RTM Increases Uptime and Decreases Freezing Duration in Vaccine Refrigerators: A Randomized Control Trial Analysis

Background

Vaccines must be kept between +2 °C and +8 °C. “Uptime” is defined as time spent between the temperatures +2 °C and +8 °C (inclusive). Vaccine refrigerators used in rural clinics are designed to maintain uptime under a variety of conditions. However, many fridges in areas with insufficient cold chain resources experience frequent and/or lengthy temperature excursions (WHO/UNICEF, March 2016). Lengthy exposure to temperatures above +8 °C or any exposure above +20 °C can damage or even destroy vaccine doses. Cold excursions are also dangerous; for freeze-sensitive vaccines, even brief exposure to temperatures below 0 °C can destroy the vaccine. A recent WHO study in India showed that 75% of freeze-sensitive vaccines exhibited signs of damage from exposure to freezing at the time they would have been administered to children (Murhekar et al. 2013). Damaged or destroyed vaccines are sometimes detected and thrown out, but often they get administered, leaving unknown numbers of children who receive these vaccine doses vulnerable to deadly diseases.

The standard protocol used to monitor fridges is as follows: twice a day a nurse records the temperature reading from a stem thermometer kept inside each fridge onto a paper chart. A technological alternative to this manual method is digital 30-day temperature recorders, known as 30DTR devices. A 30DTR device is mounted outside the fridge while an attached temperature probe continuously monitors temperature inside the fridge. A visual alarm is activated if the fridge’s temperature deviates from the acceptable range. The device display also indicates whether any such temperature excursions have occurred within the previous 29 days.

Hypothesis

With rural locations in mind, the first-generation ColdTrace remote temperature monitoring (RTM) devices used in this study were based on inexpensive smartphones. Nexleaf’s RTM devices use SMS technology to alert health facility staff when a monitored fridge has a temperature excursion. We hypothesized that fridges with RTM devices sending SMS alerts, combined with trainings for health care professionals on how to respond to those alerts, would show **higher uptimes** (defined as time spent between +2 °C and +8 °C) than fridges monitored using 30DTRs or stem thermometers.

Evaluation design

Nexleaf worked with the Mozambique Ministry of Health, VillageReach, PATH, and UNICEF to design and implement this evaluation. Health facilities were randomly assigned to three groups, controlling for the age of the refrigerator, the power source of the refrigerator (solar vs. grid power), and distance of the facility from the provincial Ministry of Health (MOH).

- Group 1 (Intervention) consisted of 29 health facilities with RTM + SMS alerts; staff received training on responding to RTM alerts, and Standard Operating Procedures (SOPs) were posted in clinics.

- Group 2 (Intervention) consisted of 28 health facilities monitoring fridges with 30DTR devices; staff received additional training on 30DTR usage.
- Group 3 (Control) consisted of 26 health facilities monitoring fridges with stem thermometers; staff recorded temperatures twice daily on paper charts.

To allow direct comparisons between the three groups, continuous temperature data was collected and transmitted from all participating health facilities using RTM devices; however, **health facility workers (and their supervisors) in Groups 2 and 3 did not have access to this data or alerts from these sites. Readings from the RTM devices were only visible, and SMS alerts sent, to health facility workers in Group 1.** The findings included here cover an evaluation period from August 15, 2014 to June 1, 2015.

Results

Fig. 1. Percent of Total Time Spent in Optimal Range or Excursion

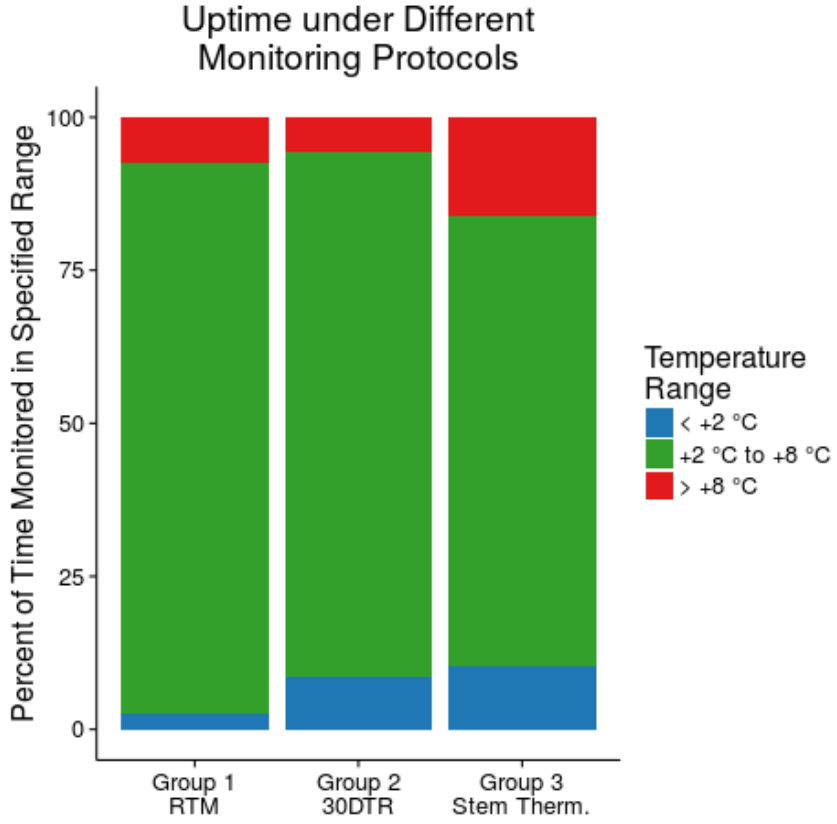

Figure 1 shows the percent of total time spent in optimal range (between +2 °C and +8 °C) or excursion (below +2 °C and above +8 °C). Over the period of this investigation, fridges monitored by ColdTrace RTM (Group 1) achieved 90% uptime; 30DTR (Group 2) achieved 86% uptime; stem thermometer (Group 3) achieved 74% uptime.

Fig. 2. Average Total Time in ColdTrace Cold Alert and WHO Freezing Alarm State

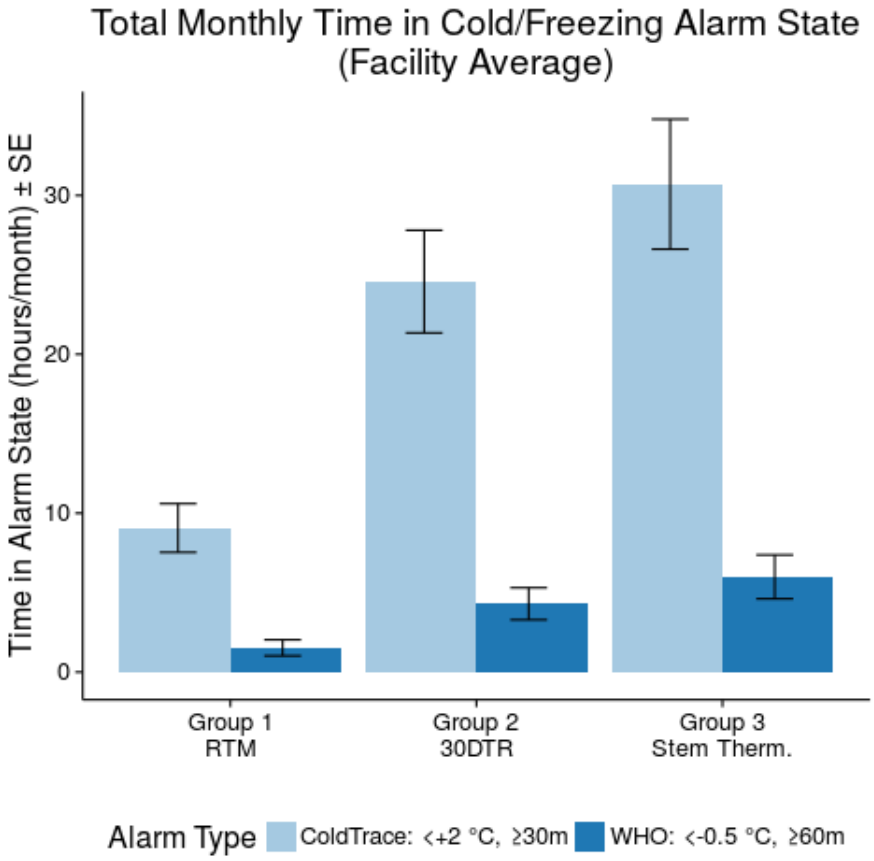

Figure 2 shows the average total monthly time in ColdTrace cold alert (below +2 °C for 30 minutes or more) and WHO freezing alarm state (below -0.5 °C for 60 minutes or more) for facilities in each group. The ColdTrace cold alert is designed to be a more conservative measure that identifies all excursions from the optimal range in order to prevent WHO freezing alarms. Fridges monitored by ColdTrace RTM (Group 1) spent an average of 9 hours in ColdTrace cold alert per month and 2 hours in WHO freezing alarm; 30DTR (Group 2) spent an average of 25 hours in alert and 4 hours in freezing alarm; stem thermometer (Group 3) spent 31 hours in alert and 6 hours in alarm.

Fig. 3. Average Total Time in ColdTrace Warm Alert and WHO Heat Alarm State

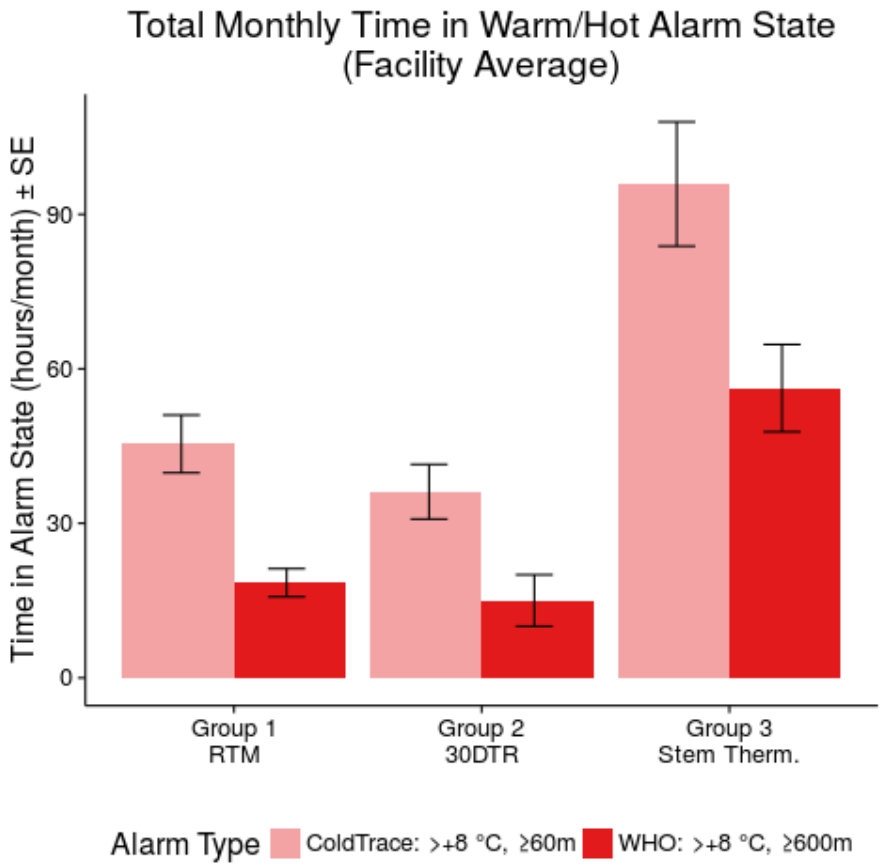

Figure 3 shows the average total time in ColdTrace warm alert (above +8 °C for 60 minutes or more) and WHO heat alarm state (+8 °C for 600 minutes or more). The ColdTrace warm alert is designed to be a more conservative measure that identifies all excursions from the optimal range in order to prevent WHO heat alarms. Fridges monitored by ColdTrace RTM (Group 1) spent an average of 45 hours in ColdTrace warm alert per month and 18 hours in WHO heat alarm; 30DTR (Group 2) spent an average of 36 hours in alert and 15 hours in heat alarm; stem thermometer (Group 3) spent 96 hours in alert and 56 hours in alarm.

Discussion

As hypothesized, of the three groups, Group 1 (RTM monitoring) achieved the highest total uptime. Group 1 also had the shortest facility average for total time spent in ColdTrace cold alert and WHO freeze alarm states. Group 1 also spent the lowest percent of total time in WHO freeze alarm state: 0.55% versus 1.9% for 30DTR and 2.3% for Group 3 (Stem Thermometer).

Group 1 (RTM) and Group 2 (30DTR) both performed better than Group 3 (Stem Thermometer) group in all three categories of evaluation.

References

Murhekar, M. V. et al. (2013). Frequent exposure to suboptimal temperatures in vaccine cold-chain system in India: results of temperature monitoring in 10 states. *Bulletin of the World Health Organization, 91, 90.* doi: http://dx.doi.org/10.2471/BLT.13.119974

WHO/UNICEF Joint Statement. (March 2016). Achieving immunization targets with the comprehensive effective vaccine management (EVM) framework. Retrieved from http://www.who.int/immunization/programmes_systems/supply_chain/EVM-JS_final.pdf?ua=1