
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

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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)

[WER 2006, vol. 81, 20, pp 198-208](#)
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(I)mmunodeficiency including HIV infection is not a contraindication to (the use of TT or dT.)

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.

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

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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.

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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 -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

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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

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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

Diphtheria

Thermostability of vaccines

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Getting started with vaccine vial monitors

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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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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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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.

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

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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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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

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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;
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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.

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

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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.

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

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

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

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

[WER 2006, vol. 81, 20, pp 198-208](#)
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Both TT and dT can be used at any time during pregnancy.

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

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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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;
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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 1: Target diseases

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page 20

Neonatal tetanus can be prevented by immunizing women of childbearing age with tetanus toxoid, either during pregnancy or outside of pregnancy. This protects the mother and enables tetanus antibodies to be transferred to her baby.

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

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People who recover from tetanus do not have natural immunity and can be infected again and therefore need to be immunized.

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

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WHO, UNICEF and UNFPA agreed to set the year 2005 as the target date for worldwide elimination of neonatal tetanus. This implies the reduction of neonatal tetanus incidence to below one case per 1000 live births per year in every district.

Because tetanus survives in the environment, eradication of the disease is not feasible and high levels of immunization have to continue even after the goal has been achieved.

To achieve the elimination goal, countries implement a series of strategies:

- Improve the percentage of pregnant women immunized with vaccines containing tetanus toxoid.

- Administer vaccines containing tetanus toxoid to all women of childbearing age in high-risk areas. This is usually implemented through a three round campaign approach.

- Promote clean delivery and childcare practices.

- Improve surveillance and reporting of neonatal tetanus cases.

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.

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

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A three-dose course of TT or Td provides protection against maternal and neonatal tetanus for at least five years. A maximum of five doses will protect women throughout their childbearing years.

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

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Administration summary: TT vaccine and tetanus toxoid immunization schedule for routine immunization of pregnant women (see Appendix 2_9)

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A woman should receive no more than five doses of TT

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You can consider that the infant was protected from NT (neonatal tetanus) at its birth (PAB- protected at birth) if the mother has received: two doses of TT during the recent pregnancy or at least three doses of TT in the past.

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

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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.

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

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At any immunization session, especially outreach, you should offer routine TT immunization to pregnant women.

Some countries also have a policy of providing TT immunization to non-pregnant or recently pregnant women during routine infant immunization sessions.

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To assess a woman's eligibility for TT immunization:

First ask if the woman has a TT vaccination card. If she has, give the dose required according to the national TT schedule. If the woman does not have a record, ask her if she has ever had a dose of TT in the past:

If she says NO: give the first dose of TT and an appointment for the second dose one month later, and give her an immunization card.

If she says YES: ask how many doses she has received in the past and give the next doses in series. Take into account any dose given in SIAs.

If she cannot remember or does not know, you should give her a dose of TT and a follow-up appointment for the next dose.

Diphtheria vaccine (WHO position paper)

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

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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.

WHO recommended standards for surveillance of selected vaccine-preventable diseases

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Neonatal tetanus (NT) is targeted by UNICEF, UNFPA and WHO for elimination as a major public health burden along with maternal tetanus. Elimination is defined as less than one NT case per 1000 live births at district level per year. High coverage with tetanus toxoid among pregnant women and in high-risk areas among all childbearing aged women (CBAW), as well as improved access to clean delivery services are primary strategies for achieving this goal. Effective surveillance is critical for identifying areas or populations at high risk for NT and for monitoring the impact of interventions. However, in the absence of reliable surveillance data, actions aimed at reducing the incidence of MT should not be postponed until the establishment or improvement of surveillance systems. In this situation, elimination strategies should be targeted at areas with high neonatal mortality to which NT is likely to be a major contributor.

Recommended types of surveillance for neonatal tetanus (NT):

- 1) Routine monthly surveillance: the number of confirmed NT cases should be included in all routine reports and should be reported separately from other (non-neonatal) tetanus.
- 2) Zero reporting: 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).
- 3) Active surveillance: major health facilities should be visited regularly (at least monthly) to identify an NT cases admitted or diagnosed in them. Such visits should preferably be made by staff not attached to the health facilities concerned. During these visits, hospital inpatient and outpatient registers should be checked and key clinical staff (e.g. in paediatric and emergency wards) should be asked whether any new NT case has been identified in the hospital since the previous visit.
- 4) Retrospective record review: hospital records should be reviewed for NT cases at least once annually in major hospitals to identify previously unreported NT cases.

For all of the above it is recommended that, at least in the short term, NT surveillance be linked to AFP (acute flaccid paralysis) surveillance. Forms and databases should be adapted and standardized so as to enable easy reporting of NT (and, as appropriate, measles) cases when AFP surveillance is carried out.

5) Community sensitization: in silent areas (i.e. where routine reporting is not functional but where other indicators suggest that neonatal tetanus could be a problem) the community should be sensitized about NT and the need to bring suspect cases/deaths to the attention of the health authorities.

6) Case investigation and case response:

A. To optimize available resources, case investigations should be conducted first in areas considered at low risk, since cases are not expected here and therefore the response should be tailored to the specific cause.

Low-risk areas are those with a clean delivery rate $> 70\%$ and/or TT2 coverage $> 80\%$ (from routine or supplementary immunization activities (SIAs)) or as specified by country-specific criteria.

B. In areas already known to be at high risk the focus should firstly be on implementing SIAs to increase immunity to tetanus, rather than on investigating every case and mounting case-response activities around each one. An NT case often represents a sentinel event indicating a more systematic problem. The findings from the case investigation should therefore help to guide the nature and extent of the immunization response. The latter should attempt to immunize all women in the area who are not adequately protected against tetanus or who are eligible for a TT dose. The NT patient should be treated in accordance with local treatment protocols and the mother of the NT case should be immunized immediately against tetanus.

WHO recommended standards for surveillance of selected vaccine-preventable diseases

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If a child was unprotected (against neonatal tetanus at birth) the mother should receive a dose of TT during the same visit and should be followed up with a subsequent TT dose if needed for protection. The same applies for mothers whose children were protected at birth but who remain eligible for another TT dose.

WHO recommended standards for surveillance of selected vaccine-preventable diseases

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Where tetanus toxoid is given in a school setting, coverage of this approach should be monitored.

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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.

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

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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.

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

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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:

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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.

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

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

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

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There was agreement from SAGE members that WHO should broaden the goals of tetanus vaccination programmes from elimination of maternal and neonatal tetanus (MNT) to protection of all ages and sexes throughout life.

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

[WER 2006, vol. 81, 21, pp 210-220](#)
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It was generally agreed (by SAGE members) that (for tetanus vaccine) there is no maximum interval between the primary series and a booster dose and that there is no need to re-start interrupted immunization schedules. Vaccination of school-age children would also help to sustain MNT (maternal and neonatal tetanus) elimination.

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

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SAGE recommended the following (regarding tetanus immunization schedules):

A 5-dose childhood immunization schedule should be promoted. The primary series of 3 doses would be given in infancy, with a booster dose ideally at age 4-7 years and another booster dose in adolescence (e.g. at age 12-15 years). The exact timing of the booster doses should be flexible to take account of the most appropriate health service contacts in different countries and of integration with other vaccines and other interventions such as bednet distribution, vitamin A therapy and deworming. In some countries, these boosters could be given through school-based approaches, but efforts to reach those not attending school will be important. A sixth dose should be recommended for adults, for example in the first pregnancy or for military recruits.

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

[WER 2006, vol. 81, 21, pp 210-220](#)
page 217

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.

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

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Surveillance of tetanus cases (all ages) and monitoring of vaccine coverage with tetanus-containing vaccines in different age groups should be strengthened. This will allow a better understanding of the burden of disease and will help identify programmatic issues.

Monitoring systems will be needed to document the number of (tetanus vaccine) doses received by individuals so that the number of doses required for women of childbearing age can be tailored to the number of doses previously received.

Tetanus vaccine (WHO position paper)

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

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)

The goals of tetanus control are primarily (i) to eliminate MNT globally (<1 case per 1000 live births at the district level); and (ii) to achieve and sustain high coverage of 3 doses of DTP and of appropriate booster doses in order to prevent tetanus in all age groups.

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Tetanus vaccine (WHO position paper)

A childhood tetanus immunization schedule of 5 doses is recommended. WHO recommends that the primary series of 3 doses should be given in infancy (aged <1 year). Where pertussis is of particular risk to young infants, DTP immunization should be started at age 6 weeks and 2 subsequent doses should be given at intervals of at least 4 weeks (e.g. at weeks 10 and 14). The exact timing of the booster doses should be flexible to take account of the most appropriate health service contacts in different countries. Ideally, a booster dose should be offered at age 4-7 years followed by another booster in adolescence, e.g. at age 12-15 years. Where a high percentage of children, including girls, attend school, school-based immunization programmes should be used where feasible to deliver the booster doses. Special efforts to reach school nonattenders will be needed.

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page 199

In addition to the childhood vaccination programme, an extra tetanus toxoid-containing dose to adults will provide additional assurance of long-lasting, possibly lifelong protection. Therefore, a sixth dose should be recommended for adults, e.g. at the time of the first pregnancy or during military service. Those who receive their first tetanus vaccine doses as adolescents or adults require a total of only 5 appropriately spaced doses to obtain the same long-term protection.

Tetanus vaccine (WHO position paper)

Even after many years, an interrupted primary- or booster-dose (tetanus vaccine) schedule should not be restarted; the schedule is simply continued with the next dose that is due.

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page 206

Tetanus vaccine (WHO position paper)

All (tetanus vaccine) doses received over an individual's lifetime should be recorded on their lifelong vaccination card.

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page 206

Tetanus vaccine (WHO position paper)

Improved national surveillance and reporting systems (for tetanus), including district-level data analysis, are essential for rational planning of immunization efforts, including high-risk approaches against MNT.

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page 200

Tetanus vaccine (WHO position paper)

Administration of adsorbed tetanus toxoid is by intramuscular injection.

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page 202

Tetanus vaccine (WHO position paper)

Tetanus toxoid-containing vaccines should be stored at +4 (2-8) C; vaccines that have been frozen should not be used.

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page 202

Tetanus vaccine (WHO position paper)

According to WHO requirements*, the potency of monovalent tetanus toxoid shall be no less than 40 IU (determined in guinea-pigs or in mice) per dose (0.5 ml), and at least 40 IU (determined in guinea-pigs) or 60 IU (determined in mice) per dose when tetanus toxoid is used in combination with diphtheria and whole-cell pertussis vaccines.

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page 202

* Requirements for diphtheria, tetanus, pertussis and combined vaccines. WHO Technical Report Series, No. 800, 1990, Annex 2; Recommendations for diphtheria, tetanus, pertussis and combined vaccines (Amendments 2003). WHO Technical Report Series, No. 927, 2005, Annex 5.

Tetanus vaccine (WHO position paper)

The interval between the tetanus toxoid-containing doses should be at least 4 weeks. Longer intervals may increase the magnitude and duration of the immune response, but should not be a reason to delay immunization.

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page 203

Tetanus vaccine (WHO position paper)

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

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page 204

Tetanus vaccine (WHO position paper)

(I)mmunodeficiency including HIV infection is not a contraindication to (the use of TT or dT.)

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page 204

Tetanus vaccine (WHO position paper)

The high-risk approach to control neonatal tetanus should be part of the neonatal tetanus elimination strategy in countries where the elimination target (<1 case per 1000 live births at district level) has not yet been reached. This approach targets all women of childbearing age and consists of campaign-style immunization (supplementary immunization activities, or SIAs) with 3 doses of TT (or dT) with an interval of at least 4 weeks between doses 1 and 2, and of at least 6 months between doses 2 and 3. Promotion of clean deliveries is part of this approach. In addition to the 3 doses provided in the SIAs, 2 further boosters are needed to provide long-term protection to women with no documented receipt of tetanus toxoid-containing vaccines in childhood.

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Tetanus vaccine (WHO position paper)

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page 205

Although adequately immunized people should have sufficient protection against tetanus, treating physicians may give a dose of tetanus toxoid-containing vaccine in the case of an injury, in addition to other preventive measures. Depending on the severity of the injury and on the reliability of the history of previous tetanus vaccinations, the vaccine should be given if the last dose was administered more than 10 years ago (or 5 years in the case of severe injuries)*. The immunization schedule should be completed as soon as possible for those who have not received all doses of the basic schedule.

In addition, passive immunization using tetanus antitoxin, preferably of human origin, may be needed for prophylaxis (e.g. in cases of dirty wounds in incompletely immunized individuals). Such antitoxin is also essential in the treatment of tetanus cases and should be readily available in all countries. From page 200: While tetanus antitoxin should be readily available in all countries, its use cannot substitute for the need to achieve and sustain high tetanus vaccination coverage.

* Summary guide to tetanus prophylaxis in routine wound management. In: Heymann DL, ed. Control of communicable diseases manual, 18th ed. Washington, DC, American Public Health Association, 2004:532; Surgical care at the district hospital. Geneva, World Health Organization, 2003:4-12.

Tetanus vaccine (WHO position paper)

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page 206

For previously non-immunized adolescents and adults, the recommended schedule is 2 (tetanus vaccine) doses administered at least 4 weeks apart followed by a third dose administered at least 6 months after the second, and subsequent boosters at least 1 year apart. Those who receive their first tetanus vaccine doses as adolescents or adults require a total of only 5 appropriately spaced doses to obtain long-term protection.

Tetanus vaccine (WHO position paper)

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page 207

In countries where MNT remains a public health problem, pregnant women for whom reliable information on previous tetanus vaccinations is not available should receive at least 2 doses of tetanus toxoid-containing vaccine (normally dT) with an interval of at least 4 weeks between the doses. To ensure protection for a minimum of 5 years, a third dose should be given at least 6 months later. A fourth and fifth dose should be given at intervals of at least 1 year, e.g. during subsequent pregnancies, in order to ensure long-term protection. Pregnant women who have received only 3 doses of DTP in early infancy should receive 2 doses of a tetanus toxoid-containing vaccine with a minimal interval of 4 weeks. Those who received 4 doses of tetanus vaccine during their childhood need only 1 booster dose, which should be given at the first opportunity. In both scenarios, to provide protection throughout childbearing age, a sixth dose would be needed after at least 1 year.

Tetanus vaccine (WHO position paper)

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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 protectiona against tetanus

HIV/AIDS and immunosuppression

Tetanus vaccine (WHO position paper)

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page 204

(I)mmunodeficiency including HIV infection is not a contraindication to (the use of TT or dT.)

Hepatitis B

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 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.

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.

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.

Hib

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 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

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Temperature sensitivity of vaccines

[WHO/IVB/06.10](#)

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Temperature sensitivity of vaccines

[WHO/IVB/06.10](#)

page 6

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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.

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

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

page 217

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

Immunization in practice: a practical resource guide for Health workers 2004 update _____ **Module 7: Monitoring and using your data**

[WHO/IVB/04.06](#)
page 32

You can consider that the infant was protected from NT (neonatal tetanus) at its birth (PAB- protected at birth) if the mother has received: two doses of TT during the recent pregnancy or at least three doses of TT in the past.

WHO recommended standards for surveillance of selected vaccine-preventable diseases

[WHO/V&B/03.01](#)
page 27

Where tetanus toxoid is given in a school setting, coverage of this approach should be monitored.

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

[WER 2006, vol. 81, 21, pp 210-220](#)
page 217

Surveillance of tetanus cases (all ages) and monitoring of vaccine coverage with tetanus-containing vaccines in different age groups should be strengthened. This will allow a better understanding of the burden of disease and will help identify programmatic issues.

Monitoring systems will be needed to document the number of (tetanus vaccine) doses received by individuals so that the number of doses required for women of childbearing age can be tailored to the number of doses previously received.

JE

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

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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

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

Temperature sensitivity of vaccines

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page 2

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Meningococcal

Temperature sensitivity of vaccines

[WHO/IVB/06.10](#)

page 2

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Mumps

Temperature sensitivity of vaccines

[WHO/IVB/06.10](#)

page 2

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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.

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

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Pertussis

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

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

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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.

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 1: Target diseases

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

Neonatal tetanus can be prevented by immunizing women of childbearing age with tetanus toxoid, either during pregnancy or outside of pregnancy. This protects the mother and enables tetanus antibodies to be transferred to her baby.

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

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

People who recover from tetanus do not have natural immunity and can be infected again and therefore need to be immunized.

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

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page 20

WHO, UNICEF and UNFPA agreed to set the year 2005 as the target date for worldwide elimination of neonatal tetanus. This implies the reduction of neonatal tetanus incidence to below one case per 1000 live births per year in every district.

Because tetanus survives in the environment, eradication of the disease is not feasible and high levels of immunization have to continue even after the goal has been achieved.

To achieve the elimination goal, countries implement a series of strategies:

- Improve the percentage of pregnant women immunized with vaccines containing tetanus toxoid.

- Administer vaccines containing tetanus toxoid to all women of childbearing age in high-risk areas. This is usually implemented through a three round campaign approach.

- Promote clean delivery and childcare practices.

- Improve surveillance and reporting of neonatal tetanus cases.

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.

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

[WHO/IVB/04.06](#)
page 12

Administration summary: TT vaccine and tetanus toxoid immunization schedule for routine immunization of pregnant women (see Appendix 2_9)

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 7: Monitoring and using your data

[WHO/IVB/04.06](#)
page 7

A woman should receive no more than five doses of TT

Immunization in practice: a practical resource guide for Health workers 2004 update_____Module 7: Monitoring and using your data

[WHO/IVB/04.06](#)
page 32

You can consider that the infant was protected from NT (neonatal tetanus) at its birth (PAB- protected at birth) if the mother has received: two doses of TT during the recent pregnancy or at least three doses of TT in the past.

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

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page 12

At any immunization session, especially outreach, you should offer routine TT immunization to pregnant women.

Some countries also have a policy of providing TT immunization to non-pregnant or recently pregnant women during routine infant immunization sessions.

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

[WHO/IVB/04.06](#)
page 12

To assess a woman's eligibility for TT immunization:

First ask if the woman has a TT vaccination card. If she has, give the dose required according to the national TT schedule. If the woman does not have a record, ask her if she has ever had a dose of TT in the past:

If she says NO: give the first dose of TT and an appointment for the second dose one month later, and give her an immunization card.

If she says YES: ask how many doses she has received in the past and give the next doses in series. Take into account any dose given in SIAs.

If she cannot remember or does not know, you should give her a dose of TT and a follow-up appointment for the next dose.

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.

[WER 2006, vol. 81, 3, pp 24-32](#)
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WHO recommended standards for surveillance of selected vaccine-preventable diseases

Neonatal tetanus (NT) is targeted by UNICEF, UNFPA and WHO for elimination as a major public health burden along with maternal tetanus. Elimination is defined as less than one NT case per 1000 live births at district level per year. High coverage with tetanus toxoid among pregnant women and in high-risk areas among all childbearing aged women (CBAW), as well as improved access to clean delivery services are primary strategies for achieving this goal. Effective surveillance is critical for identifying areas or populations at high risk for NT and for monitoring the impact of interventions. However, in the absence of reliable surveillance data, actions aimed at reducing the incidence of MT should not be postponed until the establishment or improvement of surveillance systems. In this situation, elimination strategies should be targeted at areas with high neonatal mortality to which NT is likely to be a major contributor.

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Recommended types of surveillance for neonatal tetanus (NT):

- 1) Routine monthly surveillance: the number of confirmed NT cases should be included in all routine reports and should be reported separately from other (non-neonatal) tetanus.
- 2) Zero reporting: 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).
- 3) Active surveillance: major health facilities should be visited regularly (at least monthly) to identify an NT cases admitted or diagnosed in them. Such visits should preferably be made by staff not attached to the health facilities concerned. During these visits, hospital inpatient and outpatient registers should be checked and key clinical staff (e.g. in paediatric and emergency wards) should be asked whether any new NT case has been identified in the hospital since the previous visit.
- 4) Retrospective record review: hospital records should be reviewed for NT cases at least once annually in major hospitals to identify previously unreported NT cases.

For all of the above it is recommended that, at least in the short term, NT surveillance be linked to AFP (acute flaccid paralysis) surveillance. Forms and databases should be adapted and standardized so as to enable easy reporting of NT (and, as appropriate, measles) cases when AFP surveillance is carried out.

5) Community sensitization: in silent areas (i.e. where routine reporting is not functional but where other indicators suggest that neonatal tetanus could be a problem) the community should be sensitized about NT and the need to bring suspect cases/deaths to the attention of the health authorities.

6) Case investigation and case response:

A. To optimize available resources, case investigations should be conducted first in areas considered at low risk, since cases are not expected here and therefore the response should be tailored to the specific cause.

Low-risk areas are those with a clean delivery rate $> 70\%$ and/or TT2 coverage $> 80\%$ (from routine or supplementary immunization activities (SIAs)) or as specified by country-specific criteria.

B. In areas already known to be at high risk the focus should firstly be on implementing SIAs to increase immunity to tetanus, rather than on investigating every case and mounting case-response activities around each one. An NT case often represents a sentinel event indicating a more systematic problem. The findings from the case investigation should therefore help to guide the nature and extent of the immunization response. The latter should attempt to immunize all women in the area who are not adequately protected against tetanus or who are eligible for a TT dose. The NT patient should be treated in accordance with local treatment protocols and the mother of the NT case should be immunized immediately against tetanus.

WHO recommended standards for surveillance of selected vaccine-preventable diseases

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If a child was unprotected (against neonatal tetanus at birth) the mother should receive a dose of TT during the same visit and should be followed up with a subsequent TT dose if needed for protection. The same applies for mothers whose children were protected at birth but who remain eligible for another TT dose.

WHO recommended standards for surveillance of selected vaccine-preventable diseases

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Where tetanus toxoid is given in a school setting, coverage of this approach should be monitored.

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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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 -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

[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](#)

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.

Tetanus vaccine (WHO position paper)

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

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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)

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)

The goals of tetanus control are primarily (i) to eliminate MNT globally (<1 case per 1000 live births at the district level); and (ii) to achieve and sustain high coverage of 3 doses of DTP and of appropriate booster doses in order to prevent tetanus in all age groups.

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page 199

Tetanus vaccine (WHO position paper)

A childhood tetanus immunization schedule of 5 doses is recommended. WHO recommends that the primary series of 3 doses should be given in infancy (aged <1 year). Where pertussis is of particular risk to young infants, DTP immunization should be started at age 6 weeks and 2 subsequent doses should be given at intervals of at least 4 weeks (e.g. at weeks 10 and 14). The exact timing of the booster doses should be flexible to take account of the most appropriate health service contacts in different countries. Ideally, a booster dose should be offered at age 4-7 years followed by another booster in adolescence, e.g. at age 12-15 years. Where a high percentage of children, including girls, attend school, school-based immunization programmes should be used where feasible to deliver the booster doses. Special efforts to reach school nonattenders will be needed.

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In addition to the childhood vaccination programme, an extra tetanus toxoid-containing dose to adults will provide additional assurance of long-lasting, possibly lifelong protection. Therefore, a sixth dose should be recommended for adults, e.g. at the time of the first pregnancy or during military service. Those who receive their first tetanus vaccine doses as adolescents or adults require a total of only 5 appropriately spaced doses to obtain the same long-term protection.

Tetanus vaccine (WHO position paper)

Even after many years, an interrupted primary- or booster-dose (tetanus vaccine) schedule should not be restarted; the schedule is simply continued with the next dose that is due.

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Tetanus vaccine (WHO position paper)

All (tetanus vaccine) doses received over an individual's lifetime should be recorded on their lifelong vaccination card.

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Tetanus vaccine (WHO position paper)

Improved national surveillance and reporting systems (for tetanus), including district-level data analysis, are essential for rational planning of immunization efforts, including high-risk approaches against MNT.

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page 200

Tetanus vaccine (WHO position paper)

Administration of adsorbed tetanus toxoid is by intramuscular injection.

[WER 2006, vol. 81, 20, pp 198-208](#)
page 202

Tetanus vaccine (WHO position paper)

Tetanus toxoid-containing vaccines should be stored at +4 (2-8) C; vaccines that have been frozen should not be used.

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page 202

Tetanus vaccine (WHO position paper)

According to WHO requirements*, the potency of monovalent tetanus toxoid shall be no less than 40 IU (determined in guinea-pigs or in mice) per dose (0.5 ml), and at least 40 IU (determined in guinea-pigs) or 60 IU (determined in mice) per dose when tetanus toxoid is used in combination with diphtheria and whole-cell pertussis vaccines.

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* Requirements for diphtheria, tetanus, pertussis and combined vaccines. WHO Technical Report Series, No. 800, 1990, Annex 2; Recommendations for diphtheria, tetanus, pertussis and combined vaccines (Amendments 2003). WHO Technical Report Series, No. 927, 2005, Annex 5.

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)

(I)mmunodeficiency including HIV infection is not a contraindication to (the use of TT or dT.)

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Tetanus vaccine (WHO position paper)

The high-risk approach to control neonatal tetanus should be part of the neonatal tetanus elimination strategy in countries where the elimination target (<1 case per 1000 live births at district level) has not yet been reached. This approach targets all women of childbearing age and consists of campaign-style immunization (supplementary immunization activities, or SIAs) with 3 doses of TT (or dT) with an interval of at least 4 weeks between doses 1 and 2, and of at least 6 months between doses 2 and 3. Promotion of clean deliveries is part of this approach. In addition to the 3 doses provided in the SIAs, 2 further boosters are needed to provide long-term protection to women with no documented receipt of tetanus toxoid-containing vaccines in childhood.

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Tetanus vaccine (WHO position paper)

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Although adequately immunized people should have sufficient protection against tetanus, treating physicians may give a dose of tetanus toxoid-containing vaccine in the case of an injury, in addition to other preventive measures. Depending on the severity of the injury and on the reliability of the history of previous tetanus vaccinations, the vaccine should be given if the last dose was administered more than 10 years ago (or 5 years in the case of severe injuries)*. The immunization schedule should be completed as soon as possible for those who have not received all doses of the basic schedule.

In addition, passive immunization using tetanus antitoxin, preferably of human origin, may be needed for prophylaxis (e.g. in cases of dirty wounds in incompletely immunized individuals). Such antitoxin is also essential in the treatment of tetanus cases and should be readily available in all countries. From page 200: While tetanus antitoxin should be readily available in all countries, its use cannot substitute for the need to achieve and sustain high tetanus vaccination coverage.

* Summary guide to tetanus prophylaxis in routine wound management. In: Heymann DL, ed. Control of communicable diseases manual, 18th ed. Washington, DC, American Public Health Association, 2004:532; Surgical care at the district hospital. Geneva, World Health Organization, 2003:4-12.

Tetanus vaccine (WHO position paper)

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page 206

For previously non-immunized adolescents and adults, the recommended schedule is 2 (tetanus vaccine) doses administered at least 4 weeks apart followed by a third dose administered at least 6 months after the second, and subsequent boosters at least 1 year apart. Those who receive their first tetanus vaccine doses as adolescents or adults require a total of only 5 appropriately spaced doses to obtain long-term protection.

Tetanus vaccine (WHO position paper)

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In countries where MNT remains a public health problem, pregnant women for whom reliable information on previous tetanus vaccinations is not available should receive at least 2 doses of tetanus toxoid-containing vaccine (normally dT) with an interval of at least 4 weeks between the doses. To ensure protection for a minimum of 5 years, a third dose should be given at least 6 months later. A fourth and fifth dose should be given at intervals of at least 1 year, e.g. during subsequent pregnancies, in order to ensure long-term protection. Pregnant women who have received only 3 doses of DTP in early infancy should receive 2 doses of a tetanus toxoid-containing vaccine with a minimal interval of 4 weeks. Those who received 4 doses of tetanus vaccine during their childhood need only 1 booster dose, which should be given at the first opportunity. In both scenarios, to provide protection throughout childbearing age, a sixth dose would be needed after at least 1 year.

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 protectiona against tetanus

Polio

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 -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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Neonatal tetanus can be prevented by immunizing women of childbearing age with tetanus toxoid, either during pregnancy or outside of pregnancy. This protects the mother and enables tetanus antibodies to be transferred to her baby.

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page 20

WHO, UNICEF and UNFPA agreed to set the year 2005 as the target date for worldwide elimination of neonatal tetanus. This implies the reduction of neonatal tetanus incidence to below one case per 1000 live births per year in every district.

Because tetanus survives in the environment, eradication of the disease is not feasible and high levels of immunization have to continue even after the goal has been achieved.

To achieve the elimination goal, countries implement a series of strategies:

Improve the percentage of pregnant women immunized with vaccines containing tetanus toxoid.

Administer vaccines containing tetanus toxoid to all women of childbearing age in high-risk areas. This is usually implemented through a three round campaign approach.

Promote clean delivery and childcare practices.

Improve surveillance and reporting of neonatal tetanus cases.

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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 12

Administration summary: TT vaccine and tetanus toxoid immunization schedule for routine immunization of pregnant women (see Appendix 2_9)

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

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page 12

At any immunization session, especially outreach, you should offer routine TT immunization to pregnant women.

Some countries also have a policy of providing TT immunization to non-pregnant or recently pregnant women during routine infant immunization sessions.

Tetanus vaccine (WHO position paper)

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

Tetanus vaccine (WHO position paper)

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page 207

In countries where MNT remains a public health problem, pregnant women for whom reliable information on previous tetanus vaccinations is not available should receive at least 2 doses of tetanus toxoid-containing vaccine (normally dT) with an interval of at least 4 weeks between the doses. To ensure protection for a minimum of 5 years, a third dose should be given at least 6 months later. A fourth and fifth dose should be given at intervals of at least 1 year, e.g. during subsequent pregnancies, in order to ensure long-term protection. Pregnant women who have received only 3 doses of DTP in early infancy should receive 2 doses of a tetanus toxoid-containing vaccine with a minimal interval of 4 weeks. Those who received 4 doses of tetanus vaccine during their childhood need only 1 booster dose, which should be given at the first opportunity. In both scenarios, to provide protection throughout childbearing age, a sixth dose would be needed after at least 1 year.

Program Management

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

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page 20

WHO, UNICEF and UNFPA agreed to set the year 2005 as the target date for worldwide elimination of neonatal tetanus. This implies the reduction of neonatal tetanus incidence to below one case per 1000 live births per year in every district.

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To achieve the elimination goal, countries implement a series of strategies:

- Improve the percentage of pregnant women immunized with vaccines containing tetanus toxoid.

- Administer vaccines containing tetanus toxoid to all women of childbearing age in high-risk areas. This is usually implemented through a three round campaign approach.

- Promote clean delivery and childcare practices.

- Improve surveillance and reporting of neonatal tetanus cases.

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

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page 217

There was agreement from SAGE members that WHO should broaden the goals of tetanus vaccination programmes from elimination of maternal and neonatal tetanus (MNT) to protection of all ages and sexes throughout life.

Tetanus vaccine (WHO position paper)

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The goals of tetanus control are primarily (i) to eliminate MNT globally (<1 case per 1000 live births at the district level); and (ii) to achieve and sustain high coverage of 3 doses of DTP and of appropriate booster doses in order to prevent tetanus in all age groups.

Tetanus vaccine (WHO position paper)

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All (tetanus vaccine) doses received over an individuals lifetime should be recorded on their lifelong vaccination card.

Rubella

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.

Schedule

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

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page 20

Neonatal tetanus can be prevented by immunizing women of childbearing age with tetanus toxoid, either during pregnancy or outside of pregnancy. This protects the mother and enables tetanus antibodies to be transferred to her baby.

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People who recover from tetanus do not have natural immunity and can be infected again and therefore need to be immunized.

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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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A three-dose course of TT or Td provides protection against maternal and neonatal tetanus for at least five years. A maximum of five doses will protect women throughout their childbearing years.

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page 7

A woman should receive no more than five doses of TT

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

[WHO/IVB/04.06](#)
page 12

At any immunization session, especially outreach, you should offer routine TT immunization to pregnant women.

Some countries also have a policy of providing TT immunization to non-pregnant or recently pregnant women during routine infant immunization sessions.

Diphtheria vaccine (WHO position paper)

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page 25

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.

WHO recommended standards for surveillance of selected vaccine-preventable diseases

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If a child was unprotected (against neonatal tetanus at birth) the mother should receive a does of TT during the same visit and should be followed up with a subsequent TT dose if needed for protection. The same applies for mothers whose children were protected at birth but who remain eligible for another TT dose.

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

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It was generally agreed (by SAGE members) that (for tetanus vaccine) there is no maximum interval between the primary series and a booster dose and that there is no need to re-start interrupted immunization schedules. Vaccination of school-age children would also help to sustain MNT (maternal and neonatal tetanus) elimination.

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

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SAGE recommended the following (regarding tetanus immunization schedules):

A 5-dose childhood immunization schedule should be promoted. The primary series of 3 doses would be given in infancy, with a booster dose ideally at age 4-7 years and another booster dose in adolescence (e.g. at age 12-15 years). The exact timing of the booster doses should be flexible to take account of the most appropriate health service contacts in different countries and of integration with other vaccines and other interventions such as bednet distribution, vitamin A therapy and deworming. In some countries, these boosters could be given through school-based approaches, but efforts to reach those not attending school will be important. A sixth dose should be recommended for adults, for example in the first pregnancy or for military recruits.

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)

A childhood tetanus immunization schedule of 5 doses is recommended. WHO recommends that the primary series of 3 doses should be given in infancy (aged <1 year). Where pertussis is of particular risk to young infants, DTP immunization should be started at age 6 weeks and 2 subsequent doses should be given at intervals of at least 4 weeks (e.g. at weeks 10 and 14). The exact timing of the booster doses should be flexible to take account of the most appropriate health service contacts in different countries. Ideally, a booster dose should be offered at age 4-7 years followed by another booster in adolescence, e.g. at age 12-15 years. Where a high percentage of children, including girls, attend school, school-based immunization programmes should be used where feasible to deliver the booster doses. Special efforts to reach school nonattenders will be needed.

In addition to the childhood vaccination programme, an extra tetanus toxoid-containing dose to adults will provide additional assurance of long-lasting, possibly lifelong protection. Therefore, a sixth dose should be recommended for adults, e.g. at the time of the first pregnancy or during military service. Those who receive their first tetanus vaccine doses as adolescents or adults require a total of only 5 appropriately spaced doses to obtain the same long-term protection.

Tetanus vaccine (WHO position paper)

Even after many years, an interrupted primary- or booster dose (tetanus vaccine) schedule should not be restarted; the schedule is simply continued with the next dose that is due.

Tetanus vaccine (WHO position paper)

The interval between the tetanus toxoid-containing doses should be at least 4 weeks. Longer intervals may increase the magnitude and duration of the immune response, but should not be a reason to delay immunization.

Tetanus vaccine (WHO position paper)

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

Tetanus vaccine (WHO position paper)

The high-risk approach to control neonatal tetanus should be part of the neonatal tetanus elimination strategy in countries where the elimination target (<1 case per 1000 live births at district level) has not yet been reached. This approach targets all women of childbearing age and consists of campaign-style immunization (supplementary immunization activities, or SIAs) with 3 doses of TT (or dT) with an interval of at least 4 weeks between doses 1 and 2, and of at least 6 months between doses 2 and 3. Promotion of clean deliveries is part of this approach. In addition to the 3 doses provided in the SIAs, 2 further boosters are needed to provide long-term protection to women with no documented receipt of tetanus toxoid-containing vaccines in childhood.

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Tetanus vaccine (WHO position paper)

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Although adequately immunized people should have sufficient protection against tetanus, treating physicians may give a dose of tetanus toxoid-containing vaccine in the case of an injury, in addition to other preventive measures. Depending on the severity of the injury and on the reliability of the history of previous tetanus vaccinations, the vaccine should be given if the last dose was administered more than 10 years ago (or 5 years in the case of severe injuries)*. The immunization schedule should be completed as soon as possible for those who have not received all doses of the basic schedule.

In addition, passive immunization using tetanus antitoxin, preferably of human origin, may be needed for prophylaxis (e.g. in cases of dirty wounds in incompletely immunized individuals). Such antitoxin is also essential in the treatment of tetanus cases and should be readily available in all countries. From page 200: While tetanus antitoxin should be readily available in all countries, its use cannot substitute for the need to achieve and sustain high tetanus vaccination coverage.

* Summary guide to tetanus prophylaxis in routine wound management. In: Heymann DL, ed. Control of communicable diseases manual, 18th ed. Washington, DC, American Public Health Association, 2004:532; Surgical care at the district hospital. Geneva, World Health Organization, 2003:4-12.

Tetanus vaccine (WHO position paper)

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For previously non-immunized adolescents and adults, the recommended schedule is 2 (tetanus vaccine) doses administered at least 4 weeks apart followed by a third dose administered at least 6 months after the second, and subsequent boosters at least 1 year apart. Those who receive their first tetanus vaccine doses as adolescents or adults require a total of only 5 appropriately spaced doses to obtain long-term protection.

Tetanus vaccine (WHO position paper)

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page 207

In countries where MNT remains a public health problem, pregnant women for whom reliable information on previous tetanus vaccinations is not available should receive at least 2 doses of tetanus toxoid-containing vaccine (normally dT) with an interval of at least 4 weeks between the doses. To ensure protection for a minimum of 5 years, a third dose should be given at least 6 months later. A fourth and fifth dose should be given at intervals of at least 1 year, e.g. during subsequent pregnancies, in order to ensure long-term protection. Pregnant women who have received only 3 doses of DTP in early infancy should receive 2 doses of a tetanus toxoid-containing vaccine with a minimal interval of 4 weeks. Those who received 4 doses of tetanus vaccine during their childhood need only 1 booster dose, which should be given at the first opportunity. In both scenarios, to provide protection throughout childbearing age, a sixth dose would be needed after at least 1 year.

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

VPD Surveillance

WHO recommended standards for surveillance of selected vaccine-preventable diseases

[WHO/V&B/03.01](#)
page 22

Neonatal tetanus (NT) is targeted by UNICEF, UNFPA and WHO for elimination as a major public health burden along with maternal tetanus. Elimination is defined as less than one NT case per 1000 live births at district level per year. High coverage with tetanus toxoid among pregnant women and in high-risk areas among all childbearing aged women (CBAW), as well as improved access to clean delivery services are primary strategies for achieving this goal. Effective surveillance is critical for identifying areas or populations at high risk for NT and for monitoring the impact of interventions. However, in the absence of reliable surveillance data, actions aimed at reducing the incidence of MT should not be postponed until the establishment or improvement of surveillance systems. In this situation, elimination strategies should be targeted at areas with high neonatal mortality to which NT is likely to be a major contributor.

Recommended types of surveillance for neonatal tetanus (NT):

- 1) Routine monthly surveillance: the number of confirmed NT cases should be included in all routine reports and should be reported separately from other (non-neonatal) tetanus.
- 2) Zero reporting: 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).
- 3) Active surveillance: major health facilities should be visited regularly (at least monthly) to identify an NT cases admitted or diagnosed in them. Such visits should preferably be made by staff not attached to the health facilities concerned. During these visits, hospital inpatient and outpatient registers should be checked and key clinical staff (e.g. in paediatric and emergency wards) should be asked whether any new NT case has been identified in the hospital since the previous visit.
- 4) Retrospective record review: hospital records should be reviewed for NT cases at least once annually in major hospitals to identify previously unreported NT cases.

For all of the above it is recommended that, at least in the short term, NT surveillance be linked to AFP (acute flaccid paralysis) surveillance. Forms and databases should be adapted and standardized so as to enable easy reporting of NT (and, as appropriate, measles) cases when AFP surveillance is carried out.

5) Community sensitization: in silent areas (i.e. where routine reporting is not functional but where other indicators suggest that neonatal tetanus could be a problem) the community should be sensitized about NT and the need to bring suspect cases/deaths to the attention of the health authorities.

6) Case investigation and case response:

A. To optimize available resources, case investigations should be conducted first in areas considered at low risk, since cases are not expected here and therefore the response should be tailored to the specific cause.

Low-risk areas are those with a clean delivery rate $> 70\%$ and/or TT2 coverage $> 80\%$ (from routine or supplementary immunization activities (SIAs)) or as specified by country-specific criteria.

B. In areas already known to be at high risk the focus should firstly be on implementing SIAs to increase immunity to tetanus, rather than on investigating every case and mounting case-response activities around each one. An NT case often represents a sentinel event indicating a more systematic problem. The findings from the case investigation should therefore help to guide the nature and extent of the immunization response. The latter should attempt to immunize all women in the area who are not adequately protected against tetanus or who are eligible for a TT dose. The NT patient should be treated in accordance with local treatment protocols and the mother of the NT case should be immunized immediately against tetanus.

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

[WER 2006, vol. 81, 21, pp 210-220](#)
page 217

Surveillance of tetanus cases (all ages) and monitoring of vaccine coverage with tetanus-containing vaccines in different age groups should be strengthened. This will allow a better understanding of the burden of disease and will help identify programmatic issues.

Monitoring systems will be needed to document the number of (tetanus vaccine) doses received by individuals so that the number of doses required for women of childbearing age can be tailored to the number of doses previously received.

Tetanus vaccine (WHO position paper)

[WER 2006, vol. 81, 20, pp 198-208](#)
page 200

Improved national surveillance and reporting systems (for tetanus), including district-level data analysis, are essential for rational planning of immunization efforts, including high-risk approaches against MNT.

Vaccine Administration

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

[WHO/IVB/04.06](#)
page 12

Administration summary: TT vaccine and tetanus toxoid immunization schedule for routine immunization of pregnant women (see Appendix 2_9)

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

[WHO/IVB/04.06](#)
page 12

To assess a woman's eligibility for TT immunization:

First ask if the woman has a TT vaccination card. If she has, give the dose required according to the national TT schedule. If the woman does not have a record, ask her if she has ever had a dose of TT in the past:

If she says NO: give the first dose of TT and an appointment for the second dose one month later, and give her an immunization card.

If she says YES: ask how many doses she has received in the past and give the next doses in series. Take into account any dose given in SIAs.

If she cannot remember or does not know, you should give her a dose of TT and a follow-up appointment for the next dose.

Tetanus vaccine (WHO position paper)

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page 202

Administration of adsorbed tetanus toxoid is by intramuscular injection.

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.

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 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

[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](#)

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.

Tetanus vaccine (WHO position paper)

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

page 202

Tetanus toxoid-containing vaccines should be stored at +4 (2-8) C; vaccines that have been frozen should not be used.

Vaccine Quality

Tetanus vaccine (WHO position paper)

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page 202

According to WHO requirements*, the potency of monovalent tetanus toxoid shall be no less than 40 IU (determined in guinea-pigs or in mice) per dose (0.5 ml), and at least 40 IU (determined in guinea-pigs) or 60 IU (determined in mice) per dose when tetanus toxoid is used in combination with diphtheria and whole-cell pertussis vaccines.

* Requirements for diphtheria, tetanus, pertussis and combined vaccines. WHO Technical Report Series, No. 800, 1990, Annex 2; Recommendations for diphtheria, tetanus, pertussis and combined vaccines (Amendments 2003). WHO Technical Report Series, No. 927, 2005, Annex 5.

Yellow Fever

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.