BCG

Getting started with vaccine vial monitors

Opened vials of measles, yellow fever, BCG and freeze-dried Hib vaccine cannot be used after an initial immunization session, (even if the VVM has not reached the discard point.). They must be discarded within six hours of reconstitution or at the end of the session, whichever comes first. The VVMs for these vaccines are attached to the vial caps and should be discarded when the vaccine is being reconstituted.

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

The revised (multi-dose vial) policy does not change recommended procedures for handling vaccines that must be reconstituted, that is, BCG, measles, yellow fever, and some formulations of Hib vaccines. Once they are reconstituted, vials of these vaccines must be discarded at the end of each immunization session or at the end of six hours, whichever comes first.

Cold Chain Equipment

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

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.

DPT

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

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

In multidose formulation, liquid Hib and DTP-Hib vaccines may be used at a subsequent session, even if they have been opened, according to the WHO Policy Statement on the use of opened vials of vaccine in subsequent immunization sessions.
Diphtheria

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

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.

General

Thermostability of vaccines

In multidose formulation, liquid Hib and Hib-DTP vaccines may be used at a subsequent session, even if they have been opened, according to the WHO Policy Statement on the use of opened vials of vaccine in subsequent immunization sessions.

Getting started with vaccine vial monitors

VVMs provide additional information on the heat exposure status of opened vials of liquid vaccines (DTP, TT, DT, Td, hepatitis B, OPV and liquid formulations of Hib), which can now be used for up to four weeks under the WHO policy statement: "The use of opened multi-dose vials of vaccine in subsequent immunization sessions (WHO/V&B/00.09)"

Getting started with vaccine vial monitors

Opened vials of measles, yellow fever, BCG and freeze-dried Hib vaccine cannot be used after an initial immunization session, (even if the VVM has not reached the discard point.). They must be discarded within six hours of reconstitution or at the end of the session, whichever comes first. The VVMs for these vaccines are attached to the vial caps and should be discarded when the vaccine is being reconstituted.

Introduction of Haemophilus influenzae type b vaccine into immunization programmes

The WHO multi-dose vial policy states that vials of liquid DTP, TT, HepB and OPV opened in a fixed clinic may be used at more than one immunization session provided that:

a) The expiry date has not passed.
B) The vaccines are stored under appropriate cold chain conditions.
C) The vaccine vial septum has not been submerged in water.
D) Aseptic technique has been used to withdraw all doses.
E) The vaccine vial monitor (VVM), if attached, has not reached the discard point.

Reconstituted lyophilized vaccines such as BCG, measles and yellow fever must be discarded after six hours or at the end of a session, whichever comes first.
Introduction of Haemophilus influenzae type b vaccine into immunization programmes

The WHO multi-dose vial policy applies to Hib vaccines as follows:
All liquid formulations of Hib vaccine contain a preservative and can be used in subsequent immunization sessions.
The freeze-dried formulation (lyophilized) contains no preservatives, and after being reconstituted with a diluent with no preservatives, must be discarded at the end of the session or within six hours, whichever comes first (the same as for BCG, measles, and yellow fever). - Certain formulations of lyophilized Hib vaccine are supplied with DTP (or DTP/HepB) liquid vaccine or diluent containing preservatives. These reconstituted vaccines can be used safely over an extended period. However, the application of the multidose vial policy with DTP-HepB+Hib vaccine is recommended only if specific supervision and training activities are conducted in order to ensure appropriate implementation.

Best infection control practices for intradermal, subcutaneous, and intramuscular needle injections

Prepare each injection in a clean designated area, where contamination from blood or body fluid is unlikely. Use single-dose vials rather than multi-dose vials. If multi-dose vials must be used, always pierce the septum with a sterile needle. Avoid leaving a needle in place in the stopper of the vial. Select pop-open ampoules rather than ampoules that need to be opened by using a metal file. If an ampoule that requires a metal file is used, protect fingers with a clean barrier (e.g. small gauze pad) when opening the ampoule. Inspect for and discard medications with visible contamination or breaches of integrity (e.g. cracks, leaks). Follow product-specific recommendations for use, storage, and handling. Discard a needle that has touched any non-sterile surface.

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

Multi-dose vials of OPV, DTP, TT, DT, hepatitis B, and liquid formulations of Hib vaccines from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 4 weeks, provided that all of the following conditions are met:
The expiry date has not passed; The vaccines are stored under appropriate cold chain conditions; The vaccine vial septum has not been submerged in water; Aseptic technique has been used to withdraw all doses; The vaccine vial monitor (VVM), if attached, has not reached the discard point.
The revised policy applies only to OPV, DTP, TT, DT, hepatitis B, and liquid formulations of Hib vaccines that:
meet WHO requirements for potency and temperature stability; are packaged according to ISO standards (ISO Standard 8362-2); and contain an appropriate concentration of preservative, such as thiomersal (injectable vaccines only).
Note: Vaccines supplied via UNICEF meet these requirements.
The use of opened multi-dose vials of vaccine in subsequent immunization sessions (WHO Policy Statement)

The revised (multi-dose vial) policy does not change recommended procedures for handling vaccines that must be reconstituted, that is, BCG, measles, yellow fever, and some formulations of Hib vaccines. Once they are reconstituted, vials of these vaccines must be discarded at the end of each immunization session or at the end of six hours, whichever comes first.

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

Most freeze-dried (lyophilized vaccines) do not contain preservatives and consequently must not be kept more than the manufacturers recommended limit and never longer than six hours after they are reconstituted. Death due to toxic shock syndrome has resulted when reconstituted live virus vaccines kept longer than the recommended period have been injected.

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

Liquid injectable vaccines such as DTP, TT, DT and hepatitis B contain preservatives that prevent growth of bacterial contamination. Should contamination take place within the vial, the action of these preservatives prevents any increase in bacterial growth over time and actually decreases the level of contamination. A time limit has been set in this policy for managerial reasons only. Time limits less than 4 weeks may be imposed nationally, or sub-nationally, according to the interval between immunization sessions and the average number of children immunized at a session.

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

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.

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

Health workers must be able to distinguish between vials that can be used in subsequent sessions and vials that must be discarded. Training and supervision materials should be revised to reflect the policy change.

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

The new (multi-dose vial) policy may be introduced either for all vaccines, or only for vaccines with VVMs, or delayed until all vials are supplied with vaccine vial monitors. This decision depends on the risk of heat exposure and the flexibility of health workers in dealing with changes.
The use of opened multi-dose vials of vaccine in subsequent immunization sessions (WHO Policy Statement)

Programme managers will need to re-evaluate vaccine wastage rates for vaccines affected by the new (multi-dose vial) policy. The new rate of wastage is estimated to be approximately 15% to 20%, but this figure should be confirmed locally before radically changing vaccine forecasts or orders.

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

Using opened multi-dose vaccine vials during campaigns or outreach: The new policy applies to all vaccine vials, including those that have been transported in the cold chain for outreach immunization sessions, provided that standard handling procedures are followed. This means that opened vials can be used in subsequent immunization sessions, in different sites, over several days, provided that they have been stored in vaccine carriers or cold boxes with a suitable number of frozen icepacks and all the conditions outlined in (26_5 and 26_6) are met.

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

The freeze-dried (Hib) formulation contains no preservative, and after being reconstituted with a diluent, must be discarded at the end of the session or within 6 hours, whichever comes first (the same as for BCG, measles, and yellow fever).

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

Certain formulations of lyophilized Hib vaccine are supplied with DTP liquid vaccine. However, although these can be used safely over an extended period, implementing a decision to use them requires additional management and supervision activities, and is not therefore recommended in the absence of specific training of personnel.

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

All liquid formulations of Hib vaccine contain a preservative and can be used in subsequent immunization sessions.
Ensuring the quality of vaccines at country level: Guidelines for health staff

The (multi-dose vials) policy states multi-dose vials of OPV, DTP, TT, DT, Td, hepatitis B, and liquid formulations of Hib vaccines from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of four weeks, provided that all of the following conditions are met:
- the expiry date has not passed;
- the vaccines are stored under appropriate cold chain conditions;
- the vaccine vial septum has not been submerged in water;
- aseptic technique has been used to withdraw all doses;
- the VVM, if attached, has not reached its discard point.

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

According to the WHO multidose vial policy (WHO/V&B/00.09), opened multidose vials of hepatitis B vaccine may be reused in subsequent immunization sessions for up to four weeks in fixed health facilities if all the following conditions are met.
- The expiry date has not passed.
- The vial has been stored under appropriate cold chain conditions (i.e. refrigerated between 2 C and 8 C).
- The vaccine vial septum (where the needle is put in to withdraw doses) has not been submerged in water (to prevent this from happening, well-sealed ice packs should be used in vaccine carriers and water should not be allowed to accumulate where the vials are stored).
- An aseptic technique has been used to withdraw all doses.
- The vaccine vial monitor (VVM), if attached, has not reached the discard point.

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

(O)utreach sessions, opened multidose vials of hepatitis B vaccine may be reused in subsequent immunization sessions for up to four weeks if:
- all the conditions for reuse of multidose vials in fixed health facilities are met;
- a VVM is attached to the vial.

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

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

In multidose formulation, liquid Hib and DTP-Hib vaccines may be used at a subsequent session, even if they have been opened, according to the WHO Policy Statement on the use of opened vials of vaccine in subsequent immunization sessions.

Hepatitis B

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

According to the WHO multidose vial policy (WHO/V&B/00.09), opened multidose vials of hepatitis B vaccine may be reused in subsequent immunization sessions for up to four weeks in fixed health facilities if all the following conditions are met:

- The expiry date has not passed.
- The vial has been stored under appropriate cold chain conditions (i.e. refrigerated between 2 C and 8 C).
- The vaccine vial septum (where the needle is put in to withdraw doses) has not been submerged in water (to prevent this from happening, well-sealed ice packs should be used in vaccine carriers and water should not be allowed to accumulate where the vials are stored).
- An aseptic technique has been used to withdraw all doses.
- The vaccine vial monitor (VVM), if attached, has not reached the discard point.

(0)utreach sessions, opened multidose vials of hepatitis B vaccine may be reused in subsequent immunization sessions for up to four weeks if:

- all the conditions for reuse of multidose vials in fixed health facilities are met;
- a VVM is attached to the vial.

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

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.
**Hib**

**Getting started with vaccine vial monitors**

Opened vials of measles, yellow fever, BCG and freeze-dried Hib vaccine cannot be used after an initial immunization session, (even if the VVM has not reached the discard point.). They must be discarded within six hours of reconstitution or at the end of the session, whichever comes first. The VVMs for these vaccines are attached to the vial caps and should be discarded when the vaccine is being reconstituted.

**Introduction of Haemophilus influenzae type b vaccine into immunization programmes**

The WHO multi-dose vial policy applies to Hib vaccines as follows:
All liquid formulations of Hib vaccine contain a preservative and can be used in subsequent immunization sessions.
The freeze-dried formulation (lyophilized) contains no preservatives, and after being reconstituted with a diluent with no preservatives, must be discarded at the end of the session or within six hours, whichever comes first (the same as for BCG, measles, and yellow fever).
- Certain formulations of lyophilized Hib vaccine are supplied with DTP (or DTP/HepB) liquid vaccine or diluent containing preservatives. These reconstituted vaccines can be used safely over an extended period. However, the application of the multidose vial policy with DTP-HepB+Hib vaccine is recommended only if specific supervision and training activities are conducted in order to ensure appropriate implementation.

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

The revised (multi-dose vial) policy does not change recommended procedures for handling vaccines that must be reconstituted, that is, BCG, measles, yellow fever, and some formulations of Hib vaccines. Once they are reconstituted, vials of these vaccines must be discarded at the end of each immunization session or at the end of six hours, whichever comes first.

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

The freeze-dried (Hib) formulation contains no preservative, and after being reconstituted with a diluent, must be discarded at the end of the session or within 6 hours, whichever comes first (the same as for BCG, measles, and yellow fever).

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

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

In multidose formulation, liquid Hib and DTP-Hib vaccines may be used at a subsequent session, even if they have been opened, according to the WHO Policy Statement on the use of opened vials of vaccine in subsequent immunization sessions.

Measles

Getting started with vaccine vial monitors

Opened vials of measles, yellow fever, BCG and freeze-dried Hib vaccine cannot be used after an initial immunization session, (even if the VVM has not reached the discard point.). They must be discarded within six hours of reconstitution or at the end of the session, whichever comes first. The VVMs for these vaccines are attached to the vial caps and should be discarded when the vaccine is being reconstituted.

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

The revised (multi-dose vial) policy does not change recommended procedures for handling vaccines that must be reconstituted, that is, BCG, measles, yellow fever, and some formulations of Hib vaccines. Once they are reconstituted, vials of these vaccines must be discarded at the end of each immunization session or at the end of six hours, whichever comes first.

Pentavalent

Introduction of Haemophilus influenzae type b vaccine into immunization programmes

The WHO multi-dose vial policy applies to Hib vaccines as follows:

All liquid formulations of Hib vaccine contain a preservative and can be used in subsequent immunization sessions.

The freeze-dried formulation (lyophilized) contains no preservatives, and after being reconstituted with a diluent with no preservatives, must be discarded at the end of the session or within six hours, whichever comes first (the same as for BCG, measles, and yellow fever).

- Certain formulations of lyophilized Hib vaccine are supplied with DTP (or DTP/HepB) liquid vaccine or diluent containing preservatives. These reconstituted vaccines can be used safely over an extended period. However, the application of the multidose vial policy with DTP-HepB+Hib vaccine is recommended only if specific supervision and training activities are conducted in order to ensure appropriate implementation.

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

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.
**Policy**

**Thermostability of vaccines**

In multidose formulation, liquid Hib and Hib-DTP vaccines may be used at a subsequent session, even if they have been opened, according to the WHO Policy Statement on the use of opened vials of vaccine in subsequent immunization sessions.

**Getting started with vaccine vial monitors**

VVMs provide additional information on the heat exposure status of opened vials of liquid vaccines (DTP, TT, DT, Td, hepatitis B, OPV and liquid formulations of Hib), which can now be used for up to four weeks under the WHO policy statement: “The use of opened multi-dose vials of vaccine in subsequent immunization sessions (WHO/V&B/00.09)”

**Getting started with vaccine vial monitors**

Opened vials of measles, yellow fever, BCG and freeze-dried Hib vaccine cannot be used after an initial immunization session, (even if the VVM has not reached the discard point.). They must be discarded within six hours of reconstitution or at the end of the session, whichever comes first. The VVMs for these vaccines are attached to the vial caps and should be discarded when the vaccine is being reconstituted.

**Introduction of Haemophilus influenzae type b vaccine into immunization programmes**

The WHO multi-dose vial policy applies to Hib vaccines as follows:

All liquid formulations of Hib vaccine contain a preservative and can be used in subsequent immunization sessions. The freeze-dried formulation (lyophilized) contains no preservatives, and after being reconstituted with a diluent with no preservatives, must be discarded at the end of the session or within six hours, whichever comes first (the same as for BCG, measles, and yellow fever).

- Certain formulations of lyophilized Hib vaccine are supplied with DTP (or DTP/HepB) liquid vaccine or diluent containing preservatives. These reconstituted vaccines can be used safely over an extended period. However, the application of the multidose vial policy with DTP-HepB+Hib vaccine is recommended only if specific supervision and training activities are conducted in order to ensure appropriate implementation.
Best infection control practices for intradermal, subcutaneous, and intramuscular needle injections

Prepare each injection in a clean designated area, where contamination from blood or body fluid is unlikely. Use single-dose vials rather than multi-dose vials. If multi-dose vials must be used, always pierce the septum with a sterile needle. Avoid leaving a needle in place in the stopper of the vial.

Select pop-open ampoules rather than ampoules that need to be opened by using a metal file. If an ampoule that requires a metal file is used, protect fingers with a clean barrier (e.g. small gauze pad) when opening the ampoule. Inspect for and discard medications with visible contamination or breaches of integrity (e.g. cracks, leaks). Follow product-specific recommendations for use, storage, and handling. Discard a needle that has touched any non-sterile surface.

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

Multi-dose vials of OPV, DTP, TT, DT, hepatitis B, and liquid formulations of Hib vaccines from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 4 weeks, provided that all of the following conditions are met:

- The expiry date has not passed;
- The vaccines are stored under appropriate cold chain conditions;
- The vaccine vial septum has not been submerged in water;
- Aseptic technique has been used to withdraw all doses;
- The vaccine vial monitor (VVM), if attached, has not reached the discard point.

The revised policy applies only to OPV, DTP, TT, DT, hepatitis B, and liquid formulations of Hib vaccines that:

- meet WHO requirements for potency and temperature stability;
- are packaged according to ISO standards (ISO Standard 8362-2); and
- contain an appropriate concentration of preservative, such as thiomersal (injectable vaccines only).

Note: Vaccines supplied via UNICEF meet these requirements.

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

The revised (multi-dose vial) policy does not change recommended procedures for handling vaccines that must be reconstituted, that is, BCG, measles, yellow fever, and some formulations of Hib vaccines. Once they are reconstituted, vials of these vaccines must be discarded at the end of each immunization session or at the end of six hours, whichever comes first.

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

Most freeze-dried (lyophilized vaccines) do not contain preservatives and consequently must not be kept more than the manufacturers recommended limit and never longer than six hours after they are reconstituted. Death due to toxic shock syndrome has resulted when reconstituted live virus vaccines kept longer than the recommended period have been injected.
Open Vials

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

Liquid injectable vaccines such as DTP, TT, DT and hepatitis B contain preservatives that prevent growth of bacterial contamination. Should contamination take place within the vial, the action of these preservatives prevents any increase in bacterial growth over time and actually decreases the level of contamination. A time limit has been set in this policy for managerial reasons only. Time limits less than 4 weeks may be imposed nationally, or sub-nationally, according to the interval between immunization sessions and the average number of children immunized at a session.

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.

Health workers must be able to distinguish between vials that can be used in subsequent sessions and vials that must be discarded. Training and supervision materials should be revised to reflect the policy change.

The new (multi-dose vial) policy may be introduced either for all vaccines, or only for vaccines with VVMs, or delayed until all vials are supplied with vaccine vial monitors. This decision depends on the risk of heat exposure and the flexibility of health workers in dealing with changes.

Programme managers will need to re-evaluate vaccine wastage rates for vaccines affected by the new (multi-dose vial) policy. The new rate of wastage is estimated to be approximately 15% to 20%, but this figure should be confirmed locally before radically changing vaccine forecasts or orders.
Open Vials

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

Using opened multi-dose vaccine vials during campaigns or outreach: The new policy applies to all vaccine vials, including those that have been transported in the cold chain for outreach immunization sessions, provided that standard handling procedures are followed. This means that opened vials can be used in subsequent immunization sessions, in different sites, over several days, provided that they have been stored in vaccine carriers or cold boxes with a suitable number of frozen icepacks and all the conditions outlined in (26_5 and 26_6) are met.

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

The freeze-dried (Hib) formulation contains no preservative, and after being reconstituted with a diluent, must be discarded at the end of the session or within 6 hours, whichever comes first (the same as for BCG, measles, and yellow fever).

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

Certain formulations of lyophilized Hib vaccine are supplied with DTP liquid vaccine. However, although these can be used safely over an extended period, implementing a decision to use them requires additional management and supervision activities, and is not therefore recommended in the absence of specific training of personnel.

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

All liquid formulations of Hib vaccine contain a preservative and can be used in subsequent immunization sessions.

Ensuring the quality of vaccines at country level: Guidelines for health staff

The (multi-dose vials) policy states multi-dose vials of OPV, DTP, TT, DT, Td, hepatitis B, and liquid formulations of Hib vaccines from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of four weeks, provided that all of the following conditions are met: the expiry date has not passed; the vaccines are stored under appropriate cold chain conditions; the vaccine vial septum has not been submerged in water; aseptic technique has been used to withdraw all doses; the VVM, if attached, has not reached its discard point.
Introduction of hepatitis B vaccine into childhood immunization services. Management guidelines, including information for health workers and parents

According to the WHO multidose vial policy (WHO/V&B/00.09), opened multidose vials of hepatitis B vaccine may be reused in subsequent immunization sessions for up to four weeks in fixed health facilities if all the following conditions are met:

- The expiry date has not passed.
- The vial has been stored under appropriate cold chain conditions (i.e. refrigerated between 2 C and 8 C).
- The vaccine vial septum (where the needle is put in to withdraw doses) has not been submerged in water (to prevent this from happening, well-sealed ice packs should be used in vaccine carriers and water should not be allowed to accumulate where the vials are stored).
- An aseptic technique has been used to withdraw all doses.
- The vaccine vial monitor (VVM), if attached, has not reached the discard point.

Outreach sessions, opened multidose vials of hepatitis B vaccine may be reused in subsequent immunization sessions for up to four weeks if:
- all the conditions for reuse of multidose vials in fixed health facilities are met;
- a VVM is attached to the vial.

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

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

In multidose formulation, liquid Hib and DTP-Hib vaccines may be used at a subsequent session, even if they have been opened, according to the WHO Policy Statement on the use of opened vials of vaccine in subsequent immunization sessions.

Polio

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

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.
Tetanus

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

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.

Yellow Fever

Getting started with vaccine vial monitors

Opened vials of measles, yellow fever, BCG and freeze-dried Hib vaccine cannot be used after an initial immunization session, (even if the VVM has not reached the discard point.). They must be discarded within six hours of reconstitution or at the end of the session, whichever comes first. The VVMs for these vaccines are attached to the vial caps and should be discarded when the vaccine is being reconstituted.

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

The revised (multi-dose vial) policy does not change recommended procedures for handling vaccines that must be reconstituted, that is, BCG, measles, yellow fever, and some formulations of Hib vaccines. Once they are reconstituted, vials of these vaccines must be discarded at the end of each immunization session or at the end of six hours, whichever comes first.