Contacting Manufacturer/DSHS Pharmacy

Q: Who should providers contact to determine the viability of fridge vaccines?
A: Providers can contact each vaccine manufacturer independently or the DSHS Pharmacy Branch at 512-776-7500 that will provide information on all vaccines.

Q: Does the provider report temperature excursion to the state; then do they call the manufacturer or does the state call the manufacturer?
A: Providers should immediately notify their responsible entity (Local Health Department (LHD) or DSHS Health Service Region (HSR)). The provider should then contact the State Pharmacist or manufacturer to provide all pertinent information needed to determine vaccine viability. Once a determination has been made providers should contact their responsible entity and provide them with the information obtained from the pharmacist or manufacturer.

Storage Units

Q: We recently acquired a new provider and at the time of the initial training we were not aware of the new recommendations. Should I tell this provider the combination unit they just purchased is not acceptable? Also for future providers do we tell them the laboratory storage units are the only acceptable storage units?
A: At this time combination units are allowed for vaccine storage. The CDC recommendation is that providers have a stand-alone freezer and a stand-alone refrigerator. Future providers should be made aware of the CDC recommendation and should be encouraged to purchase separate units. Additional information is available at: http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/vac-storage.pdf

Q: What is considered dormitory style? Is that only the small unit that has a freezer inside or is that any small dormitory style unit.
A: Dormitory is considered to be a single exterior door unit with an internal freezer compartment inside.

Q: I’m still confused about the use of "dorm style" refrigerators. Can these be used if they DON'T have the freezer compartment inside or not at all regardless if they have a freezer in them or not?
A: Dormitory style refrigerators, with interior freezer sections, are not allowed for storage of vaccines at any time. Small refrigerators, that do not have an internal freezer compartment, are allowed for vaccine storage. Best practice for use of small single units is to ensure that they have a temperature control and a fan for cold air circulation.
Q: Is the stand alone small refrigerator unit without freezer acceptable?
A: Yes, a small stand-alone refrigerator unit without a freezer compartment is acceptable.

Q: What type does NIST recommend?
A: NIST recommends stand-alone refrigerators and stand-alone freezers for vaccine storage.

Off Site Storage and/or Transporting
Q: What about storing vaccines when taken to off-site clinic?
A: Vaccines that are taken to offsite clinics must be maintained at the appropriate temperatures prior to transport, during transport, and while on site at the clinic. Vaccines should be stored at the recommended temperatures immediately upon arrival at the facility. Record storage unit temperatures twice daily. If vaccine must be kept in an insulated cooler, keep the cooler closed as much as possible. At a minimum, record the cooler temperature hourly.

Q: Is it allowed for a provider to store vaccines daily in coolers (ice chests) for use in a clinic and returned to the main storage unit at the end of the day?
A: Clinics that temporarily store vaccines daily in coolers should consider investing in a portable refrigerator to safeguard vaccines from temperature excursions. Insulated coolers are allowed, however, careful consideration should be given for extended use. If vaccine must be kept in an insulated cooler, keep the cooler closed as much as possible. At a minimum, record the cooler temperature hourly.

Q: When I speak to vaccine reps and manufacturers, they basically do not want to talk about procedures for moving vaccines once received. We move a lot of vaccine, sometimes multiple times. Even if we move per packing guideline, isn't moving this vaccine multiple times counterintuitive and risky?
A: Vaccines should not be transferred or moved unless it is absolutely necessary. Vaccines that are moved out of their permanent storage for any reason are subject to potential loss of potency. Providers cannot transfer vaccines without prior approval of their responsible entity (LHD or HSR). The LHD or HSR will address appropriate transport materials and identify solution to avoid need for future transfers.

Q: Can Vaxipacs be used for Varicella and MMRV?
A: Vaxipacs can be used to transport Varicella and MMRV as long as the phase change bricks have been frozen at the required temperature and for the appropriate duration. If the phase change bricks are not stored at the required temperature for the required duration, the vaxipac cannot maintain the cold chain for transport.

Q: What is the recommendation on varicella being taken to outreach activities/clinics (back to school clinics at schools)?
A: CDC and the vaccine manufacturer do not recommend transporting varicella-containing
vaccines to off-site clinics. Varicella-containing vaccines are fragile. If these vaccines must be transported to an off-site clinic, CDC recommends transport with a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C). Temperature logs must be kept on all units transporting and storing TVFC vaccine.

Q: What if the vaccines are shipped without temperature strip?
A: Shipments from McKesson, Merck, and the DSHS Pharmacy are all qualified pack outs. Qualified pack outs may not have temperature strips within the shipments. Qualified pack outs are considered viable as long as the shipment has arrived within the appropriate time frame.

Q: Why can't "conditioned" gel packs be placed back in the refrigerator units to have "on hand" for off-site vaccine transport?
A: Gel packs are not allowed to be stored in the refrigerator due to the ability of the gel pack to make the temperature too cold within the unit. Providers that wish to have conditioned gel packs on hand should store the gel pack in a unit that does not contain vaccines, such as the employee lunch refrigerator.

Vaccine Trays
Q: Are the bins being utilized in all units acceptable or should they be ones with holes for good airflow?
A: TVFC submitted our vaccine trays to CDC for approval. CDC approved all vaccine trays that have been distributed by TVFC.

Q: Shouldn't the storage trays be slotted? The ones in the pictures are enclosed.
A: CDC states that slotted trays are best practice; however trays that are open at the top are acceptable. Fully enclosed trays and those with lids are prohibited.

Site Visits and Storage and Handling
Q: I have two providers sharing vaccines; as a result I try to avoid overstocking refrigerators and I have pointed this out to the providers. Overstocking has not been mentioned by TMF during our site visit so am I to assume that this isn't a problem? This was missed on more than one occasion.
A: Issues regarding TMF site visits should be reported to your TVFC Consultant. TVFC Consultants will review issue with TMF and address it with the specific reviewer for your area.

Data Loggers
Q: Is continuous monitoring a recommendation or a requirement?
A: Continuous monitoring of vaccine temperatures is a best practice to ensure vaccine viability. Providers should be encouraged to think about safe guarding vaccines at all time. At this time continuous monitoring is not required.

Q: Are TVFC providers required to have a back-up thermometer in their storage units?
A: TVFC providers are required to have a certified calibrated thermometer in their unit. We do not mandate that they have a back-up thermometer in the storage unit.

Presentation Slides
Q: Will the presentation be made available for viewing at the end of the webinar?
Q: Will we be able to access a copy of the presentation for future reference?

A: The presentation will be posted to the TVFC website: http://www.dshs.state.tx.us/immunize/tvfc/default.shtm

Electronic Vaccine Inventory (EVI)
Q: Is there a step to take with providers who are not removing expired vaccines from EVI? I have found it very difficult to get them to update the information.

A: Providers are required to update EVI as product expires. Providers that are non-compliant with vaccine reporting should not have future orders approved.

Nonviable Vaccine Return Labels
Q: We have received numerous calls from providers saying that they have not received return labels from McKesson. What should they do if they accidently discarded or did not receive a return label?

A: Providers should contact their responsible entity if they have not received a return label within 30 days of submitting the Vaccine Loss Report (VLR). VSG will investigate the return label situation and advise on the course of action.

Q: How long does it take for providers to receive the return label once the VLR has been submitted to DSHS?

A: Due to the processing delay for VLRs, return labels could take up to one month to be received at the provider location. McKesson sends out the label 7-10 days after receiving the notification in VTrckS, which is the end process for VLRs. Issues regarding return labels should be reported to the TVFC Consultant for the HSR.

Q: In my case it has taken more like two months before I receive a label.

A: The length of time to receive a return label varies depending on the submission date of the VLR to the VSG. During peak loss times, such as flu, the amount of time to receive a return label could be extended.

Q: Who should we contact if it takes longer than 7 days to receive a return label? Sometimes it may take a few months before I receive a label.

A: Due to the processing delay for VLRs, return labels could take up to one month to be received at the provider location. McKesson sends out the label 7-10 days after receiving the notification in VTrckS, which is the end process for VLRs. Issues regarding return labels should be reported to the TVFC Consultant for the HSR.

Q: Do we need to refrigerate expired vaccine while waiting for the shipping label?
A: Expired vaccines are no longer viable and should be removed from the storage unit to prohibit accidental administration to patients. Remove from the unit, label as expired, and return to McKesson after a return label is received.

Q: It really helps if the name of the contact person is on the envelope for return vaccines labels. Can McKesson add the contact name on the envelope?

A: TVFC has submitted the request to CDC.

Q: A few providers have their temp logs within normal limits, but fridge borderline cold &/or freezer borderline warm. I "re-educate" them on temp limits, to which they say "we ARE within normal limits" Help!!

A: Providing best practice guidance is the appropriate action to take with providers that have temperatures at the low or high end of the acceptable temperature range. Educating the providers on the importance of safeguarding their vaccine supply, both public and private, is the goal. The goal is to administer appropriately stored vaccine to children to ensure that they are receiving product that will protect them from disease.

Q: If a patient is recalled how do we account for the vaccine, is it cost or is it an exchange?

A: At this time TVFC does not supply vaccine for revaccination. Providers are responsible for purchasing vaccines to revaccinated children due to negligent losses.

Q: Could you send me a list of vaccine and the proper storage for each?

A: The package insert for each vaccine will indicate the proper storage requirement.