
BCG

Thermostability of vaccines

[WHO/GPV/98.07](#)
page 30

Experimental evidence indicates that (BCG vaccine) viability is unaffected by storage at -20C or -30C or by freezing and thawing up to 10 times.

DPT

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.

Diphtheria

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.

General

Proper handling and reconstitution of vaccines avoids programme errors

[V&B update 34](#)
page 3

Vaccinators and store keepers should always ensure that no other medication or substance which might be confused with the vaccine or its diluent is stored in the refrigerator of the immunization centre

Thermostability of vaccines

[WHO/GPV/98.07](#)
page 49

In all countries, systems of refrigeration, temperature-monitoring and record-keeping are required to make sure that each vial of vaccine is maintained under appropriate conditions and that it is used before the expiry date shown on the label.

Thermostability of vaccines

[WHO/GPV/98.07](#)

page 30

Experimental evidence indicates that (BCG vaccine) viability is unaffected by storage at -20C or -30C or by freezing and thawing up to 10 times.

Thermostability of vaccines

[WHO/GPV/98.07](#)

page 37

The freezing compartment of a refrigerator in a health centre should be reserved for ice packs

WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services

[WHO/V&B/99.18](#)

page 1

The VVM enables failures in the cold chain to be highlighted in a simple, unambiguous manner and focuses managers attention and resources on the weakest links in the chain. It is therefore a tool for ensuring the quality of the cold chain at the lowest possible cost.

WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services

[WHO/V&B/99.18](#)

page 1

VVMs have been in use with oral polio vaccine (OPV) since 1996. If adequate training is provided they are well accepted by health workers and managers. They have contributed to the success of national immunization days, particularly in areas with a weak cold-chain infrastructure, and they clearly help to reduce vaccine wastage.

WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services

[WHO/V&B/99.18](#)

page 1

All users of vaccines with VVMs should monitor the wastage of vaccine resulting from the VVM indication of a cold-chain failure; all managers of immunization services should evaluate these wastage statistics and strengthen the cold chain accordingly.

WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services

[WHO/V&B/99.18](#)

page 3

When vaccine wastage is included in the system cost of using VVMs, it can be expected that there will be no increase in vaccine costs to country programmes and that there could be significant global savings.

Getting started with vaccine vial monitors

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

page 7

WHO recommends that VVMs be used for:

- ensuring that vaccine administered has not been damaged by heat;
- reducing vaccine wastage;*
- facilitating immunization outreach and increasing access and coverage;
- pinpointing cold chain problems;
- managing vaccine stocks.

*In some cases, VVM introduction may initially increase wastage. VVMs may lead to discards as they expose weaknesses in the cold chain that passed unseen before VVM introduction.

Getting started with vaccine vial monitors

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

page 9

Vaccine vial monitor readings are more accurate than cold chain monitors if the readings do not relate to freezing temperatures.

Getting started with vaccine vial monitors

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

page 11

In the coming years, it is expected that VVMs will be available on all vaccines supplied through UNICEF. Countries or agencies purchasing their own vaccines should include WHO- approved VVMs in the specifications provided to the vaccine manufacturers.

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

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

page 2

Ten key criteria for effective vaccine store management were agreed at a meeting of experts, which took place at WHO Geneva in December 2001. These criteria form the policy foundation for the effective vaccine store management initiative and are listed below. Satisfactory performance is set as the vaccine store meeting at least 80% of each criterion.

Over a period of twelve months:

1. Pre-shipment and arrival procedures have ensured that all shipments were in satisfactory condition when received in the primary stores.
2. All vaccines have been stored within WHO recommended temperature ranges.
3. The capacity of cold storage has been sufficient to meet the demand.
4. The buildings, equipment and transport available to the programme have enabled the cold store to function effectively.
5. All buildings, equipment and transport have been correctly maintained.
6. Stock management has been effective.
7. Deliveries of vaccine to the next level have been timely, sufficient and correct.
8. Minimal damage has occurred to the vaccine during distribution.
9. The facility has followed standard operating procedures.
10. Human and financial resources have been sufficient.

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

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

page 2

WHO and UNICEF strongly recommend that all countries adopt the EVSM (effective vaccine store management) initiative and conduct the necessary assessments and improvements leading to high quality management of their vaccine stores starting with the primary.

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

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

Wherever possible, refrigerators and freezers should be chosen from the WHO/UNICEF Product Information Sheets (WHO/V&B/00.13.) Similarly, wherever possible, cold rooms and freezer rooms should comply with current WHO specifications (WHO/V&B/02.33.)

Adequate arrangements should be made to ensure continuous temperature monitoring and to ensure continuous refrigeration in the event of refrigeration equipment failure. Vaccine stores should have a reliable electricity supply, with an automatic standby power supply in the event of mains failure.

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

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

Electronic data loggers, to record storage temperatures during transport, should be used for all shipments from primary stores to the first level of intermediate stores, and elsewhere where possible.

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

[WHO/IVB/04.16-20](#)
page 2

The safe operating temperature for cold rooms and vaccine refrigerators is between +2C to +8C and the safe operating temperature for freezer rooms and vaccine freezers is between -15C to -25C.

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

[WHO/IVB/04.16-20](#)
page 2

Cold rooms and freezer rooms should comply with the minimum standards listed in the table in Appendix 17_20. (Ideally they should comply with the current WHO specification in the following reference documents):

Equipment performance specifications and test procedures: E1: Cold rooms and freezer rooms (WHO/V&B/02.33).

Guideline for improving primary and intermediate vaccine stores, Sections 4 and 8 (WHO/V&B/02.34).

Users handbook for vaccine cold rooms or freezer rooms, Section 2 (WHO/V&B/02.31).

WHO/UNICEF Product Information Sheets current edition. WHO/IVB/04.18 (Module 2)

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

[WHO/IVB/04.16-20](#)
page 2

Vaccine freezers should comply with WHO specifications and be fitted with a continuous temperature recording device accurate to 0.5C. Minimum standards are listed in Appendix 17_21.

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

[WHO/IVB/04.16-20](#)
page 2

The use of CFC gases in refrigeration equipment should be phased out in accordance with UNICEF/WHO policy.

There should be a standby power supply for the vaccine store, with automatic start-up. Preferably the generator should serve the vaccine store alone.

Provide voltage regulators for all refrigeration equipment wherever voltage fluctuations exceed 15% of rated voltage (or the refrigeration equipment manufacturers voltage tolerance, whichever is lower).

Temperature alarms should be fitted to all refrigeration equipment used to store vaccine.

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

[WHO/IVB/04.16-20](#)
page 2

Icepacks come out of the freezer at a temperature of about -20C. They need to be kept at room temperature for a period of time to allow the ice at the core of the icepack to rise to 0C. This process is called conditioning. The following procedure is recommended:

Lay out icepacks, preferably in single rows, but never in more than two rows.

Leave a 5cm space all round each icepack.

Wait until there is a small amount of liquid water inside the icepacks. This will take up to one hour at +20C and rather less at higher temperatures. Shake one of the icepacks every few minutes. The ice is conditioned as soon as it begins to move about slightly inside its container.

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

[WHO/IVB/04.16-20](#)
page 0

(A)t least one freeze indicator must accompany every delivery. At the time when the vaccine is packed in the primary store, place it with the most freeze-sensitive vaccine in the shipment.

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

[WHO/IVB/04.06](#)
page 3

To condition ice-packs before the session, remove frozen ice-packs from the freezing compartment at least 30 minutes before the session begins and allow the ice-packs to sit at room temperature until the ice begins to melt and water starts to form inside. You should check if an ice-pack has been conditioned by shaking it and listening for water inside.

Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)

page 3

Temperature monitoring devices should be included in all vaccine shipments to document whether temperature limits have been exceeded. Electronic temperature devices provide the most reliable and accurate record of the above information. WHO recommends that one electronic temperature device is included in each and every international vaccine shipping carton. Furthermore, WHO no longer recommends the use of the vaccine cold chain monitor card (CCM)* and/or freeze indicators in international shipments.

(* Except under exceptional circumstances where dry ice continues to be used.)

Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)

page 4

The electronic devices should, at a minimum, meet the specifications outlined in Appendix 38_3 and have the functions outlined below.

- 1) A start function to activate the device at the time the carton is being loaded with vaccine.
- 2) A stop function to allow the recipient to stop the recording when the vaccine arrives at its destination.
- 3) A one hour initial delay function so the device can acclimatize to the temperature inside the shipping carton before it starts recording.
- 4) A history function to provide details of violations of the temperature limit in terms of time, range and duration. This function is primarily to provide information for the use of the procurement agency.
- 5) A liquid crystal display (LCD) screen to provide a visual display of the information and also to show the symbol that indicates whether the device is functional or not. This symbol, and also the alarm indicator, should be static (i.e. should not flash or blink) so as to be visible when the screen is scanned or photocopied for documentation purposes. (In addition to the LCD screen feature on which all history can be read, the data can be downloaded. However, devices with a download option but without an LCD screen are not recommended.)
- 6) An alarm set according to WHO's recommended settings (see Appendix 38_3.)

Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)

page 5

All vaccine manufacturers are encouraged to validate their Class A and B packaging with frozen icepacks in order to phase out the use of dry ice. In exceptional cases where dry ice continues to be used WHO recommends the inclusion of one cold chain monitor card per shipping carton instead of an electronic device.

Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)

page 9

Storing vaccines in the shipping containers greatly increases the volume of cold storage needed, hence involves extra cost. However, this extra cost may be justifiable at higher-level stores where vaccine is kept alongside other refrigerated pharmaceuticals. In very large cold stores, where goods are stored and moved on pallets, vaccine should be stocked in their insulated shipping containers.

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

[WHO/IVB/04.06](#)

page 6

A refrigerator in a health facility should be able to hold:
a one-month supply of vaccines and diluents in the refrigerator compartment;
a one to two-week reserve stock of vaccines and diluents (an additional 25% to 50% of the one-month supply);
frozen ice-packs in the freezer compartment; and
bottles of water or unfrozen ice packs in the refrigerator compartment (to act as a buffer to temperature changes, especially if there is a power failure).
Half the total space in the refrigerator should be left empty to allow air to circulate around the vaccines and diluents to keep them cool.

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

[WHO/IVB/04.06](#)

page 8

Previously, ice packs were used to keep vaccines cool during immunization sessions outside of vaccine carriers. It is now recommended to use the supplied foam pads for this purpose.

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 16

Vaccine refrigerators have two compartments:
A main compartment (the refrigerator) for storing vaccines and diluents, in which the temperature should be kept between +2C and +8C. The thermostat is used to adjust the temperature.
A second compartment (the freezer) for freezing ice-packs. If the refrigerator is working properly, this section will be between -5C and -15C.

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

[WHO/IVB/04.06](#)

page 19

Condition frozen ice-packs properly, by allowing ice-packs to sit at room temperature until ice begins to melt and water starts to form. You should check to see if an ice-pack has been conditioned by shaking it and listening for water. This will prevent freeze-sensitive vaccines from freezing.

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

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

(D)o not store already frozen ice-packs in the refrigerator compartment as this will increase the risk of freezing the vaccine.

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

[WHO/IVB/04.06](#)
page 22

Do not adjust thermostat to a higher (cooler) setting after a power cut. This could freeze the vaccines.

Do not adjust thermostat to a higher setting when vaccines arrive. This could freeze the vaccines.

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

[WHO/IVB/04.06](#)
page 23

In order to maintain the temperature in cold boxes and vaccine carriers:
Place the adequate number of conditioned ice packs in the cold box or vaccine carrier.

Keep the cold box or vaccine carrier in the shade.

Keep the lid tightly closed.

Use the foam pad to hold vials during immunization sessions.

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

[WHO/V&B/00.09](#)
page 9

Multi-dose vials from which at least one dose has been removed may be at risk of contamination of the vial septum. These vials should never, therefore, be allowed to be submerged in water (from melted ice for example) and the septum should remain clean and dry. NOTE: Well-sealed icepacks should be used in vaccine carriers and water should not be allowed to accumulate where the vials are stored.

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

[WHO/IVB/05.18](#)
page 34

The updated MYP should include calculations of the impact of the new vaccine on cold chain requirements at national and subnational levels.

This assessment provides an ideal opportunity to establish a national cold-chain inventory, which describes the type of equipment and its status in every part of the country. Included in that inventory should be the expected life of the item so that a planned replacement programme can be instituted. This inventory should be updated every two to three years.

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

[WHO/IVB/05.18](#)
page 48

Due to the large volume of the (rotavirus) vaccine, the impact on cold chain space should be considered before introduction.

Hepatitis B

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.

Hib

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.

JE

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

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

The freeze indicator is used to warn of freezing and is packed with vaccines that are sensitive to freezing temperatures: DTP, TT, DT, Td (freezing point of -6.5C), hepatitis B (-0.5C), liquid Hib and their combinations (DTP-HepB, and DTP-HepB+Hib vaccines) and JE.

Every refrigerator storing vaccines should have a freeze indicator (Freeze Watch). It is strongly recommended that one freeze indicator be placed in each cold box during vaccine transport and distribution. This is critical in places subject to low temperatures.

New Vaccines

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

[WHO/IVB/05.18](#)
page 34

The updated MYP should include calculations of the impact of the new vaccine on cold chain requirements at national and subnational levels.

This assessment provides an ideal opportunity to establish a national cold-chain inventory, which describes the type of equipment and its status in every part of the country. Included in that inventory should be the expected life of the item so that a planned replacement programme can be instituted. This inventory should be updated every two to three years.

Open Vials

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

[WHO/V&B/00.09](#)
page 9

Multi-dose vials from which at least one dose has been removed may be at risk of contamination of the vial septum. These vials should never, therefore, be allowed to be submerged in water (from melted ice for example) and the septum should remain clean and dry. NOTE: Well-sealed icepacks should be used in vaccine carriers and water should not be allowed to accumulate where the vials are stored.

Pentavalent

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.

Policy

Proper handling and reconstitution of vaccines avoids programme errors

[V&B update 34](#)
page 3

Vaccinators and store keepers should always ensure that no other medication or substance which might be confused with the vaccine or its diluent is stored in the refrigerator of the immunization centre

Thermostability of vaccines

[WHO/GPV/98.07](#)

page 49

In all countries, systems of refrigeration, temperature-monitoring and record-keeping are required to make sure that each vial of vaccine is maintained under appropriate conditions and that it is used before the expiry date shown on the label.

Thermostability of vaccines

[WHO/GPV/98.07](#)

page 37

The freezing compartment of a refrigerator in a health centre should be reserved for ice packs

WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services

[WHO/V&B/99.18](#)

page 1

The VVM enables failures in the cold chain to be highlighted in a simple, unambiguous manner and focuses managers attention and resources on the weakest links in the chain. It is therefore a tool for ensuring the quality of the cold chain at the lowest possible cost.

WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services

[WHO/V&B/99.18](#)

page 1

VVMs have been in use with oral polio vaccine (OPV) since 1996. If adequate training is provided they are well accepted by health workers and managers. They have contributed to the success of national immunization days, particularly in areas with a weak cold-chain infrastructure, and they clearly help to reduce vaccine wastage.

WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services

[WHO/V&B/99.18](#)

page 1

All users of vaccines with VVMs should monitor the wastage of vaccine resulting from the VVM indication of a cold-chain failure; all managers of immunization services should evaluate these wastage statistics and strengthen the cold chain accordingly.

WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services

[WHO/V&B/99.18](#)

page 3

When vaccine wastage is included in the system cost of using VVMs, it can be expected that there will be no increase in vaccine costs to country programmes and that there could be significant global savings.

Getting started with vaccine vial monitors

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

page 7

WHO recommends that VVMs be used for:

- ensuring that vaccine administered has not been damaged by heat;
- reducing vaccine wastage*;
- facilitating immunization outreach and increasing access and coverage;
- pinpointing cold chain problems;
- managing vaccine stocks.

*In some cases, VVM introduction may initially increase wastage. VVMs may lead to discards as they expose weaknesses in the cold chain that passed unseen before VVM introduction.

Getting started with vaccine vial monitors

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

page 9

Vaccine vial monitor readings are more accurate than cold chain monitors if the readings do not relate to freezing temperatures.

Getting started with vaccine vial monitors

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

page 11

In the coming years, it is expected that VVMs will be available on all vaccines supplied through UNICEF. Countries or agencies purchasing their own vaccines should include WHO- approved VVMs in the specifications provided to the vaccine manufacturers.

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

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

page 2

Ten key criteria for effective vaccine store management were agreed at a meeting of experts, which took place at WHO Geneva in December 2001. These criteria form the policy foundation for the effective vaccine store management initiative and are listed below. Satisfactory performance is set as the vaccine store meeting at least 80% of each criterion.

Over a period of twelve months:

1. Pre-shipment and arrival procedures have ensured that all shipments were in satisfactory condition when received in the primary stores.
2. All vaccines have been stored within WHO recommended temperature ranges.
3. The capacity of cold storage has been sufficient to meet the demand.
4. The buildings, equipment and transport available to the programme have enabled the cold store to function effectively.
5. All buildings, equipment and transport have been correctly maintained.
6. Stock management has been effective.
7. Deliveries of vaccine to the next level have been timely, sufficient and correct.
8. Minimal damage has occurred to the vaccine during distribution.
9. The facility has followed standard operating procedures.
10. Human and financial resources have been sufficient.

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

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

page 2

WHO and UNICEF strongly recommend that all countries adopt the EVSM (effective vaccine store management) initiative and conduct the necessary assessments and improvements leading to high quality management of their vaccine stores starting with the primary.

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

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

Wherever possible, refrigerators and freezers should be chosen from the WHO/UNICEF Product Information Sheets (WHO/V&B/00.13.) Similarly, wherever possible, cold rooms and freezer rooms should comply with current WHO specifications (WHO/V&B/02.33.)

Adequate arrangements should be made to ensure continuous temperature monitoring and to ensure continuous refrigeration in the event of refrigeration equipment failure. Vaccine stores should have a reliable electricity supply, with an automatic standby power supply in the event of mains failure.

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

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

Electronic data loggers, to record storage temperatures during transport, should be used for all shipments from primary stores to the first level of intermediate stores, and elsewhere where possible.

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

[WHO/IVB/04.16-20](#)
page 2

The safe operating temperature for cold rooms and vaccine refrigerators is between +2C to +8C and the safe operating temperature for freezer rooms and vaccine freezers is between -15C to -25C.

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

[WHO/IVB/04.16-20](#)
page 2

Cold rooms and freezer rooms should comply with the minimum standards listed in the table in Appendix 17_20. (Ideally they should comply with the current WHO specification in the following reference documents):

Equipment performance specifications and test procedures: E1: Cold rooms and freezer rooms (WHO/V&B/02.33).

Guideline for improving primary and intermediate vaccine stores, Sections 4 and 8 (WHO/V&B/02.34).

Users handbook for vaccine cold rooms or freezer rooms, Section 2 (WHO/V&B/02.31).

WHO/UNICEF Product Information Sheets current edition. WHO/IVB/04.18 (Module 2)

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

[WHO/IVB/04.16-20](#)
page 2

Vaccine freezers should comply with WHO specifications and be fitted with a continuous temperature recording device accurate to 0.5C. Minimum standards are listed in Appendix 17_21.

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

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

page 2

The use of CFC gases in refrigeration equipment should be phased out in accordance with UNICEF/WHO policy.

There should be a standby power supply for the vaccine store, with automatic start-up. Preferably the generator should serve the vaccine store alone.

Provide voltage regulators for all refrigeration equipment wherever voltage fluctuations exceed 15% of rated voltage (or the refrigeration equipment manufacturers voltage tolerance, whichever is lower).

Temperature alarms should be fitted to all refrigeration equipment used to store vaccine.

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

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

page 2

Icepacks come out of the freezer at a temperature of about -20C. They need to be kept at room temperature for a period of time to allow the ice at the core of the icepack to rise to 0C. This process is called conditioning. The following procedure is recommended:

Lay out icepacks, preferably in single rows, but never in more than two rows.

Leave a 5cm space all round each icepack.

Wait until there is a small amount of liquid water inside the icepacks. This will take up to one hour at +20C and rather less at higher temperatures.

Shake one of the icepacks every few minutes. The ice is conditioned as soon as it begins to move about slightly inside its container.

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

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

page 0

(A)t least one freeze indicator must accompany every delivery. At the time when the vaccine is packed in the primary store, place it with the most freeze-sensitive vaccine in the shipment.

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

[WHO/IVB/04.06](#)

page 3

To condition ice-packs before the session, remove frozen ice-packs from the freezing compartment at least 30 minutes before the session begins and allow the ice-packs to sit at room temperature until the ice begins to melt and water starts to form inside. You should check if an ice-pack has been conditioned by shaking it and listening for water inside.

Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)

page 3

Temperature monitoring devices should be included in all vaccine shipments to document whether temperature limits have been exceeded. Electronic temperature devices provide the most reliable and accurate record of the above information. WHO recommends that one electronic temperature device is included in each and every international vaccine shipping carton. Furthermore, WHO no longer recommends the use of the vaccine cold chain monitor card (CCM)* and/or freeze indicators in international shipments.

(* Except under exceptional circumstances where dry ice continues to be used.)

Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)

page 4

The electronic devices should, at a minimum, meet the specifications outlined in Appendix 38_3 and have the functions outlined below.

- 1) A start function to activate the device at the time the carton is being loaded with vaccine.
- 2) A stop function to allow the recipient to stop the recording when the vaccine arrives at its destination.
- 3) A one hour initial delay function so the device can acclimatize to the temperature inside the shipping carton before it starts recording.
- 4) A history function to provide details of violations of the temperature limit in terms of time, range and duration. This function is primarily to provide information for the use of the procurement agency.
- 5) A liquid crystal display (LCD) screen to provide a visual display of the information and also to show the symbol that indicates whether the device is functional or not. This symbol, and also the alarm indicator, should be static (i.e. should not flash or blink) so as to be visible when the screen is scanned or photocopied for documentation purposes. (In addition to the LCD screen feature on which all history can be read, the data can be downloaded. However, devices with a download option but without an LCD screen are not recommended.)
- 6) An alarm set according to WHO's recommended settings (see Appendix 38_3.)

Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)

page 5

All vaccine manufacturers are encouraged to validate their Class A and B packaging with frozen icepacks in order to phase out the use of dry ice. In exceptional cases where dry ice continues to be used WHO recommends the inclusion of one cold chain monitor card per shipping carton instead of an electronic device.

Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)

page 9

Storing vaccines in the shipping containers greatly increases the volume of cold storage needed, hence involves extra cost. However, this extra cost may be justifiable at higher-level stores where vaccine is kept alongside other refrigerated pharmaceuticals. In very large cold stores, where goods are stored and moved on pallets, vaccine should be stocked in their insulated shipping containers.

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

[WHO/IVB/04.06](#)

page 6

A refrigerator in a health facility should be able to hold:
a one-month supply of vaccines and diluents in the refrigerator compartment;
a one to two-week reserve stock of vaccines and diluents (an additional 25% to 50% of the one-month supply);
frozen ice-packs in the freezer compartment; and
bottles of water or unfrozen ice packs in the refrigerator compartment (to act as a buffer to temperature changes, especially if there is a power failure).
Half the total space in the refrigerator should be left empty to allow air to circulate around the vaccines and diluents to keep them cool.

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

[WHO/IVB/04.06](#)

page 8

Previously, ice packs were used to keep vaccines cool during immunization sessions outside of vaccine carriers. It is now recommended to use the supplied foam pads for this purpose.

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 16

Vaccine refrigerators have two compartments:
A main compartment (the refrigerator) for storing vaccines and diluents, in which the temperature should be kept between +2C and +8C. The thermostat is used to adjust the temperature.
A second compartment (the freezer) for freezing ice-packs. If the refrigerator is working properly, this section will be between -5C and -15C.

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

[WHO/IVB/04.06](#)

page 19

Condition frozen ice-packs properly, by allowing ice-packs to sit at room temperature until ice begins to melt and water starts to form. You should check to see if an ice-pack has been conditioned by shaking it and listening for water. This will prevent freeze-sensitive vaccines from freezing.

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

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

(D)o not store already frozen ice-packs in the refrigerator compartment as this will increase the risk of freezing the vaccine.

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

[WHO/IVB/04.06](#)
page 22

Do not adjust thermostat to a higher (cooler) setting after a power cut. This could freeze the vaccines.

Do not adjust thermostat to a higher setting when vaccines arrive. This could freeze the vaccines.

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

[WHO/IVB/04.06](#)
page 23

In order to maintain the temperature in cold boxes and vaccine carriers:
Place the adequate number of conditioned ice packs in the cold box or vaccine carrier.

Keep the cold box or vaccine carrier in the shade.

Keep the lid tightly closed.

Use the foam pad to hold vials during immunization sessions.

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

[WHO/V&B/00.09](#)
page 9

Multi-dose vials from which at least one dose has been removed may be at risk of contamination of the vial septum. These vials should never, therefore, be allowed to be submerged in water (from melted ice for example) and the septum should remain clean and dry. NOTE: Well-sealed icepacks should be used in vaccine carriers and water should not be allowed to accumulate where the vials are stored.

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

[WHO/IVB/05.18](#)
page 34

The updated MYP should include calculations of the impact of the new vaccine on cold chain requirements at national and subnational levels.

This assessment provides an ideal opportunity to establish a national cold-chain inventory, which describes the type of equipment and its status in every part of the country. Included in that inventory should be the expected life of the item so that a planned replacement programme can be instituted. This inventory should be updated every two to three years.

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

[WHO/IVB/05.18](#)
page 48

Due to the large volume of the (rotavirus) vaccine, the impact on cold chain space should be considered before introduction.

Polio

WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services

[WHO/V&B/99.18](#)
page 1

VVMs have been in use with oral polio vaccine (OPV) since 1996. If adequate training is provided they are well accepted by health workers and managers. They have contributed to the success of national immunization days, particularly in areas with a weak cold-chain infrastructure, and they clearly help to reduce vaccine wastage.

Procurement

Getting started with vaccine vial monitors

[WHO/V&B/02.35](#)
page 11

In the coming years, it is expected that VVMs will be available on all vaccines supplied through UNICEF. Countries or agencies purchasing their own vaccines should include WHO- approved VVMs in the specifications provided to the vaccine manufacturers.

Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)
page 3

Temperature monitoring devices should be included in all vaccine shipments to document whether temperature limits have been exceeded. Electronic temperature devices provide the most reliable and accurate record of the above information. WHO recommends that one electronic temperature device is included in each and every international vaccine shipping carton. Furthermore, WHO no longer recommends the use of the vaccine cold chain monitor card (CCM)* and/or freeze indicators in international shipments.

(* Except under exceptional circumstances where dry ice continues to be used.)

Guidelines on the international packaging and shipping of vaccines

[WHO/IVB/05.23](#)
page 5

All vaccine manufacturers are encouraged to validate their Class A and B packaging with frozen icepacks in order to phase out the use of dry ice. In exceptional cases where dry ice continues to be used WHO recommends the inclusion of one cold chain monitor card per shipping carton instead of an electronic device.

Rotavirus

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

[WHO/IVB/05.18](#)
page 48

Due to the large volume of the (rotavirus) vaccine, the impact on cold chain space should be considered before introduction.

Tetanus

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.

Vaccine Handling

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

[WHO/IVB/04.16-20](#)
page 2

Ten key criteria for effective vaccine store management were agreed at a meeting of experts, which took place at WHO Geneva in December 2001. These criteria form the policy foundation for the effective vaccine store management initiative and are listed below. Satisfactory performance is set as the vaccine store meeting at least 80% of each criterion.

Over a period of twelve months:

1. Pre-shipment and arrival procedures have ensured that all shipments were in satisfactory condition when received in the primary stores.
2. All vaccines have been stored within WHO recommended temperature ranges.
3. The capacity of cold storage has been sufficient to meet the demand.
4. The buildings, equipment and transport available to the programme have enabled the cold store to function effectively.
5. All buildings, equipment and transport have been correctly maintained.
6. Stock management has been effective.
7. Deliveries of vaccine to the next level have been timely, sufficient and correct.
8. Minimal damage has occurred to the vaccine during distribution.
9. The facility has followed standard operating procedures.
10. Human and financial resources have been sufficient.

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

[WHO/IVB/04.16-20](#)
page 2

WHO and UNICEF strongly recommend that all countries adopt the EVSM (effective vaccine store management) initiative and conduct the necessary assessments and improvements leading to high quality management of their vaccine stores starting with the primary.