Maintenance of the last step of the cold chain: on-farm refrigerator storage and performance

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Abstract

Maintenance of the cold chain post-manufacturing for livestock vaccines is the most important way to ensure maximum product efficacy and safety. Often, it is unknown if refrigerators used for farm storage are operating in the recommended temperature interval (RTI) for vaccine storage of 36°F to 46°F (2°C to 8°C), and whether or not they are able to maintain those temperatures as the ambient room temperature changes. In order to evaluate the performance of different styles of refrigerators on dairy farms and veterinary clinics in the southeast United States, a convenience sample of 20 refrigerators was selected for the placement of digital data loggers to monitor the internal refrigerator and ambient temperatures over 5 months from July to November 2021. The percentage of time that refrigerators spent outside the RTI ranged from 0% to 80% with a median of 22%. The percentage of time outside the RTI was significantly greater for household refrigerators (37%) compared to commercial refrigerators (2.2%), while mini-refrigerators (27%) were intermediate. The estimated mean daily temperature range (MDTR) of household refrigerators (9.5°F, 5.3°C) was also significantly greater than that for commercial (5.4°F, 3°C) or mini (5.8°F, 3.2°C) refrigerators. Implications of the study show the necessity for proper temperature monitoring, staff training and record keeping to ensure vaccine efficacy and product safety, and ultimately improve animal health and productivity.

Key words: livestock vaccines, cold chain, refrigerator monitoring

Introduction

The cold chain is the coordinated system of vaccine storage, transport and maintenance at the proper temperature in order to maintain vaccine viability, safety and effectiveness. With some exceptions, the recommended temperature interval (RTI) for vaccine storage is between 36° to 46°F (2° to 8°C).[1] Different types of vaccines have different levels of sensitivity and susceptibility to temperature fluctuations outside of the recommended range. Live and modified live vaccines contain attenuated virus or bacteria and are more sensitive to temperature excursions, where an excursion is defined as any measurement outside the recommended range.[2] Killed vaccines contain adjuvants to boost immune response, which depending on the type of adjuvant, may make them more stable in high temperatures, but more sensitive to damage from freezing.[2] While freezing a killed vaccine can lead to reduced potency as a result of ice crystal formation in the adjuvant and subsequent separation from the antigen, vaccines containing Gram-negative bacteria can also release endotoxin causing serious side effects in animals.[3] If the storage temperature at any point in the cold chain rises above (too hot) or below (too cold/freezing) the RTI for extended periods of time, there is an increased risk of loss of vaccine potency and viability for all types of vaccines.[4] The duration and degree of temperature excursions outside of the RTI are positively correlated with the probability and degree of damage to the vaccine, but this relationship is highly dependent on the formulation of the vaccine.[2] Larger volume containers of vaccine will maintain their own internal temperature above freezing for longer than smaller vials during a temperature excursion,[3] which may protect from temporary shifts in air temperature within a refrigerator.

In human medicine, extensive emphasis has been placed on the proper storage and maintenance of vaccines. The Vaccine Storage and Handling Toolkit, created by the Centers for Disease Control and Prevention (CDC), discusses best handling practices, recommendations and resources available for appropriate storage and handling of human vaccines (**https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf**). The toolkit highlights 3 main elements vital for an effective cold chain. They are a well-trained staff, reliable storage and temperature monitoring, and accurate vaccine inventory management. Additionally, human vaccine storage often requires the use of pharmaceutical-grade commercial refrigerators with narrow operating temperature ranges, designed specifically for the storage of vaccines.[1]

Aside from manufacturer's recommendations and the American Animal Hospital Association (**https://www.aaha.org/aaha-guidelines/vaccination-canine-configuration/vaccine-storage-and-handling/**), there are few specific written guidelines for vaccine and pharmaceutical storage in veterinary medicine. Additionally, the amount of research available in veterinary vaccine and pharmaceutical storage is limited. A 2015 paper from Ondrak, et al., investigated pharmaceutical storage in veterinary practice vehicles for elevated temperature excursions. All 24 vehicles tested had temperatures that exceeded the labeled storage temperatures.[5] A follow-up paper analyzed the active ingredient concentration of 5 commonly used veterinary pharmaceuticals following exposure to elevated temperatures after 0, 40, 80 and 120 days. While no change in concentration was noted, the authors acknowledged the limited circumstances and recommended adhering to the proper storage temperatures.[6] To examine refrigerated storage in the veterinary field, Williams and Paixão investigated how well farm refrigerators in southwest England maintained the correct temperature for the storage of livestock vaccines.[7] Results showed that the 17 farm refrigerators evaluated in the study spent 16% of their time outside of the manufacturer's recommended temperatures for the vaccines.[7]

The investigators' experience is that many refrigerators used for vaccine storage on regional cattle operations are older, vary in size and inventory, and are located in buildings lacking temperature control. Also, with the exception of commercial refrigerators, very few refrigerators used on local farms are equipped with internal thermometers to monitor temperatures. Many of the aforementioned refrigerators contain thousands of dollars' worth of vaccines and pharmaceuticals. Failure of the storage portion of the cold chain can result in an increase in disease risk due to the administration of non-viable vaccines, substantial economic losses for cattle owners noted as an increase in treatment costs for sick animals, and the cost of vaccine replacement and revaccination of animals. The main objective of the current study was to quantify characteristics of refrigerator operating temperatures on regional dairy and veterinary operations, including the percentage of time that refrigerators spent outside the RTI as well as the mean daily temperature range (MDTR), and to identify variables that were associated with those characteristics.

Materials and methods

In order to evaluate the storage methods used on dairy farms and local veterinary clinics, the performance of the refrigerators over time, and the risk factors for temperature excursions, a convenience sample of 20 refrigerators was selected from current University of Georgia College of Veterinary Medicine dairy cattle clients, University of Georgia and Clemson University dairy herds, other local dairy operations, and local veterinary clinics that maintain an inventory of refrigerated veterinary vaccines. The following information was recorded about the farms and clinics that agreed to participate: the location of the farm, the location of the refrigerator on the farm, whether or not the refrigerator was stored in a climate-controlled space (air conditioned in the summer and/or heated in the winter), the starting inventory and value of contents, and the type of refrigerator. Contents of the refrigerators and the area surrounding the refrigerator were photographed.

The refrigerators were designated as either mini dorm-style, household or commercial refrigerators. Mini dorm-style refrigerators are compact refrigerators ranging in size from 1.7 to 4.4 cubic feet (0.05 to 0.12 cubic meters) that fit in small areas or on shelving, and may or may not have an internal freezer in the refrigeration compartment. Household refrigerators included those that are not considered pharmaceutical-grade storage refrigerators, are designed for the storage of household food, and may or may not have a freezer compartment. These refrigerators typically have solid glass or plastic shelving that restricts internal air flow. Commercial refrigerators are those that are designed for use in commercial applications. The presence of wire shelving and circulation fans enables even temperature distribution throughout. They do not have in-the-door storage or freezer compartments. Pharmaceutical grade units are a type of commercial refrigerator that are designed specifically for the storage of vaccines and have a narrow operating temperature range.

Each of the selected refrigerators was fitted with a digital temperature data logger with a 5-mL glycol bottle surrounding the temperature probe.[a] This model of digital data logger complies with the CDC guidelines for vaccine storage and monitors both ambient (environment surrounding the refrigerator) and internal refrigerator (probe) temperatures. The calibration on the thermometer is ISO 17025 certified for 3 years and the loggers are battery operated so loss of power was not an issue. Wireless data transfer allows for easy download of information to the cloud data storage.

The 5-mL glycol bottle with temperature sensor (probe) was placed as close to the center shelf as possible and stuck to the inside of the refrigerator using adhesive pads. Placement was prioritized in an area where farm/clinic staff would be less likely to hit or move the bottle for the duration of the study. The logger unit and display, which contained the ambient temperature sensor, was attached magnetically to the front or side of the refrigerator. A magnet with the investigator's phone numbers and study information was added adjacent to the logger for the duration of the study, with a request to not move or destroy the logger and probe.

Ambient and probe temperatures were recorded every 10 minutes for the duration of the study, from July 1, 2021 until November 30, 2021. Follow-up visits were conducted as needed to ensure the device was operating correctly. Temperature data were downloaded from the logger into a cellular phone application, and then from the online logger software to separate spreadsheets. Data were then consolidated into a relational database.

Statistical methods

Descriptive statistics were reported as the median and range. The proportion of time that refrigerators spent outside of the RTI for vaccines was modeled using generalized estimating equations (GEE) with a binomial family and logit link. GEE models included refrigerator as a clustering variable and utilized robust standard errors to account for overdispersion in the binomial response. The MDTR of refrigerators averaged across the duration of the study period was calculated as the mean (daily maximum – daily minimum) and was modeled using linear regression. The normality of residuals was assessed using the Shapiro-Wilk test. Variables considered as predictors in the regression analyses included: refrigerator type (household, commercial or mini), presence of a freezer compartment, location in an air-conditioned or heated space, the mean ambient temperature, and the mean daily range of ambient temperature. Variables with $P < 0.2$ in the univariable analysis were considered for inclusion in the multivariable analysis. Multivariable model selection was performed using a manual backward step-wise procedure until only variables having $P < 0.05$ remained. Two-way interactions between predictor variables were not evaluated due to the small sample size and the exploratory nature of the analyses. Pairwise comparisons between refrigerator types were performed using the Bonferroni procedure to limit the overall type I error probability to 5%. All statistical tests assumed a 2-sided alternative hypothesis, and values of $P < 0.05$ were considered statistically significant. Analyses were performed using commercially available statistical software.[b]

Results

Temperature loggers were placed in 20 refrigerators: 16 on privately-owned commercial dairy operations, 2 on university-owned dairy operations, and 2 at local veterinary clinics. One refrigerator was located in South Carolina, one in Florida and the remaining spread throughout Georgia. Information on refrigerator characteristics, including the type of refrigerator, operating environment and inventory value at the beginning of the study, is summarized in Table 1. Refrigerators in the study were used to store vaccines, pharmaceuticals, food and

Table 1: Characteristics of 20 refrigerators used for vaccine and pharmaceutical storage in a temperature monitoring study conducted from July 1, 2021 to November 30, 2021.

Refrigerator type and number ID	Location	Inventory value	Air-conditioned space	Heated space	Freezer
Commercial #1	Commercial dairy, office by parlor	$6,945	No	No	No
Commercial #2	Veterinary clinic, near front entrance	$6,555	Yes	Yes	No
Commercial #3	Commercial dairy, holding pen shed	$5,478	No	No	No
Commercial #4	Commercial dairy, drug room	$15,429	Yes	Yes	No
Household #1	Veterinary clinic, back room	$1,302	No	No	Yes
Household #2	Commercial dairy, supply room	$832	Yes	Yes	Yes
Household #3	Commercial dairy, storage room	$7,845	Yes	No	No
Household #4	Commercial dairy, breeding shed	$4,394	Yes	No	Yes
Household #5	Commercial dairy, storage room	$646	Yes	Yes	Yes
Household #6	Commercial dairy, breeding shed	$79	No	No	Yes
Household #7	Commercial dairy, breeding shed	$416	No	No	Yes
Household #8	Commercial dairy, storage room	$1,091	No	No	Yes
Household #9	Commercial dairy, drug room	$1,147	No	No	Yes
Household #10	Commercial dairy, chicken house	$1,729	No	No	Yes
Household #11	Commercial dairy, office	$1,235	No	No	Yes
Mini #1	University dairy, office	$1,844	Yes	Yes	Yes
Mini #2	Commercial dairy, shed by barn	$1,032	No	No	No
Mini #3	University dairy, drug room	$1,734	No	No	Yes
Mini #4	Commercial dairy, heifer barn	$673	No	No	No
Mini #5	Commercial dairy, treatment area	$894	No	No	Yes

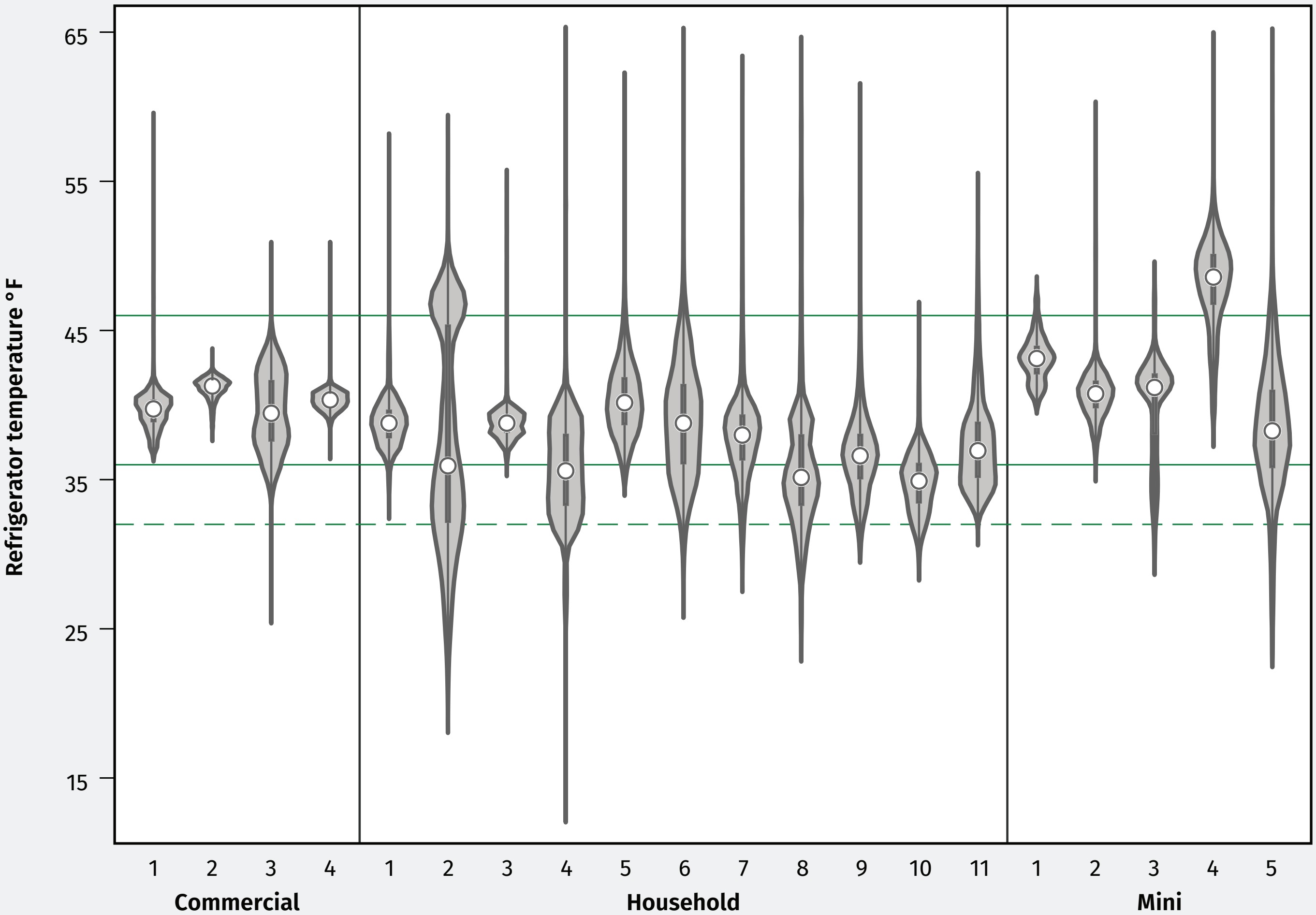
beverages, and milk samples. The inventory value of vaccines and pharmaceuticals in the refrigerators at the beginning of the study ranged from $79 to $15,428 with a median value of $1,268. Temperature measurements were recorded in 10-minute increments from July 1, 2021 to November 30, 2021 for all refrigerators except one (Household #5), in which the temperature probe stopped recording on November 10.

The overall distribution of temperature measurements is illustrated for all 20 of the refrigerators in Figure 1. Detailed time-series plots of the refrigerator and ambient temperatures are shown in Figure 2 for 12 refrigerators, which were selected as general representatives for each of the refrigerator size categories. The primary outcomes of interest were the percentage of time that refrigerators spent outside the RTI of 36°F to 46°F (2°C to 8°C), and the extent of intraday variability in refrigerator temperatures as measured by the MDTR.

Across all refrigerator types, the percentage of time that refrigerators spent outside the RTI ranged from 0% to 80% with a median of 22% (Figure 3). Based on a GEE logistic regression analysis, only refrigerator type was significantly associated with the percentage of time that refrigerators spent outside the RTI ($P < 0.001$). In pairwise comparisons between refrigerator types, the predicted percentage of time spent outside the RTI was significantly lower for commercial refrigerators (2.2%) compared to household refrigerators (37%), while the predicted percentage of time spent outside the RTI by mini-refrigerators was intermediate (27%), and did not differ significantly from either of the other 2 refrigerator types. Measurements below 36°F (2°C) accounted for most of the time spent outside the RTI (Figure 3). The percentage of time that refrigerators spent below 32°F (0°C) ranged from 0% to 24% with a median of 0.05%. One refrigerator (Mini #4) spent 80% of its time above 46°F (8°C).

The MDTR across all refrigerator types ranged from a minimum interval width (daily maximum – daily minimum) of 1°F (0.6°C), to a maximum interval width of 14°F (8°C) with a median interval width of 8°F (4°C). Results of a linear regression analysis for the prediction of MDTR are summarized in Table 2, and the distribution of MDTR values is illustrated by refrigerator type in Figure 4. The MDTR of refrigerators was significantly associated with refrigerator type ($P = 0.002$), mean ambient temperature ($P = 0.020$), and mean daily range of the ambient temperature ($P < 0.001$). Compared to household refrigerators, which had an estimated mean MDTR of 9.5°F (5.3°C), the MDTRs of commercial refrigerators (5.4°F; 3°C) and mini refrigerators (5.8°F; 3.2°C) were both significantly smaller, after adjusting for the mean ambient temperature and the mean daily range of ambient temperature. For every 1°F (0.6°C) increase in mean ambient temperature, the MDTR increased by 0.37°F (0.2°C). And for every 1°F (0.6°C) increase in the mean daily range of ambient temperature, the mean

Figure 1: Violin plot of temperature distributions for each of 20 refrigerators used to store vaccines by refrigerator type. Temperatures were recorded in 10-minute increments between July 1, 2021 and November 30, 2021. For each refrigerator, the light grey shaded area illustrates the density of measurements in different temperature ranges, the dark grey bar represents the interquartile range (25th to 75th percentiles), the white circle represents the median, and the thin vertical lines extend to the maximum and minimum recorded temperatures. Solid horizontal lines indicate the recommended temperature interval for vaccine storage (36°F to 46°F; 2°C to 8°C), and the dotted horizontal line indicates the freezing point of water (32°F; 0°C).



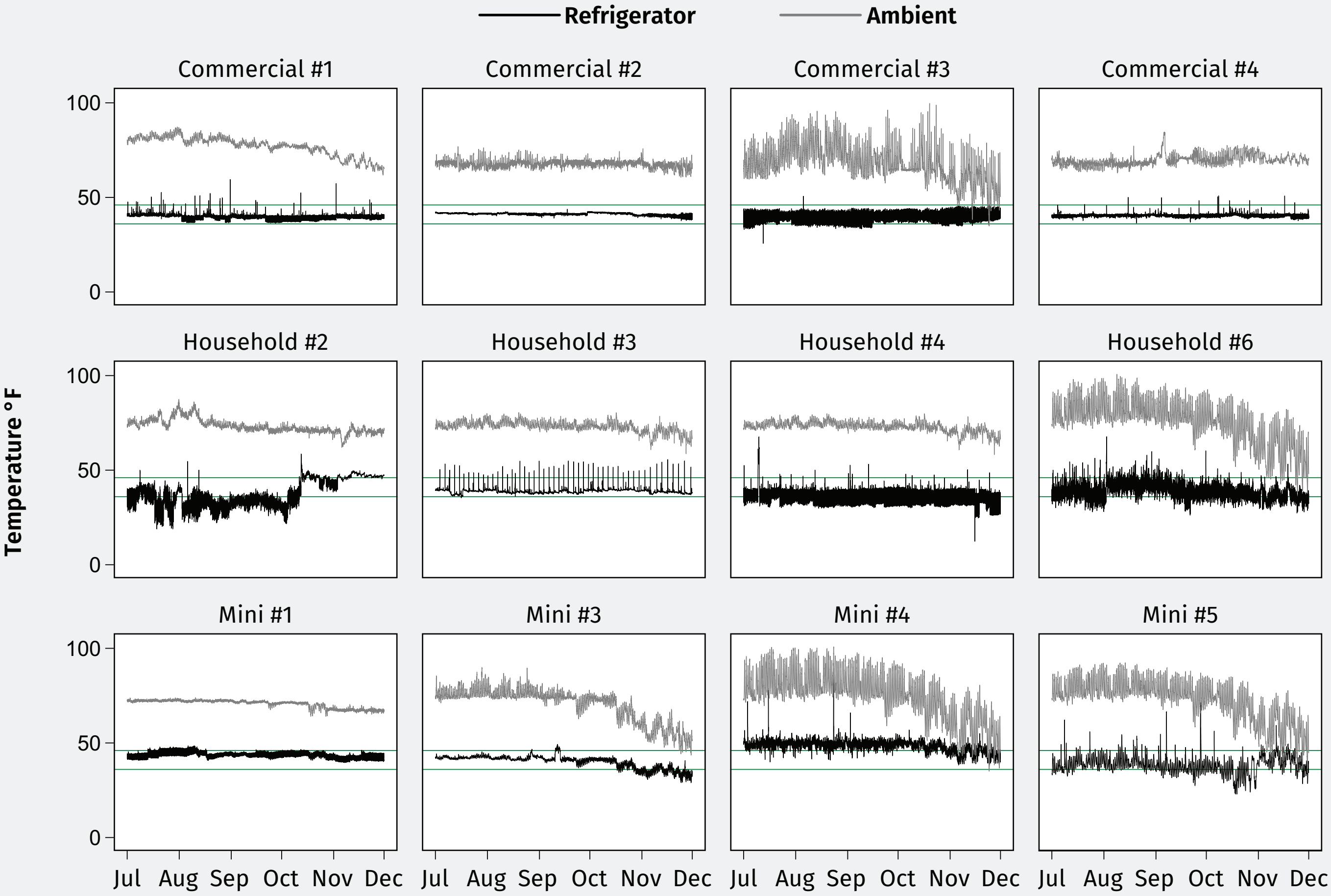
MDTR increased by 0.23°F (0.1°C). Consequently, placement of refrigerators in environments that were warmer and that had larger fluctuations in ambient temperatures was associated with increased variability in refrigerator temperatures, after adjusting for the refrigerator type. The coefficient of determination for the final multivariable regression model was R^2 = 0.78, indicating that the model explained approximately 78% of the variability in MDTR. Residuals from the final regression model were approximately normally distributed (Shapiro-Wilk test, $P = 0.34$).

Discussion

The type of refrigerator was significantly associated with both the percentage of time spent outside the RTI and the MDTR. Household refrigerators tended to run colder than either of the other types of refrigerators and operated more frequently below 32°F (0°C). While placement of the refrigerator in an air-conditioned or heated space was not significantly associated with the time spent outside the RTI, the mean ambient temperature and mean daily range in ambient temperature were significantly associated with the variability in refrigerator temperatures as measured by MDTR. Consistent ambient temperatures would be expected to lead to more consistent refrigerator temperatures regardless of the refrigerator type.

The number of refrigerators included in the study is small, specifically with only 4 commercial refrigerators and 5 mini refrigerators represented. However, based on the data obtained, the commercial refrigerators appeared to avoid deviations from the RTI on average more effectively than either of the other types of refrigerators (see Figure 2). Commercial refrigerators also exhibited less intraday temperature variability than the other refrigerator types, with the commercial refrigerator that displayed the most variability (Commercial #3) being one that was located in an environment that was not temperature controlled (Figure 1 and Figure 2). This finding is supported by best practices from the CDC which recommends the use of purpose-built pharmaceutical-grade commercial refrigerators for vaccine storage due to their relatively narrow operating temperatures and specific design for the storage of biologics.[1] These refrigerators typically have overhead fans for thorough air dispersion throughout the unit to prevent the formation of cold or warm air pockets, have adjustable wire shelves to allow for better

Figure 2: Time-series plots of refrigerator (black) and ambient (grey) temperatures for 12 selected refrigerators by refrigerator type. Temperatures were recorded in 10-minute increments between July 1, 2021 and November 30, 2021.



air circulation, a micro-processor and a digital thermostat for temperature control, and lack storage bins and shelves on the doors.[8] A glass front on a commercial refrigerator would ideally result in shorter periods of temperature fluctuation due to door opening as the required product has already been identified and located prior to opening the door. We were unable to evaluate this in the current study, however, because only 2 of the monitored refrigerators had glass doors.

Household refrigerators are useful due to their ready availability and relatively cheaper price. While a few of the household refrigerators performed well during the study, on average they showed the largest amount of variability in mean daily temperature range among all the refrigerator types. Additionally, 7 out of the 11 household refrigerators spent from 3% to 25% of their time below 32°F (0°C), increasing the likelihood of exposing vaccines to freezing temperatures. While the results of this study did not show that the presence of a freezer was significantly associated with the percentage of time spent outside of the RTI, it is possible that these lower temperatures are due to a build-up of colder air adjacent to the freezer compartment and a lack of air circulation when the compressor is not running. A case study conducted by the Australian Centre for International Agriculture in 2015 found that over a 24-hour period, only the middle and bottom shelves of a 2-door, frost-free domestic (household) refrigerator were suitable for the storage of vaccines.[9] That study also found that the compressors in household refrigerators were much slower to react to temperature changes and the thermostats have a much wider acceptable range as a household refrigerator's primary storage use is for food, not vaccines. According to a 2017 research review into human vaccine storage in household refrigerators conducted by Hanson, et al., approximately 33% and 37% of vaccine storage in wealthier and lower income countries, respectively, were considered too cold.[10] Given the overall temperature variability inherent to these refrigerators, it is understandable that our results showed more variability in household refrigerators compared to the other 2 types of refrigerators.

If a farm already owns a household refrigerator but would like to decrease potential vaccine losses, precautions can be taken to reduce the impact of temperature excursions. The refrigerator should be placed in a clean and level area, with plenty of space left around the refrigerator to allow for adequate air flow. The refrigerator should only be used to store vaccines. The addition of food is not only a health hazard, but can lead to more frequent refrigerator door opening and subsequent temperature excursions. If other pharmaceuticals are stored with vaccines, they should be stored on a shelf below the vaccines, to reduce the risk of contamination dripping down onto the vaccine. Wire shelves that allow for better air flow are preferable over solid shelving. Finally, the CDC recommends creating a buffer zone using water bottles placed on the top and bottom shelves standing up, with additional bottles lining the door shelves.[1] This will decrease the impact of

Figure 3: Dot plot of the percentage of time that 20 refrigerators used to store vaccines spent in various temperature ranges by refrigerator type. Temperatures were recorded in 10-minute increments between July 1, 2021 and November 30, 2021.

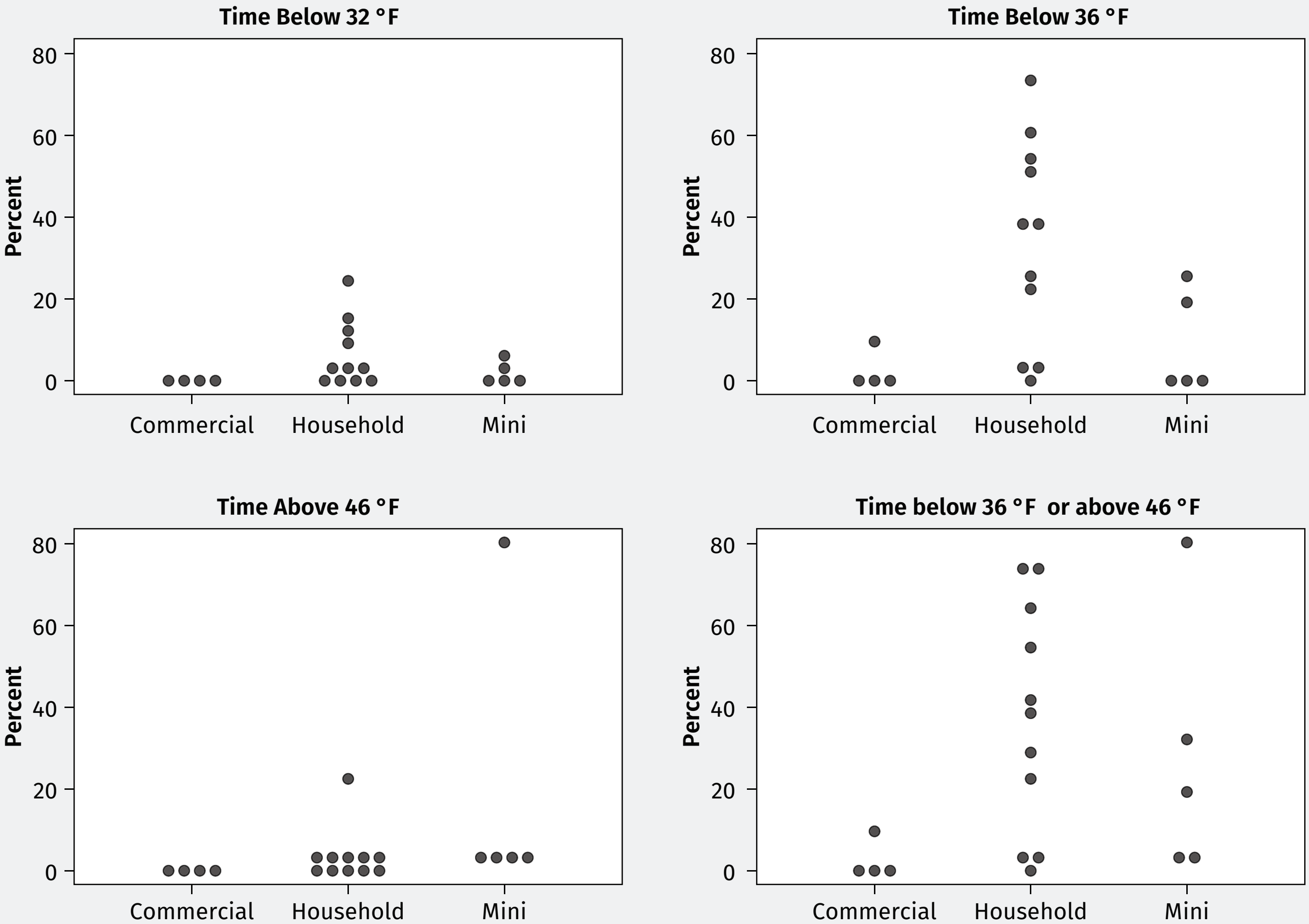
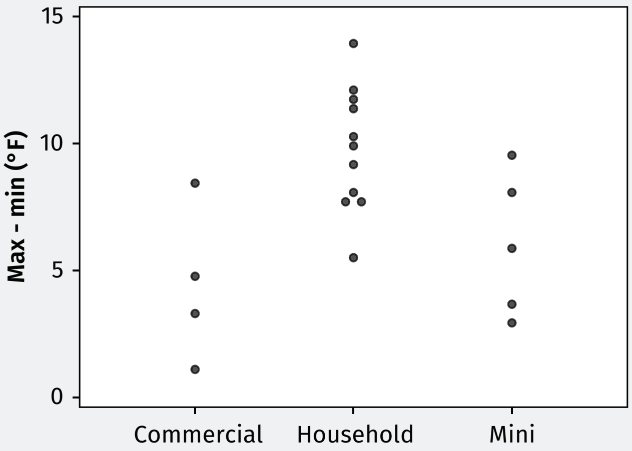


Table 2: Multivariable linear regression analysis for the prediction of mean daily temperature range (maximum – minimum) in °F for 20 refrigerators used for vaccine storage. R^2 = 0.78.

Variable	Coefficient (SE)	95% CI	*P*
Refrigerator type			0.002
Household (n = 11)	Reference	Reference	
Commercial (n = 4)	-4.06 (1.17)	-6.54, -1.60	0.003
Mini (n = 5)	-3.66 (1.01)	-5.82, -1.51	0.002
Mean ambient temperature (°F)	0.37 (0.14)	0.07, 0.68	0.020
Mean daily range of ambient temperature (°F)	0.23 (0.06)	0.11, 0.35	0.001
Constant	-23.9 (10.2)	-45.6, -2.2	0.033

Figure 4: Dot plot of the mean daily temperature range (maximum – minimum) in °F for 20 refrigerators used to store vaccines by refrigerator type.



temperature excursions as a result of power failure, opening and closing the door, and loading and unloading the refrigerator. The bottles will also prevent the storage of vaccine in low air flow areas. While this will decrease overall space in the refrigerator, it is the best way to ensure vaccine viability.

When investigating domestic refrigerators in southwest England, Williams and Paixão found that during their study, 10 of the 17 farm refrigerators recorded at least one temperature above or below their desired reference range of 36° to 46°F (2°C to 8°C) every month of the study. These variations coincided with the increases and decreases in the registered ambient temperatures.[7] In a refrigerator function study, Chojnacky, et al., found that increased packing density, increased room (ambient) temperature, and power outage negatively impacted a mini refrigerator's ability to maintain the RTI. At least 1 vial's internal temperature became elevated outside the reference range in almost every mini refrigerator vaccine trial.[11] The consensus among the CDC and the World Health Organization is not to use mini refrigerators as vaccine storage devices. In general, the temperatures inside the mini refrigerators are deemed too unstable to maintain the viability of vaccines.[1,12] The exception to this rule would be pharmaceutical-grade mini refrigerators designed specifically for vaccine storage. In the current study, mini refrigerators were found to have less temperature variability than household refrigerators, and they were intermediate between commercial refrigerators and household refrigerators in their ability to maintain temperatures within the RTI.

Williams and Paixão found that very few farms (29%) had refrigerators dedicated to the storage of livestock vaccines.[7] The authors concluded that all of the domestic refrigerators used in their study at some point failed to maintain the proper storage temperatures.[7] Similarly in this study, one of the 20 refrigerators was dedicated for vaccine storage, while 45% were used for vaccine and pharmaceutical storage. Likewise, only 1 of the 11 household refrigerators in this study (Household #3) was able to maintain the RTI consistently throughout the study, most likely influenced by placement in an air-conditioned space and lack of exposure to ambient temperature extremes. Interestingly, this refrigerator did regularly exhibit short-term temperature spikes that exceeded the upper limit of the RTI, presumably coinciding with the refrigerator's defrost cycle (Figure 2). The amount of time spent outside of the RTI, however, was negligible.

The Vaccine Storage and Handling Toolkit (2021) states that a calibrated temperature monitoring device must be installed in all refrigerators used for the storage of vaccines. This will allow trained observers to detect temperature excursions in order to reduce the risk of adverse events or product loss due to heat or freezing damage and the resultant loss of viability. A digital data logger is recommended due to the ease of operation and ability to download data and review temperature trends. A quality digital data logger with a thermocouple placed in a glycol vial (as used in this study) is more cost effective than the replacement of non-viable vaccines or cattle losses due to illness or death.[1] All but one of the commercial refrigerators in this study had a built-in digital thermometer display to monitor the change in refrigeration temperature and an alarm to alert in the event of temperature variation outside of reference range. The other commercial refrigerator had an analog-style thermometer placed on the top shelf that required monitoring for temperature variations but could be used to set the cooling to a specific temperature. The remaining household and mini refrigerators in the study had dial-style controllers with markings from either 1 to 5, 1 to 9, or cold to coldest. One household refrigerator did have a prepositioned digital thermometer in place that was added by the producer. Owner manuals do not typically specify what temperatures correspond to the number or word settings on the dials of the household and mini refrigerators. Without the installation of an after-market thermometer, farm owners are placing heavy reliance on the refrigerator manual recommended setting, feel of the refrigerator, and/or whether or not the contents are cold enough or frozen. A practical example of the use of digital data loggers is from McColloster, et al.[13] They noted a positive correlation between the increased number of pertussis cases in Houston, Texas, and the increased incidence of freezing in refrigerators while not monitored after-hours or over weekends. Without the installation of data loggers, these freezing events would have gone unnoticed.[13]

Limitations to the current study are first and foremost that the farms and veterinary clinics were selected for the study by convenience, and they are not a random or representative sample of farms. The geographical location and season were not completely representative of conditions across the United States and Canada, as they had little exposure to very cold weather. In many dairies located in cold parts of the U.S. and Canada, refrigerators may be exposed to very cold temperatures if not housed in heated buildings, and this may increase the risk of vaccine freezing. In this study, there were very few time points where the ambient temperature was below the RTI, and thus this effect could not be analyzed. Additionally, the study would have had more power to identify variables associated with temperature control with a larger sample size. Finally, given the distance to some of the farms and the download of data occurring at the end of the study, the reason behind temperature excursions in specific refrigerators is unknown as the farm may not know the excursion occurred or the time from occurrence was too far removed for memory.

Despite the aforementioned limitations, the findings in this study confirm the importance of temperature monitoring and recognizing the inherent differences between refrigerator types. Temperature excursions occur frequently in household and mini refrigerators which can negatively impact vaccines.

Commercial refrigerators performed the best in all aspects of this study and are the favored device for the storage of vaccines on the farm or in the clinic. The recommendation to add proper temperature monitoring devices can be accomplished at a relatively low expense to the farm. Training plans for staff on the proper reference ranges, record keeping, and what to do in the event of a temperature excursion are available on the CDC website.[1] Additionally, well-maintained records and active monitoring reduces the risk of using damaged or unsafe product and subsequent disease risk, thereby protecting vaccine viability and reducing economic loss in the long run. Stressing the importance of maintaining vaccines at the correct RTI and the subsequent financial impact to farm owners should be a priority.

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Endnotes

[a]InTemp Bluetooth Temperature with Glycol Bottle (VFC/CDC) (CX402-VFC205), Onset Computer Corporation, Bourne, MA 02532

[b]Stata version 17.0, StataCorp LLC, College Station, TX

Acknowledgements of any conflicts of interest

The authors declare that there were no conflicts of interest in this study.

Author contributions

Dr. Cynthia Fallness was the primary author and assisted with on-farm/clinic setup, data collection and analysis, and results interpretation. Dr. Emmanuel Rollin coordinated farm and clinic participation, assisted with setup and collection of data, and drafting of the manuscript. Dr. Roy Berghaus assisted with statistical analysis, interpretation of the data and manuscript drafting. Dr. Bradley Heins assisted with concept, project design and manuscript editing.

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