TN Department of Health

Memorandum for Record

Date: May 12, 2021

Subject: TDH response and recommendations regarding COVID vaccine mismanagement and wastage by the Shelby County Health Department, 2021.

Situation Summary: On 2/19/2021, Tennessee Department of Health (TDH) was notified of 1,578 expired doses of COVID-19 vaccine at Shelby County Health Department (SCHD). A TDH team was deployed on 2/19/21 to meet with SCHD leadership and determine the cause of this large amount of vaccine wastage. The team determined wastage had been accumulating over weeks and identified an excessive amount of unused vaccine on-site, as well as a lack of formalized policies and procedures for the storage and handling of COVID vaccines. The team also identified a communication breakdown between pharmacy and SCHD nursing staff contributing to ongoing but preventable vaccine wastage, use of unapproved coolers, failure to incorporate Vaccines for Children (VFC) regional immunization representatives in planning, no designated records repository, and an ongoing failure to report administered doses in a timely and accurate fashion.

A follow-up team was deployed on 2/22/21 to provide on-site assistance and collect information, identifying 840 additional expired doses, 64 unused doses, and 12 unaccounted doses. Additionally, a report of suspected theft of vaccines by a volunteer was brought to the attention of the investigating team. This incident was reported to law enforcement but not to the TDH immunization program at the time it occurred. The team was provided a report of a separate incident involving the unauthorized administration of vaccines to two children. While an incident report was provided, the administration of these vaccines was not reported to the Vaccine Adverse Event Reporting System (VAERS) as an administration error, as required. Due to inventory mismanagement and accumulating unused doses of vaccine, a transfer of all onsite inventory and vaccine operations to the City of Memphis was completed on 2/24/2021 and all available vaccine temperature monitoring data was downloaded and sent to TDH Central Office for evaluation. Upon review by TDH Vaccine-Preventable Diseases and Immunization Program (VPDIP), it was apparent that these data were incomplete, did not clearly associate temperature data with specific vaccination sites, and did not clearly document which vaccine lots were being monitored by a given device. The onsite team repeatedly requested written documentation of temperature monitoring, but documents were not readily available at the time of the initial response and, when provided, remained incomplete. Providers are required to document hourly temperatures on the Hourly Vaccine Temperature Log and print the digital data logger report and attach it to the temperature log at the end of clinic days. The Vaccine Coordinator should review and sign the DDL report to ensure no temperature excursions occurred during the day before returning any vaccine to the refrigerator. SCHD did not follow these required procedures as outlined in the Mass Vaccination Module.

On 3/1/2021, in response to a TDH VPDIP request for CDC support, TDH staff and CDC subject matter experts arrived onsite for additional investigation. Objectives included Vaccines for Children (VFC) program assessment, supporting City of Memphis vaccine operations, and retrieving and reviewing all available vaccine stability data to determine if COVID vaccines administered by SCHD were effective or if revaccination of vaccine recipients should be considered. Further detailed review of SCHD vaccine management was necessary because of overall vaccine management concerns and the lack of readily available temperature monitoring data. VPDIP reviewed temperature excursion (TE) data from Digital Data Loggers (DDLs) with the CDC team. Review of lot numbers potentially impacted by TEs was performed using the Tennessee Immunization Information System (TennIIS). Due to deficiencies in SCHD record keeping and apparent data entry errors, confidence in this data was limited. Issues identified included inability to associate vaccine lot numbers with specific DDL TEs and inaccurate vaccine lot numbers recorded in patient records in TennIIS. Initially data was reviewed from 11 DDLs. Further evaluation narrowed the scope to four DDLs that were specifically used for COVID vaccine events and had experienced TEs. CDC initiated a detailed review of SCHD processes and documentation to establish if evidence supported cold chain maintenance for COVID vaccine from pharmacy to patients, and to better inform the need for and scope of potential revaccination.

Data Collection and Sources: Data for this summary were collected by TDH, VPDIP, and CDC subject matter experts including representatives from the CDC COVID-19 Vaccine Task Force and VFC program.

Data sources on storage and handling, as well as maintenance of cold chain for the COVID vaccine were prioritized for collection and review. Detailed stakeholder interviews were conducted with SCHD staff including the Director and representatives of SCHD Emergency Preparedness, Operations, Logistics, and Nursing teams, the Employee Health Director, and Pharmacy staff. Key informant interviews were unable to be completed with the Chief of Nursing and Pharmacist who were no longer employed by the SCHD. Multiple phone call attempts were made by SCHD staff and TDH staff, including the State Epidemiologist and program staff from the central office. In addition, the team requested all available printouts of temperature data from DDLs known to be specifically used for COVID vaccine, copies of all hand-written temperature logs, calendars of field vaccine site events, pharmacy requisitions with vaccine quantity, dates and locations, and inventory and wastage logs. A combination of key informant interviews, review of data logs and pharmacy inventory records were used to assess SCHD COVID Vaccine cold chain process, detailed below and graphically in **Appendix 1.**

COVID-19 Vaccine Storage and Handling Overview:

SCHD Pharmacy Operations

Upon receipt, Pfizer vaccine was appropriately stored in the SCHD pharmacy in ultra-cold shipping containers which were refilled with dry ice according to standard operating procedures. A supply of dry ice was maintained to allow continuous refill of dry ice into the shippers without delay or missed days. Moderna vaccine was moved directly to a freezer (Freezer #5) for frozen storage.

The day prior to COVID Vaccine Point of Distribution (POD) events, the Director of Nursing provided the numbers of vaccines needed for each of several PODs managed by SCHD and the City of Memphis. The pharmacy technician removed one tray (1,170 doses) of Pfizer vaccine from the ultra-cold shipping container and placed it in a refrigerator (refrigerator #3) to thaw. Once thawed, the vials were placed in bags of 20 vials (100 doses) per bag, and those bags were then placed into larger bags for individual POD locations, based upon the number of vaccination appointments scheduled for that POD. Bags were annotated with the count of doses, POD location and date, and the vaccine expiration date, and the bags were placed in a separate refrigerator (refrigerator #7), which was designated the "POD Ready" unit. Lot numbers were written on a separate piece of paper and maintained on inventory sheets within the pharmacy records. Moderna vaccine was moved as needed into refrigerator #3 for thawing the day prior to POD events and was similarly packaged and moved to refrigerator #7, once prepared.

Unused vials from PODs were returned to Refrigerator #7 and labeled as "use first". Returned vaccines were taken to PODs scheduled the following day. On weekends, vaccine was prepared and packed for transport by the lead pharmacist, who was unavailable for interview. Because there was no access to the Pharmacy on weekends, vaccines for Saturday PODs were prepped on Fridays and taken to the Employee Health refrigerator where they were picked up on Saturday mornings prior to the PODs.

No other refrigerators or freezers were used for COVID vaccine storage in the SCHD Pharmacy. Digital Data Loggers (DDLs) for temperature monitoring were attached securely to Refrigerators #3, #7 and freezer #5 (DDL identification numbers: 160500014470, 130500066071, 160500014464); these were not moved between units. DDL data were reviewed by pharmacy staff each week to assess for TEs and records maintained for years 2020 and 2021. These records were made available to TDH and CDC staff.

COVID-19 Vaccine Transport and Vaccine POD Operations

There were 92 POD events planned and executed, from 12/28/2020 through 2/24/2021, which may have used vaccine shipped after 12/18. After count and preparation in the pharmacy, vaccine was packed into an AccuTemp vaccine transport cooler by the pharmacy technician, with a DDL attached to the cooler at time of transport. Key informants from the pharmacy and logistics team reported that the protocol followed did not allow the vaccine cooler to leave the pharmacy if the DDL temperature was out of range (target: 2-8°C). DDLs were not labeled as to which cooler they were attached, and they were moved between cooler units daily. As mentioned, vaccines for Saturday PODs were prepped on Fridays and taken to the Employee Health refrigerator where they were picked up. Transport DDLs were stored in the Employee Health refrigerator between uses and they were left on regardless of vaccine presence. Temperature was reportedly monitored by the logistics team while in transport, with emphasis on maintaining appropriate temperature at all times during transport. There were no additional temperature logs during transport.

On arrival at the POD, vaccine was maintained in the AccuTemp coolers. Coolers were only opened for vaccine access/distribution. Key informants reported that nursing staff were trained and familiar with the process of vaccine administration. The standing policy was reported to be notification of nursing leadership should any TE be noted. Cooler temperature was monitored on an hourly basis and

recorded on a paper record. A variety of paper records were used and 65 out of 92 records (70.7%) were eventually provided to the TDH/CDC team by SCHD.

Vials of unused vaccine sent to POD events were returned in a closed AccuTemp cooler to the Employee Health Clinic refrigerator (detailed below) after business hours. Vaccine was placed directly in the refrigerator within the labeled bag. The Employee Health clinic was locked after business hours and only accessible using a master key. The temperature monitoring DDL from the cooler was placed on an adjacent counter with the probe also in the refrigerator or left in the cooler. Refrigerator temperature was monitored by two separate dedicated temperature monitors.

POD management of volunteer personnel and tracking of vaccine administration was lacking. Management of the POD alternated regularly, a mechanism to ensure the number of vaccines administered matched the number of intake forms received was absent, volunteers regularly disregarded directives from POD management, and reported concerns were not acted upon appropriately. In one instance, a provider witnessed unusual behavior by a volunteer on multiple occasions and believed the volunteer may have been removing vaccine doses from the POD site for unauthorized use. While the provider who witnessed the behavior reported the concerns to management, no adequate follow-up was completed, and the volunteer returned multiple times. The Department of Health has concluded in the course of its investigation that the volunteer in question did in fact unlawfully remove five doses of vaccine from the POD site.

Employee Health Refrigerator Storage

On 1/4/2021, the Employee Health Clinic nursing director reported that COVID vaccine began to be stored in the refrigerator after POD events to facilitate after hours returns of unused vaccine. There is a single refrigerator in the Employee Health (EH) clinic, which was normally utilized for small volumes of occasional PPD and influenza vaccine for HD staff prior to use for COVID vaccine.

The EH refrigerator was not approved by TDH VPDIP to store COVID vaccine. Temperature of the EH refrigerator was monitored continuously by two temperature units mounted on the exterior of the refrigerator, manufactured by Streck and Fisher Scientific. These two units do not provide digital data, though a record of daily min/max temperatures was recorded in a paper binder next to the refrigerator with data available for years 2020 and 2021. Records regarding calibration of the thermometers were not available. Both thermometers were observed to record consistent temperatures.

DDLs used for the vaccine transport coolers were also stored in this refrigerator when not in use to maintain probe thermoregulation (Identification numbers: 160500036023, 160500036317, 160500036331, 160500036323). Note these DDLs were interchangeable and were not labeled at any point as to which was used for which POD or transport event. No DDL was used to monitor the EH refrigerator.

Each morning Monday – Friday, the pharmacy technician prepared an AccuTemp cooler and transported vaccine from the EH refrigerator back to Pharmacy refrigerator #7, the “POD Ready” unit. Returned vaccines were designated as “use first” on the bag and sent out with the prepared vaccine for

the PODs planned that day in a "last in, first out" model. No vaccine was known to have been returned to the EH refrigerator on more than one occasion after a POD.

Temperature Monitoring Data:

- ***Observation***: Temperature logs in the SCHD pharmacy were reviewed for 90 days (December – February), which represents all possible time COVID vaccine was stored. No TEs were noted on any of the three refrigerator and freezer units used for COVID vaccine, and the pharmacy technician confirmed these DDLs were not moved between units. Pfizer shipping containers were used to maintain ultracold temperatures for storage of Pfizer vaccine, as is directed by the manufacturer.

  Interpretation: DDL data taken from the pharmacy shows freezer and refrigerator units used for COVID vaccine storage maintained appropriate temperatures without variation from manufacturer recommendations for Pfizer or Moderna vaccine, both for storage and thawing. Additionally, staff interviews indicate no gaps in dry ice refills to the Pfizer vaccine shippers to maintain ultracold temperatures required for storage.

- ***Observation***: Interviews with logistics and operations staff indicate that they received training on maintaining appropriate temperatures within the vaccine coolers during transport and during POD events. Pharmacy staff confirmed that vaccine would not leave the pharmacy without being within the 2-8°C range. Logistics staff reported training for team members regarding the importance of keeping the vaccine 2-8°C. No reports of excursions were called to logistics or nursing leadership.

  Interpretation: Staff involved in transport and POD temperature monitoring were aware of the manufacturer-recommended temperature ranges and the process required should there be an excursion event.

- ***Observation***: There were 4 DDLs stored in the EH refrigerator for use during transport of COVID vaccine in AccuTemp coolers and for POD event monitoring. These DDLs were not labeled and were left on continuously, regardless of whether or not they were in use. The transport-specific DDLs recorded 45 TEs occurring 1/2/2021-2/24/2021. An algorithm was developed and followed to assess each TE for plausibility, ultimately leading to four events of concern from DDLs to present to the vaccine manufacturers for input on vaccine stability under the reported conditions. The worst-case scenario was presented for each TE based on available DDL data.

  Interpretation: The majority of TEs occurred on days without PODs or outside of business hours. Additionally, TEs of extremely long duration and implausible duration, and TEs at room temperature when DDLs were being stored and not in use for vaccine transport or monitoring,

were excluded. All TEs determined to be plausible were presented to the manufacturers for evaluation.

- ***Observation***: Temperature monitoring was required on an hourly basis at all POD events. These temperatures were recorded on handwritten data sheets. Complete paper temperature logs were produced by SCHD for 65 (70.7%) POD events, of which 8 (8.7% total events) showed documented TEs and 57 (62.0% total days) showed zero TEs[1]. Details surrounding the 8 TEs are as follows**:**
    - TEs 1-3: TEs were documented prior to start of POD events, one at 7:21am, one at 7:56am and one at 8:00am, with maximum temperatures and durations of 12.3°C for less than 60 minutes, 8.3°C for less than 60 minutes, and 8.6°C for less than 60 minutes, respectively. The subsequent temperatures recorded at all PODs were within the 2-8°C range. For the last event, no date was documented on the site temperature log.
    - TEs 4-6: TEs were documented at the close of a POD or end of operating hours at three events. One at 6:30pm (last reading of the day) and two at 5pm (subsequent temperature 5.7°C). In two of these cases, duration of excursion was less than 60 minutes as vaccine was returned to the EH refrigerator following POD events. The final event was less than 2 hours with a maximum temperature of 8.8°C.
    - TE 7: One excursion event was documented for approximately 9 hours, with a minimum temperature of 0.9°C, and notation from staff that the temperature sensor was against an ice pack, resulting in an inaccurate reading (ice would read 0°C). Sensor was repositioned after this time and temperatures were within range for the remainder of the POD.
    - TE 8: One excursion event occurred for approximately 3 hours, with a maximum temperature of 9.4°C. Documentation indicates this vaccine was marked "Do Not Use" and TDH was contacted for direction on whether or not the vaccine was stable to administer.

  Interpretation: Available objective evidence from POD events shows that vaccine was stored at appropriate temperatures for a majority of the time it was monitored (87.7% of available temperature logs show no TE). Documentation and annotations by SCHD staff demonstrated that efforts were made to maintain temperatures according to manufacturer recommendations within coolers. All excursions documented by SCHD were assessed retrospectively with the relevant manufacturer including brief (<60 min) and small temperature excursions of less than 1 degree. While SCHD had clear deficiencies in processes to retain and produce all written temperature logs, review of available data and staff interviews indicates that staff of POD events were consistent in their temperature monitoring approach.

- ***Observation***: The Employee Health (EH) refrigerator was continuously monitored by the EH nursing director using two temperature probes directly attached to that refrigerator. These two probes were directly observed by TDH and CDC staff to consistently read the same temperature value. Each business day, minimum and maximum temperatures were written down on a daily

[1] Updated data as of 3/12/2021.

documentation record. Three months of data (December – February), was reviewed by TDH and CDC staff, during which time there was one TE noted on 1/14/2021 at 8.2°C. Historical data for this refrigerator was also reviewed during 2020, during which time no excursions were noted. No certificates of calibration were requested.

Interpretation: The EH refrigerator reliably maintained temperature ranges of 2-8°C. There was no evidence that the cold chain was not maintained in this unit based on the written temperature log. Vaccine was removed the day following a POD event and returned to the pharmacy refrigerator. One documented TE was recorded during a time when vaccine was not present.

- ***Observation***: Eight TE events were identified from the paper temperature monitoring data, as discussed above. Of these, one was addressed in real-time by the SCHD staff monitoring vaccine temperature and the vaccine was marked as "do not use" until discussion with the TDH VPDIP storage and handling subject matter experts. The second was annotated with a clear and plausible reason for the low documented temperature (i.e., probe directly in contact with ice, and therefore determined not to be representative of the ambient temperature surrounding vaccine). Four TEs were identified from the transport DDL data, also discussed above. A list of 10 COVID vaccine TEs from written temperature logs were presented to vaccine manufacturers for their input. Vaccine manufacturers and lot numbers were matched with these specific excursions using pharmacy inventory data.

  Applicable lot number, date, duration, and maximum or minimum temperature data were presented to Pfizer-BioNTech and Moderna. Data from each company supported the stability of vaccines administered during the period of interest based on the review of SCHD data and vaccine cold chain management.

  Interpretation: All TEs of concern were presented to their respective manufacturer for review. Both manufacturers provided data to support the stability of vaccines outside of the recommended temperatures. In addition, Pfizer's most recent Storage and Handling Document supported a broader range of temperature stability than any of the documented excursions.

Conclusions:

Multiple deficiencies were identified in the SCHD management of vaccine inventory including wastage, a large accumulation of unused doses, and inadequate record keeping. TDH responded immediately and moved all vaccine inventory and operations to the City of Memphis to ensure there was no disruption in COVID vaccination for Shelby County residents. Once this most urgent action was completed, a comprehensive assessment of COVID vaccine cold chain processes at SCHD was conducted. Health department staff consultation and analysis of available data from 12/28/20 (first POD) to 2/24/2021 (vaccine transferred to City of Memphis) identified deficient record keeping but cold chain data indicated that practices were consistent with acceptable storage of COVID vaccine. Extensive assessment and critique of all available evidence by TDH, CDC, FDA, and both vaccine manufacturers supported that vaccine was maintained within acceptable temperatures from receipt in the pharmacy to

the point of administration. All plausible documented TEs identified at POD events were presented to the vaccine manufacturers and stability data from the manufacturers supported that the vaccines did not experience extremes of temperatures sufficient to render them ineffective.

Limitations in these data exist due to deficiencies in SCHD protocols and record keeping. Temperature data from the DDL transport logs were not clearly labeled nor clearly associated with the presence of vaccine. DDL data was assessed to identify plausible excursions at PODs without a paper temperature logs. Following assessment of all available data, in combination with results of multiple key informant interviews and consultation with CDC, FDA, and vaccine manufacturers, it is unlikely COVID vaccines could have reached extremes of temperature affecting their stability during the period of interest.

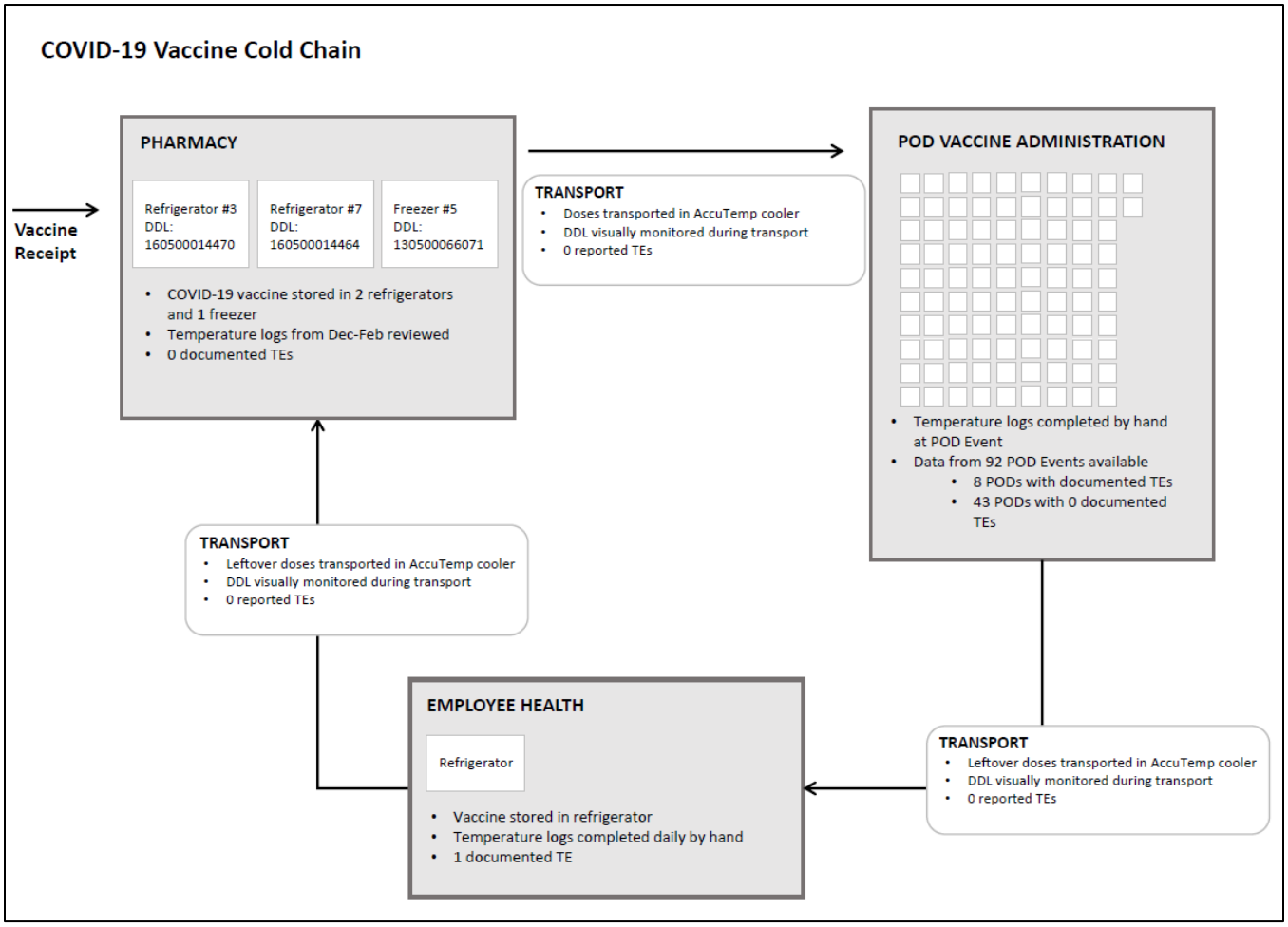
Recommendations:

- Ongoing assessment and corrective actions to support the vaccine program should be carried out once new leadership is identified in SCHD. A comprehensive list of action items will be provided to SCHD by CDC and TDH for remediation.
- Available evidence supported that individuals received stable COVID vaccine doses from SCHD POD sites, and revaccination is not recommended based on these data.
- SCHD should review and formalize processes for training, pharmacy operations, cold chain management, and record keeping before implementing any future large-scale vaccine operations.
- Clear chain of command and defined responsibilities from POD operations to headquarters need to be adopted to ensure reporting of mishandling, wastage, or other improper activity is addressed promptly and adequately.

Attachments:

Appendix 1: Vaccine Cold Chain Overview

Appendix 1:


COVID-19 Vaccine Cold Chain
Vaccine Receipt
PHARMACY
Refrigerator #3 DDL: 160500014470
Refrigerator #7 DDL: 160500014464
Freezer #5 DDL: 130500066071
• COVID-19 vaccine stored in 2 refrigerators and 1 freezer
• Temperature logs from Dec-Feb reviewed
• 0 documented TEs
TRANSPORT
• Doses transported in AccuTemp cooler
• DDL visually monitored during transport
• 0 reported TEs
POD VACCINE ADMINISTRATION
• Temperature logs completed by hand at POD Event
• Data from 92 POD Events available
• 8 PODs with documented TEs
• 43 PODs with 0 documented TEs
TRANSPORT
• Leftover doses transported in AccuTemp cooler
• DDL visually monitored during transport
• 0 reported TEs
EMPLOYEE HEALTH
Refrigerator
• Vaccine stored in refrigerator
• Temperature logs completed daily by hand
• 1 documented TE
TRANSPORT
• Leftover doses transported in AccuTemp cooler
• DDL visually monitored during transport
• 0 reported TEs