Utilizing temperature data loggers to monitor temperature deviations in delivered and stored animal health vaccine shipments

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The use of biological products (vaccines) to prevent disease in livestock is a widely accepted management practice. In many instances, they are shipped long distances to distributors at multiple locations and finally to other retailers and end users. The opportunity for temperature abuse is real unless specific protocols are in place to provide proper shipping, handling instructions and training. Our research shows that although shipped products undergo wide temperature fluctuation, they do so for only a very short duration, and storage facilities and shipping containers are adequate for decreasing the risk of temperature abuse for biologic products.

Summary

The objective of this project was to document the prevalence of temperature deviations in shipped containers of biological products. Biologics are shipped from manufacturing facilities to distributors and then to veterinary businesses, animal health dealers and, ultimately, end users. This shipping is done via commercial carriers with instructions to keep containers cool, with a wide range of cool temperatures. Once the shipment has been delivered, the containers are stored in a refrigerated unit until the vaccine is shipped or received by the end user and stored or administered. Vaccines are relatively intolerant of extreme temperature ranges. Most vaccines are labeled to be stored at 2 to 8 C (36 to 46 F). The labels also say DO NOT FREEZE and to protect the vaccines from light. Temperature fluctuations can occur at any time following the vaccines' release from the manufacturing facility. Three of four temperature storage facilities maintained consistent recommended temperatures for biologic products. Shipped products were found to undergo wide temperature fluctuation, albeit for very short duration. Our study demonstrated storage facilities and shipping containers are adequate for decreasing the risk of temperature abuse for biologic products.

Introduction

Biological products used in livestock production, primarily vaccines to prevent infectious disease, are shipped from manufacturing locations to distributers. From distribution centers, they are shipped to retail outlets and, finally, to the end user. The specifications for storing and shipping of biological products from manufacturers to distributers are clearly documented and held to a high standard.

The specifications for storing at distribution and retail centers would equal that of the manufacturers; however, the oversight may not be at the same stringent level. That is, the refrigeration units in place to maintain a tight control over temperature variation may, at times, completely fail without notice or allow too much temperature variation, even while appearing to work properly. Storage units at the end consumer level rarely are checked for accuracy and proper storage temperatures.

Storage while shipping also is part of this process and is a control point that appears to be monitored rarely. This temperature-monitoring survey attempts to find the control points in the storage and shipping process that need additional oversight.

Experimental Procedures

Twenty individual temperature-monitoring devices were purchased to be placed in strategic locations in distribution and retail storage units and in shipping containers delivered to end users. The monitoring devices were LogTag TRIX-8 Temperature Recorders (LogTag Recorders; Northcote, Auckland, New Zealand). These devices were programmed to record temperature every five minutes and can record up to 8,000 data points during a 28-day period. Four storage units — two distributor and two end-user units — and eight shipments to end users were monitored.

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Results and Discussion

Three of four distribution and retail storage units were found to be in compliance with recommended temperature settings. The storage unit (unit 1) that fell outside of compliance had an average storage temperature of 45.3 F, with a standard deviation of 2.1 F. The range of temperatures for this unit was 39.3 to 51.5 F. The recommended temperature for vaccine storage is from 36 to 46 F.

During the recording period, the temperature would remain above 46 F for as long as three days. For storage unit 4, only once did the temperature reach 49.4 F and only for 10 minutes. It is important to remember that short term, moderate temperature abuse is not likely to result in the same temperature change of the contents of vaccine containers. This means that a short duration, moderate temperature change in temperature of the storage unit would not be expected to impact the efficacy of the product.

The problem with storage unit 1 was that the temperature remained out of compliance for approximately three days during the recording phase. While we may assume that most temperature-sensitive products in this cooler were not negatively impacted by this moderate out of compliance storage temperature, any shipping done without adequate temperature protection protocols may impact the safety and efficacy of these products.

All of the shipped products showed a wide variation in temperature readings. To be clear, most of these shipments arrived at their destination within one day without any evidence of severe temperature abuse. However, in one shipment, the fact that the shipped product did not contain an adequate measure of temperature protection in the container was apparent.

The product was shipped on Oct. 24 with a beginning temperature of 35.3 F; during shipment, the temperature rose to 70 F and remained at that temperature for approximately 12 hours before additional cooling was provided. This shipment may be considered to have a loss of efficacy, depending on the contents of the package.

All other shipped products were in compliance or did not suffer severe temperature abuse.

One of the additional research steps in a project such as this is to determine efficacy as a function of temperature abuse. The objective would be to determine whether extreme cold or heat and the duration of such impacts efficacy of product.

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Table 1. Average temperature and range of temperatures for vaccine storage units.

Storage Unit 1				
Analysis variable: Readings (F)				
Mean	Std Dev	Minimum	Maximum	N
45.3	2.15	39.3	51.5	4,025
Storage Unit 2				
Analysis Variable: Readings (F)				
Mean	Std Dev	Minimum	Maximum	N
37.35	0.93	35.2	39.7	2,281
Storage Unit 3				
Analysis variable: Readings (F)				
Mean	Std Dev	Minimum	Maximum	N
36.45	1.75	31.20	41.50	7,992
Storage Unit 4				
Analysis Variable: Readings (F)				
Mean	Std Dev	Minimum	Maximum	N
43.4	2.11	37.3	49.4	7,976

The average temperature and range of temperatures in shipped products were much more variable.

Table 2. Average temperature and range of temperature for shipped vaccine products.

Distributor 1	Shipped Oct. 24 – Received Oct. 25			
Analysis variable: Readings (F)				
Mean	Std Dev	Minimum	Maximum	N
51.7	15.5	32.2	71.6	495
Distributor 1	Shipped Oct. 21 – Received Oct. 22			
Analysis variable: Readings (F)				
Mean	Std Dev	Minimum	Maximum	N
40.7	1.85	37.8	42.6	250
Distributor 2	Shipped Oct. 15 – Received Oct. 16			
Analysis variable: Readings (F)				
Mean	Std Dev	Minimum	Maximum	N
64.05	4.9	50.3	71.2	265
Distributor 2	Shipped Oct. 7 – Received Oct. 8			
Analysis variable: Readings (F)				
Mean	Std Dev	Minimum	Maximum	N
38.8	3.02	29.3	47.5	222
Distributor 2	Shipped Oct. 15 – Received Oct. 16			
Analysis variable: Readings (F)				
Mean	Std Dev	Minimum	Maximum	N
46.7	1.2	42.5	48	224
Distributor 3	Shipped Nov. 18 – Received Nov. 19			
Analysis variable: Readings (F)				
Mean	Std Dev	Minimum	Maximum	N
34.3	0.93	33.1	36.2	290
Distributor 3	Shipped Nov. 18 – Received Nov. 20			
Analysis variable: Readings (F)				
Mean	Std Dev	Minimum	Maximum	N
46.2	4.3	38.2	52.1	642
Distributor 3	Shipped Nov. 18 – Received Nov. 19			
Analysis variable: Readings (F)				
Mean	Std Dev	Minimum	Maximum	N
41.6	4.1	34.7	47.4	247