

Assessment of Unrefrigerated Shipping Methods Used by Mail-Order Pharmacies and Exposure of Medications to Unsafe Temperatures

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Background

- Nearly **70%** of Americans, aged 40-79 years old, have used **at least 1 prescription drug** within the **past 30 days**.¹
- Currently, unrefrigerated medications are mailed out in bubble-padded envelopes **without** temperature monitors.²
- Deviations from the USP/NF recommended temperature storage ranges may decrease medication efficacy and jeopardize patient health outcomes.³⁻⁶

Objective

- Evaluate if the shipping methods used by mail-order pharmacies expose the contents of unrefrigerated packages to unsafe temperatures.

Methods

- The Package System:**
 - 4 x 8 in. and 6.5 x 10 in. HBLife® Bubble Mailers
 - Elitech® Temperature logger
 - United States Postal Service (USPS)



- Seasons:**
 - Winter: **MKT < 15°C**; consider adulterated
 - Summer: **MKT > 30°C**; consider adulterated

- Mean Kinetic Temperature (MKT):**
 - Simplified way of expressing the overall effect of temperature fluctuations during storage or transit of perishable goods.^{3,7}

Results

Table 1: Mailing Destinations' Characteristics

Destination	Travel Distance (Miles)	Average Temperature		Average Trip Duration	
		Summer* (°C) High/Low	Winter† (°C) High/Low	Summer (Hours)	Winter (Hours)
Tucson, AZ	779	36.8/23.1	18.3/3.9	112	78
Palo Alto, CA	756	30.2/16.1	17.0/5.9	96	83
Largo, FL	2,357	32.3/22.5	20.7/10.8	113	83
Chicago, IL	1,407	29.8/19.1	1.8/-3.9	162	89
Baltimore, MD	2,094	30.2/19.4	6.5/0.9	107	89
Katy, TX	1,477	33.7/21.6	16.8/4.4	143	97

*Summer season: June 2020-August 2020

† Winter season: December 2019-February 2020

Figure 1: Winter Season Mailings

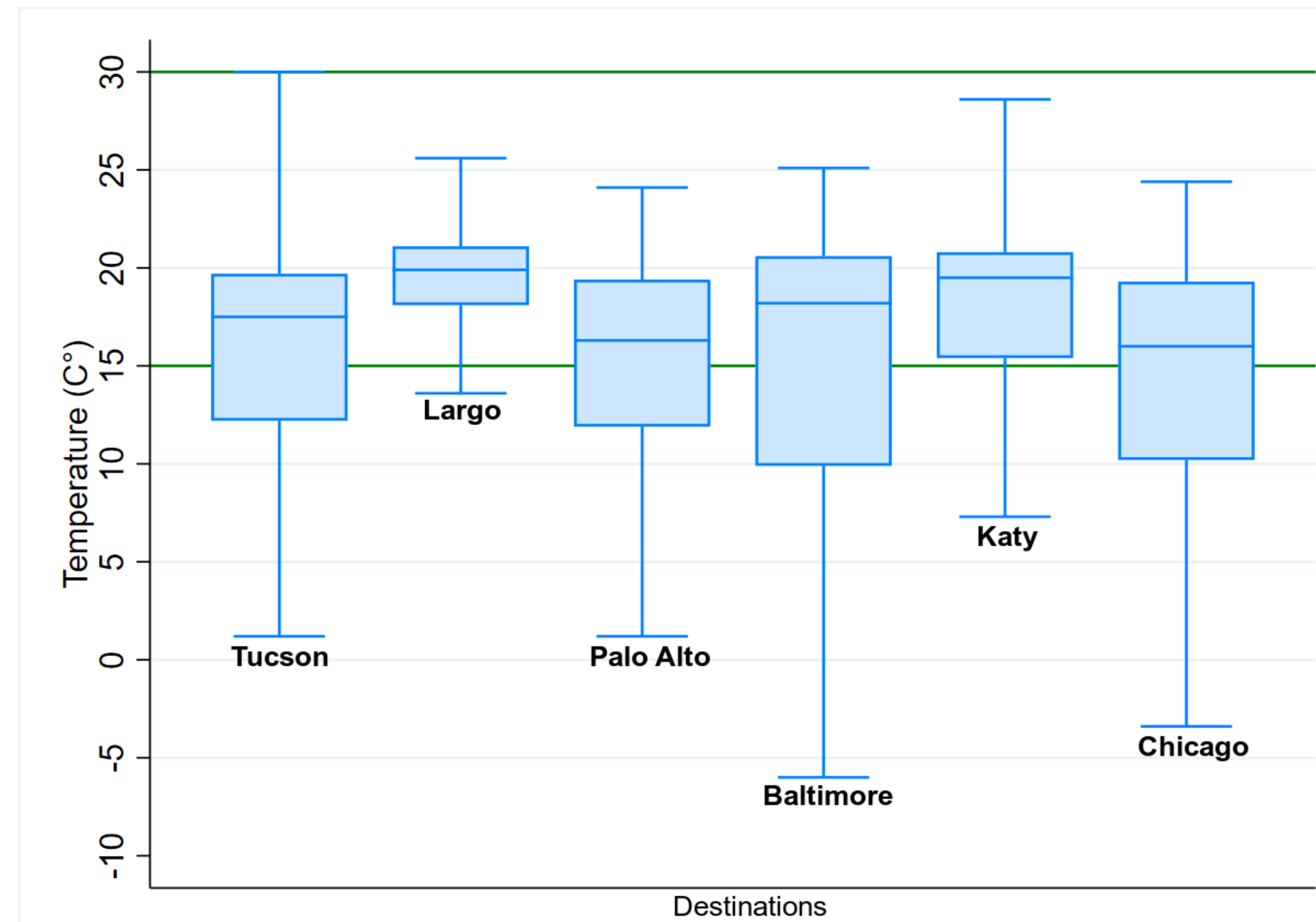
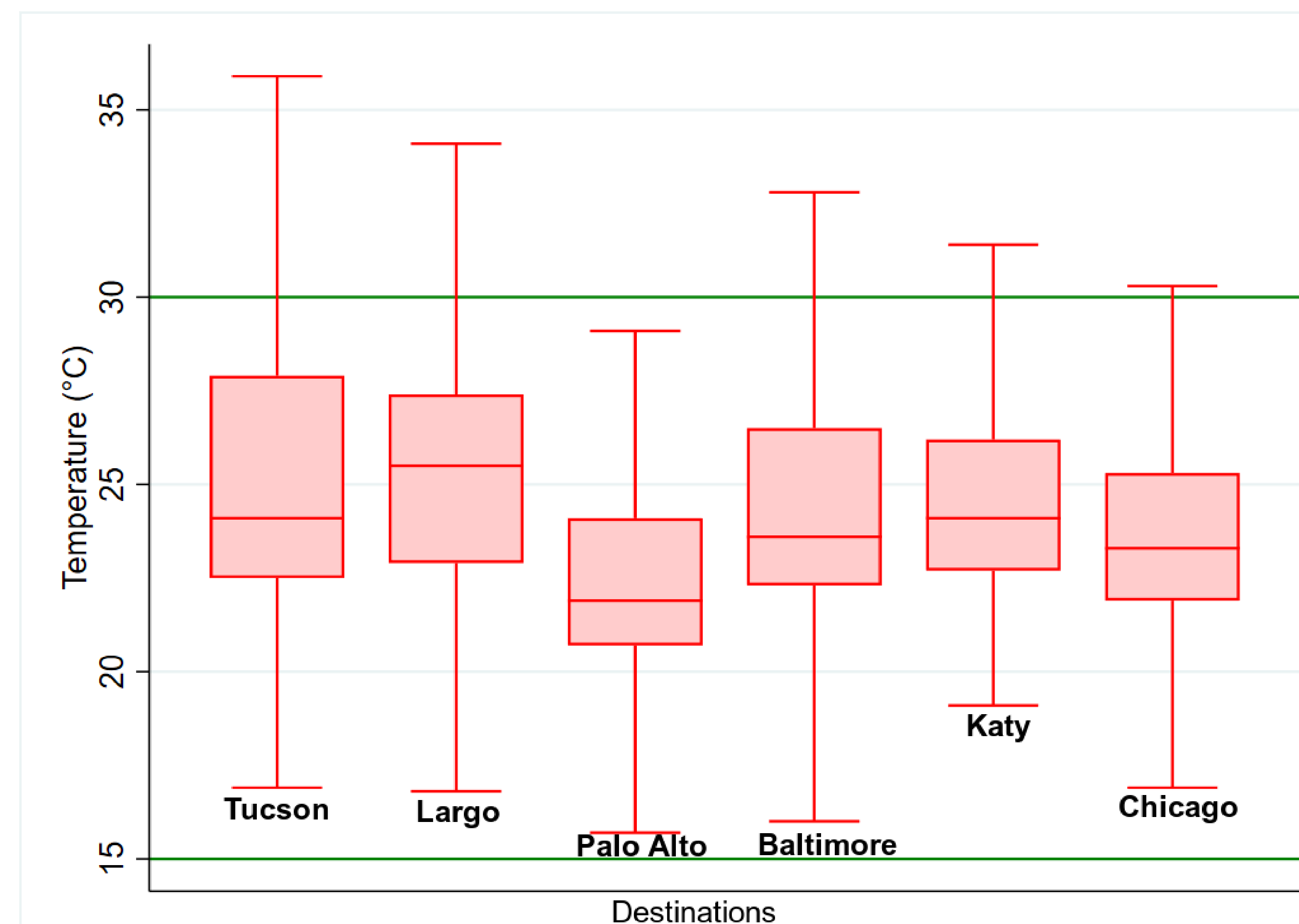


Figure 2: Summer Season Mailings



- Percentage of time outside of excursion range was **significantly higher** in the **winter** season compared to the **summer** season.
- No association** between delivery distance/time and percentage of time package was exposed to inappropriate temperatures.

Table 2: Percentage of Time Package was Outside of Excursion Temperature Range

Destination	Winter Mailings	Summer Mailings	p-value
Tucson, AZ	35%	15%	<0.001
Palo Alto, CA	43%	4%	<0.001
Largo, FL	30%	9%	<0.001
Chicago, IL	38%	6%	<0.001
Baltimore, MD	27%	7%	<0.001
Katy, TX	17%	7%	<0.001

Limitations

- Number of mailings
- Assessed only unrefrigerated packaging
- COVID-19's impact on the United States Postal Service

Conclusions

- Current shipping methods used by mail-order pharmacies expose the contents of unrefrigerated packages to potentially unsafe temperatures.**
- Future studies are needed to assess the potential decrease in efficacy in medications following such an exposure.
- Advocate for the increased regulation of mail-order pharmacies to ensure appropriate storage conditions are maintained throughout transit.

References

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