# ColdTrace Year One: Feedback from the Field

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NEXLEAF ANALYTICS

VILLAGE REACH
Starting at the Last Mile

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## Introduction

This report serves as an assessment of the ColdTrace pilot currently deployed in the southern part of Gaza province. The goals of this assessment and report are the following:

- To establish the *utility and acceptability* of the ColdTrace system
- To identify *barriers* that may impact the Ministry of Health's ability to adopt and scale-up the ColdTrace system
- To determine the *government capacity*, including technical support and the cold chain technicians' system management capabilities, needed to adopt the system
- To obtain *lessons learned* for incorporation into the pilot to two additional provinces during year two

The report contains a brief narrative of the pilot and an analysis of the first year's quantitative data from the ColdTrace data system. Additionally, the report considers themes and ideas that appeared in interviews conducted with health authorities at the national and provincial levels, health centers staff, and cold chain technicians, and ends with a list of feasible recommendations based on stakeholder opinions, lessons learned from the Gaza pilot, the larger Mozambique context, and global influences. These recommendations should aid in the roll-out of the ColdTrace pilot in Tete and Niassa and any other future expansions.

# I. Background:

ColdTrace, a remote temperature monitoring (RTM) system developed by the Los Angeles based non-profit, Nexleaf Analytics, was installed in 83 health centers and district warehouses across eight districts in Gaza in June 2014. Additionally, three devices were installed at provincial level fridges and five were installed in cold rooms at the national level. In total there were 91 installations, which were all part of a pilot program to evaluate the system's contribution to strengthening the cold chain system as a whole. The ColdTrace system includes: a cellphone device that sends temperature data and SMS messages and alerts; an online data dashboard with data on power outages and refrigerator performances; and monthly status reporting emailed to managers via PDF reports. The ColdTrace device is designed to send an SMS alert to the health center nurse when the refrigerator is outside of the 2°C-8°C range, the ideal vaccine storage temperature zone. If the temperature continues to remain out of range, the alerts will be escalated to district, provincial, and national Expanded Program on Immunization (EPI) staff until the temperature is corrected.

The pilot study compared the effectiveness of the ColdTrace device at decreasing cold chain down time to alternative cold chain temperature devices – stem thermometer and Fridgetag. The vaccine refrigerators were randomized to one of the following groups:

- Group 1 (29 clinics): Informed about temperature excursions through: ColdTrace device with SMS alerts and monthly PDF summary reports
- Group 2 (28 clinics): Informed about temperature excursions through: Fridgetag (visual alerts)
- Group 3 (26 clinics): Informed about temperature excursions through: Stem Thermometer only

In Group 1, ColdTrace SMS alerts are sent to health facility staff when refrigerator temperature is less than 2°C for 30 minutes or more than 8°C for 5 hours. Escalated SMS alerts are sent to supervisors when refrigerator temperature is less than 2°C for 60 minutes or more than 8°C for 10 hours. The other two groups did not receive SMS alerts.

## II. Quantitative Data Review

This section presents a review of the temperature data between the three groups over time in the last year.

*Methodology*

The most appropriate metric of excursion duration is monthly time in which a fridge falls outside of a specified range (Freezing: <-0.5˚C; Cold: <2˚C; Hot: >8˚C). Number of excursion events was not used, as this metric tells nothing about how long a fridge was out of range and may, in fact, be misleading.

For each site, hours in excursion per monitored month is used, where "month" is defined as 30.4 days starting at the time the first temperature datum was recorded in each site. In this way, months were consistent across sites and time. For each site, the monthly time in excursion status was calculated for each month, and then averaged across all months. Data were analyzed using traditional linear models to compare among groups. Differences in the number of hours per month in excursion status among power sources (wall power vs. solar), while accounting for differences among groups, were also analyzed.

Data were excluded if: temperatures read less than -10˚ C for just one reading; data points had the same time/date stamp (duplication); or if the monitoring site had less than two months of data for the entire duration of the pilot.

*Results*

A total of 81 sites were included in the final analysis. Group 1 consisted of 29 sites (18 on wall power, 11 on solar), Group 2 consisted of 26 sites (14 on wall power, 12 on solar), and Group 3 consisted of 25 sites (13 on wall power, 12 on solar). Most sites were monitored for 9.5 months, but sites were monitored for as little as 3.8 months in this analysis.

Sites in Group 1 on average spent 73-74% less time per month below 2˚C (in cold excursion status) than sites in either Groups 2 or 3 ($p<0.02$). Additionally, sites in Group 1 spent 56% less time per month over 8˚C (in hot excursion status) than sites in group 3. Although sites in Group 1 spent approximately 70% less time per month below -0.5˚C (freezing) than sites in either of the other two groups, due to high variability among sites these differences were not statistically significant at the 0.05 level (Table 1).

| Response | Group | Mean | Percent difference | p-value |
|---|---|---|---|---|
| Freezing hours per month | 1 | 4.57 | NA | |
| | 2 | 15.03 | -69.56 | 0.21 |
| | 3 | 16.53 | -72.33 | 0.16 |
| Cold hours per month | 1 | 17.84 | NA | |
| | 2 | 64.98 | -72.55 | **0.02** |
| | 3 | 69.28 | -74.25 | **0.01** |
| Hot hours per month | 1 | 52.06 | NA | |
| | 2 | 39.37 | 32.23 | 0.65 |
| | 3 | 118.69 | -56.14 | **0.02** |

***Table 1.*** *Summary of analysis of differences among groups in hours in excursion status (freezing, cold, and hot) per month. Percent difference represents the difference between Group 1 and the group shown; negative numbers mean that Group 1 values are less than the other group by the specified percentage.*

No statistically significant differences were detected in hours of excursion of any type among power sources either overall or in any one treatment group, although on average fridges on solar power spent more time per month out of range (Figure 1).

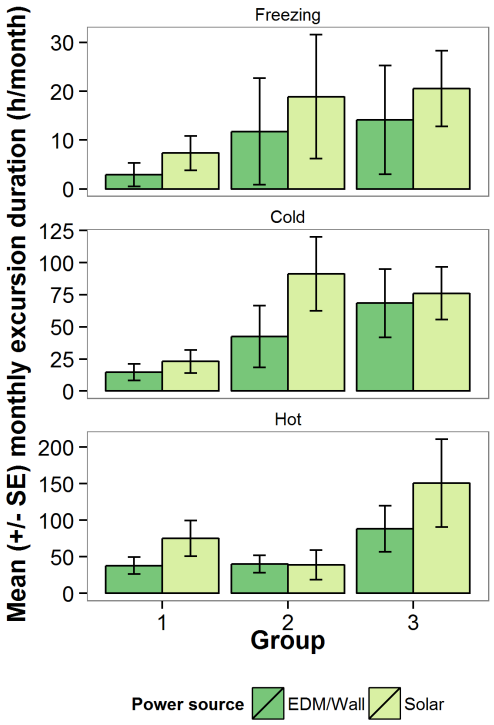

***Figure 1.*** *Mean +/- SE hours in excursion status (freezing, cold, or hot) for each group and power source. No statistically significant differences existed in mean hours spent in any type of excursion among power sources either overall or within any treatment group.*

## III. Cost Analysis

A cost analysis of the ColdTrace system was completed by PATH in order to estimate the cost per device per year. The cost components included: recurrent SMS costs, server charges, installation kits, per diems, staff trainings, and transportation costs, as well as the cost of the ColdTrace devices and the associated customs and shipping fees. The analysis calculated that the life of a device was three years. After three years, the analysis assumed the device will need to be replaced and all associated costs (installation, travel, etc.) will recur. The average yearly cost of the ColdTrace system was found to be $208 per health center using the lower range of cost estimates and $295 when using higher price assumptions. To put this in perspective, a health center serving an annual target population of 250 children stores approximately.

## IV. Qualitative Data Review

*Methodology*

In order to assess the reactions and attitudes toward the ColdTrace system (device and the SMS alert escalation system as deployed for Group 1), two types of informational surveys were designed and administered. Survey One, administered to health center staff, was designed to mirror the baseline survey that was conducted at the beginning of the pilot program. This allowed an opportunity to determine if the ColdTrace system changed the health center staff's awareness of temperature excursions and the way they performed preventative maintenance. Survey Two was a more in-depth questionnaire that aimed to elucidate opinions regarding the strengths and weaknesses of the ColdTrace system, lessons learned from the pilot, and barriers to implementation in new provinces.

Survey One was administered at 30 health centers (10 from each group in the pilot program); Survey Two was administered to thirteen individuals working at the national Ministry of Health, Gaza Provincial Directorate of Health, UNICEF, and WHO.[1] All individuals interviewed worked closely with the cold chain and/or vaccination programs at health clinics in Gaza or central Ministry of Health in Maputo.

This section is organized around primary themes from the interviews. Primary themes are defined as topics that were mentioned at least twice in three of the Survey Two interviews. Themes that did not meet this criterion but were important to the overall continuity and sustainability of the ColdTrace project are included here as secondary themes.

### *Primary Themes*

There are three primary themes that carried through the key informant interviews. These themes are: level of acceptability for the ColdTrace system; roadblocks to potential adoption of ColdTrace, and system response capacity to reports/alerts.

[1] Please refer to the Appendix, attached, for the survey questions.

## Level of Acceptability ColdTrace system

General feedback from the interviewees on the ColdTrace system was very positive. Health center staff appreciated the daily real-time temperature updates as well as the SMS alerts that are sent in the event of a sustained temperature excursion. The provincial and national EPI staff appreciated the monthly refrigerator performance summary reports that were emailed to them at the end of every month. It should be noted that they preferred the monthly PDF reports to the live online data dashboard. No one mentioned the dashboard as their primary method of accessing the ColdTrace data. Additionally, everyone appreciated that the data was reliable and accurate.

> "Remote temperature monitoring allows you to know what is happening with the fridge even when you are away. It permits the fridge manager to take corrective steps to prevent wastage or vaccine spoilage."
>
> *- Key Informant, Provincial Level*

The health center staff especially liked the fact that, with the ColdTrace system, there is now 24/7 supervision of the refrigerators even when the nurses and health center staff are not physically present.

## Barriers to Potential Adoption of the Device

Generally, there was interest in expanding the use of the ColdTrace system at all levels. However, various roadblocks and bottlenecks were identified and would need to be addressed before widespread adoption could occur.

*Funding*

Interviewees at all levels mentioned funding, both the funding of the SMS messages as well as the maintenance and replacement of the devices as the main barrier to any long-term plans with the ColdTrace system. A stable budget-line needs to be established before the Ministry of Health will be able to manage the system in its entirety without outside funding. Additionally, the Ministry of Health would like a detailed look at cost of ownership and how much each device would cost to use and maintain.

> "It's not only about the cost of the device, it's also the money for the airtime, the human capacity to really interpret the information you are receiving."
>
> *- Key Informant, National Level*

*Ensure Long-Term Investment and Support in the System*

All interviewees were concerned that partners would pull their support abruptly. They believed that support would be pulled immediately after the conclusion of the project. Interviewees expressed concern that an abrupt departure would risk the progress made thus far and hinder any efforts regarding future expansions. While the Ministry did express interest in one day taking ownership of the system, they first would like to know all costs associated with ownership. Their willingness to pay for the system depends on the total costs and the device's effectiveness.

National level interviewees mentioned the ColdTrace system needs to be prequalified before it can expand to be used nationally. Prequalification (PQS) is a WHO mechanism which aims to ensure devices

meet a global quality standard[2]. Obtaining prequalification is a long-term processes and interviewers worried that partners would leave before enough evidence was gathered to support eventual prequalification and adoption. There is currently no application out for one sensor RTM devices but once an application is out, the ColdTrace device can be considered for PQS.

Prequalification is covered in more detail in the recommendation section, including actions and conversations taking place at the global level to establish PQS for RTM devices.

## System Response Capacity to Reports/Alerts

*Human Capacity Constraints, including electrical expertise gap*

While there is interest in system adoption, interviewees mentioned the insufficient number of cold chain technicians available to respond to alerts for refrigerator maintenance alerts as a limitation. There is currently one cold chain technician for Gaza at the provincial level. At the district level, EPI supervisors are responsible for ensuring the function of the refrigerators but do not have any formal maintenance training. Interviewees expressed concern that the shortage of technicians will become more pronounced as ColdTrace expands to North Gaza. It was suggested that the Ministry of Health needs to increase capacity by training more technicians; however they would need both technical and practical assistance in training and funding new technicians.

Additionally, interviewees identified a need for a technician with electrical expertise. The interviewees at the provincial level, which included the provincial cold chain technician, advocated strongly for a technician with electrical expertise as this is particularly important for installing ColdTrace on solar refrigerators and for health centers that experience frequent power surges.

*System management*

All levels expressed interest in learning more about the day-to-day management of the system, including how the data is maintained, analyzed, and reported. Provincial and district staff want to learn the details of what daily management of the ColdTrace device/SMS alerts system/data analysis and maintenance entail, and would like to have more responsibility regarding device management, data review, and cost analysis. At present, they are unaware of these details which they feel is a roadblock to potential adoption and having a clear understanding of what they would be responsible for in the future.

*Spare parts for refrigerators*

The interviewees noted that visibility into regular refrigerator problems has increased knowledge of what repairs and parts are needed to increase the function and reliability of the refrigerators. Multiple interviewees were concerned with the expense of these spare parts, both for the ColdTrace device and for the refrigerators. No one was aware of the estimated lifespan of the ColdTrace phones and chargers and did not know how often they would need to be replaced. Without this information, they had no way of estimating the annual replacement costs. Currently, there is a shortage of refrigerator spare parts and many health centers explained that the technicians often do not have the required parts to fix a refrigerator, which has resulted in a reduced maintenance capacity.

[2] WHO Health Topics: Prequalification, http://www.who.int/topics/prequalification/en/

*Solar refrigerators perceived as problematic*

The topic of solar refrigerators being problematic only came up in the provincial and district level interviews and the opinions towards them were strong. All of these interviewees strongly discouraged the use of the ColdTrace device in solar refrigerators, maintaining that the solar refrigerators have frequent fluctuations in temperatures and, as such, generate a lot of SMS alerts. Additionally, current solar refrigerators in facilities require additional equipment (AC/DC current regulator and a 24/12V current convertor), which increases the installation and maintenance costs. The new solar refrigerators that are currently being distributed will not have this issue, but those already installed will continue to have this problem.

> "ColdTrace should only be used at health centers with electric fridges as the solar fridges register too many high temperatures and require extensive maintenance."
>
> *- Key Informant, District Level*

*ColdTrace device interface (user screen)*

There is strong interest in making changes to the ColdTrace device. Most interviewees suggested that it would be better if the cell phone screen displayed the refrigerator temperature. Currently, the device collects temperature readings every 10 minutes through the temperature sensor probe located inside the refrigerator The interviewees prefer that the externally located phone itself display the temperature reading from the internally placed temperature sensor; the phone would then be in a transparent box (rather than the current black box) so it would be visible to the health worker who would read and record the temperature from the phone rather than the thermometer. This would make more use of the phone and reduce the necessity of opening the refrigerator to get a temperature reading, thereby preventing multiple door openings and closures. Nexleaf is currently working on a new version of the ColdTrace device where the temperature can be easily viewed.

*Expansion of alerts and updating which individuals receive them*

Many individuals expressed that they either want to receive alerts about additional health centers or want more people to receive alerts for specific refrigerators. The rationale for this is that many health facility staff want more people involved in case they are unable to respond to alerts immediately. There are also individuals at the province and district levels who would like to receive alerts for every refrigerator in their province or district.

Additionally, interviewees spoke of instances where it was unclear whom to contact to be added or removed from the alerts list. Individuals also requested the ability to transfer alerts to an alternate in instances when they are on leave or traveling extensively and unable to take action from afar.

## *Secondary Themes*

*Dedicated ColdTrace cellphone*

The interviewees who worked at the national level of the EPI felt that it was essential to provide all individuals who receive alerts through the ColdTrace program an institution phone that can be used specifically for receiving the alerts. They believe that personal phones are often broken or lost, which

then means those individuals no longer receive the alerts and cannot respond to temperature excursions appropriately. However, the Ministry does not have the funds to supply phones to all the personnel and would need external funding for the phones.

*Apprenticeship for technicians*

Two interviewees asked for the establishment of an apprenticeship style training for new cold chain technicians. These individuals, one working at the district level, and another at the provincial level, want a dedicated ColdTrace technician in Gaza who can manage all of the devices and respond to alerts. They stated that the apprenticeship could be a long-term (6 month) commitment and the technician would shadow the ColdTrace technical coordinator from VillageReach to learn about the system before going to work in the field.

*Cell phone coverage*

There is some concern that the ColdTrace cell phones do not have good network connectivity in some locations where the installed devices are not transmitting data due to poor signal (with both Movitel and Mcel). Nexleaf and VillageReach are currently working on a contingency plan for cold chain monitoring in the event that there is not adequate signal in some areas. RTM devices are only recommended for places that have GPRS or SMS upload connectivity. For locations that do not have this connectivity, RTM is not of great use and other temperature trackers are recommended.

*Group Communication*

Over the course of the interviews, it became clear there was (1) less than expected communication and follow-up with stakeholders on a regular basis; (2) instances where conflicting messages were being given from within the same team; (3) each level of the health system not knowing their main point of contact for updates on the project.

## V. Recommendations and Lessons Learned

The main purpose of this report is to establish the utility and acceptability of the ColdTrace system while also compiling a list of lessons learned that can be used to inform future expansions. The following recommendations and lessons learned take into consideration the information gathered during the interviews, the quantitative data from the ColdTrace device, cost analysis, the overall Mozambique context, the Ministry's sustainability goals, and global policies related to cold chain monitoring and maintenance.

1. *Lessons Learned for Expanding to Other Provinces*

### *Documentation of standard operating procedures (SOPs)*

Interviews conducted at the health centers, districts, and province demonstrated the need for clear, easy to find documentation of standard operating procedures (SOPs). Currently, SOPs are in place for the SMS alerts escalation system and the necessary actions to be taken at each level, but that SOP alone does not

cover the knowledge gaps revealed during the interviews. Below are a preliminary list of recommended SOPs needed for expansion:

a) Changing/updating who SMS alerts are sent to; whom to contact to make this happen; how much time should be given for the change to occur (particularly when someone is on leave/traveling and unable to take action)
b) ColdTrace equipment and SMS phones: installation; parts needed for the device and accessories; how to install new phone numbers for SMS alerts. Note – while two individuals mentioned the need for a dedicated ColdTrace phone to receive SMS alerts, this is unsustainable and impractical use of limited funding. The bulk of the SMS alerts are received by health center staff; yet, in all 30 Survey Ones, no one reported having a problem receiving alerts on their personal phones since there is no charge for incoming messages. At this point, we recommend continuing with the practice of using personal phones for SMS alerts as long as there are no charges borne by the individuals.
c) Easily accessible training guides for refresher training and new personnel training; customized to each level of the system that is impacted by the ColdTrace system.
d) Handover training guide as part of ownership transfer plan: the Gaza-based ColdTrace technical coordinator should be given the responsibility of transferring all ColdTrace related knowledge to a group of individuals selected by the province and MOH; a detailed training guide should be created as part of this knowledge transfer following a Trainer of Trainers approach. This would also address the request for an apprenticeship program for new cold chain technicians of the future – they would be trained by the previously trained, etc.

### *Improve Training and Communication*

Over the course of the interviews, it became clear that there were several communication problems regarding the ColdTrace system management. All of this information was communicated during training, but was lost over the course of the pilot, as health center staff changed and new priorities arose. For future expansions, there is a need to improve training so the key information will be better retained. This could include planning occasional refresher trainings, follow-up reminders or notes around the health center to help remind staff of the key information and main contacts. Having the key information readily accessible should limit the misperceptions regarding the project and its updates.

*2. Invest time in determining the government's capacity to fund, operate and create policies for use for the system*

The response to the ColdTrace system has been positive across all levels. Based on feedback from the interviews, the Ministry of Health is showing interest in the system and the possibility of using it beyond Gaza province. The interview questions focused on elucidating the details of a potential transfer plan and possible barriers and bottlenecks to achieving a complete and sustainable transfer.

However, a limitation of the questionnaires is the lack of questions regarding how national policy and strategy surrounding the cold chain and RTM need to change before adoption can occur. Currently, the Ministry of Health's strategy for the cold chain only places RTM at the national and provincial levels. Budget for RTM at these levels are provided by Gavi and partner funding. Presently, there is no source of funding for supporting RTM at health facility level. Inclusion in the Social Economic Plan (PES) is unlikely if the Ministry of Health's strategy and policy do not align. Furthermore, the Ministry of Health does not

have an established policy to govern mHealth innovations or guidelines on the process of adopting new devices.

In order to establish conditions for adoption, policy and strategy discussions within the Ministry of Health must first happen. Discussing transfer of ownership before ensuring that the Ministry's policy and strategy match is risky as it may limit funding and long-term sustainability. To help this process occur, VillageReach and Nexleaf must work to demonstrate that the ColdTrace system is an all-round improvement on the current cold chain temperature monitoring. Additionally, partners must generate and present compelling evidence to the Ministry of Health and its partners about the importance of including an RTM system as part of their national cold chain temperature monitoring strategy at health facility level.

While this work is being done, it is recommended that the partners and Ministry also assess the government's capacity to manage and fund the system alone. From the interviews, many felt that there was insufficient human capacity to maintain and manage the system alone. Before a potential transfer of ownership can be discussed, capacity-building practices should be considered. Capacity building includes training workers to adequately respond to the system, increasing data management expertise, and ensuring regular access to spare parts and funding. Capacity should be increased before discussions on transferring ownership begin. Inadequate capacity is a major limitation to effective response and management of the system.

*3. Dashboard/Information Technology*

Many interviewees suggested improvements to the dashboard to increase its use; this process is currently underway. VillageReach and Nexleaf are working on integrating the ColdTrace dashboard with SELV (the information management system built on the OpenLMIS platform currently in use) and making the data more user-friendly. Once these updates are in place, they must be tested for six months and then a review process should begin where users can provide input for what they like and do not like with the updated resource.

Displaying the temperature on the device screen would be beneficial to the cold chain, as it would prevent unnecessary refrigerator openings and thermometer handling. Interviewees suggested that while they liked receiving the twice-daily temperature readings via SMS, they would also like to be able to read the temperature themselves via the ColdTrace device's screen.

Currently, the temperature is displayed on the screens of the ColdTrace phones. However, the phones are kept in a locked black box to prevent theft, and, as such, the nurses cannot see or access the phones. If the phone was visible, the phone would take the place of the stem thermometer and reduce the amount of equipment in the cold chain, but this benefit would need to be weighed against the possibility that having the phone visible would increase the chances of the device getting stolen. The current policy for temperature monitoring in health centers is for nurses to open the fridge, check the stem thermometer or Fridgetag and record the temperature on paper twice per day. If the phones replace the thermometer, the Ministry policy should also need to change to accommodate the ColdTrace facilities so there is no contradiction in policy and practice. This could also include assessing the utility of the paper forms if data is being collected automatically by a RTM device.

*4. Longer-term approaches to potential long-term sustainability*

UNICEF and WHO have strong preferences for prequalified devices and will not make recommendations for use of a device until it is prequalified. As RTM devices for health facility level are so new to the market, there is not a PQS process established as of yet, although global discussions have begun to evaluate the utility of these systems. ColdTrace meets many of the required descriptions[3] for an effective temperature monitoring system as defined by UNICEF.

While the Ministry of Health did not directly comment on whether or not they would consider adopting a device that had not been prequalified, they look heavily to UNICEF/WHO guidance regarding the management of the cold chain. In order for the ColdTrace system to be sustainable in the long term, the Ministry must decide if they are willing to use a device that has not been prequalified or if they will only follow the guidelines put forth by the EPI logistics and cold chain expertise working groups.

## VI. Conclusion

Across the board, whether at the health center level or at the Ministry offices in Maputo, there was clear appreciation of the ColdTrace system and want to see its continued use in Gaza and beyond. People believe the system does a remarkable job of improving refrigerator uptime and preventing vaccine exposure to freezing.

It is thus hoped that this report makes a useful contribution towards the sustainability of this system in-country while providing a roadmap for further deployments in the future in Mozambique and elsewhere. The recommendations presented here are just the starting point for continuing the conversation on the best approaches for the next phases for the ColdTrace system deployment in Mozambique.

[3] http://www.unicef.org/supply/files/Temperature_Monitoring_Devices_Vaccine_Storage_and_Distribution.pdf