frozen, especially in combinations with DTP, as freezing may damage the immunogenicity of the product

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 2: The vaccines[WHO/IVB/04.06](#)

page 25

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[WHO/IVB/04.06](#)

page 12

Vaccines containing tetanus toxoid :
TT/DT/Td/DTP vaccines should never be frozen. The shake test will determine if the vaccine has been damaged by freezing. If the vaccine fails the shake test you must discard it.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 21

Liquid Hib should never be frozen, especially in combinations with DTP, as freezing may damage the immunogenicity of the product

Tetanus vaccine (WHO position paper)

[WER 2006, vol. 81, 20, pp 198-208](#)
page 207

See Appendix 83_18 for a summary table of immunizations with diphtheriatetanuspertussis (DTP) and diphtheria toxoid (Td) vaccines required to obtain long-term protection against tetanus

Polio**Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 2: The vaccines**

[WHO/IVB/04.06](#)
page 24

Typical immunization schedule for children (see Appendix 2_19.)

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

[WHO/IVB/04.16-20](#)
page 1

WHO recommended vaccine storage conditions (Appendix 17_3).

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 6: Holding an immunization session

[WHO/IVB/04.06](#)
page 19

See Appendix 6_19 for chart entitled, "Administering vaccines to infants" BCG, DTP, DTP-HepB, HepB, measles, yellow fever, OPV"

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

[WHO/IVB/05.18](#)
page 32

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

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

[WHO/V&B/00.09](#)
page 0

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.

Temperature sensitivity of vaccines

[WHO/IVB/06.10](#)
page 2

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.

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 2: The vaccines

[WHO/IVB/04.06](#)
page 25

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

Rubella

Temperature sensitivity of vaccines

[WHO/IVB/06.10](#)
page 2

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.

Schedule

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 1: Target diseases

[WHO/IVB/04.06](#)
page 20

Immunizing infants and children with DTP or DT and adults with Td prevents tetanus.

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 2: The vaccines

[WHO/IVB/04.06](#)
page 24

Typical immunization schedule for children (see Appendix 2_19.)

Diphtheria vaccine (WHO position paper)

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The recommended schedule for vaccination against diphtheria varies considerably between countries. According to the WHO/EPI schedule, the primary series of DTwP- or DTaP-containing vaccines should be administered in 3 doses, starting as early as 6 weeks of age and given with a minimum interval of 4 weeks. Where resources permit, additional doses can be given after the completion of the primary series. Many national immunization programmes offer 1-2 booster doses, for example one at 2 years of age and a second at age 4-7 years.

Diphtheria vaccine (WHO position paper)

For previously un-immunized children aged 1-7 years, the recommended schedule (for diphtheria vaccine) is 2 doses 2 months apart, and a third dose after 6-12 months using DTwP or DTaP. The recommended schedule for primary immunizations of older children, adolescents and adults using the dT combination is 2 doses -months apart and a third dose after 6-12 months. People living in low-endemic or non-endemic areas should receive booster doses of DT approximately 10 years after completing the primary series and subsequently every 10 years throughout life. Special attention should be paid to immunizing health-care workers who may have occupational exposure to *C. diphtheriae*. Booster responses can still be elicited after intervals of 25-30 years, so repeat primary immunization is not required when boosters are delayed.

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

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

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Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 2: The vaccines

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

[WHO/IVB/04.06](#)
page 25

Tetanus vaccine (WHO position paper)

See Appendix 83_18 for a summary table of immunizations with diphtheriatetanuspertussis (DTP) and diphtheria toxoid (Td) vaccines required to obtain long-term protectiona against tetanus

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Tetanus

Thermostability of vaccines

If it is suspected that adsorbed DTP, DT, TT or hepatitis B vaccines have been frozen they should be examined for physical changes. Where these are found the vaccines should be discarded.

[WHO/GPV/98.07](#)
page 12

Getting started with vaccine vial monitors

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.

[WHO/V&B/02.35](#)
page 9

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 1: Target diseases

[WHO/IVB/04.06](#)
page 20

Immunizing infants and children with DTP or DT and adults with Td prevents tetanus.

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 6: Holding an immunization session

[WHO/IVB/04.06](#)
page 4

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 3: The cold chain

[WHO/IVB/04.06](#)
page 13

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 -6.5C), hepatitis B (-0.5C), 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.

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The shake test can help give an idea whether adsorbed vaccines (DTP, DT, Td, TT or hepatitis B) have been subjected to freezing temperatures likely to have damaged them. The test should be conducted for all boxes where freeze indicators are found to be activated or temperature recordings show negative temperatures.

Identify and separate all vaccines that may have been frozen and ensure that none are distributed or used.

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

[WHO/V&B/00.09](#)
page 0

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.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 2

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°C and +8°C. All other vaccines should be stored at between +2°C and +8°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/06.10](#)

page 6

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.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 13

If it is suspected that adsorbed DTP, DT, or TT have been frozen they should be examined for physical changes. Where these are found the vaccines should be discarded. The amount of antigen in a non-homogeneous vaccine can vary greatly, and the administration of such a vaccine may be associated with a reduced immune response or an increased incidence of local reactions.

Immunization in practice: a practical resource guide for Health workers 2004 update _____ Module 2: The vaccines[WHO/IVB/04.06](#)

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Vaccines containing tetanus toxoid :
TT/DT/Td/DTP vaccines should never be frozen. The shake test will determine if the vaccine has been damaged by freezing. If the vaccine fails the shake test you must discard it.

Tetanus vaccine (WHO position paper)[WER 2006, vol. 81, 20, pp 198-208](#)

page 207

See Appendix 83_18 for a summary table of immunizations with diphtheriatetanuspertussis (DTP) and diphtheria toxoid (Td) vaccines required to obtain long-term protection against tetanus

Vaccine Administration

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

[WHO/V&B/01.29](#)
page 2

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.

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Administration summary: DTP vaccine (see Appendix 2_1)

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See Appendix 6_19 for chart entitled, "Administering vaccines to infants" BCG, DTP, DTP-HepB, HepB, measles, yellow fever, OPV"

Diphtheria vaccine (WHO position paper)

[WER 2006, vol. 81, 3, pp 24-32](#)
page 31

In most cases, diphtheria toxoid is administered in fixed combination with other vaccines. For childhood vaccination, DTwP or DTaP is generally used, often in combination with other antigens administered at the same time, such as Haemophilus influenzae type b, poliomyelitis, and hepatitis B vaccines, in order to reduce the number of injections. This is a positive development as long as adverse events remain infrequent and the immunogenicity of the individual components is ensured.

Vaccine Handling

Thermostability of vaccines

[WHO/GPV/98.07](#)
page 12

If it is suspected that adsorbed DTP, DT, TT or hepatitis B vaccines have been frozen they should be examined for physical changes. Where these are found the vaccines should be discarded.

Getting started with vaccine vial monitors

[WHO/V&B/02.35](#)
page 9

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.

Introduction of Haemophilus influenzae type b vaccine into immunization programmes

[WHO/V&B/00.05](#)
page 12

If more than one type of DTP is being stored, DTP that is not approved for reconstitution should not be stored where there is any chance of confusion with the DTP that is approved for reconstitution.

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

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page 1

WHO recommended vaccine storage conditions (Appendix 17_3).

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page 4

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.

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page 26

The shake test can help give an idea whether adsorbed vaccines (DTP, DT, Td, TT or hepatitis B) have been subjected to freezing temperatures likely to have damaged them. The test should be conducted for all boxes where freeze indicators are found to be activated or temperature recordings show negative temperatures.

Identify and separate all vaccines that may have been frozen and ensure that none are distributed or used.

Temperature sensitivity of vaccines

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page 2

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.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 6

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.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 8

The shake test should NOT be conducted under following circumstances and vials should be discarded immediately, without the need for any confirmatory test:

1. When a solid frozen vaccine vial(s) has been found
2. With a vial for which a homogeneous solution CANNOT be obtained after vigorous shaking. In such cases, the white lump/sediment cannot be separated from the walls of the glass vial. This happens only with DTP vials that are exposed to subzero temperatures without freezing.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 13

If it is suspected that adsorbed DTP, DT, or TT have been frozen they should be examined for physical changes. Where these are found the vaccines should be discarded. The amount of antigen in a non-homogeneous vaccine can vary greatly, and the administration of such a vaccine may be associated with a reduced immune response or an increased incidence of local reactions.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

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Liquid Hib should never be frozen, especially in combinations with DTP, as freezing may damage the immunogenicity of the product

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page 12

Vaccines containing tetanus toxoid :
TT/DT/Td/DTP vaccines should never be frozen. The shake test will determine if the vaccine has been damaged by freezing. If the vaccine fails the shake test you must discard it.

Temperature sensitivity of vaccines[WHO/IVB/06.10](#)

page 21

Liquid Hib should never be frozen, especially in combinations with DTP, as freezing may damage the immunogenicity of the product

Yellow Fever

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page 24

Typical immunization schedule for children (see Appendix 2_19.)

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

[WHO/IVB/04.16-20](#)
page 1

WHO recommended vaccine storage conditions (Appendix 17_3).

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See Appendix 6_19 for chart entitled, "Administering vaccines to infants" BCG, DTP, DTP-HepB, HepB, measles, yellow fever, OPV"

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

[WHO/IVB/05.18](#)
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WHO recommends the following schedule for infants (Appendix 39_5).

Temperature sensitivity of vaccines

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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.