

# Improving Vaccine Temperature Monitoring Using an Automated Continuous Temperature Monitoring System

Susan Erickson<sup>1</sup>, MA, RN, Brian Kennedy<sup>2</sup>, R.Ph, Amrika Ramjewan<sup>3</sup>, MSc, Glenn Mattson<sup>4</sup>, Amanda Swanson<sup>4</sup>, Brian Augustin<sup>4</sup>  
 Department of Nursing<sup>1</sup>, Department of Pharmacy<sup>2</sup>, Division of Management Engineering and Internal Consulting<sup>3</sup>, Division of Facilities Services<sup>4</sup>  
 Mayo Clinic Health System, Red Wing, MN

## Abstract

**Background:** On January, 1, 2018, the Minnesota Department of Health (MDH) revised its requirements for the Minnesota Vaccines for Children (MnVFC) program to include continuous temperature monitoring for all storage units that hold Vaccines for Children (VFC).<sup>1</sup>

This presented an opportunity for Mayo Clinic Health Systems (MCHS) sites in Southeast Minnesota (SE MN) to improve patient safety by streamlining vaccine temperature monitoring practices across these sites.

**Objective:** Improve patient safety and staff satisfaction by streamlining vaccine temperature monitoring practices across six (6) Mayo Clinic Health Systems (MCHS) sites to be compliant with the revised MDH guidelines.

**Methods:** The DMAIC quality improvement framework was used to guide the improvement efforts.

**Results:** Implementation of an automated continuous temperature monitoring system (TempTrak® Enterprise), together with supporting policies and procedures reduced the risk of adverse patient safety events due to cold-chain failure and improved staff satisfaction from 7.1% to 64.2%.

**Conclusions:** Implementation of an automated continuous temperature monitoring system together with supporting policies and procedures can significantly reduce the risk of adverse patient safety events due to cold-chain failure, as well as improve staff satisfaction.

## Introduction

Vaccines protect children from serious illness and preventable diseases but must be stored within strictly controlled temperature ranges at all times.<sup>2</sup>

Exposure of vaccines to inappropriate temperatures can reduce vaccine potency and efficacy, increasing the risk that children are not provided with maximum protection against illness and diseases.<sup>3,4</sup>

At MCHS sites in the River Corridor of SE MN, all six (6) hospitals and clinics in that region used min-max thermometers for measuring the temperatures of storage units that held MnVFC. These temperature checks were manually performed twice daily and documented on paper log sheets.

At three (3) of the six (6) sites, the min-max thermometers could only be manually read, therefore if a temperature excursion were to occur, it would not be caught until someone physically read the thermometer during one of the daily checks. This meant that vaccine could potentially be exposed to inappropriate temperatures for several hours.

At the remaining three (3) sites, an automated temperature monitoring system was in place which triggered alerts when temperatures went out of range, but the system was not supported by robust processes.

These were critical gaps that needed to be addressed.

Under the direction of the SE MN Clinical Practice Committee, a multidisciplinary team was formed to improve vaccine temperature monitoring practices to meet the new MDH guidelines.

## Methods

Using the DMAIC quality improvement framework, a multidisciplinary team comprised of Nursing, Pharmacy and Facilities Services collaborated to:

- Define existing gaps in vaccine temperature monitoring practices (see Table 1)
- Measure patient safety, reputational and financial risk of cold-chain failure as well as staff satisfaction with current processes
- Analyze factors contributing to gaps in vaccine temperature monitoring practices (see Figure 1)
- Improve vaccine temperature monitoring practices across six (6) MCHS hospitals and clinics within 10 months by:
  - Implementing an automated continuous temperature monitoring system (TempTrak® Enterprise)
  - Implementing policies, operational procedures and emergency response plans to ensure proper vaccine temperature monitoring, storage and handling practices
  - Training staff to ensure knowledge of policies, operational procedures and emergency response plans, optimal operation of storage units, maintenance of correct temperature ranges, and maintenance of daily temperature logs
- Control the changes by implementing an operational transition plan to ensure continuity.

## Results

An automated continuous temperature monitoring system (TempTrak® Enterprise) was installed across six (6) MCHS sites. Implementation of this system improved daily vaccine temperature monitoring rates from twice per day (via manual temperature checks) to up to 288 times per day (or every 5 minutes within a 24 hour time period). This represented an improvement of 98%.

Standardized policies, procedures and emergency response plans were also implemented to support the implementation of TempTrak® Enterprise. Overall, staff satisfaction improved from 7.1% to 64.2% following the system and process changes.

No adverse patient safety events were recorded from Jan 1, 2017 – Dec. 31, 2017. It is anticipated that the improvements implemented will further reduce the risk of adverse patient safety events related to vaccine cold-chain failure.

## Figure 2: Paper Storage Log

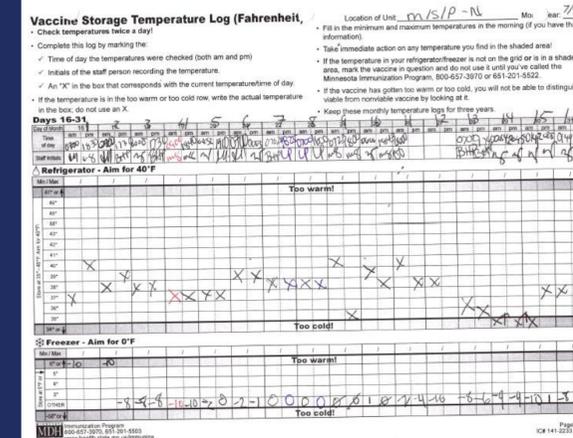


Figure 2: Example of Paper Vaccine Temperature Storage Logs (used before implementation of continuous temperature monitoring)

## Figure 3: Electronic Log



Figure 3: 24-Hour History Chart Showing Electronic Temperature Storage Log (all data points shown on the chart can be found in a table below the chart in the temperature monitoring software).

## Lessons Learned

- Formation of a multidisciplinary team early in the project was crucial to the project's success
- Use of quality improvements tools such as checklists, the cause and effect chart and failure mode and effects analysis (FMEA) provided structure and facilitated collaboration between team members
- Clear communication and involvement of all stakeholders from different functional areas helped to ensure the successful implementation of the new system, policies and procedures

## Conclusions

Vaccine temperature monitoring practices can be significantly improved through:

- Implementation of an automated continuous temperature monitoring system such as TempTrak® Enterprise
- Training and implementation of robust policies and procedures that include clearly delineated roles and responsibilities for staff members from different functional areas.

## References

- Minnesota Department of Health. MnVFC Guide to Temperature Monitoring Devices, February 2018, <http://www.health.state.mn.us/divs/idepc/immunize/mnvc/tempguide.pdf>. Accessed on 03/12/2018.
- U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Vaccine Storage and Handling Toolkit, January 2018, <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>. Accessed on 02/18/2018.
- Department of Health and Human Services, Office of Inspector General. Vaccines for Children Program: Vulnerabilities in Vaccine Management, June 2012, <https://oig.hhs.gov/oei/reports/oei-04-10-00430.pdf>. Accessed on 08/10/2018.
- Kroger AT, Duchin J, Vázquez M. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf>. Accessed on 09/05/2018.

## Table 1: Existing Gaps

Table 1: Existing Gaps in Temperature Monitoring, and Vaccine Storage and Handling Practices

Area	Current State	Identified Gaps
Temperature Monitoring	<ul style="list-style-type: none"> <li>Min-max thermometers used to perform twice daily temperature checks in RW, CF, LC, EL, PL, ZU*</li> <li>Twice daily temperature checks documented on paper Vaccine Storage Temperature Logs across all six (6) MCHS sites</li> <li>TempTrak installed in RW, CF, and LC and used to push alerts to Facilities and Pharmacy departments when temperatures go out of range (not fully used for temperature monitoring capabilities). The expectation was that Facilities Services respond and address the problem, moving medication if needed.</li> <li>LC maintained on a separate TempTrak database from RW, CF</li> </ul>	<ul style="list-style-type: none"> <li>Use of min-max thermometers do not meet 2018 MDH requirements for continuous temperature monitoring</li> <li>Unable to tell exactly when temperatures began to trend out of range with min-max thermometers or how long they were out of range for</li> <li>TempTrak not being fully utilized for temperature monitoring and documentation in RW, CF, LC</li> <li>Only licensed staff members can move medication/vaccines. This posed a problem after hours when facilities engineers received alerts and there was no nurse or pharmacist on site to assist with moving medication/vaccines.</li> <li>In CF, facilities engineers have no access to the pharmacy refrigerators and freezers to investigate potential problems when an alert is received.</li> </ul>
Vaccine Storage and Handling	<ul style="list-style-type: none"> <li>Minnesota Vaccines for Children Policies and Procedures Manual 2018 used for guidance along with CDC's 2018 Vaccine Storage &amp; Handling toolkit</li> <li>No documented organizational policy or procedure existed for River Corridor/SE MN outlining clear roles and responsibilities for different functional areas.</li> </ul>	<ul style="list-style-type: none"> <li>No organizational policy or procedure document existed that outlined key roles of different functional areas in the process.</li> <li>No role existed to coordinate or own the vaccine temperature monitoring and storage and handling functions.</li> </ul>

## Figure 1: Cause and Effect

