NORTH DAKOTA

OFFICE OF THE STATE AUDITOR

State Auditor Joshua C. Gallion

North Dakota Department of Health

Audit Report for the Biennium Ended June 30, 2021

Client Code 301

This audit has been conducted by the Office of the State Auditor pursuant to authority within North Dakota Century Code Chapter 54-10

Office of the State Auditor

Office of the State Auditor

REPORT HIGHLIGHTS

North Dakota Department of Health

Audit Report for the Biennium Ended June 30, 2021 | *Client Code 301*

WHAT WE LOOKED AT AND WHY

North Dakota state law requires that our team perform an audit once every two years. This includes a review of financial transactions and determining that expenditures are correct. Our audit reports any errors, internal control weaknesses or potential violations of law identified in significant or high-risk functions of the agency.

AUDIT REPORT HIGHLIGHTS

Inaccurate Inventory and Storage Locations

The DoH did not have evidence for reconciliation of COVID-19 vaccine inventory and storage location to the statewide inventory list.

Read more on page 7

Vaccines Issued From Storage Location with No Temperature Data

Out of 144,988 issued doses, 12,828 doses were issued out of a storage location we could not verify temperature data for.

Read more on page 10

Improperly Stored and Tracked Vaccines

Multiple records were incorrectly tracked or missing, leading to errors in the chain of custody and cold chain.

Read more on page 13

Not Following Lab Policy for Approval of Microplates

The DoH State Lab does not have evidence of approval of RT-PCR test runs with more than 25% positivity rate per testing microplate. This could result in inaccurate test results reported to individuals.

Read more on page 18

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HAVE QUESTIONS? ASK US.

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Introduction

North Dakota Department of Health

August 31, 2022

We are pleased to submit this audit of the North Dakota Department of Health for the biennium ended June 30, 2021. This audit resulted from the statutory responsibility of the State Auditor to audit or review each state agency once every two years. The same statute gives the State Auditor the responsibility to determine the contents of these audits.

The primary consideration in determining the contents of these audits is to produce informative audits to improve government. Statutory audit requirements are an important part of these audits and are addressed by our standard audit objective. Whenever possible, additional audit objectives are included to increase responsiveness and effectiveness of state government.

Allison Bader was the audit manager. Inquiries or comments relating to this audit may be directed to the audit manager by calling (701) 328-2241. We wish to express our appreciation to the Department of Health's staff for the courtesy, cooperation, and assistance they provided to us during this audit.

Respectfully submitted,

/S/

JOSHUA C. GALLION
NORTH DAKOTA STATE AUDITOR

TERMS USED IN REPORT

Appropriation: An amount authorized by the North Dakota Legislative Assembly to be spent for a specific purpose.

Blanket Bond Coverage: Insurance to state agencies for any default or wrongful act on the part of any public employee or public official.

Centers for Disease Control and Prevention (CDC): The national public health agency for the United States. It is a federal agency, under the Department of Health and Human Services and is responsible for protecting the health, safety and security threats, both foreign and in the U.S.

Cold Chain: A cold chain is a temperature-controlled supply chain that includes all vaccine-related equipment and procedures. The cold chain begins with the cold storage unit at the manufacturing plant, extends to the transport and delivery of the vaccine and proper storage at the provider facility, and ends with the administration of the vaccine to the patient (see page 6 for an example).

ConnectND (Peoplesoft): The accounting system for North Dakota.

Digital Data Logger (DDL): A device used to collect and record physical data such as temperature to ensure vaccine quality and regulatory compliance during storage, transportation, and handling.

Emergency Use Authorization: In emergencies, the FDA can authorize unapproved medical products to be used during the emergency to diagnose, treat, or prevent serious or life-threatening diseases, when certain criteria are met.

Food and Drug Administration (FDA): A federal agency under the U.S. Department of Health and Human Services. They are responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices.

ICAM: Inventory system used by the North Dakota Department of Health for tracking and monitoring vaccines and other supplies.

Internal Control: Policies and procedures that ensure reliable financial reporting, safeguard assets, promote accountability and efficiency, and prevent fraud.

Issued Vaccine: Vaccine taken out of the warehouse for use with a provider or removed from the ICAM system but physically left in the warehouse, intended for a pop-up clinic and no longer available for distribution elsewhere.

iPassport: The lab's information technology system for tracking their employee's competency and required education.

Licensed Ambulance Operation: Entity that provides emergency medical services to the citizens of North Dakota.

Noncompliance: Failure to act in accordance with a wish or command.

North Dakota Century Code (N.D.C.C.): Collection of all the statutes passed by the North Dakota Legislative Assembly.

North Dakota Immunization Information System (NDIIS): System used by the Health Department to record and track vaccines including the COVID-19 vaccine.

RT-PCR Test: Reverse Transcriptase Polymerase Chain Reaction tests are considered the "gold standard" tests for detecting COVID-19. These tests are authorized to give a qualitative (positive or negative) result under the Emergency Use Authorization for the SARS-CoV-2 virus.

Stock Vaccine: Vaccine still in the ICAM system available to be distributed elsewhere or removed from the ICAM system but physically left in the warehouse, intended for a North Dakota Department of Health pop-up clinic.

Audit Results

COVID-19 Vaccine Storage and Handling

OBJECTIVE

Are COVID-19 vaccines that originated from the North Dakota Department of Health (DoH) warehouse in Bismarck stored and handled according to Center for Disease Control and Prevention (CDC) Guidelines?

CONCLUSION

We found instances where the COVID-19 vaccines originating from the state warehouse were not adequately stored or handled according to CDC guidelines.

BACKGROUND

On May 15, 2020, the White House announced Operation Warp Speed to accelerate the development, production, and distribution of the COVID-19 vaccine, therapeutics, and diagnostics to deliver 300 million doses of vaccines by January 2021.[1]

Our team determined there was potential for increased risk to the citizens of North Dakota associated with the COVID-19 vaccine storage and handling because of the following:

- Distribution logistics involving the cold chain.
- Potential for fraud, waste, and abuse because the vaccine was in high demand, and was not readily available to the public.
- Complexities of three new vaccines with three different storage and handling requirements. If CDC guidelines, based on manufacturer's requirements, are not met for the COVID-19 storage and handling, there is potential for an ineffective vaccine response. This could lead to the need for revaccination, inadequate immune response, ineffective protection against the COVID-19 virus, and waste of the vaccine.[2]

According to the CDC[3], for reliable storage (cold chain), three elements must be in place:

- Well-trained staff (See Finding 2021-03).
- Reliable storage and temperature monitoring equipment (See Finding 2021-02).
- Accurate vaccine inventory management (See Finding 2021-01).

Cold Chain Definition

A cold chain is a temperature-controlled and monitored supply chain that must be maintained with all vaccine-related equipment and procedures. The cold chain begins with the cold storage unit at the manufacturing plant, extends to the transport and delivery of the vaccine and proper storage at the provider facility, and ends with the administration of the vaccine to the patient[4] (see following page).

Two Scope Limitations Identified

Limitation One: Unable to Connect Digital Data Loggers with Vaccine Shipment

The DoH used digital data loggers (electronic devices which record temperature data) to monitor and store the temperature of shipments of vaccines while in transportation. In addition, a DoH employee oversees the transport and completes a written log of the vaccine including amount of vaccine in transport, 30 minute interval temperature readings from the digital data logger

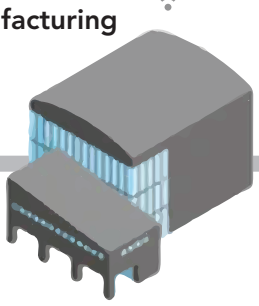
[1] *Operation Warp Speed Delivers Best Early Vaccination Rate of the G20 published by the Council of Economic Advisers, Executive Office of the President of the U.S. January 15, 2021.*

[2,3] *Vaccine Storage and Handling Toolkit published by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services. March 4, 2021. page 3, 5-6.*

[4] *Storage and Handling: Epidemiology and Prevention of Vaccine-Preventable Diseases 14th Edition published by the CDC. August 2021. Page 53.*

Cold Chain Process

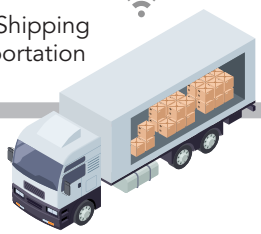
Vaccine Manufacturing



Dose Vial Packaging

Temperature-sensitive Packaging

Large Shipping Transportation



Large Shipping Cases

Temporary Warehouse Storage

DoH State Warehouse

Small Shipping Cases

Small Shipping Transportation

Temperature Controlled Storage

Points of Care

Administration of Vaccination

- Transport Digital Data Loggers
- Static Temperature Monitoring Device

and additional required information. The digital data loggers did record temperature data, but the shipment of vaccine they were transported with was not tracked. Our team was not able to locate some of these logs and we found some logs were not completed correctly. Because of this, there was no way to verify the written log records with digital data logger temperatures to determine what time vaccines were in transport and whether vaccines transported were kept at the documented temperature during shipping.

See Finding 2021-03 for more information on the digital data loggers.

Limitation Two: Missing Temperature Documentation

Temperature documentation was missing for vaccines transported to pop-up clinics and providers. Because of the missing documentation, our team was unable to verify completeness of the records and some storage temperatures. See Finding 2021-03 for additional information.

The DoH was also unable to provide documentation to verify when vaccine was stored in two fridges located at the state warehouse. The two fridges located at the loading dock (referred to by the DoH as dock fridges) were used to store vaccines that were returned from pop-up clinics. There was no documentation for when vaccines were placed in the dock fridges and these fridges had a history of not keeping proper temperatures.

Because of this, our team could not verify when vaccines were located in the fridge or if they were stored at the correct temperature. See Finding 2021-03 for additional information.

Our team was also not able to obtain temperature readings from an ultra-cold temperature unit. During the audit period, ICAM (inventory system used by the DoH for tracking and monitoring supplies of COVID-19 vaccines and other supplies and vaccines) records showed Pfizer vaccines were issued from the unit. This particular vaccine needed to be kept at ultra-cold temperatures, but without documentation of the temperature readings, we could not verify this vaccine was kept within correct temperature ranges while at the state warehouse location. Read more under Finding 2021-02.

FINDING 2021-01

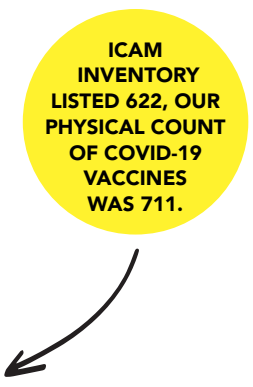
Inaccurate Inventory and Storage Location of COVID-19 Vaccine Vials

WHAT HAPPENED

The DoH could not provide evidence they routinely reconcile COVID-19 vaccine inventory and storage location to the ICAM inventory list. We also could not identify the last time a reconciliation was performed.

Count of COVID-19 Vaccines During Audit

VACCINE MANUFACTURER	ICAM INVENTORY	PHYSICAL COUNT
Johnson & Johnson	11	11
Moderna	405	493
Pfizer	206	207
Totals	**622**	**711**



Physical Count of Vaccine Vials Did Not Match Inventory Records

A physical inventory count done by our audit team on August 8th, 2021 found the number of vaccine vials did not match ICAM inventory records.

DoH warehouse staff were present during the inventory and counted the vaccine inventory with our audit team. The ICAM inventory records identified 622 vials of vaccine on August 8th, 2021, while our actual physical count was 711 vials of vaccine (see page 7).

Physical Location of Vaccine Did Not Match Inventory Records

The physical vaccine count also found the actual vaccine storage location was different than what was listed in the ICAM system.

During the August 8th physical inventory count, our team found 140 doses of the Moderna vaccine in the freezer but they were listed in ICAM in the fridge location.

The Moderna vaccine needs to be stored frozen between -15° and -50° Celsius. This vaccine can be stored at fridge temperatures of 2° to 8° Celsius, but that decreases expiration of the vaccine to 30 days from the date its taken from the freezer to be stored at fridge temperatures. The Moderna vaccine cannot be placed back in the freezer once it has been stored at fridge temperatures.[6]

Because the physical inventory was performed on a specific date, we are not able to determine if the vaccine was at one time located in the fridge as shown in the ICAM inventory record. The vaccine was located in the freezer during our count, where it would have had the maximum shelf life.

DoH Couldn't Identify Already Issued Vaccine vs. Stock Vaccine

We discovered some vaccines were issued out of the ICAM system for future administration at planned DoH pop-up vaccination clinics without physically setting the vaccine aside and labeling it for future use or stock vaccine. Because of this, it was included in the physical inventory count.

DoH staff indicated vaccines for pop-up clinics are held in bins labeled with future pop-up clinic locations. During our August 8th physical count, we found this to be true in the fridge location, but in the freezer location, it was not possible to differentiate what was stock vaccine still in ICAM and what was issued out of ICAM designated for pop-up clinics. These vaccines in bins were not counted in our totals because it was inventory that had already been issued out of ICAM for DoH use at pop-up sites.

DoH indicated that vials of vaccine that would soon be expiring were returned to their warehouse for distribution to other sites, but were not added back into ICAM, as it had already been transferred out through NDIIS (North Dakota Immunization Information System). Additionally, DoH indicated approximately 80 vials of the errored count vials were inventory that had been issued out of ICAM to the DoH for use at pop-up clinic sites, but the vaccine was not separated from the general warehouse inventory in the freezer location.

BACKGROUND

Vaccine inventory should be reconciled with a physical count and review of vaccine location at least on a monthly basis.[7]

COVID-19 vaccine products are temperature-sensitive and must be stored and handled correctly to ensure efficacy and maximized shelf life.[8] Proper inventory reconciliations can help prevent improper storage and waste of the vaccine.

Inaccurate records could lead to:

- Waste by disposal of vaccines because of incorrect storage.
- Shortened expiration dates of vaccine.
- Vaccine ineffectiveness when administered.[5]

[5] *COVID-19 Vaccine Storage and Handling Toolkit. March 21. Page 3.*

[6] *Moderna Covid-19 Vaccine Storage and Handling Summary published by the Centers for Disease Control and Prevention. April 23, 2021.*

Internal control procedures should include reconciliations, ongoing monitoring, and corrective actions for deficiencies (GAO-14-704G para 16.04, 16.05, 17.05, 17.06, 10.10).

RECOMMENDATION

We recommend the Department of Health follow CDC guidance to reconcile all vaccines in storage on a monthly basis, including verifying the location in ICAM to maintain accurate vaccine inventory records.

DEPARTMENT OF HEALTH RESPONSE

DoH team members responsible for storage and handling had inventory systems in place, using spreadsheets to track data and communicate between the vaccine coordinator and the vaccine distribution team. This process assured efficacy and maximized the shelf life of the vaccine. DoH agrees to perform reconciliation between physical inventory and storage locations in the warehouse and ICAM data monthly.

STATE AUDITORS OFFICE RESPONSE

The inventory system referenced by the DoH relates to having sufficient vaccine on hand and is unrelated to the finding. We discovered discrepancies between the vaccine inventory locations and counts in ICAM compared to the physical counts and storage locations (fridge/freezer/ultra-cold) in the warehouse on our August 8, 2021 inspection. Vaccine distribution staff could not identify the cause of these discrepancies during the inspection.

[7] *Vaccine Storage and Handling Toolkit published by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services. March 4, 2021. Page 17.*

[8] *COVID-19 Vaccination Program Interim Operational Guidance - Jurisdictional Operations published by the CDC. October 29, 2020. Page 33.*

FINDING 2021-02

Vaccine Issued Out of Incorrect Storage Location

WHAT HAPPENED

As of June 30, 2021, the state warehouse issued 144,988 doses of the COVID-19 vaccine. We reviewed all issued vaccines out of the ICAM inventory system to determine if there were any irregularities noted with the ICAM listed storage location of the vaccine, compared to the specific manufacturers' vaccine storage temperature requirements.

We found all of the Johnson and Johnson vaccines were issued out of the correct storage location. The Pfizer vaccines were issued out of the correct storage location, but we did not receive temperature readings for one of the ultra-cold units for which documentation shows some Pfizer vaccine was stored in. Our team did identify errors in the listed storage location in ICAM for the Moderna vaccines.

Of the 144,988 issued doses, ICAM records identified:

- 1,600 doses of the Moderna vaccine were issued out of the ultra-cold storage location at less than -60° Celsius, which is the incorrect storage temperature for the Moderna vaccine. 1,455 of those 1,600 doses were administered to patients.

- 6,000 doses of the Moderna vaccine were issued out of the fridge location. Moderna vaccines need to be stored at freezer temperatures. While they can be stored at fridge temperatures, their shelf life decreases to only 30 days. Our team found at least 457 doses and up to potentially 701 doses of the Moderna vaccine were administered beyond this 30-day window.[9]

[9] *The range of potential doses administered is due to more than one issue date of vaccine with the same lot number shipped to the same provider. While the CDC recommends providers use the first shipment received prior to use of another shipment, we were unable to test this and had to go strictly by the dates of the vaccine being placed at fridge temperatures and when they were administered. Because of the multiple dates of issue, we had a variability in the numbers of possibly administered vaccine after the recommended 30 days at fridge temperatures.*

COVID-19 Vaccine Vial* Storage Requirements

Pfizer	moderna	Johnson & Johnson
PRIOR TO VIAL USE: -80°C to -60°C. Up to 5 days in fridge. No more than 30 minutes at room temperature.	**PRIOR TO VIAL USE:** -15°C to -50°C. Refrigerated between 2°C and 8°C up to 30 days. Unrefrigerated up to 12 hours.	**PRIOR TO VIAL USE:** Refrigerated between 2°C and 8°C no more than 3 months. Unrefrigerated between 9°C and 25°C up to 12 hours.
ONCE VIAL IS FIRST USED: Store between 2°C and 25°C no more than 6 hours.	**ONCE VIAL IS FIRST USED:** Store between 2°C and 25°C no more than 6 hours.	**ONCE VIAL IS FIRST USED:** Room temperature up to 2 hours. Refrigerated between 2°C and 8°C no more than 6 hours.

VACCINES CANNOT BE REFROZEN | *Vials contain multiple doses

- 12,828 doses of the Pfizer vaccines were issued out of an ultra-cold unit that our team did not receive any temperature readings for. Because of the missing temperature readings, we cannot determine storage temperatures were within correct ranges for these doses while at the state warehouse location. The DoH stated that this unit was not used for vaccine storage, meaning these doses were recorded in an inaccurate storage location in ICAM.

Out of 144,988 issued doses, **12,828 doses** were issued out of a storage location we **could not verify temperature data for.**

The DoH states that no Moderna vaccines were ever stored at ultra-cold temperatures, but because the ICAM data reported it was stored there, we are unable to verify this claim based on the data we received. At the time of our audit, the DoH considered the ultra-cold location in ICAM a clerical error and therefore they determined it was not necessary to notify individuals who were administered Moderna vaccines from the ultra-cold storage location.

We cannot determine if the cause of these findings is related to record-keeping errors in ICAM because of a lack of inventory reconciliation (see Finding 2021-01), or if it was because of actual improper storage of the COVID-19 vaccines.

The DoH issued vaccines from incorrect storage locations according to their records and is not recording accurate storage locations in ICAM records.

BACKGROUND

The CDC states the jurisdiction (in this case, the DoH) must use a temperature monitoring device that supports temperature tracking. That includes the time the vaccine leaves the manufacturer until the vaccine is administered.[10]

The DoH also must be able to provide data to the CDC that meet defined manufacturer standards.[10] That means if the CDC requested it, the DoH would need to be able to provide documented storage (cold chain) from the manufacturer up until the vaccine is administered. A reliable cold chain requires accurate inventory management.[10]

COVID-19 vaccine products are temperature-sensitive and must be stored and handled correctly to ensure efficacy and maximize shelf life.[8] Incorrect storage of the COVID-19 vaccine could potentially render the vaccine ineffective, leaving citizens unaware that they are not protected against COVID-19 or unaware that they would need additional doses of vaccine. The CDC recommends states should work with staff at each COVID-19 vaccination provider site to ensure appropriate vaccine storage and handling procedures are established and followed.[11]

RECOMMENDATION

We recommend the Department of Health record accurate storage locations in ICAM records and/or properly store vaccines according to manufacturer temperature requirements, and monitor vaccine shelf life according to storage temperatures.

DEPARTMENT OF HEALTH RESPONSE

DoH states that no Moderna vaccines were ever stored at ultra-cold temperatures and that the ultra-cold location in ICAM was a clerical error and did not impact the viability of the vaccine. DoH uses redundant systems to ensure proper monitoring and distribution of vaccines prior to end of shelf life. The use by date is written on the cap of vaccines to reflect the correct shelf life. Shelf life is also documented on an inventory spreadsheet. This information is also written on the ICAM packing slip for providers, which the provider signs and the courier returns to the warehouse. DoH properly stores vaccines according to manufacturer temperature requirements. DoH agrees

[10] *The COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations, page 33 and 39, October 2020,*

to perform reconciliation between physical inventory and storage locations in the warehouse and ICAM data monthly. DoH has adopted an upgrade to ICAM that includes an inventory auditing module. The ICAM system will now keep records of the dates that the inventory was checked, who checked the inventory, and what was done to correct the differences, if any.

STATE AUDITORS OFFICE RESPONSE

The systems referenced by the DoH to ensure proper monitoring and distribution were ineffective as ICAM inventory records and storage locations were not reconciled with discrepancies corrected (see Finding 2021-01). Inventory records indicated vaccines were administered after their expiration and Moderna was incorrectly stored at ultra-cold temperatures. There is no support to confirm any clerical errors.

FINDING 2021-03

Improperly Stored and Tracked Vaccines

WHAT HAPPENED

We found documentation errors and omissions in many vaccine records. These included missing recorded temperature documentation (cold chain errors), incorrect frequency of temperature documentation, and missing documentation regarding returns and quantities of vials returned. This led to errors in the process (known as chain of custody errors). The CDC requires storage records for COVID-19 vaccines to be saved and stored for three years.[11]

The DoH developed the SFN 60561 form to track vaccine temperatures and quantities throughout the transport process. This form is important to ensure temperature readings are being monitored and documented every 30 minutes to remain within the manufacturer guidelines for temperature requirements. It also ensures temperature and location accuracy for chain of custody and cold chain documentation requirements while in transport. See page 14 for example.

The DoH developed a vaccine transport log form to guide documentation when vaccines are transported. When vaccines are transported, these temperature logs (SFN 60561) should be used to document temperatures from calibrated digital data-loggers (DDL),[11] which is essential for tracking vaccines in transport and verifying correct vaccine storage temperatures.

When vaccines are returned from pop-up vaccine clinic sites, the number of vaccine doses returned and the time they were returned should also be documented. We found multiple errors in the use of SFN 60561 by DoH staff.

We requested and received the training information the DoH staff were given prior to transporting vaccines or working at the pop-up vaccine clinic sites. Our team received a PowerPoint presentation and new nurse orientation training given to nurses and pop-up clinic staff for training prior to vaccine clinics. The PowerPoint presentation and the new nurse orientation did not review form SFN 60561 requirements for documentation.

We also inquired about the training that the transport staff received regarding COVID-19 transport and handling. In response, we were given the vaccine manufacturer guidelines specific to each vaccine manufacturer. The DoH stated the transporters were given these same guidelines and received additional on-the-job training, which included review of the form SFN 60561 and its documentation requirements, but there is no employee documentation of this.

Errors and Missing Documentation for Vaccines Transported to Other Providers

We reviewed 60 randomly selected samples from 2,715 issued vaccine shipments from the state's Vaccine Inventory Monitoring System (ICAM). Each shipment would consist of multiple vials of vaccine for use at pop-up COVID-19 vaccination clinics.

We reviewed the shipment records that included information of temperatures and handling documentation for each transported site tested. These samples were transported from the state's warehouse facility in Bismarck to providers all around the state. These vaccines then became custody of the provider who ordered them, and they were administered by that provider.

We found the following:

- 27 of the 60 sample shipments were missing the SFN 60561 form, which included temperature readings.

[11] *Vaccine Storage and Handling Toolkit published by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services. March 4, 2021. Pages 11 and 50.*

The frequency of temperature monitoring and actual temperatures during transport were all documented as errors.

- All 60 had errors due to not being able to connect the digital data logger reports to the proper vaccine shipments at the end of the transport.

Of the remaining 33 shipment records that we could review, the following errors were found:

- Three had errors of delays in required temperature documentation intervals (for example, temperatures were read at 45 minute intervals when DoH Policy requires 30 minutes).

- Three were missing documented temperature readings.

Errors and Missing Documentation for Vaccines Transported to Pop-up Vaccine Clinics and Returned to the State Warehouse

We reviewed 45 randomly selected samples from 324 pop-up site vaccination clinics within our audit period. Each shipment would consist of multiple vials of vaccine estimated for use at the pop-up COVID-19 vaccine sites. We reviewed the shipment records that included information of temperatures and handling documentation for each pop-up site tested.

The pop-up clinics were established and run by the DoH to bring COVID-19 vaccines into communities across the state. The vaccines were taken from the warehouse location to specific sites across the state. The vaccines were then administered on-site, and the remaining vaccines were transported back to the warehouse location by DoH staff.

We found the following:

- 11 of the 45 pop-up clinics we sampled were missing the SFN 60561 form, which included temperature readings. The frequency of temperature monitoring and actual temperatures during transport were all documented as errors. There were also errors in the documentation of vaccine amounts returned and the time they were returned.

- All 45 had errors due to not being able to connect the digital data logger reports to the proper vaccine shipments at the end of the transports.

Of the 34 remaining records we reviewed, the following additional errors were found:

- Nine had errors of delays in required temperature documentation intervals (for example, temperatures were read at 45 minute intervals when DoH Policy requires 30 minutes).

- 12 had errors for documenting the number of vaccines returned to the warehouse at the end of the pop-up clinics.

- 18 had documentation errors for the time the vaccine ran out at the pop-up clinic or when they were returned to the warehouse. If the site ran out of vaccine, it should be noted on the form to validate why the storage and temperature records end.

- 30 had longer transportation times reported than the CDC recommendation time for COVID-19 vaccine transportation.

Errors in Use of Digital Data Loggers

The DoH requires the digital data loggers (DDL) to be downloaded at the end of a transport (Celsius Temperature Log for Vaccine Transport - DoH). In addition, a DoH employee oversees the transport and is responsible to complete a written record of the vaccine throughout the transport. Our audit team was provided files of DDL downloads, but the DoH did not track which DDL was placed with each shipment. Because of this, there was no way of determining which DDL was with each vaccine shipment, what time those vaccines were in transport, and whether vaccines were kept at correct storage temperatures.

Errored SFN 60561 Form

Example of log pulled from DoH records.

THE TIMES VACCINES ARE REMOVED AND RETURNED TO THE FRIDGE MUST BE DOCUMENTED

NORTH Dakota | Health
Be Legendary.

CELSIUS TEMPERATURE LOG FOR VACCINE TRANSPORT
NORTH DAKOTA DEPARTMENT OF HEALTH
IMMUNIZATION PROGRAM
SFN 60561 (01-19)

Date vaccine transported	Time vaccine is removed from refrigerator	Time vaccine is returned to refrigerator
6/1/21		

Types of vaccines transported	Number of doses transported	Number of doses returned
Johnson and Johnson	25	

THE NUMBER OF DOSES RETURNED TO THE FRIDGE MUST BE DOCUMENTED

Required temperature range for refrigerated vaccines

Time	Staff Initials	<2	Danger! Temperature below 2°C is too cold, take immediate action.	2	3	4	5	6	7	8	Danger! Temperature above 8°C is too warm, take immediate action.	>8
8:20							5.5					
							5.5					
							5.5					
							5.6					
							5.6					
							5.6					

TEMPERATURE NEEDS TO BE DOCUMENTED EVERY 30 MINUTES AND THE TIME MUST BE RECORDED

1. *Use a portable refrigerator or a prequalified cooler for vaccine transport.*
2. *Use a calibrated data logger thermometer with probe in glycol bottle for vaccine transport.*
3. *Keep the glycol bottle in the refrigerator for hours to cool it before you use it.*
4. *Limit doses of vaccine transported only to the amount needed.*
5. *Document the time when vaccine is removed from refrigerator.*
6. *Document the types of vaccine and number of doses transported.*
7. *Document temperature on the above chart every* ***30 minutes*** *.*
8. *If the temperature is out-of-range, record the exact out-of-range temperatures in the column provided.*
9. *Do not place vaccine in the trunk of a vehicle, place it on passenger seat.*
10. *Document the number of doses and types of vaccine returned and the time when it was returned.*
11. *Download the data logger at the end of vaccine transport.*
12. *If excursion occurred for more than 15 minutes during vaccine transport, do not use the vaccine.*
13. *For temperature excursions, follow the trouble shooting guide available at: www.ndhealth.gov/Immunize/Documents/Providers/Forms/Troubleshooting.pdf.*

800.472.2180 www.ndhealth.gov/Immunize/

In addition to the data provided by a DDL, shipments also had a DoH employee overseeing the transport. The written record SFN 60561 includes 30-minute interval temperature checks of the vaccine. Because the DDL's were not tracked with the vaccine shipments, we were unable to verify the written temperature checks on the forms were correct according to the DDL readings.

In our review of the DDL files, we found temperatures that would be considered out-of-range.

We asked the DoH about these out-of-range temperatures. They stated it could be because of turning the DDL on prior to transporting the vaccine and allowing the DDL's to get to the temperature of the storage unit transporting the vaccine. They also shared it could be because of not turning the DDL's off at the end of transport, possibly causing the DDL to read ambient room temperatures.

We were unable to test these out-of-range temperatures times or periods for any specific vaccine, because the DoH did not track the DDL with vaccine shipments. This leaves us unable to determine if vaccine was in transport during the times of the out of range temperatures.

Missing Documentation for Fridge Alerts for Out-of-Range Temperatures

The DoH could not provide documentation to identify the dates of vaccine storage in the commercial fridges known by DoH staff as dock fridges 1 and 2 located in warehouse storage. We found instances of the dock fridges falling out of the vaccine manufacturer recommended temperature range.

The DoH could not provide documentation to show the out-of-range temperature alerts were working properly. We reviewed all nine different dates of noted temperatures out-of-range for dock fridges 1 and 2, and of those nine dates, DoH provided one temperature alert notification on June 7th, 2021. Temperature alert controls are easily disabled and the DoH could not show evidence of when they enacted or did not enact these alerts.

Not tracking the vaccine while it's in the dock fridges is a break in the chain of custody (handling) and potentially a break in the cold chain (storage), creating potential for the vaccine to be ineffective.

BACKGROUND

COVID-19 vaccine products are temperature-sensitive and must be stored and handled correctly to ensure efficacy and maximum shelf life.[8] Proper storage and handling practices are critical to minimize vaccine loss and limit risk of administering COVID-19 vaccine with reduced effectiveness. The CDC recommends states should work with staff at each COVID-19 vaccination provider site to ensure appropriate vaccine storage and handling procedures are established and followed.[13]

The CDC states the jurisdiction (in this case, the DoH) must use an information technology tracking system that supports dose-level accountability. That includes the time the vaccine leaves the manufacturer until the vaccine is administered or any unused vaccine is returned.[13]

To correctly monitor the cold chain of vaccines, every vaccine storage container must have a temperature monitoring device. This is required at all times, including during transportation of the vaccine to another site.[12] The CDC recommends digital data loggers (DDLs) to track vaccine temperature.[12] A digital data logger is a stand-alone device that can read various types of electronic signals and store the data in internal memory for later download and analysis.

The CDC requires record retention of all temperature documentation for COVID-19 vaccine for a minimum of three years.[12] The DoH claims they had not yet developed a records retention schedule.

[12] *Vaccine Storage and Handling Toolkit published by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services. March 4, 2021. Page 51.*

[13] *The COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations, Pages 33 and 39.*

The DoH also must be able to provide data to the CDC that meet defined manufacturer standards. That means if the CDC requested it, the DoH would need to be able to provide documented storage (cold chain) from the manufacturer up until the vaccine is administered. A reliable cold chain requires accurate inventory management.[13]

RECOMMENDATION

We recommend the DoH:

- Ensure data logger data is identifiable by transport.
- Improve training and perform internal monitoring procedures to ensure complete and accurate vaccine chain of custody records and cold chain temperature readings.
- Ensure records retention, document internal monitoring procedures, and perform subsequent corrective actions.

DEPARTMENT OF HEALTH RESPONSE

DoH policy is that it follows the three-year CDC requirements for document retention and agrees to update the state retention schedule and retain records. DoH redundant systems, used to track temperatures, exceeded CDC guidelines:

- o DoH recorded temperatures every 60 seconds during transport and every 5 minutes for stationary units. CDC recommends recording a minimum and maximum temperature.
- o The DoH manually records temperatures of cold chain equipment storing vaccine twice daily. CDC recommends temperatures be checked once daily.

Potential and actual excursions were identified through alarm systems, beyond what was required by CDC. Any vaccine reported to be out of range was quarantined and not used until the manufacturer reviewed the situation and determined viability. The public was protected through these processes. DoH agrees to continue to improve training, internal monitoring, recording procedures and perform any corrective actions to ensure that the DOC fridge and data logger data is tied to transport and is documented throughout the cold chain process. DoH has already implemented new forms and processes to address this recommendation.

STATE AUDITORS OFFICE RESPONSE

The redundant systems referenced by the DoH to exceed CDC guidelines are ineffective. The audit identified data logger temperature data not being tied to specific vaccines, movement of vaccines to the dock fridge not being identified in records, and incomplete and missing temperature documentation. The audit also identified that temperature alert controls are easily disabled and there was no evidence of when alerts were enacted.

[13] *The COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations, Pages 33 and 39.*

COVID-19 Testing

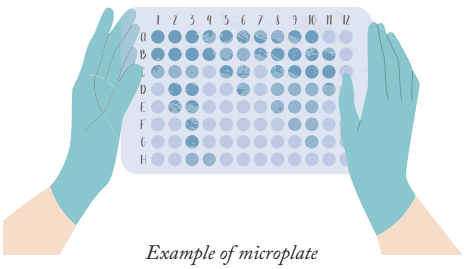
OBJECTIVE

Is the State Lab performing quality control procedures when processing COVID-19 RT-PCR tests with a proper control sample and proper approval of high positivity rates?

CONCLUSION

We found no errors in the positive and negative control samples for COVID-19 RT-PCR tests. DoH policy requires a lead lab technician to approve test results if they had a positivity percentage greater than 25%. The lab added the lead technician approval to help ensure accurate results.[16] Our team did not find evidence of lead lab technicians approving the microplates prior to releasing test results to the public. This could result in inaccurate test results reported to individuals and the public.

Without evidence of approval, the State Lab is not able to monitor and separately evaluate that their quality assurance procedures are operating effectively. Inaccurately high positivity rates of COVID-19 diagnosis could lead to improper decisions and responsive actions by health officials and the state government.



Example of microplate

BACKGROUND

RT-PCR testing is generally considered the "gold standard"[14] test methodology for diagnosis of COVID-19 disease and many other infectious diseases. Results of RT-PCR analysis were used for decision-making for state officials, school administrators, and healthcare providers in the state during the COVID-19 pandemic.

PCR means polymerase chain reaction. It's a test to detect genetic material from a specific organism, such as a virus. The test detects the presence of a virus, if you have the virus at the time of the test. The test could also detect fragments of the virus even after you are no longer actively infectious.[14]

FINDING 2021-04

Not Following Lab Policy for Approval Process for RT-PCR Microplates with Greater Than 25% Positivity

WHAT HAPPENED

Our audit team reviewed the quality analysis procedures for RT-PCR testing for COVID-19 tests. We gained an understanding through review of policy and procedure manuals or Standard Operating Procedures (SOPs) and a review of manufacturer package inserts of four different testing instruments. We noted a portion of the internal quality review policy was similar for these testing instruments found in the lab's own SOP, but was not found in any of the manufacturer package inserts.

DoH Lab Standard Operating Procedure

"Any run that comes off with a positivity rate of 25% or greater needs to have a Lead Tech in that area approve it before it goes out. When in doubt or if you have questions about a run, please reach out to a lead."[15]

[14] *Cleveland Clinic - https://my.clevelandclinic.org/health/diagnostics/21462-covid-19-and-pcr-testing. Last Reveiwed by a Medical Professional on August 24, 2021.*

[15] *The SOP was found in three of the Department of Health's policy manuals - Abbott RealTime SARS CoV-2 PCR, Amplitude SARS-CoV-2 PCR, and Thermo Fisher TaqPath COVID-19 Combo Kit.*

The lab stated they established this policy that goes above and beyond the manufacturer recommendations for results analysis. According to the DoH, this additional review process is a "trigger point used to help reduce the inherent subjectivity of run analysis and reduce variability of assessment." The additional review was "to help ensure accurate results."[16]

These procedures were implemented by writing them into the lab's SOP and putting them in the labs information technology system for tracking their employee's competency and required education (iPassport) for all pertinent staff to review and sign off on these changes. Additionally, we discovered this policy was sent in a group email for DoH microbiology staff on November 28, 2020, emphasizing the policy.

The audit team found the DoH does not have a formal lab review process for Lead Technicians to consistently review high positivity rates of COVID-19 RT-PCR tests with evidence of their approval. The DoH indicated staff use their experience and training to ensure accurate results.[16]

Our analysis of COVID-19 tests found 438 runs, with 10 or more tests per run, and having a positivity rate of 25% or more. In these 438 runs, there were 45,892 test results which did not have consistent procedures for lead technician approval prior to results being accepted and released to the public.

Internal control procedures should include documented approvals and monitoring of the internal control system through ongoing monitoring, separate evaluations and corrective actions for deficiencies (GAO-14-704G para 16.04, 16.05, 17.05, 17.06, OV4.08).

According to the State Lab's Quality Assessment Plan, the procedures in iPassport contain: step by step directions of the procedure, how to interpret results and testing criteria, and quality control procedures and remedial action if control results fail to meet the lab's criteria for acceptability. This policy was found in iPassport within the SOPs for the instruments used for RT-PCR testing for COVID-19. While the DoH added these additional steps to ensure accurate results, they did not have procedures in place to make sure those steps were happening.

Standard Operating Procedures for employees in the State Lab requires the Lead Laboratory Technicians to review and approve RT-PCR runs with greater than 25% positivity rates for COVID-19. These procedure policies are maintained in iPassport and are assigned to the appropriate lab individuals to receive automated emails from iPassport for review of the procedures any time there is a change, update, or an annual review is required. The employees must acknowledge these procedures to maintain competency on the testing instruments to perform test procedures and report test results promptly and accurately (Quality Assessment Plan for the DoH, Division of Microbiology).

RECOMMENDATION

We recommend the DoH document approval and perform monitoring procedures that ensure lead laboratory technicians review and approve PCR runs with greater than 25% positivity rates for COVID-19 in accordance with their Standard Operating Procedures.

DEPARTMENT OF HEALTH RESPONSE

DoH asserts that quality assurance procedures were in place and accurate test results were reported to the public. A recent CLIA audit found no issues with the lab practices. More than one million tests were processed over this period and the State Auditor's Office also found no errors in the positive and negative control samples for COVID-19 RT-PCR tests. DoH agrees that some documentation regarding lead technician review was not available - as noted by the audit report, that requirement is above and beyond the requirements of the manufacturer. Current practice is that all runs greater than 15% positivity are assessed by the

[16] *Email from DoH Source. "RE: QA Processes for PCR Testing." December 8, 2021.*

medical laboratory scientist/technician that is trained, competent, and demonstrates proficiency on the platform. All SARS-CoV-2 methods have been reviewed and minor adjustments have been made to accurately reflect the work being completed.

STATE AUDITORS OFFICE RESPONSE

The DoH established this policy to help ensure accurate test results were reported to the public. Any runs with a positivity rate of 25% or greater were to have a Lead Tech's approval before it went out. This approval is separate from the assessment of runs with greater than 15% positivity and there were no exceptions to this approval in policy. Our audit identified instances where Lead Techs were not approving high positivity rate COVID-19 RT-PCR plates to verify the accuracy of the test results. The remainder of the DoH response is irrelevant to the finding and recommendation. In times of crisis, shortcuts and noncompliance with policies and procedures increase the risk of errors.

COVID-19 Dashboard

OBJECTIVE

Are COVID-19 dashboards properly reporting statistics required to be collected by the CARES Act?

CONCLUSION

COVID-19 dashboards properly reported statistics required to be collected by the CARES Act.

BACKGROUND

The dashboards are presented to the public and state and national leaders to make decisions for public health and safety. Inaccuracies in the data could lead to public fear and uninformed decisions by state and national leaders. State and national leaders have made decisions that have had economic impact to individuals, local, and state governments.

Primary Objective

OBJECTIVE

Are there any errors, internal control weaknesses, or potential violations of law for significant and high-risk functions of the agency?

CONCLUSION

No areas of concern were identified.

Audit Procedures

COVID-19 Vaccine Storage and Handling Objective

INTERNAL CONTROL

We obtained an understanding of internal control through inquiries, observations, and inspection of documentation and electronic data records. We planned our audit work to assess the design, implementation, and effectiveness of those internal controls that were significant to our audit objective.

The specific internal control testing completed for this audit objective is identified below:

- Conducted a physical inventory inspection and count of COVID-19 vaccine on hand at the state DoH warehouse and reconciled against the ICAM state warehouse inventory tracking system for both location stored (fridge, freezer, or ultra-cold) and total count of the vaccine on hand.

- Inspected alarm notifications generated when the temperature storage units went out-of-range.

SCOPE

Our team reviewed COVID-19 vaccines delivered to the North Dakota state warehouse distribution center located at 1509 Grumman Lane, Bismarck, ND. We reviewed the systems and equipment used to track, store, monitor, and transport the COVID-19 vaccines as well as the specific cold chain requirements according to the manufacturer specifications for each vaccine type.

Our audit did not review the storage and handling procedures or temperature documentation of private providers, as those vaccines were no longer in the possession of the DoH. Our audit did include administered vaccine records in the North Dakota Immunization Information System (NDIIS), which the DoH monitors and reports this information to the CDC.

Throughout the pandemic, the CDC broadened guidelines for storage temperature, duration, and expiration of the vaccine. Our team used the guidelines that were in place at the time of our audit to use as the criteria at the time of testing.

The vaccine manufacturer identified the specific storage and handling guidelines for their specific vaccine. The CDC used these guidelines from the vaccine manufacturer to publish Storage and Handling Summary sheets. Within the report, references to the vaccine manufacturer guidelines were also accepted and adopted by the CDC through the summary sheets.

Two scope limitations were identified. See page 5.

METHODOLOGY

To meet this objective we:

- Interviewed appropriate agency personnel.

- Observed the Department's processes and procedures.

- Performed a physical inventory of COVID-19 vaccines at the state warehouse site on August 8, 2021, and reconciled inventory counts and location in ICAM records to its physical location.

- Selected a random sample of vaccines issued from the state warehouse to determine if the vaccines were stored and handled properly while being transported.

- Selected a random sample of vaccines that originated from the state warehouse for vaccine pop-up clinics to determine if the vaccines were stored and handled properly while transported and stored at pop-up clinic sites.

- Reviewed transported vaccine documentation for frequency of temperature recordings, number of vaccines

transported and returned, times of vaccines departure from warehouse, and time of receipt of vaccines or time they were returned.

- Reviewed if digital data logger was downloaded at the end of vaccine transports.

- Performed data analytics of temperature logs for all stationary fridge, freezer, and ultra-cold freezers used for COVID-19 vaccine storage within our audit period to determine if temperatures stayed within the recommended manufacturer ranges.

- Performed inspection of records for storage units that went out of range to identify whether vaccines were in the unit at the time of the out-of-range temperature. Inspected records to identify DoH performed the appropriate follow up according to the manufacturer specifications if there was a temperature excursion of vaccines.

- Selected a random sample of DoH pop-up vaccine administration sites active during the audit period to determine if the vaccine cold chain was documented according to manufacturer guidelines.

- Compared accuracy of vaccine expiration dates within NDIIS to specific manufacturers and associated lot numbers.

- Analytically reviewed NDIIS data to determine if COVID-19 vaccines were administered within the manufacturer specified expiration date.

- Analytically reviewed accuracy of all vaccine manufacturer lot numbers in NDIIS to see if they matched to available lot numbers on the manufacturer websites or provided list of lot numbers.

- Reviewed all the vaccine issue locations in ICAM and looked for incorrect or inconsistent storage locations according to the manufacturer recommendations for temperatures.

- Identified the vaccines that were issued out of incorrect storage locations for temperature and determined if they had been administered.

- Identified the vaccines in ICAM records that should be stored at freezer temperatures but instead were stored at fridge temperatures to determine if those vaccines were administered within the shortened expiration date.

COVID-19 Testing Objective

INTERNAL CONTROL

We obtained an understanding of internal control through inquiries, observations, and inspection of documentations and electronic data records. We planned our audit work to assess the design, implementation, and effectiveness of those internal controls that were significant to our audit objective.

The specific internal control testing completed for this audit objective is identified below:

- Analyzed test runs performed on Abbott, Amplitude, Hologic, and Thermo Fisher testing platforms to identify quality control samples (positive and negative) were in each test run, or were listed according to instrument specifications.

The audit attempted to identify evidence of approval of test runs with high positivity rates according to the DoH State Lab's Standard Operation Procedures. The audit found that evidence of approval did not exist. See Finding 2021-05.

SCOPE

The scope of this objective included the RT-PCR testing performed at the DoH State Lab in Bismarck, ND.

The location was selected based on the level of activity. The state lab in Bismarck completed the majority of RT-PCR testing in the state during the COVID-19 pandemic. Antigen testing was not included in the scope of the audit.

METHODOLOGY

To meet this objective, we:

- Interviewed appropriate agency personnel.
- Observed the DoH processes and procedures.
- Analyzed and selected random samples of test runs performed on Abbott, Amplitude, Hologic, and Thermo Fisher testing platforms to identify quality control samples (positive and negative) were in each test run or as specified by the instrument manufacturer.
- Compared State Lab standard operating procedures and policies in iPassport to manufacturer package inserts for performing and reviewing RT-PCR testing.

COVID-19 Dashboard Objective

INTERNAL CONTROL

The audit did not identify any significant internal controls related to this audit objective.

SCOPE

The scope of the objective included records related to COVID-19 testing and vaccinations collected by the DoH. Testing information included test results, number of cases, and number of deaths. We did not review records related to hospitalizations.

The scope is limited to the dashboards published during the months at the height of the pandemic quantitatively (in terms of numbers of cases) and qualitatively (in terms of when most executive orders and decision-making occurred) during our audit period. These months were March through May 2020 (qualitative) and September through December 2020 (quantitative). North Dakota's first case was on March 11, 2020, and its first vaccination was December 14, 2020.

Records from the following key information systems were reviewed:

- Maven — infectious disease case management system.
- LIMS — Covid-19 tests at the State Lab (2635 E. Main Avenue in Bismarck, ND).
- NDIIS — Covid-19 vaccinations for ND residents.
- PrepMod — data recorded at vaccination sites.

METHODOLOGY

To meet this objective, we:

- Reconciled tests and results from LIMS to Maven for the audit period.
- Reconciled deaths from Maven to Vital Records for the audit period.
- Selected a random sample of 21 days of dashboards and press releases. Recalculated counts of positive cases, tests, deaths, and daily positivity rate for the days sampled.
- Performed analytics for duplicate records of test results.
- Analyzed common fictitious names to determine if dashboard numbers were artificially inflated.
- Selected two different two-week periods to reconcile vaccinations by clinics in PrepMod to NDIIS.
- Reconciled NDIIS data received to dashboard as of June 30, 2021.

Primary Objective

INTERNAL CONTROL

We obtained an understanding of internal control through inquiries, observations, and inspection of documentations and electronic data records. We planned our audit work to assess the design, implementation, and operating effectiveness of those internal controls that were significant to our audit objectives.

The specific internal control testing completed for this audit objective is identified below:

- Segregated preparation and approval of expenditures were tested statewide in the audit of the State of North Dakota Annual Comprehensive Financial Report.
- Inspected the built-in formulas to determine formula components and grant amounts within spreadsheets used in the ambulance service operation funding distribution were working properly and producing accurate amounts.
- Inspected sub-recipient schedules and ensured the agency tracked the total grant amount, scheduled annual payments, and remaining grant award balances for student loan repayments for healthcare professionals to ensure that the loan repayments did not exceed the maximum amount per year or five-year period.
- Tested expenditures for contracts in the Program Reporting System (PRS) for proper approval by the program administrator, division director, and accounting.
- Tested purchase card expenditures for proper approval by supervisors within the division expenditures were for.
- Inspected employees' procurement officer certification training was proper for the types of procurements conducted and tasks performed.

There were no deficiencies identified.

SCOPE

The North Dakota Department of Health has operations in the following locations. Each location was included in the audit scope:

- The central office in the State Capitol building has the following sections:
  - Fiscal & Operations
  - Healthy Resources
  - Healthy & Safe Communities
- The Medical Services sections at 2635 East Main, Bismarck, ND.
- The Emergency Preparedness and Response sections is located at 1720 Sykes Drive, Bismarck, ND.

METHODOLOGY

To meet this objective, we:

- Interviewed appropriate agency personnel.
- Observed the Department of Health's processes and procedures.
- Inspected documentary evidence.
- Queried the ConnectND (PeopleSoft) system for data analysis. Performed detailed analytical procedures. These procedures were used to identify high risk transactions and potential problems for additional testing.
- Analyzed accounts charged to each appropriation class to determine that expenditures were not charged to an inappropriate class to circumvent appropriation spending authority (N.D.C.C. 54-16-03).
- Analyzed and tested expenditures to determine the Department of Health did not expend more than appropriated (N.D.C.C. 54-16-03 (2019 Session Laws House Bill 1004 section 1)).

- Tested compliance with the documented intent of special appropriation laws, including one-time funding items.

- Analyzed and performed random expenditure testing to determine that $334,272 of the $354,554 of federal funds was used for a WIC system upgrade (2019 Session Laws House Bill 1004 section 2).

- Inspected the contract and analyzed expenditures and determined that $482,660 of the $483,000 was used for microbiology lab technology updates (2019 Session Laws House Bill 1004 section 2).

- Inspected the contract and analyzed expenditures and determined that $1,216,882 of $1,220,000 of tobacco prevention and control trust funds was used for microbiology laboratory capital improvements (2019 Session Laws House Bill 1004 section 2 and section 4).

- Analyzed expenditures and reviewed the ambulance service operation funding distribution process. Determined that the data used in calculations in the distribution agreed to grantee-submitted supporting documentation and that the grantee did not receive more than the total calculated grant amount. Also, determined that $1,125,000 from the insurance tax distribution fund and $5,747,563 from the general fund was used for these distributions (2019 Session Laws House Bill 1004 section 3 and House Bill 1268 section 4).

- Analyzed and performed random expenditure testing to determine that $1,302,176 of $1,405,324 of tobacco prevention and control trust funds were used for the following:
  - o $299,999 of $300,000 was used for domestic violence offender treatment grants.
  - o $477,177 of $580,324 was used for cancer programs.
  - o $525,000 of $525,000 was used for grants to local public health units (2019 Session Laws House Bill 1004 section 4).

- Inspected vital records receipts and ensured that the fee collected did not exceed $15 per item. Also, analyzed vital record fees and deposits to ensure that $2 for each certified copy of a birth record was deposited into the children's trust fund. In addition, we determined that at the end of the biennium any vital records fees collected in excess of the appropriation were transferred to the general fund (2019 Session Laws House Bill 1004 section 5).

- Inspected receipts and determined that the minimum fee charged for life and safety construction or renovation plan review of small projects for facilities was reduced from $750 to $500 (2019 Session Laws House Bill 1004 section 6).

- Inspected testimony to the Information Technology Committee made on July 1, 2020, which stated that the Department of Health felt that implementing kiosks to provide electronic access to vital records was not a viable solution; however, they did request online ordering options through improved mobile application capabilities. Due to the pandemic, these upgrades were on hold at the ND Information Technology Department (2019 Session Laws House Bill 1004 section 7).

- Analyzed expenditures for student loan repayments for health care professionals and determined that the loan repayments did not exceed the maximum amount per year or 5-year period and that the payments were made directly to the Bank of North Dakota or to another participating lending institution. Also, determined that the proper matching percentage was met (2019 Session Laws Senate Bill section 1).

- Analyzed and performed random expenditure testing to determine that $9,681,287 of the $173,532,232 was used for the COVID-19 response (2021 Session Law House Bill 1394 section 1).

- Identified non-appropriated fund activity to ensure the Department of Health had legislative approval for all non-appropriated expenditures (N.D.C.C. 54-44.1-09).
  - o Health and Consolidated Lab Fund authorized by N.D.C.C. 23-01.

  - o Insurance Recovery Property Fund authorized by N.D.C.C. 54-44.1-09.1.
  - o Environmental Quality Restoration Fund authorized by N.D.C.C. 23.1-10-02.
  - o Statewide Conference Fund authorized by OMB Policy 211.
  - o Organ/Tissue Transplant Fund authorized by N.D.C.C. 23-01-05.1.
  - o Abandoned Motor Vehicle Fund authorized by N.D.C.C. 23.1-15-10.
  - o Wastewater Operators Certification Fund authorized by N.D.C.C. 23.1-07-05.
  - o Marijuana Medical Fund authorized by N.D.C.C. 19-24.1-40.

- Tested compliance with the documented intent of appropriation adjustments (N.D.C.C. 54-16-03).

- Evaluated the adequacy of blanket bond coverage by comparing coverage to state bonding guidelines (N.D.C.C. 26.1-21-08, N.D.C.C. 26.1-21-10(1)).

- Analyzed and tested a random sample of expenditures to determine the Department of Health properly accounted for expenditures using the correct account, fund, and class. Also, determined that the expenditures were reasonable (2019 Session Laws House Bill 1004 section 1).

- Analyzed and tested high-risk general ledger correcting entries and determined entries were properly coded and supported (N.D.C.C. 54-16-03).

- Analyzed and tested a random sample of expenditures from the Program Reporting System (PRS) to determine the Department of Health properly accounted for expenditures using the correct account, fund, and class. Also, determined that the expenditures were reasonable (2019 Session Laws House Bill 1004 section 1).

- Selected a random sample of purchase card expenditures to ensure receipts were present to support the expenditures, the expenditure was reasonable, and that proper coding was used (2019 Session Laws House Bill 1004 section 1).

- Analyzed and tested a random sample of expenditures from the legislatively restricted community health trust fund to determine if charges were in accordance with fund restrictions (N.D.C.C. 54-27-25).

- Analyzed and performed testing of random and high-risk procurement expenditures to determine if good and services were properly procured in accordance with competitive purchasing requirements (N.D.C.C. 54-44.4, N.D.A.C. Title 4-12, and OMB State Procurement Manual policies and guidelines).

AUTHORITY AND STANDARDS

This biennial audit of the North Dakota Department of Health has been conducted by the Office of the State Auditor pursuant to authority within North Dakota Century Code Chapter 54-10.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The standards used to evaluate internal control are published in the publication Standards for Internal Control in the Federal Government issued by the Comptroller General of the United States (Green Book, GAO-14-704G).

Responses to LAFRC Audit Questions

1. WHAT TYPE OF OPINION WAS ISSUED ON THE FINANCIAL STATEMENTS?

Revenues, expenditures, and appropriation information was not prepared by the Department of Health in accordance with generally accepted accounting principles so an opinion is not applicable. The agency's transactions were tested and included in the state's basic financial statements on which an unmodified opinion was issued.

2. WAS THERE COMPLIANCE WITH STATUTES, LAWS, RULES, AND REGULATIONS UNDER WHICH THE AGENCY WAS CREATED AND IS FUNCTIONING?

Other than the findings of this report, the North Dakota Department of Health was in compliance with significant statutes, laws, rules, and regulations under which it was created and is functioning.

3. WAS INTERNAL CONTROL ADEQUATE AND FUNCTIONING EFFECTIVELY?

Other than the findings of this report, we did not identify any deficiencies in internal control that were significant within the context of our audit objectives.

4. WERE THERE ANY INDICATIONS OF LACK OF EFFICIENCY IN FINANCIAL OPERATIONS AND MANAGEMENT OF THE AGENCY?

No.

5. HAS ACTION BEEN TAKEN ON FINDINGS AND RECOMMENDATIONS INCLUDED IN PRIOR AUDIT REPORTS?

The Department of Health has implemented all recommendations included in the prior audit report.

6. WAS A MANAGEMENT LETTER ISSUED? IF SO, PROVIDE A SUMMARY BELOW, INCLUDING ANY RECOMMENDATIONS AND THE MANAGEMENT RESPONSES.

No, a management letter was not issued.

LAFRC Audit Communications

7. IDENTIFY ANY SIGNIFICANT CHANGES IN ACCOUNTING POLICIES, ANY MANAGEMENT CONFLICTS OF INTEREST, ANY CONTINGENT LIABILITIES, OR ANY SIGNIFICANT UNUSUAL TRANSACTIONS.

There were no significant changes in accounting policies, management conflicts of interest, contingent liabilities, or significant unusual transactions identified.

8. IDENTIFY ANY SIGNIFICANT ACCOUNTING ESTIMATES, THE PROCESS USED BY MANAGEMENT TO FORMULATE THE ACCOUNTING ESTIMATES, AND THE BASIS FOR THE AUDITOR'S CONCLUSIONS REGARDING THE REASONABLENESS OF THOSE ESTIMATES.

The North Dakota Department of Health's revenues, expenditures, and appropriation information does not include any significant accounting estimates.

9. IDENTIFY ANY SIGNIFICANT AUDIT ADJUSTMENTS.

Significant audit adjustments were not necessary.

10. IDENTIFY ANY DISAGREEMENTS WITH MANAGEMENT, WHETHER OR NOT RESOLVED TO THE AUDITOR'S SATISFACTION RELATING TO A FINANCIAL ACCOUNTING, REPORTING, OR AUDITING MATTER THAT COULD BE SIGNIFICANT TO THE FINANCIAL STATEMENTS.

None.

11. IDENTIFY ANY SERIOUS DIFFICULTIES ENCOUNTERED IN PERFORMING THE AUDIT.

None.

12. IDENTIFY ANY MAJOR ISSUES DISCUSSED WITH MANAGEMENT PRIOR TO RETENTION.

This is not applicable for audits conducted by the Office of the State Auditor.

13. IDENTIFY ANY MANAGEMENT CONSULTATIONS WITH OTHER ACCOUNTANTS ABOUT AUDITING AND ACCOUNTING MATTERS.

None.

14. IDENTIFY ANY HIGH-RISK INFORMATION TECHNOLOGY SYSTEMS CRITICAL TO OPERATIONS BASED ON THE AUDITOR'S OVERALL ASSESSMENT OF THE IMPORTANCE OF THE SYSTEM TO THE AGENCY AND ITS MISSION, OR WHETHER ANY EXCEPTIONS IDENTIFIED IN THE SIX AUDIT REPORT QUESTIONS TO BE ADDRESSED BY THE AUDITORS ARE DIRECTLY RELATED TO THE OPERATIONS OF AN INFORMATION TECHNOLOGY SYSTEM.

The systems used were ConnectND Financials, Human Resource Management System, Data Logger, NDIIS, ICAM, Reese, Maven, PowerBI, PrepMod, and LIMS.

Financials

Revenues and Expenditures

REVENUES AND OTHER SOURCES	JUNE 30, 2021	JUNE 30, 2020
Federal Revenue	$ 137,534,207	$ 40,435,024
WIC/Medication Rebates	6,062,265	3,187,204
Vital Records Services Fees	1,510,376	1,336,630
Licenses, Permits, and Fees	1,515,673	1,797,625
Medical Marijuana Fees	1,130,959	743,415
Reimbursement From Others	486,821	738,575
Contributions and Private Grants	85,246	4,004,491
Other Revenue	158,015	487,430
Transfers In	103,231,691	28,517,215
Total Revenue and Other Sources	**$ 251,715,253**	**$ 81,247,609**

Source: ConnectND Financials

Continued on the following page

Financials

Revenues and Expenditures

EXPENDITURES AND OTHER USES	JUNE 30, 2021	JUNE 30, 2020
Grants	$ 91,631,811	$ 31,766,043
Lab/Emergency Supplies	52,856,794	12,270,572
Salaries and Benefits	46,701,526	20,237,897
Professional Fees and Services	37,245,784	5,250,153
Equipment	9,295,999	4,009,570
WIC Benefits	7,475,002	8,014,096
Information Technology	6,703,896	2,430,685
Travel	2,683,803	627,463
Repairs	1,948,781	1,553,212
Medicine and Drugs	1,553,662	1,693,413
Supplies	1,534,539	922,684
Rent	1,425,495	1,039,004
Operating Fees and Services	1,219,742	329,249
Postage	815,009	288,806
Bond Payments	384,468	225,341
Miscellaneous Expenses	802,855	590,591
Transfers Out	400,000	3,998,872
Total Expenditures and Other Uses	**$ 264,679,166**	**$ 95,247,651**

Source: ConnectND Financials

Appropriations

For the Biennium Ended June 30, 2021

EXPENDITURES BY LINE ITEM	FINAL APPROPRIATION	EXPENDITURES	UNEXPENDED APPROPRIATIONS
Salaries and Wages	$ 37,774,574	$ 35,813,900	$ 1,960,674
Operating Expenses	36,443,080	26,217,898	10,225,182
Capital Assets	3,699,616	2,790,347	909,269
Capital Assets Carryover	1,693,865	1,536,161	157,704
Grants	53,582,292	49,105,126	4,477,166
Tobacco Prevention	12,902,064	12,096,943	805,121
WIC Food Payments	19,780,000	15,326,450	4,453,550
CARES Act Funding - 2020	447,686,203	212,125,983	235,560,220
Totals	**$ 613,561,694**	**$ 355,012,808**	**$ 258,548,886**

EXPENDITURES BY SOURCE	FINAL APPROPRIATION	EXPENDITURES	TOTAL
General	$ 36,350,393	$ 34,298,438	$ 2,051,955
Other	577,211,301	320,714,370	256,496,931
Totals	**$ 613,561,694**	**$ 355,012,808**	**$ 258,548,886**

Source: ConnectND Financials

Status of Prior Recommendations

Improper Distribution of Rural Emergency Medical Services Grant (Finding 2019-01)

Implemented

Recommendation: We recommend the North Dakota Department of Health ensure the calculation of the rural emergency medical services grant distribution is correct and that all supporting documentation is retained.

Status: Implemented.

Appropriation Exceeded (Finding 2019-02)

Implemented

Recommendation: We recommend the North Dakota Department of Health ensure compliance with appropriation limits set by the North Dakota Legislature.

Status: Implemented. Various session laws were tested and were found to be in compliance with appropriation limits set by the North Dakota Legislature.

Office of the State Auditor

NORTH DAKOTA STATE AUDITOR
JOSHUA C. GALLION

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