
Adverse Event

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.

Diphtheria vaccine (WHO position paper)

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(W)ith the increasing number of doses (of diphtheria toxoid) that are now recommended, reactogenicity is likely to increase. Although further purification of extraneous proteins residing in the toxoid may help to ameliorate this problem, optimal future diphtheria vaccines should provide protection of longer duration, with fewer injections.

BCG

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

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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.

Contraindications

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

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Because it contains high levels of diphtheria toxoid, (DT) should not be given to children older than six years old or adults.

Td, or tetanus-diphtheria toxoids adult dose vaccine, is the same vaccine as DT, but with a lower diphtheria toxoid dose. It is suitable for children older than six years old and adults, including pregnant women.

DPT

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;
- 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**

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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**

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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)

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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)

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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.

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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)

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

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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 -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

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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.

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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 protectiona against tetanus

General

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;
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 2: The vaccines

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page 12

Because it contains high levels of diphtheria toxoid, (DT) should not be given to children older than six years old or adults.

Td, or tetanus-diphtheria toxoids adult dose vaccine, is the same vaccine as DT, but with a lower diphtheria toxoid dose. It is suitable for children older than six years old and adults, including pregnant women.

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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.

Diphtheria vaccine (WHO position paper)

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The occurrence of diphtheria reflects inadequate coverage of the national childhood immunization programme. Therefore, obstacles to optimal vaccine delivery must be identified and forceful measures taken to improve immunization coverage.

Diphtheria vaccine (WHO position paper)

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[24-32](#)

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Epidemiological surveillance ensuring early detection of diphtheria outbreaks should be in place in all countries, and all countries should have access to laboratory facilities for reliable identification of toxigenic *C. diphtheriae*.

Diphtheria vaccine (WHO position paper)

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Adequate quantities of diphtheria antitoxin should be available nationally or regionally for medical management of cases. Diphtheria antitoxin is not recommended for prophylaxis.

Diphtheria vaccine (WHO position paper)

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(A)ccording to WHO requirements, the potency of diphtheria vaccine used for the immunization of children shall be no less than 30 IU per single human dose. Vaccines of lower potency are used for immunization of children aged ≥ 7 years and adults. This reduction of diphtheria toxoid potency minimizes reactogenicity at the injection site but is still sufficient to provoke an antibody response in older children and adults.

Diphtheria vaccine (WHO position paper)

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[24-32](#)

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Vaccines containing diphtheria toxoid should be stored at about +4 (2-8) C. Vaccines that have been frozen should not be used.

Diphtheria vaccine (WHO position paper)

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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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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Diphtheria vaccine (WHO position paper)

Unfortunately, diphtheria infection does not always confer protective immunity. Individuals recovering from the disease should therefore complete active immunization with diphtheria toxoid during convalescence.

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Diphtheria vaccine (WHO position paper)

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.

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Diphtheria vaccine (WHO position paper)

To compensate for the loss of natural boosting, industrialized countries should add childhood boosters of diphtheria toxoid to the primary immunization series of infancy. The optimal timing for and the number of such booster doses should be based on epidemiological surveillance as well as on immunological and programmatic considerations. Boosting at the age of 12 months, at school entry and just before leaving school are all possible options. In addition to these childhood immunizations, people living in low-endemic or non-endemic areas may require booster injections of diphtheria toxoid at about 10-year intervals to maintain life-long protection.

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Diphtheria vaccine (WHO position paper)

To further promote immunity against diphtheria, diphtheria toxoid and tetanus toxoid rather than tetanus toxoid alone should be used when tetanus prophylaxis is needed following injuries.

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Diphtheria vaccine (WHO position paper)

(W)ith the increasing number of doses (of diphtheria toxoid) that are now recommended, reactogenicity is likely to increase. Although further purification of extraneous proteins residing in the toxoid may help to ameliorate this problem, optimal future diphtheria vaccines should provide protection of longer duration, with fewer injections.

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WHO recommended standards for surveillance of selected vaccine-preventable diseases

(Diphtheria) surveillance data can be used to monitor levels of coverage (target >90%) and disease as a measure of the impact of control programmes.

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WHO recommended standards for surveillance of selected vaccine-preventable diseases

Recommended types of surveillance for diphtheria:

_ Routine monthly reporting of aggregated data on probable or confirmed cases is recommended from the peripheral level to the intermediate and central levels.

_ Designated reporting sites at all levels should report at a specified frequency (e.g. weekly or monthly) even if there are zero cases (often referred to as zero reporting).

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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)

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

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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 -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

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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

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.

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Diphtheria vaccine (WHO position paper)

(Vaccines containing diphtheria toxoid should be administered) by intramuscular injection only.

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WHO recommended standards for surveillance of selected vaccine-preventable diseases

(F)or diphtheria:

_ All outbreaks should be investigated immediately and case-based data should be collected.

_ In countries achieving low incidence (usually where coverage is >85-90%), immediate reporting of case-based data of probable or confirmed cases is recommended from the peripheral level to the intermediate and central levels.

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

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.

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page 12

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

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

[WER 2006, vol. 81, 21, pp 210-220](#)

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Tetanus vaccine (WHO position paper)

Vaccines containing DT are used for children aged <7 years and dT-containing vaccines for individuals aged =7 years.

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

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Tetanus vaccine (WHO position paper)

As a rule, vaccine combinations containing diphtheria toxoid (D or d) and tetanus toxoid, rather than tetanus toxoid alone, should be used when immunization against tetanus is indicated.

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

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Tetanus vaccine (WHO position paper)

Both TT and dT can be used at any time during pregnancy.

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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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Hepatitis B

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.

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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.

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

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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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

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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 -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

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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.

Hib

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;
- 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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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.

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

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page 0

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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.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

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

Immunization Coverage

WHO recommended standards for surveillance of selected vaccine-preventable diseases

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(Diphtheria) surveillance data can be used to monitor levels of coverage (target >90%) and disease as a measure of the impact of control programmes.

JE

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.

MMR

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.

Measles

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.

Meningococcal

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.

Mumps

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.

Open Vials

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.

Outbreak Control

WHO recommended standards for surveillance of selected vaccine-preventable diseases

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(F)or diphtheria:

_ All outbreaks should be investigated immediately and case-based data should be collected.

_ In countries achieving low incidence (usually where coverage is >85-90%), immediate reporting of case-based data of probable or confirmed cases is recommended from the peripheral level to the intermediate and central levels.

Pentavalent

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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.

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.

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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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.

Pertussis

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

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

Policy

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.

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

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Because it contains high levels of diphtheria toxoid, (DT) should not be given to children older than six years old or adults.

Td, or tetanus-diphtheria toxoids adult dose vaccine, is the same vaccine as DT, but with a lower diphtheria toxoid dose. It is suitable for children older than six years old and adults, including pregnant women.

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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.

Diphtheria vaccine (WHO position paper)

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The occurrence of diphtheria reflects inadequate coverage of the national childhood immunization programme. Therefore, obstacles to optimal vaccine delivery must be identified and forceful measures taken to improve immunization coverage.

Diphtheria vaccine (WHO position paper)

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Epidemiological surveillance ensuring early detection of diphtheria outbreaks should be in place in all countries, and all countries should have access to laboratory facilities for reliable identification of toxigenic *C. diphtheriae*.

Diphtheria vaccine (WHO position paper)

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Adequate quantities of diphtheria antitoxin should be available nationally or regionally for medical management of cases. Diphtheria antitoxin is not recommended for prophylaxis.

Diphtheria vaccine (WHO position paper)

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(A)ccording to WHO requirements, the potency of diphtheria vaccine used for the immunization of children shall be no less than 30 IU per single human dose. Vaccines of lower potency are used for immunization of children aged ≥ 7 years and adults. This reduction of diphtheria toxoid potency minimizes reactogenicity at the injection site but is still sufficient to provoke an antibody response in older children and adults.

Diphtheria vaccine (WHO position paper)

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Vaccines containing diphtheria toxoid should be stored at about +4 (2-8) C. Vaccines that have been frozen should not be used.

Diphtheria vaccine (WHO position paper)

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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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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Diphtheria vaccine (WHO position paper)

Unfortunately, diphtheria infection does not always confer protective immunity. Individuals recovering from the disease should therefore complete active immunization with diphtheria toxoid during convalescence.

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Diphtheria vaccine (WHO position paper)

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.

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Diphtheria vaccine (WHO position paper)

To compensate for the loss of natural boosting, industrialized countries should add childhood boosters of diphtheria toxoid to the primary immunization series of infancy. The optimal timing for and the number of such booster doses should be based on epidemiological surveillance as well as on immunological and programmatic considerations. Boosting at the age of 12 months, at school entry and just before leaving school are all possible options. In addition to these childhood immunizations, people living in low-endemic or non-endemic areas may require booster injections of diphtheria toxoid at about 10-year intervals to maintain life-long protection.

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Diphtheria vaccine (WHO position paper)

To further promote immunity against diphtheria, diphtheria toxoid and tetanus toxoid rather than tetanus toxoid alone should be used when tetanus prophylaxis is needed following injuries.

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Diphtheria vaccine (WHO position paper)

(W)ith the increasing number of doses (of diphtheria toxoid) that are now recommended, reactogenicity is likely to increase. Although further purification of extraneous proteins residing in the toxoid may help to ameliorate this problem, optimal future diphtheria vaccines should provide protection of longer duration, with fewer injections.

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WHO recommended standards for surveillance of selected vaccine-preventable diseases

(Diphtheria) surveillance data can be used to monitor levels of coverage (target >90%) and disease as a measure of the impact of control programmes.

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WHO recommended standards for surveillance of selected vaccine-preventable diseases

Recommended types of surveillance for diphtheria:

_ Routine monthly reporting of aggregated data on probable or confirmed cases is recommended from the peripheral level to the intermediate and central levels.

_ Designated reporting sites at all levels should report at a specified frequency (e.g. weekly or monthly) even if there are zero cases (often referred to as zero reporting).

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

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](#)

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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 -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

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.

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Diphtheria vaccine (WHO position paper)

(Vaccines containing diphtheria toxoid should be administered) by intramuscular injection only.

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WHO recommended standards for surveillance of selected vaccine-preventable diseases

(F)or diphtheria:

_ All outbreaks should be investigated immediately and case-based data should be collected.

_ In countries achieving low incidence (usually where coverage is >85-90%), immediate reporting of case-based data of probable or confirmed cases is recommended from the peripheral level to the intermediate and central levels.

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

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.

[WHO/IVB/04.06](#)

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Tetanus vaccine (WHO position paper)

Vaccines containing DT are used for children aged <7 years and dT-containing vaccines for individuals aged =7 years.

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

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Tetanus vaccine (WHO position paper)

As a rule, vaccine combinations containing diphtheria toxoid (D or d) and tetanus toxoid, rather than tetanus toxoid alone, should be used when immunization against tetanus is indicated.

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

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Tetanus vaccine (WHO position paper)

Both TT and dT can be used at any time during pregnancy.

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

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Tetanus vaccine (WHO position paper)

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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

Polio

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.

Pregnant Women

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Because it contains high levels of diphtheria toxoid, (DT) should not be given to children older than six years old or adults.

Td, or tetanus-diphtheria toxoids adult dose vaccine, is the same vaccine as DT, but with a lower diphtheria toxoid dose. It is suitable for children older than six years old and adults, including pregnant women.

Tetanus vaccine (WHO position paper)

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Both TT and dT can be used at any time during pregnancy.

Program Management

Diphtheria vaccine (WHO position paper)

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The occurrence of diphtheria reflects inadequate coverage of the national childhood immunization programme. Therefore, obstacles to optimal vaccine delivery must be identified and forceful measures taken to improve immunization coverage.

Diphtheria vaccine (WHO position paper)

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Adequate quantities of diphtheria antitoxin should be available nationally or regionally for medical management of cases. Diphtheria antitoxin is not recommended for prophylaxis.

Research

Diphtheria vaccine (WHO position paper)

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(W)ith the increasing number of doses (of diphtheria toxoid) that are now recommended, reactogenicity is likely to increase. Although further purification of extraneous proteins residing in the toxoid may help to ameliorate this problem, optimal future diphtheria vaccines should provide protection of longer duration, with fewer injections.

Rubella

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.

Schedule

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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 12

Because it contains high levels of diphtheria toxoid, (DT) should not be given to children older than six years old or adults.

Td, or tetanus-diphtheria toxoids adult dose vaccine, is the same vaccine as DT, but with a lower diphtheria toxoid dose. It is suitable for children older than six years old and adults, including pregnant women.

Diphtheria vaccine (WHO position paper)

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(A)ccording to WHO requirements, the potency of diphtheria vaccine used for the immunization of children shall be no less than 30 IU per single human dose. Vaccines of lower potency are used for immunization of children aged =7 years and adults. This reduction of diphtheria toxoid potency minimizes reactogenicity at the injection site but is still sufficient to provoke an antibody response in older children and adults.

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)

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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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Unfortunately, diphtheria infection does not always confer protective immunity. Individuals recovering from the disease should therefore complete active immunization with diphtheria toxoid during convalescence.

Diphtheria vaccine (WHO position paper)

To compensate for the loss of natural boosting, industrialized countries should add childhood boosters of diphtheria toxoid to the primary immunization series of infancy. The optimal timing for and the number of such booster doses should be based on epidemiological surveillance as well as on immunological and programmatic considerations. Boosting at the age of 12 months, at school entry and just before leaving school are all possible options. In addition to these childhood immunizations, people living in low-endemic or non-endemic areas may require booster injections of diphtheria toxoid at about 10-year intervals to maintain life-long protection.

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Diphtheria vaccine (WHO position paper)

To further promote immunity against diphtheria, diphtheria toxoid and tetanus toxoid rather than tetanus toxoid alone should be used when tetanus prophylaxis is needed following injuries.

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Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

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

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Tetanus vaccine (WHO position paper)

Vaccines containing DT are used for children aged <7 years and dT-containing vaccines for individuals aged =7 years.

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Tetanus vaccine (WHO position paper)

As a rule, vaccine combinations containing diphtheria toxoid (D or d) and tetanus toxoid, rather than tetanus toxoid alone, should be used when immunization against tetanus is indicated.

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Tetanus vaccine (WHO position paper)

Both TT and dT can be used at any time during pregnancy.

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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 protection against tetanus

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Tetanus

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;
- 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.

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page 12

Because it contains high levels of diphtheria toxoid, (DT) should not be given to children older than six years old or adults.

Td, or tetanus-diphtheria toxoids adult dose vaccine, is the same vaccine as DT, but with a lower diphtheria toxoid dose. It is suitable for children older than six years old and adults, including pregnant women.

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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.

Diphtheria vaccine (WHO position paper)

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To further promote immunity against diphtheria, diphtheria toxoid and tetanus toxoid rather than tetanus toxoid alone should be used when tetanus prophylaxis is needed following injuries.

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)

[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

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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

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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.

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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.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

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

Tetanus vaccine (WHO position paper)

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Vaccines containing DT are used for children aged <7 years and dT-containing vaccines for individuals aged =7 years.

Tetanus vaccine (WHO position paper)

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As a rule, vaccine combinations containing diphtheria toxoid (D or d) and tetanus toxoid, rather than tetanus toxoid alone, should be used when immunization against tetanus is indicated.

Tetanus vaccine (WHO position paper)

Both TT and dT can be used at any time during pregnancy.

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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 protection against tetanus

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VPD Surveillance

Diphtheria vaccine (WHO position paper)

Epidemiological surveillance ensuring early detection of diphtheria outbreaks should be in place in all countries, and all countries should have access to laboratory facilities for reliable identification of toxigenic *C. diphtheriae*.

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WHO recommended standards for surveillance of selected vaccine-preventable diseases

(Diphtheria) surveillance data can be used to monitor levels of coverage (target >90%) and disease as a measure of the impact of control programmes.

[WHO/V&B/03.01](#)
page 10

WHO recommended standards for surveillance of selected vaccine-preventable diseases

Recommended types of surveillance for diphtheria:

_ Routine monthly reporting of aggregated data on probable or confirmed cases is recommended from the peripheral level to the intermediate and central levels.

_ Designated reporting sites at all levels should report at a specified frequency (e.g. weekly or monthly) even if there are zero cases (often referred to as zero reporting).

[WHO/V&B/03.01](#)
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Vaccine Administration

Diphtheria vaccine (WHO position paper)

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.

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Diphtheria vaccine (WHO position paper)

(Vaccines containing diphtheria toxoid should be administered) by intramuscular injection only.

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Vaccine Handling

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.

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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.

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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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Diphtheria vaccine (WHO position paper)

Vaccines containing diphtheria toxoid should be stored at about +4 (2-8) C. Vaccines that have been frozen should not be used.

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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.

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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 -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

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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

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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.

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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.

Yellow Fever

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.