



ColdChainIQ
Temperature Control Logistics
& Quality Network

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COLD CHAIN IQ BENCHMARKING REPORT 2014

**7 BEST PRACTICE
CASE STUDIES FOR
THE TEMPERATURE
CONTROLLED
LOGISTICS & QUALITY
COMMUNITY**

Featuring case studies from world leading pharmaceutical companies

Generics

Local Storage Environment

Pharmaceutical Track & Trace

Passive Vaccine Storage Device

Temperature-Sensitive Payloads

CRT

Trailer Qualification

Last Mile

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INTRODUCTION

It is only through benchmarking performance that we can improve

The Cold Chain IQ: Benchmarking Report 2014 will highlight some of the best case studies of leading pharmaceutical and biotech companies in the world and showcase those who are striving to overcome the challenges of a complex global life sciences supply chain.

In this report we highlight 7 best-in-class case studies demonstrating return on investment and improvements in efficiency and quality management, from ensuring that controlled room temperature (CRT) products are protected to improving supply chain traceability.

Cold Chain IQ would like to thank all the contributors and advisors on this report, we hope you enjoy reading!

Best regards



Andrea Charles
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CASE STUDY 1:

HOW TO ENSURE CONTROLLED ROOM TEMPERATURE (CRT) PRODUCTS ARE PROTECTED DURING SHIPMENT



SITUATION APPRAISAL

Company: The management team of an international pharmaceutical manufacturer that focuses on attention deficit hyperactivity disorder (ADHD), human genetic therapies, gastrointestinal diseases, regenerative medicines, and other therapeutic areas needed re-evaluation of its thermal packaging qualification process for its sold oral dosages to confirm they met new regulatory expectations within the current channels of distribution.

Aggressive in-licensing, merger and acquisition efforts are focused on products in specialty markets or 'orphan' drugs with strong intellectual property protection and global rights. The formulations for the specialty pharmaceuticals are

typically in the form of solid dosages and require controlled room temperature (CRT) storage per label requirements. However, the transport temperature ranges have not been defined. The current interpretation of global regulatory requirements requires shipment at CRT temperature ranges until additional stability profiles can be developed and shared with global regulatory agencies. The thermal packaging qualification process for their sold oral dosages needed re-evaluation to confirm they met new regulatory expectations within the current channels of distribution. The current approach was not scalable and may not support planned product/country registration plans in the future.

THE FOCUS OF THE CRT THERMAL PACKAGING QUALIFICATION PROCESS REDESIGN WAS:

- ▶ Enhance regulatory compliance by updating current Standard Operating Procedure (SOP) that is currently utilized for thermal packaging qualification, transport lane qualification, and thermal packaging performance qualification for product licensing/registration.
- ▶ Modify the current thermal packaging qualification to a 'platform' approach that allows for quick integration of new products and countries being added to the portfolio and geographic coverage.
- ▶ Establish warehouse pack out procedures, change control, and quality management system procedures for the thermal packaging in the distribution centers globally.

APPROACH

Short-term improvements. The short-term improvements focused on improving 'inspection readiness' for inter-site shipments of both bulk and finished goods in pallet quantities. The goal was to ensure all current transport lanes and pallet shippers used to supply drug product in the logistics network were mapped, assessed, and an approach for verification was documented in the quality management system.

A map of the current and projected logistics network was developed based on both current transport lanes and expected product launch strategy. This logistics network map drove the thermal profile selection process, identified types of thermal packaging to be qualified (e.g. small parcel, pallets, or active refrigeration, etc.), and informed the thermal packaging qualification process design. The thermal profiles chosen were a public standard developed by the International Safe Transit Association (ISTA). Both the ISTA 7D and 7E profiles were investigated. The choice of the 7E profile was driven by comparing actual lane data and ambient air profiles to the foundation data. The ISTA 7E profile was calculated to show a 99.95% confidence level for both current and future transport lanes.

Conduct risk assessment. The current thermal qualification data, logistics network, and regulatory guidance were

assessed with a proprietary Hazard and Operability (HAZOP) tool developed by Modality Solutions to identify opportunities to reduce regulatory exposure and to guide short-term process improvements. The HAZOP tool used focused guide words and a prepopulated list of potential hazards and harms i.e. the environmental and operational hazards in the 'typical' temperature-controlled logistics network developed for pharmaceuticals.

Change control records were created to manage the planning and control of revisions to thermal packaging qualification, process parameters, and procedures to prevent unintended consequences. These change control records were focused on the changes informed by the risk assessment conducted and documented in a risk management plan that was developed as the 'road map' to reduce the highest risks first. It is important to note, low level risks identified were also reviewed, and it was determined that no immediate action was required. This approach, documented in the change control, identified high risks that would be mitigated and low risks that were considered acceptable by the management team.

Revise current SOPs to match current approach. Current SOPs were reviewed to identify the enhancements required to match the current approach followed in current protocols

and in the reports to data which are collected in the shipping lane verification studies. This compliance risk was identified during the risk assessment. Before any long-term improvements were started, the current practice and the current SOPs were harmonized. Ultimately, the current processes were not scalable. However, they were compliant except in one significant aspect -- the written procedures did not match the current practice. This critical compliance gap was addressed immediately.

Current thermal packaging qualification was enhanced by completing a technical assessment of current documentation to justify current qualification data. This technical assessment was used to support the use of the current thermal shippers for monitored shipments. Aligning the thermal qualification documentation of the current shippers closed another critical compliance gap. Even though the shipments were being monitored and temperature excursions were within the expected number of incidents, it was important to ensure the documentation of the qualification process was brought in line with current regulatory expectations.

Long-term improvements. Long-term improvements were designed to make global expansion of new products and new markets possible by providing a scalable approach. A 'platform' approach for shipper qualification was designed for all current shippers. Both inter-site pallet shippers and small parcel shippers used at distribution centers will be evaluated against the new approach.

Design 'platform' approach to thermal packaging qualification process. The current SOP was replaced with a 'platform' approach to thermal packaging qualification. Three separate SOPs were created: thermal packaging qualification; transport lane qualification; and transport performance qualification. The thermal packaging qualification focused on defining the 'design space' of the shippers in a controlled laboratory environment. These laboratory tests focused on qualifying the shippers against the ISTA 7E hot and cold profile. The transport lane qualification process was designed to confirm the global thermal profiles selected

would be effective in any new transport lanes. Lane qualification gave the management team confidence that any previously qualified thermal packaging would be effective in maintaining temperature in any added transport lanes.

The 'platform' approach to the thermal packaging qualification process was aligned with the ongoing Request for Proposal (RFP) to ensure the proper Operational Qualification (OQ) data package was prepared by prospective suppliers. If the provided OQ data was considered unacceptable, a gap analysis was conducted to determine remediation steps.

Validate the pallet thermal packaging systems. The small parcel shippers selected in the Request for Proposal (RFP) were validated. Operational qualification of shippers according to the new qualification program was required to be conducted by a selected vendor. Once the selected vendor presented a successful OQ executed to the pharmaceutical manufacturer's requirements documented in the quality management system, Modality Solutions supported the manufacturer in execution of the PQ portion of the validation process. The combination of the technical assessment of the stability data and the review of the temperature data in current transport lanes, coupled with a successful vendor-executed OQ and manufacturer-executed PQ, met all requirements for process validation as outlined by all major regulatory agencies around the world.

Create pack out SOPs for current thermal packaging solutions. The thermal packaging systems selected required pack out SOPs for each thermal packaging shipping system. These SOPs were used to uniformly train warehouse personnel to correctly pack out the new packaging systems. The validated thermal packaging system required a monitoring and controls system to ensure proper maintenance of the validated cold chain. The monitoring and controls system design identified the appropriate technology, use and placement, and management review required to ensure compliance to cGMP requirements.

RESULTS

In 2013, the management team with the assistance of Modality Solutions:

- ▶ Reviewed and approved document changes, technical assessments, and validation approach in the quality management system to support regulatory inspections.
- ▶ Developed and implemented a new temperature controlled shipper qualification process.
- ▶ Evaluated and selected a preferred global supplier of CRT shipping solutions.
- ▶ Implemented a new 'platform' approach to thermal packaging qualification.

CONCLUSION

A CRT thermal packaging solution was selected and validated with a documentation package including standardized pack out SOPs available for all internal and third-party distribution centers globally.

CASE STUDY 2:

TRAILER QUALIFICATION APPROACH FOR PHARMACEUTICAL PRODUCT



SITUATION APPRAISAL

Company: The management team of a leading global generic and branded pharmaceutical manufacturer that distributes and supplies the market with a wide range of products encompassing multiple therapeutic areas needed to implement changes in its network to improve compliance and document control for shipments of refrigerated (2-8C) and controlled room temperature (20-25C) (CRT) of drug products shipped in controlled temperature trailers. This change was driven by an internal requirement as well as a GDP/GMP expectation.

Temperature-controlled trucks are used to convey palletized shipments of pharmaceutical products from the manufacturer to the distribution centers and in many cases between distribution centers. Fleets of trucks owned by third-party logistics companies (3PLs) were utilized by the pharmaceutical manufacturer on a contract basis.

APPROACH

Develop a qualification strategy. The qualification strategy Modality Solutions was to develop had to establish a standards-based approach for trailer qualification. This strategy leverages the manufacturing standards of the 3PL that are followed in the design and construction of the trailers and identified key studies. These studies need to be executed by the pharmaceutical company to verify the pick and load at their distribution centers and the transport, operating, and monitoring instructions given to the 3PL.

After the qualification strategy was developed, Modality Solutions would write protocols and reports for both refrigerated and CRT that would establish the rationale for:

- ▶ Trailer inspection
- ▶ Number and placement of temperature monitors
- ▶ Loading patterns
- ▶ Temperature set points of the trailer

Updated standard operating procedures (SOPs) for trailer loading were also needed. The qualification showed that proper air flow around the product key to maintaining temperature. Proper air flow can only be maintained with standard operating procedures that ensure spacing between pallets and a gap between the product and trailer walls. The

The regulatory expectations, expressed in numerous GDP guidance documents, are for the pharmaceutical manufacturer to establish the suitability of these contracted trucks for the intended purpose. This expectation includes the capability of maintaining the temperature of the products at acceptable temperatures during the time the product is carried in the trucks.

However, the management team felt the industry practice of 'temperature mapping' refrigerated trailers was neither practical nor scalable in their current network. The network of multiple 3PLs and two temperature ranges made the measurement of individual trucks in a contracted fleet in a multi-use environment time consuming, inefficient, and ultimately did not meet regulatory expectations. A different approach would be needed.

employees were trained and tested on loading procedures that matched the results in the qualification.

Establish an operating standard for carriers. The operating standard for the carrier was needed to ensure proper maintenance, operation, and that the monitoring was in place prior to the shipment. Proper set points, full tank of fuel for compressors, security procedures, including specific routes for each lane, and a host of other details were included in the operating procedure. Once the operational requirements were defined in qualification, it was important to ensure these needs were translated into operating procedures for the carrier that were clear, concise, and easy to follow.

Once the procedures were established, an enforcement mechanism was required. The approach had to allow for some flexibility in the execution, but ensure the requirements were met. A Quality Agreement (QA) template was created for use with contract carriers with temperature-controlled trailers. This template was used to discuss their requirements with their contracted third-party partners and was included in the contract language as part of the renewal of the freight contracts which outlined the business terms.

RESULTS

In 2013, the management team with the assistance of Modality Solutions prepared a data and documentation package to:

- ▶ Ensure compliance with cGMP expectations for temperature control for temperature-controlled trailers used during shipment of drug products.
- ▶ Gain alignment with corporate procedures.
- ▶ Select a cost-effective approach to temperature monitoring of shipments.

The project incorporates a 'family' approach to trailer validation by leveraging the existing trucking industry standards and certifications that serve as the IQ/OQ for refrigerated trailers. Procedural controls are adopted by the pharmaceutical manufacturers to address the critical aspects of trailer inspection and approved loading patterns. These are the critical components that have a material impact on each individual shipment.

Without attention to trailer loading, the qualification process cannot be considered as completed. It is only through a good understanding of how the loading affects airflows within the trailer that an optimal location for temperature monitors can be ascertained.

Inspection of the trailer is a shared responsibility contractually defined in a quality agreement. Defined roles that assure proper maintenance and inspection of the critical components are important items to include in the quality agreement.

CONCLUSION

Following the validation approach used by pharmaceutical companies within the 'four walls' of the GMP environment, a robust and scalable program can be extended to and implemented in 3PL distribution. Identification and stratification of the many factors that may cause a non-compliant shipment allows the pharmaceutical company and 3PLs to effectively establish a working relationship that identifies and controls the critical items to assure consistent results.

CASE STUDY 3:

PASSIVE VACCINE STORAGE DEVICE

SUMMARY:

The Passive Vaccine Storage Device (PVSD) is designed to keep life-saving vaccines at appropriate temperatures for a month or more with repeat vaccine retrievals and no need for electricity.

BACKGROUND:

More than 23 million children do not receive routine immunizations annually and more than 1.5 million children under the age of five die each year from vaccine-preventable diseases, like tuberculosis. This is partially due to limitations in the temperature-controlled supply chain that is needed to prevent vaccines from spoiling between their point of manufacture and their use.

APPROACH:

Over the course of four years of rigorous scientific, material and user research, development and testing, Global Good and the Intellectual Ventures Laboratory teams focused on inventing and building an easy-to-use device with state of the art materials and processes. Throughout the invention process, there were a number of key challenges to address:

1. Required a system that could stay cold using only ice for energy storage and provide reliable GSM and GPS performance while meeting 45-day vaccine safe storage temperature and life cycle requirements.
2. The integrity of the insulation properties of the device needed to be upheld under harsh environmental conditions where the device might be dropped or be subjected to rough transport and extreme heat.
3. Spoiled vaccines don't necessarily look spoiled. A constant log of temperature changes was required to keep track of the vaccines' efficacy.
4. The device needed to be intuitive and easy-to-use, as well as portable, so that the people loading, transporting or administering the vaccinations could easily and efficiently retrieve the vaccines repeatedly without letting too much warm air in.

SOLUTION:

The result is the Passive Vaccine Storage Device (PVSD), an insulated container designed to keep vaccines at the appropriate temperatures for a month or more on a single batch of ice.

By employing super insulation techniques similar to those used to store cryogenic fluids and protect spacecraft from extreme temperatures, that once stocked a single batch of ice, the PVSD can keep vaccines between 0-10 degrees Celsius for 35 to 50 days (depending on ambient temperature), without electricity. Vaccines can be retrieved as needed without jeopardizing the remaining vials, and the device can be easily serviced, restocked and redeployed into the field.

It is comprised of a ruggedized vacuum-insulated container, ice blocks and a telemetry module. Vaccines are stored in three "stacks" comprised of interlocking "cups" optimized

RESULTS/CONCLUSION:

Global Good is driven by impact rather than profit, but believes that for-profit market incentives play an important role to encourage applicable, affordable, and accessible technology that can save lives in developing countries. That's why in 2013, Global Good signed a commercialization agreement for the manufacturing and distribution of the PVSD with AUCMA, one of world's leading refrigeration companies. AUCMA has the expertise and scalability needed to help the PVSD extend the vaccine supply chain in even the most remote parts of the world, and to do so at the lowest cost-per-fully-immunized-child possible. To date, the device has undergone field trials with the support of Ministries of Health in some of the lowest vaccinated populations in

This cold supply chain is well established in many parts of the world, but poor infrastructure and unreliable power prevent vaccines from reaching many developing countries. Global Good, a collaboration between Intellectual Ventures and Bill Gates to invent technology that improves life in developing countries, set out to address this problem by developing a device that can keep vaccines cold for months with no external energy.

for the vaccine schedules of specific countries and interchangeable sizes to suit different vaccine configurations. The device can store up to 300 doses of vaccines or enough to serve a community of 6,000 for more than a month.

The device is also equipped with technology to monitor its location, internal temperature and the number of times vaccines have been retrieved from it. This information can be communicated via daily SMS transmissions and downloaded via a USB port to inform future vaccination campaign planning. In comparison, existing cold boxes can store vaccines for little more than four days. Unlike solar refrigerators, the PVSD is cheaper (both initially and over ten years) and require minimum maintenance, both critical factors for widespread use in developing countries.

Southeast Asia, Uganda, Gambia, Ethiopia, Senegal, and Nigeria where, for the first time, a reliable supply of vaccines is available to families who did not have access to the reliable vaccines and at a lower cost per dose than expensive outreach campaigns by governments and NGOs.



CASE STUDY 4:

EFFECTIVE COLD CHAIN AND VACCINE MANAGEMENT DOWN TO THE LOCAL STORAGE ENVIRONMENT

SITUATION:

Mass Vaccination Programs are Expanding to Control Spread of Diseases

The world's population is not getting any smaller and with this global expansion of people, infectious diseases are on the increase due to over-crowding, especially in third world countries and poorer regions of the globe. To help combat the spread of common childhood and adult illnesses such as, influenza, measles, and tuberculosis, mass immunization programs are expanding in the United States and around the world.

CURRENT MAJOR GLOBAL IMMUNIZATION PROGRAMS INCLUDE:

- ▶ In Liberia, a new program for protection against one of the leading vaccine-preventable killers of children, this is a pneumococcal vaccine (PCV)
- ▶ In India, improved measles and polio control (now 3 years without a major polio outbreak)
- ▶ In Haiti, a "5 in 1" pentavalent vaccine protects children from diphtheria, tetanus, whooping cough, hepatitis B and Haemophilus influenzae type b (Hib) which causes pneumonia and meningitis
- ▶ In Mexico, Brazil, Ecuador, San Salvador, Panama and Bolivia, rotavirus immunization programs have been implemented
- ▶ In China, hepatitis B vaccination for newborn infants in rural regions of the country

- ▶ CDC Global Action Plan for Immunization, a program focused on mass Influenza vaccination

In order to provide an adequate supply of effective vaccines to support these programs, measures need to be in place to ensure these medicines are maintained at peak efficacy, are free from adverse shipment or storage events, and are temperature safe at all points in the logistics supply chain; even down to local storage at patient distribution centers.

These regulations and guidelines cover vaccines during storage and handling, including main distribution warehouses, transportation of products, and in storage refrigerators at local pharmacies, clinics and doctors' offices.

UNIQUE CHALLENGES:

Global Distribution and Storage of Vaccines and Cold Chain Product is Highly Regulated

Existing and new regulations for Good Distribution Practices (GDP) and Good Supply Practices (GSP) are multi-national in nature.

Although a vaccine manufacturer, distributor, or program administrator may be based primarily in one region of the world, they will most likely ship products to and between other global regions. Therefore, they will be bound by global and not just local GDP and GSP regulations.

In March of 2013 the EU released new guidelines for GDP and in June of 2013 the Chinese FDA implemented their new guidelines.

Both are very similar in content and define recommendations for key factors related to total supply chain risk aversion planning and cold chain product temperature management. Highlighted in both these regulations are staff training, warehouse and storage management, plus transportation monitoring of temperature controlled products from source to patient.

Consequently, these regulations will now apply to potentially everybody that handles these vitally important pharmaceutical products and will become a future focus for compliance auditing.

THE SOLUTION:

1. Follow GDP and GSP Requirements, Implement Use of Temperature Management Tools

The primary solution is for all applicable companies to comply with these new and current guidelines, regulations, and recommendations, including ensuring regulatory compliance related to areas like:

- ▶ Having a documented quality management system - (QMS).
- ▶ Performing a risk assessment and having a documented risk aversion plan.

- ▶ Managing and monitoring of temperature for warehousing, transporting and distribution to the final point in the supply chain

2. DeltaTrak's Cold Chain Management Solutions

DeltaTrak offers a full range of solutions to manage your cold chain and ensure compliance with guidelines from FDA, CDC, WHO, and other regulatory agencies. Our products focus on helping to ensure and maintain efficacy and safety of pharmaceuticals as they are stored and transported from source to patient.

These solutions include the FlashLink Certified Vaccine Data Logger with Glycol Bottle, which recently received WHO prequalified status. It meets WHO, CDC and FDA guidelines for collecting temperature data in refrigerated units used for storing vaccines and medicinal products in warehouses, pharmacies, clinics, and even in doctors' offices.

This reusable logger provides permanent electronic records for audit purposes, and a flashing red LED will alert when

excursions occur, so corrective action can be taken to prevent the loss of stored vaccines and ensure their efficacy for patient safety. The unit has a temperature probe enclosed in a liquid glycol buffer to avoid false alarms during expected temperature fluctuations under normal use, such as, frequent door openings.

EXPECTED RESULTS AND BENEFITS FROM USING THESE PRODUCTS AND SOLUTIONS

In many cases, without taking appropriate action when temperature excursions occur, whole batches of drugs may need to be disposed of. By monitoring various high risk areas within the supply chain, corrective action can be taken and these products can potentially be saved.

Mitigating supply chain risks can be accomplished by using a combination of solutions, such as real-time environmental monitoring systems, product packaging and temperature monitoring devices (e.g. data loggers) which have been validated and profiled for performance accuracy and reliability.

Companies who implement good distribution and cold chain management practices will minimize their loss of

products and exposure to fines related to dispensing of pharmaceuticals with compromised efficacy. Reducing the amount of drugs disposed of due to non-compliance with manufacturers' storage and handling guidelines will not only limit financial losses, but also avoid jeopardizing inventory levels of critical vaccines and pharmaceuticals needed by global programs.

Primary benefits of GDP, GSP and compliance with regulatory guidelines will be the assurance of adequate supplies of safe, effective vaccines to meet global program demands, ensuring patients are safely and successfully immunized, resulting in long term improvements in global health.

CASE STUDY 5: PHARMACEUTICAL TRACK AND TRACE SYSTEM

SITUATION:

For the last couple of years, the number of counterfeited drugs has increased. Pharma Counterfeiting has become a global problem. Consistent education of the public and stricter laws didn't make a significant effect of combating the issue. As counterfeiters become more sophisticated, we have concluded that we need a more sophisticated approach to this problem.

In developed countries it is less but the average counterfeit ratio of drugs is 10%, according to the WHO. However: illegitimate internet pharmacies ship their illegal products worldwide. In some countries, the ratio of counterfeited drugs is over 50%. These drugs can harm the health and even the lives of patients.

Therefore, the problem is not just counterfeit, it is in fact MURDER!!! In Turkey we have saying of Seyh Edebali: "Let people live so the state would live". We have approached the problem from this point of view and targeted guaranteeing the lives of people.

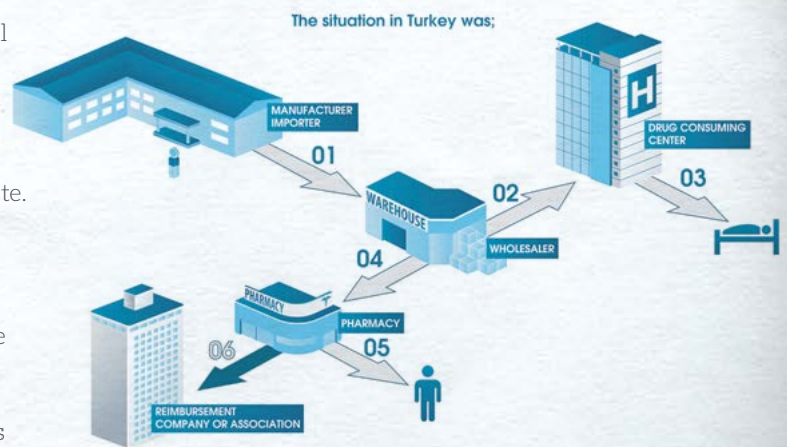
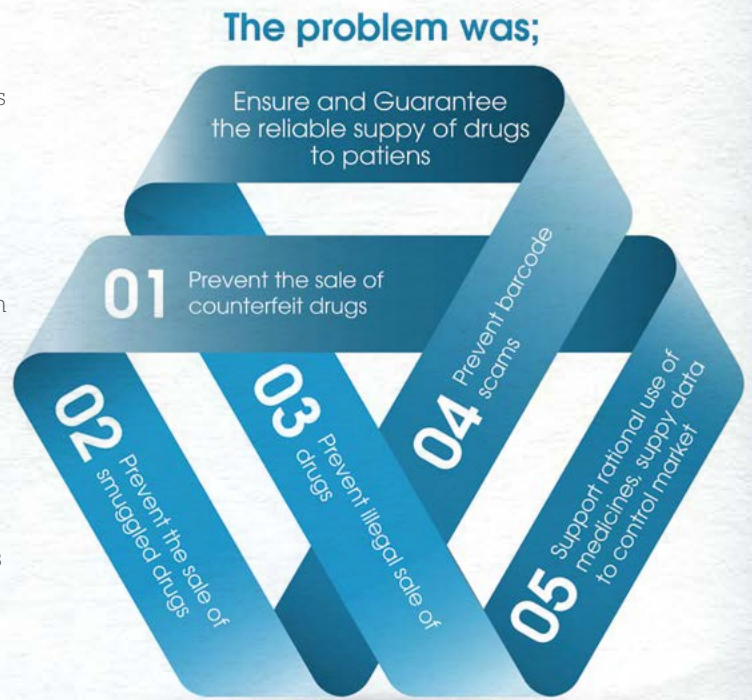
It is glad to see the awareness and consequent improvements about fighting counterfeiting in pharmaceuticals. In EU, Falsified Medicines Directive is forcing the industry to develop a Track and Trace solution by electronic records. In Turkey we have a working one for more than 4 years. So as a best practice and a case study, it would be better to understand the situation in Turkey, learn from the experiences.

The main problem in Turkey was to ensure and guarantee the reliable supply of drugs to the patients, the secondary problems that we faced were preventing the sale of illegal drugs, smuggled drugs, illegal sale of drugs, barcode scams, and of course by using this valuable data, support rational use of medicines. We reached a result at the end that includes all of them, moreover not limited to these.

REGULATIONS AND SUPPLY CHAIN IN TURKEY:

All stakeholders have licenses from Medicines and Medical Devices Agency in Turkey. And also all drugs are getting registered to the system of the Agency after getting the permission from the scientific committee. The price of a drug is also defined by the agency and 91 percent of the drugs are paid by the reimbursement association of the state. By knowing all these, you may conclude that the biggest customer of the industry is the state.

The rest is very likely to other countries: A manufacturer manufactures a drug and sells it to a wholesaler. And if the wholesaler sells these drugs to a drug consuming center such as hospitals, family physicians, polyclinics, i.e. the stakeholders that don't sell the drug to the patient just uses the drug on the patient; the wholesaler enters a tender and



sells the drugs in big amounts. But if the wholesaler sells the drugs to a retail pharmacy, which in Turkey should be managed by a pharmacist, then the wholesaler sells the drugs by small amounts but in high frequencies. The drug consuming centers are clearly opens the drug pack and uses every tablet on a different patient but don't sell the drug.

The retail pharmacies sell the drug pack to the end user and rarely get the price in cash but mostly send the invoice to the reimbursement association or an insurance company if the patient has a private insurance and paid by the reimbursement entity.

THE SOLUTION:

Let's talk about "the solution". The solution is traceability, which is defined as track, trace, authentication, pedigree, returns and recalls.

So the solution is ITS, which is the word by word translation of Pharmaceutical Track and Trace System in Turkish. Formerly all drug packs in Turkey was containing GS1 GTIN (Global Trade Item Number) and barcode to make it machine readable. In ITS we first made the drug packs to be serialized by a serial number which is a GS1 standard and marked them with another GS1 standard Datamatrix to make it machine readable. Then we constructed a centralized repository to make all the stakeholders to notify the central management system about every action that they take on

the drug pack. So ITS doesn't have any interface that is designed for the stakeholder. It has some reach points named as web services that can be used by the software applications that stakeholders use. I mean all stakeholders are using their own management systems and those management system has interfaces for the use of the stakeholder and in the background, the management system communicates with ITS to notify about the action taken on the drug pack. In this manner ITS can track and trace a drug by using its serial number from the point of manufacture to the point of dispense. By this way, it is for sure that ITS is a fully interoperable, electronic, unit-level serialization-based track & trace system for pharmaceuticals.



As a result, we changed the situation of the pharmaceutical sector from being a high profit/low risk sector for criminals, to a high risk/low profit. So criminals are still criminals but they moved to other sectors, such as tobacco, food supplements and other stuff. Now in Turkey we are working to apply this system in other sectors also.

THE SITUATION IN TURKEY AFTER ITS:

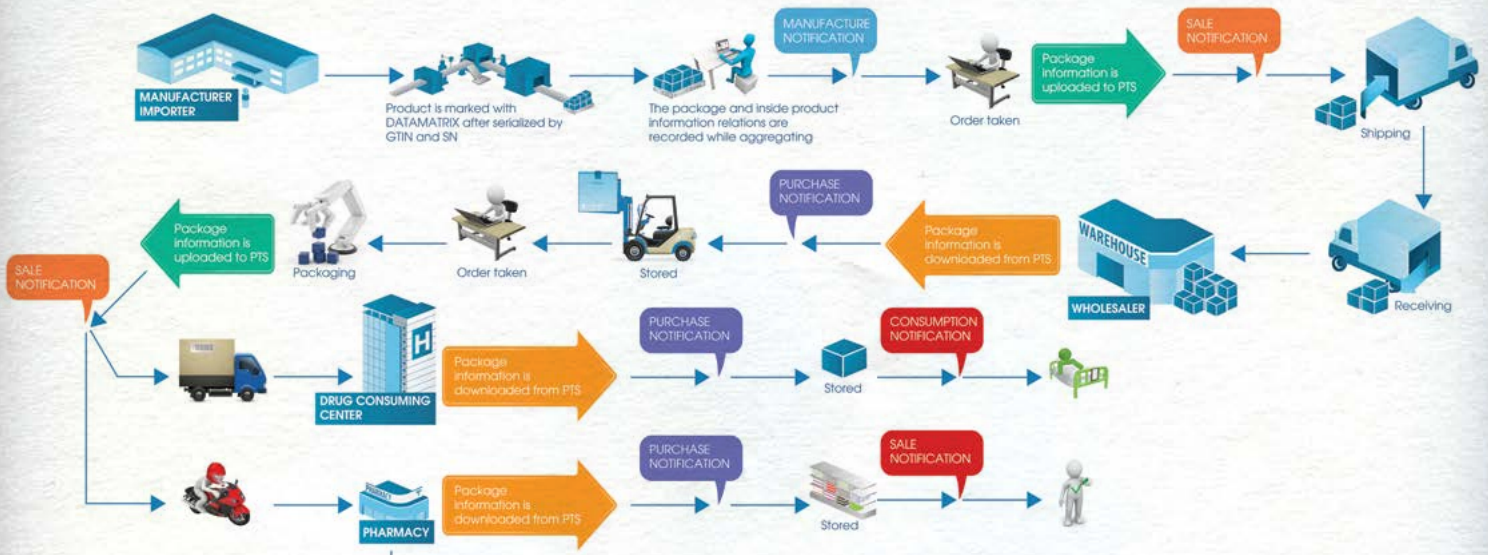
So first we have ITS, a centralized repository for serialized pharmaceuticals, and we have PTS, a centralized file sharing platform. PTS is the Package Transfer Service. In ITS we are tracking and tracing the drugs by individual packs, i.e. ITS is working on the basis of drug packs but the real trade doesn't go that way. Real trade is going by cartoons, boxes, palettes and so on. So we created a new standard of language that can be used between the stakeholders to share the hierarchical data that containers include and named it as PTS XML Standard. First stakeholder who is making a container is creating an XML file that contains the information of which container includes which drug packs and uploads this XML file to PTS. After the physical transaction is done, the second stakeholder downloads the XML file from PTS and learns the hierarchy of the container. Then resamples some of the drug

packs in the container to verify the XML file data is correct, and uses the data of drug packs in the XML file to notify the action to ITS.

Let's have a look at the work flow: A manufacturer manufactures a drug pack and sends a "manufacture notification" to ITS. This is the birth record of the drug pack. Then after an order comes from a wholesaler, the manufacturer sends the sale notification to ITS for the drug packs that he will deliver and creates an XML file containing the container hierarchy and uploads it to PTS. After the shipment is done and delivered to the wholesaler, the wholesaler first downloads the XML file from PTS and uses the drug pack information in XML file to notify ITS about the purchase action. After the wholesaler sends the purchase notification to ITS, the ownership of the drug changes.

The same way, a retail pharmacy or a drug consumer center sends an order to the wholesaler. The wholesaler sends the sale notification to ITS and uploads the XML file that he constructed to PTS. Then he sends the drugs to the corresponding stakeholder. The retail pharmacy or the drug consuming center downloads the XML file from PTS, and uses the information of drug packs to notify the purchase action to ITS. For the drug consuming centers, the consume notification is done right before opening the drug pack.

And this is the death of the drug in the system and the system prevents this drug to be used twice. But for the retail pharmacy, after getting the prescription from the patient he sells the drug pack to the patient and sends the invoice to the reimbursement association. The reimbursement association queries the sale from ITS and verifies if all the information that the retail pharmacy sent are correct before paying the price to the retail pharmacy.



IMPLEMENTATION PHASES:

We implemented the solution in 3 phases. First phase was preliminary phase including workshops with the industry, creating and defining the common standards, making the legislations and defining the timeline. The second phase is named as Phase 1 which is including meeting technology standards for serialization and printing datamatrix on the drug pack and consequently in this phase manufacture notification of manufacturers and sale notification of pharmacies was obligatory. And the reimbursement association was querying the sale before paying the price to the pharmacies. In the third and the last phase which

is named as Phase 2; the aggregation is done. By different words, all notifications are obligatory for all stakeholders. And as the government the monitoring and support decision systems are developed.

We have more than 40 thousand stakeholders included in the system and we tracked and traced more than six and a half billion drug packs by ITS. And nearly 4 billion of them are sold. For the technical people who are curious our response time is 0.03 seconds, i.e. 30 milliseconds and our uptime ratio is 99.999 percent which is over Tier 4 standard.

OUTCOMES OF THE SYSTEM:

If you can remember, our main objective was to ensure the reliable supply of drugs to the patients. But we achieved more. We prevented the sale of counterfeit and smuggled drugs, prevented illegal sale of drugs, barcode scams and also drug thefts. These 5 issues give us a saving of 1 billion dollars annually. By considering that pharmaceutical industry is 10 billion Dollars in Turkey this saving has a significant effect. And also we removed some of the bureaucratic things that saved our time. And the system gave us some instruments to support the fight against narcotics and black market.

We can do more complex recalls and they can be instantly applied. We can recall a batch or a half batch of a drug from just some type of stakeholders and we can do the recall

way such as stopping the sale or allow to go backwards in the supply chain and at the time we enter this recall to the system it starts instantly and no one can threat against the rule.

The data in the system is a valuable data, we can use this data to support rational use of medicines, create administrative reports, monitor the industry or prevent tax fraud. Faster decisions and more consistent estimations can be made by using this instantly updated data.

You can learn all details and updated statistics from the website <http://its.technarts.com>

CASE STUDY 6:

HOW TO ENSURE TEMPERATURE-SENSITIVE PAYLOADS ARE PROTECTED DURING SHIPMENT

INTRODUCTION:

The fast growing trends of globalization and long distance shipping make the transportation of temperature-sensitive products an increasing concern. In recent years, healthcare companies' concern about temperature related product loss has doubled, and less than half of the companies believe they are successfully managing supply chain costs.

As healthcare companies ship temperature-sensitive products across further distances, they must heighten their consideration of payload requirements and shipping options. Below, we highlight how two companies optimized their process for shipping temperature-sensitive payloads in controlled room temperature (CRT) and deep frozen ranges.

#1 HOW TO MAINTAIN CRT RANGE WITHOUT A COMPLICATED ONE-OF-A-KIND TEST REQUIRES TEMPERATURE CONTROL

Developed by Oxford Immunotec, the T-SPOT®.TB test is a revolutionary "one and done" diagnostic test for the diagnosis of both active and latent tuberculosis.

While the new test offers an improved patient experience and more confidence in the results, the blood specimens must

be delivered to the Oxford Diagnostic Laboratories for testing within 30 hours. To ensure clinical accuracy and comply with FDA requirements, **the specimens must be kept within a very narrow controlled room temperature range until they are analyzed.**

A COMPLEX PROCESS CONFUSES CUSTOMERS

After a short trial using EPS boxes, Oxford Immunotec tried containers made with vacuum insulated panels (VIPs), with phase change material (PCM) to maintain blood sample temperature during transport between physicians' offices and their lab. This shipping method required the physicians to follow a detailed set of instructions, with two potential pack-outs for different seasons, and pre-conditioning of the PCM.

If these steps were not followed correctly, the product would fail in transit.

The success of the exchange depended heavily on the customer's ability to carefully read and follow the instructions, and near-perfect shipping conditions. When packages failed due to noncompliance, customer complaints added up, and the need for an easier return process became clear.

SUPERIOR VIP SOLUTION MAKES IT FOOLPROOF. COMPLAINTS AND FAILED SHIPMENTS DROP TO ZERO

In 2010, Oxford Immunotec began exploring other options that would simplify the return process. "We needed something fail-safe, without complicated packing instructions that required customers to make decisions and educated guesses about temperature," said John Kelly, Director of Operations at Oxford Immunotec. "At the same time, since our customers stock the test kits, size was a critical factor. We needed a solution that fit our test kit, and was as compact and light as possible."

The company connected with American Aerogel, and together they developed a VIP solution to address their reverse logistics challenges. The result was a more efficient,

custom solution that included Aerocore boxes and a unique temperature control system with new phase change materials, lowering costs and benefiting the environment.

The new PCMs eliminate the guesswork for end-users. Each container includes two gel packs and simple instructions to pack one solid and one liquid. Regardless of what the package encounters in transit, the gel packs control the temperature. As an alternative to off-the-shelf VIP containers, the Aerocore solution was custom-designed for the payload and the use. Better insulation and intelligent design resulted in easier, cost-effective shipments.

COMPLAINTS AND FAILED SHIPMENTS DROP TO ZERO

The American Aerogel shipping solution has not only improved the end-user's experience by making the pack-outs easy, but has also dramatically reduced Oxford Immunotec's need to provide customer support. Company employees can focus on what they do best— testing for tuberculosis— without the concern for whether the patient's valuable product will arrive safely. In addition to enhancing Oxford Immunotec's value proposition, the Aerocore solution also saves them money. The robust boxes are designed to be used

multiple times, reducing the "per-turn" cost of the container and disposal costs

Our main goal was to improve customer satisfaction, so we could stand out as a company that was providing physicians' offices with a great new service, not adding a hassle to the workday," said John Kelly. "American Aerogel not only helped us to do that, but they lowered our shipping costs with a foolproof solution designed specifically for us."

#2 HOW TO MAINTAIN -75°C DURING SHIPMENT AND UPON ARRIVAL AT THE RECEIVING SITE

NEED A SHIPPING CONTAINER THAT SERVES AS THE HOSPITAL'S FREEZER.

The product being shipped is a bioengineered product containing living cells that work with the patient's own skin to better heal hard-to-treat ulcers. Because the product contains living cells, it must be kept cryogenically frozen to work—from the moment it is produced in the manufacturer's advanced labs, until the moment it is used to treat patients in the operating room of hospitals across the country. Packing the tissue in dry ice maintains the required

temperature of -75°C (±10°C), but the dry ice sublimates quickly at room temperatures, and even in conventional freezers. Few hospitals or physicians' offices have the special cryogenic freezing equipment to store the tissue for long periods. So in addition to making sure the samples arrive at dry-ice temperature, the shipping solution must maintain temperature at the receiving hospital until the procedure takes place.

PUR PRESENTS PROBLEMS

When this temperature-sensitive product was first introduced, the manufacturer delivered it using polyurethane boxes with three-inch-thick walls and plenty of room to surround the tissue samples with dry ice. The dry ice was delivered in blocks, which had to be manually shaped to fit specially designed slots.

This typical solution for dry-ice shipping had several limitations. It was rated to maintain temperature for 48 hours, which meant that almost any overnight shipping delay could result in product failure. The short temperature window also presented a scheduling challenge: operations

had to take place within hours of package arrival, and could never occur on Monday because a Friday or Saturday delivery would result in lost product over the weekend.

The polyurethane boxes provided room for two tissue samples per container, which limited the ability of physicians to choose the proper graft—up to five different options are available. If an operation had to be rescheduled because of a change in the patient's condition, the short temperature window also limited the hospital's ability to return product so that it could help another patient.

A TEMPERATURE-SENSITIVE SOLUTION

The manufacturer's shipping team used a best practices approach and worked with American Aerogel to develop a new shipping solution that would address these limitations. Together they designed a solution that employs one inch-thick Aerocore vacuum insulated panels (VIPs), which offer the highest insulating properties of any commercially available insulation.

Each Aerocore insulated box holds up to five tissue samples with a relatively small amount of dry ice. The American Aerogel solution maintains temperature for 110 hours, or nearly five days, with outside ambient temperature of 40°C—and even longer at more typical ambient temperatures. This gives both the shipper and receiving hospitals much greater flexibility.

The durable Aerocore insulated boxes are shipped in standard corrugated containers and are designed to be used multiple times. So in addition to being able to return samples that can't

be used, most hospitals routinely ship the empty containers back to reduce waste, which lowers costs and benefits the environment.

Just as the tissue product represents an innovative new treatment option for diabetic patients, the shipping solution represents an innovative new option for the physicians who use it.

- ▶ Aerocore boxes deliver dramatically lower shipping costs while eliminating the risk of product loss due to temperature failure.
- ▶ Physicians and hospitals using the product have greater scheduling flexibility and the ability to return product that can't be used.
- ▶ Tens of thousands of patients are being treated, in part because of more reliable access to an effective therapy.

CONCLUSION

When choosing an insulated shipper to protect your payload, take the time to apply best practices - understand your product specifications and logistical requirements, review available shipper performance data, test the available shippers, and determine which insulated solution will give you the most protection for the required duration. Also, factor in the size of the available shipping solutions and the weight of the necessary coolant for your temperature profiles. Do not assume that ordinary shippers will adequately protect your payload simply because they are

commonly used - you may be settling for an inferior solution that puts your payload at risk. It is only after you take the time to understand the available options, that the best solution will become evident.

In two scenarios with different temperature ranges, the best solution for each customer was the American Aerogel insulated shipper. Insulated with Aerocore VIPs, these shippers provide best-in-class payload protection and represent the superior choice for temperature-sensitive shipments

CASE STUDY 7:

REQUIREMENTS AT THE LAST MILE

SITUATION:

To ensure the optimal viability of vaccines, their storage and handling need careful attention. Vaccines are highly thermo-sensitive biological substances which have a fixed shelf-life and lose viability over time. The loss of viability is irreversible and accelerated if proper storage and temperature conditions are not maintained. A vaccine vial must remain between 2 and 8 degrees Celsius throughout the entire cold chain system – when it is transported, when it is stored in a refrigerator or cold store, and when it is used at an immunization session. In addition to maintaining adequate refrigeration needs, proper handling practices need to be understood and practiced by all personnel along the supply chain.

Monitoring and maintaining the viability of vaccines is important for several reasons:

1. **Product efficacy:** Vaccine failures caused by administration of compromised vaccines may result in child mortality and the re-emergence or occurrence of preventable infectious diseases.

2. **Resource management:** Vaccines are expensive and are often in short supply in rural communities with challenging transportation environments.
3. **Lost opportunities:** Loss of vaccines may result in lost opportunities to immunize on a large-scale, especially in hard-to-reach areas and resource-poor settings.
4. **Confidence in public health:** Re-vaccination for those who have received an ineffective vaccine compromises public confidence in the health system.

This lack of infrastructure and inadequate monitoring of uptime and its resulting impact on the cold chain is illustrated in the following statement from Dr. K.O. Antwi Agyei, head of the Expanded Program on Immunizations in Ghana: “We have good coverage rates in Ghana including in the North, but recently we had a measles outbreak because vaccine potency [viability] was compromised when the cold chain failed. We then had to organize a special campaign and this cost us additional resources.”

The World Health Organization reports that the Effective Vaccine Management assessment (carried out in more than 70 countries between 2010 and 2012) found that only 29% of countries met its minimum recommended standards for temperature control.

CHALLENGES TO MAINTAINING THE COLD CHAIN:

Many challenges and complexities exist in ensuring the effective management of cold chain monitoring and maintenance at each level of distribution, as highlighted below:

Insufficient equipment and infrastructure

- ▶ Underdeveloped infrastructure in low-resource settings often results in an unreliable power supply with sporadic and frequent power cuts. This situation leads to an ineffective cold chain with greater reliance on human supervision and regulation and can result in inadequate and ad-hoc approaches to resolving cold chain problems.
- ▶ Unreliable communication networks limit data flow, the ability for the health system to coordinate resources, and increase response times to failures in the cold chain.
- ▶ Investment in the cold chain has not kept up with investments in vaccine development and deployment (see Figure 1). WHO estimates that about \$200 million US dollars is needed per year to address the cold chain needs in low-income countries.
- ▶ The use of solar refrigerators has been proven to compensate for power supply reliability but has several challenges of its own. Provincial staff lack sufficient technical knowledge needed for installation and maintenance. Further, batteries must be replaced every five

years, requiring robust maintenance plans and budgets for equipment maintenance, neither of which exist uniformly in Mozambique. Additionally, solar panels must be securely installed to prevent theft, raising the cost of installation.

- ▶ In Mozambique, more than 10 different brands and types of refrigerators are installed in rural health centers across the country. With such diversity in equipment, the Ministry of Health is challenged to store all of the spare parts necessary and to ensure there is requisite technical knowledge to conduct maintenance and repairs.
- ▶ The vaccine vial monitor (VVM), which changes color as it is exposed to heat, informs health workers at a glance if the viability of a vaccine has been compromised. However, no equivalent detection method exists for freezing exposure, which can be more common and more damaging to the vaccines than heat exposure. One review article of 35 temperature studies found that 34 of the studies cited freezing temperatures in the cold chain, and 14 of those found more than 50 percent occurrence of freezing among recorded temperatures.

¹Milstien J, Kartoglu U, Zaffran M. Temperature sensitivity of vaccines. Geneva: World Health Organization; 2006. [WHO/IVB/06.10]. ²WHO. Ensuring the quality of vaccines at country level. Geneva: World Health Organization; 2002. [WHO/V&B/02.16]. ³Sarley, David. When RED meets RED: How Coca Cola and the Health Systems in Ghana are learning from each other, 2013.

Vaccine and cold chain spending: A growing gap?

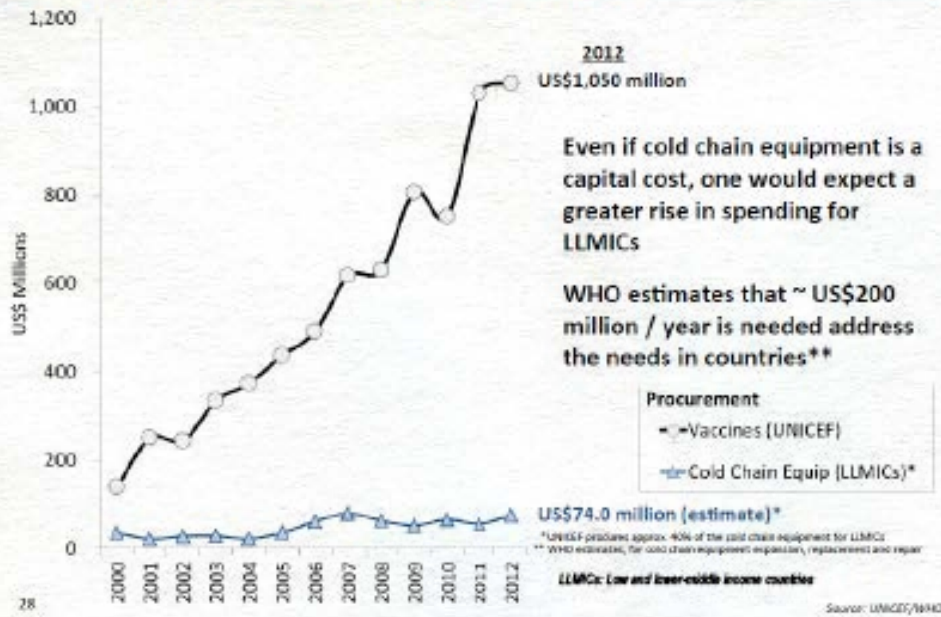


Figure 1: The Growing Gap between Vaccine Spending and Cold Chain Investments

▶ In Mozambique, the Ministry of Health uses mobile brigades (teams of traveling health personnel) to extend the reach of the vaccination program to rural areas. In addition to the challenges of ensuring the availability of transport, fuel and personnel to ensure routine outreach services, mobile cold chain equipment must guarantee the viability of vaccines during these sessions.

Adherence to appropriate vaccine stock management practices

- ▶ Over-stocking of vaccines in cold storage and poor shelving of packages leads to restricted air flow, which can present freezing risks or increased exposure to heat. Additionally, over-stocked or poorly stored vaccines can complicate adherence to the earliest-expiry-first-out (EEFO) principle, running the risk of excessive discarding of expired vaccines.
- ▶ High staff turnover, particularly in rural settings, impedes knowledge on and adherence to stock management and cold chain maintenance. Trained health workers will often be transferred to other geographic areas and health departments; new personnel coming into the immunization department do not receive proper training in these areas. This turnover exacerbates issues with stock management and other poor practices, such as using the refrigerators for personal food or beverage items. Additionally, there is a common misconception that as long as vaccines are kept cold, their viability cannot be compromised, resulting in misinformed health center staff setting vaccine refrigerators at lower than optimal temperatures.

▶ The temperature monitoring form should be manually completed twice a day by the health workers recording refrigerator temperature. These forms are often improperly completed. There is anecdotal information of the forms being filled out at the end of the week or just before a supervisor’s visit.

Insufficient technical personnel

▶ Each province in Mozambique has only one technician employed by the Provincial Directorate of Health (Direcção Provincial de Saúde - DPS), responsible for maintenance and repair of the cold chain for typically more than 100 health centers, 10-15 district-level refrigerators, and the provincial-level cold storage facilities.

New vaccine introduction

▶ Within this Decade of Vaccines, Mozambique will be introducing two new vaccines, Rotarix and HPV. These introductions present a great opportunity for the country but also increases its cold chain needs dramatically. For example, compared with the DTP vaccine, the packed volume of Rotarix is seven times greater, requiring much larger cold chain space at each level of distribution.

The lack of availability of sufficient vehicles and poor roads can make it impossible for the sole technician working in each province to reach all health centers on a regular basis and in a timely manner.

⁴ WHO. November 2013 Meeting Presentation from the Strategic Advisory Group of Experts on Immunization. Geneva: World Health Organization; 2013.
⁵ Matthias DM, Robertson J, Garrison MM, Newland S, Nelson C. Freezing temperatures in the vaccine cold chain: a systematic literature review. Vaccine. 2007; 25(20): 3980-3986.

SOLUTIONS FOR THE LAST MILE

The DLS Approach

The DLS approach takes a simple but innovative approach to cold chain maintenance by integrating maintenance activities into vaccine delivery. This approach was created to fit current equipment, infrastructure and transportation conditions, human resource capacity and personnel expertise. It builds on other global experience in cold chain maintenance. Field coordinators are responsible for distribution of vaccines and data collection. To address the challenges maintaining the cold chain, they are also trained to provide basic maintenance of equipment during distribution visits. This approach broadens the capacity of the system to maintain the cold chain. The field coordinators serve as an extension of the one technician in each province and can provide an extra set of eyes to monitor the cold chain. This method differs from the traditional system of vaccine deliveries by placing a shared responsibility for data collection and cold chain maintenance at the last mile rather than solely at the district and national levels.

The field coordinators have specific tasks for basic preventive maintenance during distribution visits:

- ▶ Check the refrigerator thermometer to ensure refrigerator temperature is optimal;
- ▶ Confirm that the temperature-monitoring form is correctly updated;
- ▶ Verify the refrigerator is clean and only being used for vaccines;
- ▶ Verify the refrigerator is at a proper distance from walls to prevent overheating;
- ▶ Ensure adequate power supply for refrigerators;
- ▶ Regulate refrigerator temperature monitors to respond to seasonal weather changes, particularly in hotter months;
- ▶ Ensure vaccines in refrigerators are shelved efficiently to provide effective airflow, with older vaccines placed in front to for first use; and
- ▶ Provide technical assistance to the health workers at the health centers to ensure they understand basic preventive maintenance techniques.

These field coordinators are the very foundation of the entire cold chain maintenance strategy. Having dedicated personnel with technical capacity who reach every health center each month brings enormous benefits to the cold chain. Preventive maintenance can confirm the equipment is working properly to avoid emergency situations and outages. As normal wear and tear can result in diminishing efficiency, preventive maintenance can conserve the energy and life of the equipment.

Additionally, preventive maintenance costs less and takes less time to facilitate than a costly repair or replacement. These simple monthly check-ups help avoid costly breaches in the cold chain.

Before the DLS was implemented in these provinces, anecdotal evidence points to recurring problems with the cold chain, with health center staff from the Cabo Delgado province noting that on average, about 40% of the health centers encountered breaches in the cold chain on a regular basis.

Box 1: Notes from the Field: Cold Chain Maintenance in Action

In a recent assessment in one province using the DLS approach, of 160 refrigerators, 37 were not functioning at the time of the assessment. Of those not functioning, 26 (70%) were solar powered, reflecting the enormous challenge of having a constant supply of batteries available to the technician and the DPS for corrective maintenance.

As a result of an emphasis on cold chain preventive maintenance and the provision of extra sets of eyes on the cold chain, VillageReach coordinated efforts among partnering organizations to raise the issue of the need for more batteries for the solar cold chain equipment. A partnering NGO provided several batteries to the DPS, and VillageReach organized transport for the technician to visit these health centers to install them. As a result of these efforts, five more health centers have working refrigerators and can provide vaccines once again.

Breaks in the cold chain are inevitable, even with basic preventive maintenance: equipment will fail and batteries will expire. In these situations, corrective maintenance is practiced. The health workers at the health centers are required to inform the district officers and field coordinators immediately and arrange for the vaccines to be stored at the district store or a nearby health center to avoid vaccine spoilage. In addition, the field coordinators arrange for corrective maintenance in instances when a simple and immediate repair is not possible. Corrective maintenance includes changing a fuse or replacing a battery for solar refrigerators, for example. In the case of complete equipment failure, the whole device may need to be replaced. Field coordinators collaborate with DPS equipment technicians and VillageReach staff to schedule time and transport to get the technician to these rural areas with the required spare parts.

As a result of this more proactive approach to equipment monitoring and repair, the uptime of the cold chain increases. However, despite these improvements, the DLS approach is not without its own challenges:

- ▶ With only one technician per province, the required level of corrective maintenance is difficult to achieve.
- ▶ The only verifiable data on refrigerators' uptime at the health centers is when the field coordinators make their monthly visits and check the temperature of the refrigerators. Apart from this single monthly point-in-time check, the uptime of the cold chain is not monitored beyond the staff at the health center. As a result, changes in temperature between field coordinator visits may go unnoticed by health center staff, with no chance for possible follow-up action to test vaccine viability or mal-functioning refrigerators.
- ▶ Emphasizing prevention still does not resolve the numerous other issues of transport availability, the need for maintenance plans, and an accessible supply of spare parts (see Box 1).
- ▶ It is difficult to incentivize leadership to support this approach, as preventive maintenance activities are not as "high profile" or "high visibility" activities as is fixing a non-functioning refrigerator. This obstacle of placing just as much value or more on the proactive values associated with preventive maintenance is one of the first to be overcome when introducing the DLS.

The uptime of the cold chain in the four provinces in which the DLS operates is at least 95% or higher, as recorded by field coordinators during monthly distribution visits.

GLOBAL INNOVATIONS FOR THE LAST MILE

Innovation in Equipment

Much investment is being made in alternative and improved cold chain equipment to respond to existing power sources. Approximately 50% of health facilities in sub-Saharan Africa are likely to remain functionally off-grid for the foreseeable future. In Mozambique, Ministry of Health surveys of its ten provinces show that 50-80% of the health centers are off-grid.

Technical design and special materials are being used in the manufacture and assembly of insulated vaccine carriers and cold boxes that prevent freezing even when fully frozen ice packs are used. Additionally, new technologies are being used to respond to the need for carriers that can transport larger volumes of vaccines and make more efficient use of transport volumes. Other technologies have been developed to produce highly-insulated containers that maintain a constant temperature for up to a month between ice changes. Examples include:

- ▶ Savsu Nano-Q: a stationary passive cooling device designed for long storage times during shipment and for emergency long-term storage in remote areas; and
- ▶ Intellectual Venture's Global Good Passive Vaccine Storage Device: designed to keep vaccines at the appropriate temperatures for one month or more despite repeat opening of the container and with no need for electricity.

As the need for longer-life, larger-capacity cooling technologies becomes necessary, more innovative technologies are expected to be developed.

Innovation in Data Management

Telematics and telemetry, or machine-to-machine communications (M2M), present the global health community with an opportunity to improve the quality of data reported from the field. Using telemetry to digitize paper-logged

inventories of vaccines and other medical commodities, to automate performance reporting on equipment found in health centers, or to transmit data collected at remote points to receiving equipment for monitoring all could significantly enhance health systems' ability to make more cost-efficient, informed decisions and prioritize effectively.

In high-income countries, telemetry is a mature commercial marketplace: the sector has grown to become a \$40 billion industry. Many sectors (banking, food perishables, energy, retail and healthcare) apply telemetry to provide remote monitoring of their cold chain equipment, inventory management, asset tracking and infrastructure assessment. A growing number of application providers, device manufacturers and service providers are participating.

The global health community's increasing interest in telematics (integrated use of telecommunications and informatics) reflects significant advances in wireless communications and power supply for rural communities. Recent improvements in cell coverage and the provision of alternate power (non-grid) together suggest a growing potential for both telematics and telemetry to enable improved data reporting from the field. In the communications sector in particular, there has been an explosive growth of cell phone usage in Africa, leapfrogging fixed-line deployments (the GSMA estimates Africa wireless connections at 500 million in 2013, with 18% annual growth over the past five years). Today, mobile networks are the primary mode of access to the Internet in the region.

In Mozambique, VillageReach will be piloting the ColdTrace monitoring platform, developed by Nexleaf. This device uses a low-cost wireless sensor to remotely monitor the temperature of cold chain equipment and transfer the monitoring data via telemetry to decision makers. Through this device, any breach in the cold chain can be immediately brought to the attention of the technician and program supervisor for them to respond accordingly.

CONCLUSION THE NEXT STEP: MORE DATA, INCREASED TRANSPARENCY, KNOWLEDGE SHARING

The many challenges of vaccine distribution systems in low-income countries highlight the need for innovative solutions regarding the cold chain. Knowledge on cold chain uptime is crucial to ensuring vaccine viability. At the time of this writing, little evidence is available on the ways in which low-income country governments and NGOs are recording continuous cold chain uptime. More studies are needed to augment the evidence-base in order to gain a better understanding of the cost-effectiveness of investing in cold chain uptime monitoring. Detailed studies that monitor both time and temperature exposure across the entire length of the cold chain could provide the richest source of

information for such purposes. If cost-effective solutions are in practice, it is vital this information and knowledge is shared and disseminated widely within the global health vaccine community. Further, doubts about data quality and equipment uptime can also be avoided by investing, testing, and introducing new cost-effective technologies that provide continuous temperature monitoring and recording.

VillageReach. *Keeping the Cold Chain Cold / Vaccine Supply Chains: Reaching the Final 20 Policy Paper Series*. Seattle: VillageReach; 2014.

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