



A SURVEY OF HOME STORAGE TEMPERATURE OF IN-USE INSULINS AND ANALYSIS OF THEIR STABILITIES UNDER THE SIMULATED HIGHEST HOME TEMPERATURE

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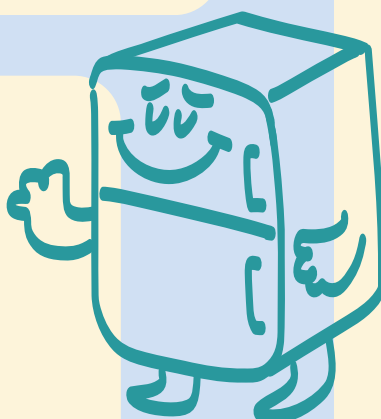
BACKGROUND



Human insulins remain essential for people living with diabetes worldwide. As a biological product, it is susceptible to heat, light and sheer conditions. Little is known about actual household storage temperature of insulin, especially in tropical climate setting where room temperature is far beyond 25°C, under which insulin stability might be compromised.

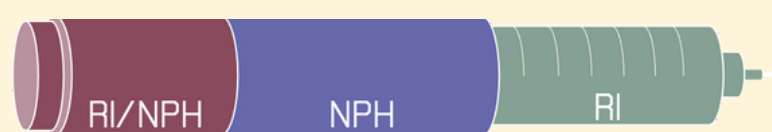
AIM AND OBJECTIVES

- 1) to determine home storage temperature of in-use human insulins among ambulatory type 2 diabetes (T2D) people
- 2) to subsequently test insulin stability under the simulated highest storage temperature identified.



MATERIALS & METHODS

Population & setting



Ambulatory people with T2D receiving a reusable pen with either regular insulin (RI), isophane (NPH) or premixed RI/NPH insulins at a tertiary hospital (N = 47).

Methods

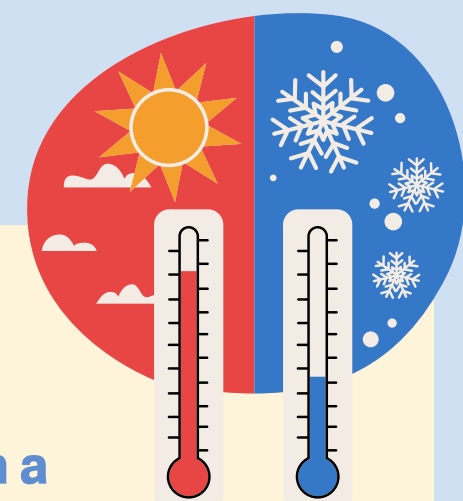


The participants were given a temperature logger to track home storage temperature of their insulins for 5-7 days. The maximum out of the recommended range temperature identified was then simulated in a laboratory where similar insulins (3 batches each) were kept, with 2-8 °C & standard room temperature (up to 30 °C) served as control temperatures. The percentage label amount (LA) of the insulins were then determined at a weekly interval for 4 weeks. The insulin assay followed that of the 42nd ed. United State Pharmacopoeia. The acceptable range of percentage LA is 95 -105% with reference to standard.

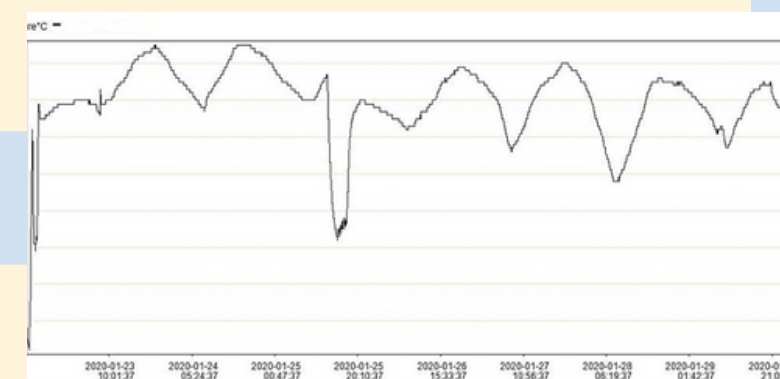
Data analysis

Descriptive statistics were used to present the recorded temperatures. T-test was used for comparison of the percentage LA of insulins at different time interval between the simulated and the control temperatures.

RESULTS



- Of the patients keeping insulin in a refrigerator (N = 22), 18 had temperatures outside the 2 to 8°C range, with the average times amounted to 8 hours 30 minutes per day.
- The temperature was above 30°C for all patients (N =25) keeping insulin outside a refrigerator, (maximum 43.6 °C), with the average times corresponding to 7 hours 57 minutes per day.
- In laboratory, at the simulated isothermal 42±2°C, all insulins had percentage LA decreased significantly at 2, 3 and 4 weeks, respectively, but their percentage LA remained in the acceptable range (95 to 105%).



CONCLUSION

Actual home storage temperatures of in-use insulins were totally out of the recommended range for room temperature storage. However, under the simulated temperature of 40-44°C in-use human insulins retained acceptable content with regular insulin being stable up to week 2; week 3 and week 4 for NPH and the premixed form, respectively. The results were in line with the study in Kenya (1) which tested the maximum temperature at 37°C. Pharmacist should be aware of true household storage temperature of insulin products and take into account the number of days it takes for one insulin cartridge to be finished against with the probable stability duration.

REFERENCE

1. Kaufmann B, Boulle P, Berthou F, et al. Heat-stability study of various insulin types in tropical temperature conditions: New insights towards improving diabetes care. PLoS ONE 2021;16: e0245372.

