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How to manage COVID-19 vaccines without VVM at vaccination service points?

COVID-19 vaccines must be stored, transported and handled under appropriate conditions. This includes maintaining cold chain conditions according to the emergency use listing (EUL) recommendation and as specified in the product insert¹. Every time a vaccine is exposed to improper conditions such as over exposure to heat, cold or light, its potency is reduced. This loss is cumulative and irreversible. **Once lost, vaccine potency cannot be restored.** The vaccine vial monitor or VVM is a reliable indicator that registers whether the cumulative heat exposure has reached a point when the vaccine can no longer be used.

Initial supply of most COVID-19 vaccines does not have VVM, and the required temperature during storage and while in use differs among the products.



Vaccine appearance is not a reliable indicator to determine if a vaccine has been frozen, re-frozen, or exposed to harmful heat. This is why it is of utmost importance that the temperature is monitored and managed as vaccines travel through every step of the supply and distribution chain. All known temperature excursions (i.e. temperature reading outside the recommended range for specific vaccine product) must be documented, reported and assessed to determine if a cold chain breach occurred and if the vaccine can be safely used.

The policies and guidelines, reliable equipment, management tools, and well-trained staff must be in place to ensure that the cold chain is effectively maintained all the way to the vaccination site and only safe and effective vaccines are administered.

At the service point, all COVID-19 vaccines can be stored at +2 to +8 °C for a limited period, depending on the product (see page 2).

To ensure that vaccines are kept at +2 to +8 °C during vaccination sessions, health workers are encouraged to plan the session in advance and prepare the following.

It is important for health workers to know the requirements for COVID-19 vaccines while in use, as without VVM there is no way to confidently assess cumulative heat exposure above +8 °C.



Equipment	Use	Task
Freeze-free vaccine carrier ² with frozen water packs	Main vaccine storage during transport and vaccination sessions	<ul style="list-style-type: none"> Estimate number of vaccine vials needed for the target population per session. Check status of coolant packs every time a new vial is taken out. Do not allow the frozen water packs to melt; immediately replenish as needed.
Regular vaccine carrier with conditioned water packs	Storage of open vaccine vials during vaccination sessions	<ul style="list-style-type: none"> After opening a vaccine vial and while in use, keep it in the foam pad supplied with the vaccine carrier. Ensure that the label is dry and intact. Open one vial at a time. Ensure that water packs are conditioned properly and not in direct contact with the vaccine vials.
Regular vaccine carrier or small thermal shipper with spare frozen water packs	Storage of reserve frozen water packs	<ul style="list-style-type: none"> Ensure adequate number of frozen water packs is available to re-supply all vaccine carriers mid-session. Ensure that frozen water packs are conditioned before use in a regular vaccine carrier.

¹ It is important that vaccines are used according to the information in the approved product insert, as this is a legal document. Using product off-label or outside of recommended specifications implies liability.

² If not available, standard vaccine carrier with cool water packs or conditioned water packs may be used while applying good practice to prevent accidentally freezing the vaccine. To choose the appropriate water packs, the ambient temperature at the service point should be considered.

If you identify a temperature excursion at the service point, document the details (temperature and duration of the excursion), place the vaccines in a separate container away from other vaccines and mark **'DO NOT USE'**, and inform your supervisor immediately. **Always follow your national policy!**

Handling WHO EUL COVID-19 vaccines without VVM at the vaccination site, to ensure that safe and potent vaccines are administered (information available as of 31 August 2021):

COVID-19 vaccine product	Temperature requirement and shelf-life while in use	Temperature excursion occurs if:
Pfizer BioNTech - Comirnaty		
Undiluted thawed vaccine	+2 to +8 °C for 31 days +8 to +30 °C for 2 hours	<ul style="list-style-type: none"> • Temperature is lower than +2 °C • Temperature is higher than +8 °C for more than 2 hours • Temperature is higher than +30 °C within the 2-hour timeframe
Diluted thawed vaccine	+2 to +8 °C for 6 hours	<ul style="list-style-type: none"> • Temperature is lower than +2 °C or higher than +8 °C within 6 hours after dilution <p>Discard 6 hours after dilution!</p>
Moderna		
Thawed unopened vaccine (before first puncture)	+2 to +8 °C up to 30 days +8 to +25 °C up to 12 hours	<ul style="list-style-type: none"> • Temperature is lower than +2 °C • Temperature is higher than +8 °C for more than 12 hours • Temperature is higher than +25 °C within 12-hour timeframe
Thawed punctured vaccine vial	+2 to +8 °C for 6 hours	<ul style="list-style-type: none"> • Temperature is lower than +2 °C or higher than +8 °C within 6 hours after first puncture <p>Discard 6 hours after first puncture!</p>
AstraZeneca		
Unopened vaccine vials (before first puncture)	+2 to +8 °C until expiry date	<ul style="list-style-type: none"> • Temperature is lower than +2 °C or higher than +8 °C
Opened punctured vaccine vials	+2 to +8 °C for 6 hours	<ul style="list-style-type: none"> • Temperature is lower than +2 °C or higher than +8 °C within 6 hours after first puncture <p>Discard 6 hours after first puncture!</p>
Janssen		
Thawed unopened vaccine vials (before first puncture)	+2 to +8 °C for up to 4.5 months (18 weeks)* <small>*For the lots produced in US sites and donated through COVAX Facility, WHO recommends the storage at +2 to +8 °C for 6 months.</small>	<ul style="list-style-type: none"> • Temperature is lower than +2 °C or higher than +8 °C within 4.5-month/18-week timeframe
Thawed punctured vaccine vial	+2 to +8 °C for 6 hours	<ul style="list-style-type: none"> • Temperature is lower than +2 °C or higher than +8 °C within 6 hours after first puncture <p>Discard 6 hours after first puncture!</p>
CoronaVac/Sinovac, BIBP Sinopharm		
Unopened single dose vials and monodose syringes	+2 to +8 °C until expiry date	<ul style="list-style-type: none"> • Temperature is lower than +2 °C or higher than +8 °C <p>Discard 6 hours after first puncture!</p>