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Reducing the loss of vaccines from accidental freezing in the cold chain: The experience of continuous temperature monitoring in Tunisia

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ABSTRACT

Accidental freezing of vaccines is a growing threat and a real risk for national immunization programs when the potency of many vaccines can be compromised if these are exposed to sub-zero temperatures in the cold chain. In Tunisia, this issue is compounded by using sub-standard domestic cold chain equipment instead of equipping the program with medical refrigerators designed specifically for storing vaccines and temperature sensitive pharmaceuticals. Against this backdrop, this paper presents the findings of a demonstration project conducted in Tunisia in 2012 that tested the impact of introducing several freeze prevention solutions to mitigate the risk of accidental freezing of vaccines. The main finding is that, despite the continued use of underperforming domestic refrigerators, continuous temperature monitoring using new technologies combined with other technological interventions significantly reduced the prevalence of accidental exposure to freezing temperatures. These improvements were noticed for cold chain storage at regional, district and health center levels, and during the transport legs that were part of the demonstration conducted in the regions of Kasserine in the South-Eastern part of Tunisia. Subsequent to introducing these freeze prevention solutions, the incidence of freeze alarms was reduced and the percent of time the temperatures dropped below the 2 °C recommended threshold. The incidence of freeze alarms at health center level was reduced by 40%. Lastly, the solutions implemented reduced risk of freezing during transport from 13.8% to 1.7%. Although the solution implemented is not optimal in the longer term because domestic refrigerators are used extensively in district stores and health centers, the risk of accidental freezing is significantly reduced by introducing the practice of continuous temperature monitoring as a standard. The management of the cold chain equipment was strengthened as a result which helps protect the potency of vaccines to the areas of most difficult access.

1. Introduction

Some immunization programs in the world may be vaccinating their population with vaccines that have lost their potency [1] due to cold rather than heat as the better-known hazard. Vaccine freezing is a known problem in many countries [2,3] and in Tunisia the need to find a solution was triggered by three key concerns. Firstly, an effective vaccine management evaluation (EVM [4]) included a small scale temperature monitoring study conducted in 10 refrigerators used to store vaccines at district and health center facilities which showed persistent challenges in the vaccine supply chain and indicated that 60% of the refrigerators had regular negative temperature excursions [5]. And while the EVM assessment revealed that refrigerator temperatures were monitored by standard thermometers twice a day as recommended, freezing temperatures were frequently occurring in certain refrigerators and for prolonged periods [6]. Secondly, Tunisia's national immunization program has been equipping its districts and health facilities with domestic refrigerators procured on the local market in preference to pre-qualified, imported cold chain equipment. Results from laboratory testing of the best performing domestic models used in the country showed that these failed to meet the norms [1] and standards set by the World Health Organization (WHO) [7]. Thirdly, as Tunisia plans to introduce newer and more

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[1] "*WHO/PQS Test Procedures E003/Guide 1.3: Failures at +32C and +43C tests (Day Night, holdover,stable-running).*

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expensive vaccines that are highly sensitive to freezing, a solution to prevent vaccine freezing was urgently needed.

Against this backdrop, this paper describes the findings of a demonstration that was a part of project Optimize—a WHO and PATH collaboration aimed at demonstrating transformational solutions for vaccine supply systems in low and middle income countries [8]. This demonstration in Tunisia documents the impact on accidental freezing incidence of introducing a continuous temperature monitoring system and procedure into the vaccine supply chain. The findings from this research will contribute to the evidence based on new approaches and solutions to safeguard the potency of vaccines in an end-to-end in-country vaccine supply chain.

2. Methods[2]

The methodology used for this research triangulated three sequential activities in a pilot region of Kasserine between the year 2011 and 2012. The first activity was to generate better evidence on the performance of the cold chain system by conducting a baseline assessment of key temperature metrics. The second activity was to implement a temperature monitoring solution in agreement with the Ministry of Health in Tunisia. The third activity was to measure the impact of the solution against the same baseline assessment temperature metrics. In the remainder of Section 2, each activity will be described in more depth.

2.1. Baseline assessment

The Baseline assessment took place in 2011 for transport and in January and February 2012 for storage. Temperature metrics of storage were collected using two different approaches. The first was to track temperature in a field setting and the second was to track temperature performance of the cold chain by testing various models of equipment in a laboratory setting. A specialized laboratory in Tunis conducted the tests according to WHO norms and protocols. However, due to delays in testing, the results were not available until April 2012 [9]. The 2011 temperature study in the field helped guide the selection of four refrigerator models assembled and available in the Tunisian market. The models with the least energy consumption, corresponding to recent Government regulations, and with a record of reliability in the district stores and health centers were chosen. Since all regional vaccine stores, were equipped with refrigerator models that met WHO/PQS norms for storing vaccines (WHO prequalified), Kasserine regional store equipment was not laboratory tested.

In the field, standard stem or dial thermometers are used for temperature monitoring and the practice for health workers is to check the thermometer temperatures twice daily, and manually record the temperatures on a tracking sheet. Unfortunately, for the purposes of this study, a thorough review of these temperature tracking sheets is not an effective way to gauge if inadvertent freezing temperatures are occurring in the cold chain. As a remedy, continuous recorded temperatures data was required for the analysis. As such, the baseline temperature assessment for vaccine storage was conducted for a two month period between January and February 2012. Temperature data were collected using continuous temperature recorders,[3] configured to make readings at 15 min intervals and placed inside each refrigerator at the center of the vaccine load. A total of 43 refrigerators were monitored as follows: six refrigerators at the Kasserine regional store; one refrigerator each of the 12 district stores in Kasserine, and 25 health centers located within the three key project districts of Feriana, Foussana, and Hassi-el-Frid. For vaccine transport, the assessment took place from September to November 2011 and was planned to include two for the Optimize project districts. The transport leg between Kasserine regional store and two district stores were tracked, and subsequently the leg between the two districts and the 25 health centers. A total of 31 deliveries to the health centers were assessed. Note that the standard practice in Tunisia is to transport vaccines in domestic cooler boxes filled with frozen-water packs without any temperature monitoring devices. For the baseline assessment, the configuration of temperature recorders was reduced to a 5 min interval to ensure there are sufficient readings for the shortest of the transport journeys monitored. In the same manner as for refrigerators, the temperature recorders were placed at the center of the vaccine load inside the cooler box.

For the analysis of the baseline temperature metrics, the data from various temperature loggers were compiled and aggregated. For storage in fixed cold chain equipment, a total of 504,874 readings were made throughout the baseline reporting period. For storage in mobile cold chain equipment, a total of 516 readings were made along various transport routes, and retrieved for analysis.

2.2. Implementing the vaccine freeze-prevention solution

In collaboration with the Ministry of Health at national and local levels, a two-pronged approach to reduce the risk inadvertent freezing in the vaccine cold chain of Tunisia was implemented in the same facilities where the baseline assessment was conducted. The demonstration was conducted for a 6-month period between March and September 2012. The first approach was to introduce the technology and practice of continuous temperature monitoring for both vaccine storage and vaccine transport procedures. The second approach was to introduce new high performance containers used to transport vaccine, and to switch to “Phase Change Material” (PCM) packs. Each of the two approaches is described in more detail below.

2.2.1. Introducing continuous temperature monitoring of storage and transport

In replacement of stem or dial thermometers with verification twice daily where research shows that this approach fails to safeguard against damaging temperature excursions [10], continuous temperature recording devices were installed in the 43 refrigerators and for 30 vaccine transport journeys—a few more than were assessed in the baseline. The same baseline configuration for the temperature loggers was kept so that comparisons between the baseline and the demonstration temperatures could be made. Visual temperature alarms setting were made according to the WHO time and temperature threshold as follows: a low alarm would be triggered in the cold chain if temperatures were at −0.5 °C or less for 60 consecutive minutes [11]. When a low alarm is triggered, there is a high risk that vaccines would have lost

[2] The paper is based on the current WHO Freeze alarm criteria (>60 consecutive min @ <−0.5 °C). −0.5 °C is the scientific freezing point of liquid vaccine. The actual freezing point is not a stable reference point although it is in most cases well below −0.5 °C. Unfortunately, because below −0.5 °C the vaccines freeze point is variable and unreliable, WHO has the policy to check vaccines that have been exposed with the shake test, but not to expose vaccines below the alarm standard for storage.

[3] 30-day temperature recorders meeting WHO/PQS Performance Specification E006/TR06.3: Models used in the Optimize study were: Storage – Log-tag TRED 30/7 with external temperature sensor. Transport – Log-tag TRID 30/7 with internal temperature sensor. Configuration of recorders in 2011 was not the same as in the 2012 baseline; in 2012 both the baseline and intervention recordings were made with identical configuration.