

A REPORT
TO DAVIS COUNTY HEALTH DEPARTMENT LEADERSHIP AND
THE DAVIS COUNTY AUDIT COMMITTEE



A Fraud Audit of Davis County Health Department Immunization
Department

February 7, 2023

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Scope:

Three reports filed through Lighthouse (Davis County Fraud & Ethics Hotline), by employee's working in the Davis County Health Department-Immunizations Center, alleged that fraud had occurred. The type of fraud reported was falsification of medical records, specific to immunizations administered through the Health Department.

It was reported that the Immunizations Bureau Manager instructed staff to "borrow" from the Vaccines for Children (VFC) program when the Health Department's private stock would run out. To conceal the "borrowing" medical records (encounter forms) and labels on the vaccine vials were peeled off and replaced. Then at a later date in time when a vaccine from the Health Department's private stock would arrive labels would be removed from individual vials then relabeled and placed in the VFC stock.

All reports alleging fraud are investigated by the Davis County Auditor's Office; that same process was followed in this case.

Interviews were conducted with key staff members working within the Davis County Immunizations Clinic, other support staff, and members of management within the Health Dept. In addition, other documentation such as Utah VFC provider requirements were reviewed to determine if the Immunization Clinic was in compliance. Further, a review of Utah State Statute 58-31b-101 (Nurse Practice Act) was conducted to determine if unprofessional conduct occurred related to the handling of medical records.

Key Facts One:

Utah Vaccine for Children (VFC) program requirements explicitly state that borrowing from public stock (VFC Stock) is prohibited. Per the VFC requirements, it states; "Maintain sufficient inventory to prevent using public vaccine for non-VFC eligible patients as well as ensuring available for VFC-eligible patients. Borrowing between stocks is not allowed."

Daily VFC provider requirements state that public and private vaccine stock must be stored separately and cannot be stored in the same refrigerator. VFC vaccine stock must also be stored in original packaging. Further, all spoiled and expired public vaccine stock must be returned to the Utah VFC program. Other daily VFC requirements state; "Submit to the Utah Statewide Immunization Information System (USIIS) within 14 days of administration detailed information regarding all administered doses of vaccines, regardless of patient age or eligibility status. Vaccine record submission will include specifics about the vaccine and eligibility category." As stated above all vaccine doses must be accounted for and reported to the Utah VFC. Lastly, VFC provider requirements state: "Operate in a manner that prevents fraud and abuse of the VFC program."

Monthly VFC provider requirements state that a written physical inventory be maintained and reconciled. Quarterly provider requirements include a provision that requires a dose's administered report be submitted by the 15th of the month after the quarter ends.

Yearly VFC provider requirements include the following:

- Review and update the provider Vaccine Management Plan
- Completion of annual re-enrollment documents
- Completion of annual training due for the primary and back-up contact by the provider
- Participation in compliance site visits and other educational opportunities associated with VFC program requirements

Section 3-5.5 of the Utah VFC Provider Requirements defines what misuse and borrowing is, then goes on to explain why borrowing is not allowed, see requirements below:

- The Utah VFC program does not allow borrowing and/or replacement of doses between vaccine supplies under any circumstances.
- Administration of any publicly supplied vaccine to a non-eligible patient is not allowed. In addition, replacement of a provider's private vaccine supply with any publicly supplied vaccine is not allowed.
- Vaccine borrowing includes intentional or accidental administration of any publicly supplied vaccine to a patient who does not meet eligibility requirements with the intent of replacing from the provider's private vaccine supply.
- Providers must maintain separate vaccine inventory for publicly and privately purchased supplies.

Section 3-5.5 also explains what must occur if intentional or accidental misuse or borrowing occurs:

- The provider is required to notify the Utah VFC Program immediately after discovering the incident.
- The provider must also provide specific information for each dose including patient information, vaccine information including lot numbers, vaccine manufacturer, a reason for use of wrong, and plan of action to prevent future misuse.

The Utah VFC Program may request reimbursement of each dose misused. Other outcomes might include referral to Medicaid Program Integrity and removal from the VFC Program.

Section 3-5.6 describes the restitution process if vaccines are misused or borrowed:

- ...“VFC providers must comply with all Vaccine Management requirements for vaccine storage, handling, and accountability in an effort that avoids fraud, abuse, and waste. Upon signing the VFC provider profile and enrollment agreement, the provider agrees to replace vaccine loss on a dose-per-dose basis.”

Key Findings One:

The Davis County Immunizations team led by the Bureau Manager violated the Utah VFC provider requirements by borrowing from VFC public stock to supplement private stock doses administered and vice a versa, see ([attachment A](#)).

Medical records were altered/edited (patient encounter forms) and labels removed/switched from vaccine doses to conceal the borrowing between VFC public stock and Davis County Health Department's private vaccine stock, see ([attachment B](#)). According to VFC provider requirements borrowing cannot occur under any circumstances, as defined by these requirements, fraud and abuse of the vaccine supply occurred then was concealed. This practice of borrowing between public and private vaccine supplies has been occurring since 2014. Due to the concealment of this practice, the Davis County Health Department cannot account for every dose this occurred to.

Because borrowing between private and public stock was occurring then concealed, another issue was created. Vaccines from different lot numbers or manufactures created a potential safety issue since the person receiving the vaccine cannot be traced and notified in the event of a recall, see ([attachment C](#)).

Recommendation One:

Davis County Health Department Management should continue to work with the Utah VFC Program to report the results of this audit along with any additional details management has discovered while investigating this matter internally. Management should work with the Utah VFC to mitigate any damages from the practice of borrowing, then implement procedures to ensure borrowing never occurs again.

Change the culture of the immunizations department so that employees feel empowered to report questionable behavior noticed within the department. Cultivate an environment where employees are able to speak up and report issues outside the ordinary chain of command.

Key Facts Two:

Utah State Statute 58-31b-101 Nurse Practice Act, defines professional standards of conduct for nurse's practicing in the state. As defined in subsection 58-31b-502 (k) and (q), unprofessional conduct occurred related to the practice of borrowing and concealment of that borrowing, see below:

- (k) failure to file or record any medical report as required by law, impeding or obstructing the filing or recording of such a report, or inducing another to fail to file or record such a report
- (q) falsely making an entry in, or altering, a medical record with the intent to conceal:
 - A wrongful or negligent act or omission of an individual licensed under this chapter or an individual under the direction or control of an individual licensed under this chapter

Utah State Statute 58-31b-503 describes penalties and administrative actions for unlawful conduct or unprofessional conduct. Section 503-6a states the following:

1. 6(a)
 - a. If upon inspection or investigation, the division concludes that a person has violated the provisions of Section 58-31b-401, 58-31b-501, 58-31b-502, Chapter 1, Division of Occupational and Professional Licensing Act, Chapter 37, Utah Controlled Substances Act, or any rule or order issued with respect to these provisions, and that disciplinary action is appropriate, the director or the director's designee from within the division shall:
 - i. promptly issue a citation to the person according to this chapter and any pertinent administrative rules;
 - ii. attempt to negotiate a stipulated settlement; or
 - iii. notify the person to appear before an adjudicative proceeding conducted under Title 63G, Chapter 4, Administrative Procedures Act.

Key Findings Two:

As part of the audit procedures conducted, all six licensed nurse's working in the Davis County Immunizations program and under the direction of the Bureau Manager, were interviewed. All six licensed nurse's participated in the borrowing between public and private vaccine stock. When asked why they participated two reasons were cited. First, all nurse's stated that they were acting under the direction and instruction of the Bureau Manager. Second, they claimed they did not know it was a violation of VFC provider requirements or any other standards.

While the nursing staff working in the Davis County Immunizations department may not have known that borrowing violated the requirement of VFC guidelines they should have known that altering medical records was a violation of the Nurse Practice Act. Further, the nursing staff would have to ask the records/billing department for a copy of the patient encounter forms waiting to be scanned, so they could then change the vaccine label on the form to a different vaccine label once new stock came in. Once the document was edited by nursing staff members, it was scanned into the system. This essentially eliminated the paper trail of what actual occurred and concealed the borrowing. In addition, it is impossible to go back in time and track or quantify how often this occurred.

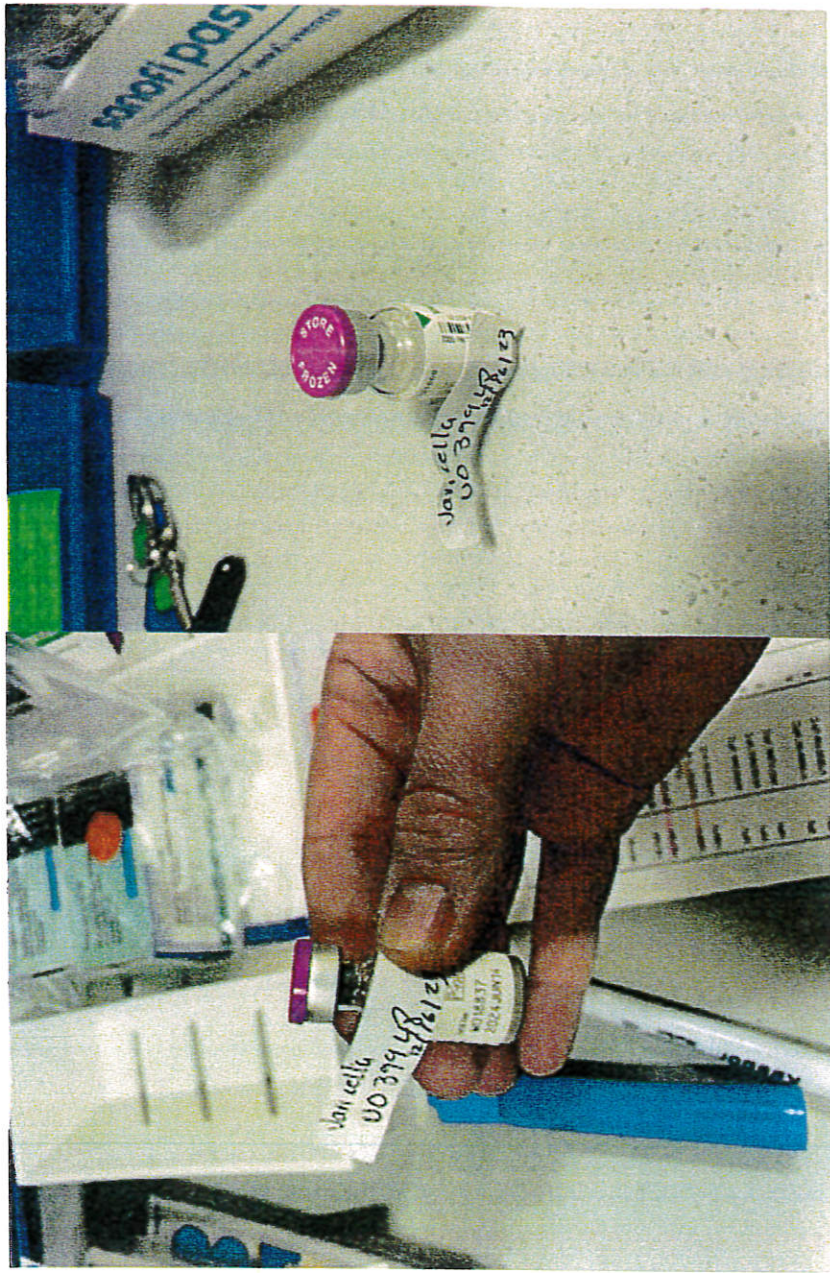
Recommendation two:

Based on the guidance provided in 58-31b-503 disciplinary action may be appropriate for the nurse's involved in the editing of medical records and the concealment of those actions. While the nurse's acted under the direction of the Bureau Manager, it appears that each licensed nurse should be reported to the Division of Occupational and Professional Licensing (DOPL).

Conclusion:

As reported through the Davis County Fraud Hotline, It was confirmed during the audit process that medical records were edited/alterd in order to facilitate the borrowing of vaccines between the private stock purchased by Davis County and public stock issued to the county by the Utah VFC program. As documented in the VFC provider requirements, the act of borrowing form VFC vaccine stock is strictly prohibited. Even if this borrowing occurs accidently, Utah VFC requires the provider to give a detailed explanation for each and every dose of vaccine this occurred with. The actions of the Davis County Immunization department under the direction of the Bureau Manager constitute a misuse, fraud/abuse, of public VFC vaccine stock.

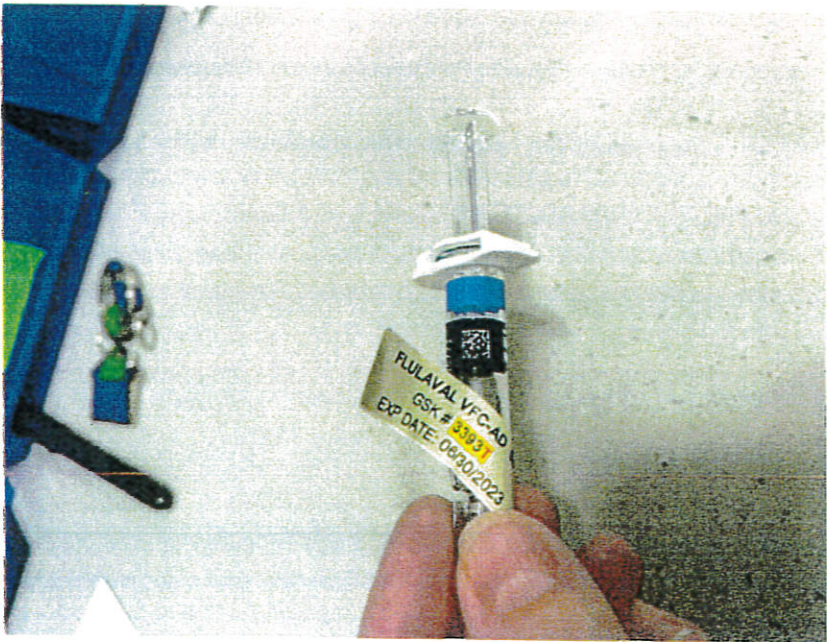
Recommendations have been made that Davis County Health Department continue to work in cooperation with the Utah VFC program to remedy the damage done from the misuse and abuse of the public VFC vaccine stock, along with working out the appropriate steps to provide adequate restitution as required. If Davis County Health Department Management provides a written response to this audit it will be included as part of the audit report.



- Label placed on vial is wrong
- Borrowed supply, replacement



Private lot
given to VFC to replace borrowed doses.
Lot # covered, wrong lot # placed on box/labels for charting



Label placed is wrong



VFC lot
Lot # covered / Replaced to wrong lot # to replace borrowed supply

TO BE COMPLETED BY THE VACCINE ADMINISTRATOR

Vaccine Type	CPT	Manufacturer Lot # / Exp Date	Vaccine Administration Date		Nurse Initials	VIS Date	D&D
			Site	Dose Route			
DTAP (DAPTACEL) Age (2,4,6,15-18 mo, 4-6 yrs)	90700		RD/VL	0.5 ml IM		08/06/2021	
HEP A PED (HAVRIX) (0,6 mo) Age 12 mo - 18 yrs	90633		LD/VL			10/15/2021	
HEP B PED (ENGERIX) (0,1,6 mo) Birth - 19 yrs	90744					10/15/2021	
HIB (PEDVAX) Age (2,4,6,12-15 mo)	90647					08/06/2021	
HPV9 (GARDASIL) (9-14 yr/0,6mo) (15-26 yr/0,2,6 mo)	90651					08/06/2021	
MCV4 (MENQUADFI) Age (12, 16yrs & older)	90619					08/06/2021	
MEN B (BEXERO/TRUMEMBA) (0,1 mo) (Age 16 yrs - 23 yrs) / (0, 6 mo)	90620 90621					08/06/2021	
MMR Age (12-18mo & 4-6 yrs) or (0-1 mo)	90707					08/06/2021	
PCV13 / PPSV23	90670 90732					10/30/2019	
POLIO (IPOL)	90713					08/06/2021	
ROTAVIRUS (ROTATEQ) Age (2,4,6-8 mo)	90680					10/15/2021	
TDAP (ADACEL) 7 yrs & up	90715		RD LD	0.5 ml IM		08/06/2021	
VARICELLA (VARIVAX) (12-18 mo & 4-6 yrs) / (0-1 mo)	90716	VARICELLA PRIVATE MERCCK # U039948 EXP DATE: 12/16/2023	RA/LV LA/VL	0.5 ml SQ	OS	08/06/2021	
DTAP / POLIO (KINRIX / QUADRACEL) 4-6 yr (5 Dose Dtap & 4 Polio)	90696		RD LD	0.5 ml IM		10/15/2021	
DTAP / POLIO / HEP B (PEDIARIX) 2,4,6 mo/ 1st 3 doses DTaP Age (6wks - 6yrs)	90723		RD/LV LD/VL	0.5 ml IM		10/15/2021	
DTAP / HIB / POLIO (PENTACEL) 2,4,6 mo/ 1st 4 doses DTaP Age (6wks - 4yrs)	90636		RD/LV LD/VL	0.5 ml IM		10/15/2021	
MMR / VARICELLA (PROQUAD) (12-18mo & 4-6yr) Age (12mo-12 yrs)	90710		RA/LV LA/VL	0.5 ml SQ		10/15/2021	
DTAP / POLIO / HEP B / HIB (VAXELIS) (2, 4, 6 mo) Age (6 wks - 4 yrs)	90697		RD/LV LD/VL	0.5 ml IM		10/15/2021	
TYPHOID INJ (TYPHIM) 2 yrs & older	90691		RD LD	0.5 ml IM		10/30/2019	
TYPHOID ORAL (VIVOTIF) 6 yrs & older	90690		ORAL	0.5 ml PO		10/30/2019	
YELLOW FEVER (YF-VAX) 9 mo & older	90717		RA/VL LA/VL	0.5 ml SQ		04/01/2020	
JAPANESE ENCEPHALITIS 2 yrs & older (0, 7 d) 13 yrs (0,28d)	90738		RD/VL LD/VL	0.5 ml IM .25 ml IM		08/15/2019	
OTHER							

Example of lot # switching occurring if wrong type given.
i.e. Private stock given put VFC eligible

COVID-19 Last dose: _____ Date: _____ 1st Dose 2nd Dose 3rd Dose Booster

Vaccine Type	CPT	Manufacturer Lot # / Exp Date	Site	Dose Route	Nurse Initials	EUA	D&D
PFIZER		COVID 5-11Y DCHD PFIZER # FL2757 EXP DATE: 09/30/2022	RD/VR LD/VL	0.3 ml IM	OS		
MODERNA			RD/VR LD/VL	IM			

PAYMENT SECTION (For Office Use Only)

Cash \$	Credit \$	Check # / \$	VFC Eligible <input type="checkbox"/>	By
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Attachment C

Date	Client Name	Private vaccine name & lot #	Given as VFC name & lot #
11/19/21	#323752	Given VFC name Lot # 1024300	Private VFC should be private
11/22/21	#323752	Lot # 3085	Lot # 3085
8/30/22	#328796	EP47E Hep. A Peds	Hep. A Peds CN3G5
10/14/22		W018835	W018837
10/18/22		W018836	W018837
11/23/22		W018836	U029496 ✓
		Private borrowed vfc	
11/29/22		W019930	U029496 ✓
11/29/22		Arizpe W019930	U029496 ✓
12/1/22		W019930	W019937 ✓
			U029496 ✓
12/2/2022		W018835	W018837 ✓
		W018836	U029496 ✓
12/2/2022		W018836	W018837 ✓

from BTF =>

POX