Temperature control tools and supply chain management









T. Prusik, Ph.D.

Why bother about temperature monitoring



Temperature monitoring: detects excursions and can help avoid future excursions





Temperature sensitivity of vaccines



Note: This graphic illustrates relative sensitivity across antigens, as the same type of vaccine from different manufacturers may have different vaccine vial monitors (VVMs). For more information, see \rightarrow Section 3.3.4.



Principles and considerations for adding a vaccine to a national immunization programme



Currently heat excursions are easier to detect than freezing if VVM is applied

<u>Too hot</u>

. .

"Easier to detect"



Health worker in Niger shows bottles with vaccine vial monitors. Source: WHO



Continuous temperature monitoring

What do we know from the EVM Data Analysis



"What about excursions during weekends?"

<u>Too cold</u> "Harder to detect"



Example of Freeze indicators



Shake test. Source WHO

Only 11 % of facilities pack freeze indicators with deliveries of freeze-sensitive vaccines

Temptime
 Improving Global Health™

Live attenuated influenza vaccine lacks effectiveness due to high temperature exposure in US distribution

No VVM used in US Ineffective influenza vaccine administered to children

/accine 34 (2016) 5066-5072



Association of vaccine handling conditions with effectiveness of live attenuated influenza vaccine against H1N1pdm09 viruses in the United States



Herve Caspard *, Kathleen L. Coelingh¹, Raburn M. Mallory, Christopher S. Ambrose Medimmune, One Medimmune Way, Gaithersburg, MD 20878, USA

Conclusions: This study showed that the lack of vaccine effectiveness observed with LAIV in the US against H1N1pdm09 viruses was associated with exposure of some LAIV lots to temperatures above recommended storage conditions during US distribution, and is likely explained by the increased susceptibility of the A/California/7/2009 (H1N1pdm09) LAIV strain to thermal degradation.

Vaccine. 2016 Sep 30;34(42):5066-72. doi: 10.1016/j.vaccine.2016.08.079. Epub 2016 Sep 6



Examples and main use of WHO recommended temperature monitoring devices for storage and transportation of vaccines

	Device	Int. transport	Primary store	In-country transport	Intermediate store	In-country transport	Service level
	Electronic temperature monitor with LCD screen						
	Vaccine cold chain monitor						
	Vaccine vial monitor						0
	Freeze indicator	Freeze-tag Mar et al. (1) Mar et al. (1) Ma	Freeze-Sag mer refere mer refere Sage - 1 Mer Sage - 1 Mer Mer - 1 Mer - 1 Mer Mer - 1 Mer - 1 Mer Mer - 1 Mer - 1 Mer - 1 Mer Mer - 1 Mer - 1	Freedo-lag with restance with restance 	Precise log with a rest of the same sector of the same with a rest of the same sector of the same with a rest of the	Press And The second second The second second The second second second The second	Process-lag and an account of the account and an account of the account account of the account of the account account of the account of the account of the account account of the account of the acc
	Multi-channel computerized temperature recording sys.						
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() Tem	Downloadable electronic temperature data logger	LogTag • ***	LogTag •	LogTag Aust T	LogTag	LogTag	LogTag Mart A set
Improving	Global Health™					Dr Ilmit I	(artoglu - WHO

Dr. Umit Kartoglu - WHO

3. Routine temperature monitoring

3.2 Monitoring heat exposure using vaccine vial monitors

Vaccine vial monitors (VVMs)

- Only temperature monitoring devices that routinely accompany vaccines through the entire supply chain
- Applied by vaccine manufacturers
- VVMs record cumulative heat exposure through a gradual color change
- If the color of the inner square is the same or darker than the outer circle, the vaccine should be discarded
- VVMs do not record exposure to freezing temperatures









3.3 Monitoring international vaccine shipments

Cold chain monitor (CCM) cards

- Only used for international shipment of OPV packed with dry ice
- Cumulative exposure to temperatures up to +34°C is indicated by blue staining along the length of the white indicator strip marked A, B, C.
- Exposure to a single event above +34°C is indicated by blue staining of the white dot in section D of the indicator
- Shipping details s are recorded on the card itself by the manufacturer at the point of dispatch and by the receiving store at the point of arrival







3.3 Monitoring international vaccine shipments

Electronic shipping indicators

- Record the temperature at time intervals of 10 minutes or less for up to 20 days
- They have digital displays and pre-set alarm thresholds to reflect the heat and/or freeze sensitivity of the vaccine being shipped
- Some brands are able to download the temperature data to a computer.

Figure 4. Electronic shipping indicators









Q-Tag CLm® Doc











unicef®

3.4 Monitoring in primary and subnational stores

Programmable electronic temperature and event logger systems – best option for primary and subnational stores

- Temperature sensors should be placed in every cold room, freezer room, vaccine refrigerator or vaccine freezer in the store and directly linked to a central computer-based monitoring point via wired or wireless connections
- Central data storage allows temperature records to be analyzed electronically, and the system can be configured to produce periodic reports
- Systems can also be configured with sensors which monitor door openings as well as other performance characteristics such as relative humidity and voltage fluctuations
- Can also be equipped with local audible alarms and/or alarm strobes and configured to send alerts to responsible staff via auto-dialer, email and SMS
- Internet or intranet connectivity options are also available; these allow for remote monitoring and alarm reporting from multiple sites on a national basis.





Remote temperature monitoring devices

	E00	6:	Temperatur	e monitoring devices
- C	PQS cod	w.	E006/039	
	Descript		Remote Tempe	rature Monitorion Device
220	Manufac	turer's ref.	ColdTrace 5	
	Manufac	funed in:	India	
1111	Company	r .	Nexleaf Analytic	a
1 Mart	Address		2355 Peham A Los Angeles CA 60054 USA	venue
	Telephon	e:	+12139156729	
	Erral.		Info@nexteal.org	
	We5 add	952.	www.nevileat.org	
Specification	ns			
Product type:	Remote Temperature Monitoring System	Dispia	y medium:	LCD, Computer, Phone, Tablet
Mode of operation:	Electronic	Weigh	4	0.25
Minimum temperature:	-30°C	Mainin	naterial.	Polycarbonale and ABS
Maximum temperature:	+55°C	Dimer	sions:	140 mm x 150 mm x 30 mm
MECHANICAL AND ELEC	CTRONIC DEVICES ONLY			1777 March
Acouracy.	0.510	Min lo	gging Interval:	1 mittude
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Bollery type:	LHon	Useri	nierlace.	Web Based
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Price per unit.	USS 77 per year on a 3 yea agreement	rly Volum	e per carton:	0.002 m3
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				W0.C0.28		
Specifications						
Product type: R	emote Temperature Ionitoring System	Displa	y medium:	Onbaord LCD and online		
Mode of operation: E	Electronic		t	1.5		
Minimum temperature: -1	-10		naterial:	PS		
Maximum temperature: 55	5	Dimen	siona:	23.0 x 8.0 x 26.0 cm		
MECHANICAL AND ELECTRO	DNIC DEVICES ONLY					
Accuracy: 0.	.5°C	Min log	gging interval:	60 seconds		
Power source: M	Mains + backup battery		type:	Acoustic		
Battery type: P	anansonio 18650B	User Ir	terface:	Internet browser		
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N	TC temeprature probes \$39	Weigh	t per carton:	1.5		
A	nnual fee \$480 per year	Incoter	rme:	FCA		
Verification report:		Verific	ation laboratory:			
Current PQS status: P	re-qualified ; 11 Nov 2015		Valid until:	May, 2017		
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Specification	19			
Product type:	Remote Temperature	Diepu	y modium:	Onboard LCD and Online (v)
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Minimum temperature:	-5010	Main r	tabetat	PO.
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- 4	Company	r.	Schechter Tech	LLC DBA Temperature@iert	
	Address		108 Lincoln St., BA Boston, MA	02111	
	Telephon	r:	+1617326736	99	
	Email:		sales@tempalert	com	
	Web addr	PSS:	http://www.tempe	raturealert.com	
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Specification	15				
Product type:	Remote Temperature Monitoring System	Displa	y medium:	LCD, computer, phone, tablet	
Mode of operation:	Electronic	Weigh	t	0.5kg	
Minimum temperature:	-55°C	Main r	natorial:	ABS	
Maximum temperature:	+55°C	Dimen	slona:	21.6 x 6.35 x 12.7	
MECHANICAL AND ELEC	CTRONIC DEVICES ONLY				
Accuracy:	±0.5°C	Min lo	gging Interval:	5 min	
Power source:	replaceable batteries	Alarm	type:	Acoustic	
Battery type:	Lillon	User li	nterface:	Web based or mobile phone	
Battery shelf life:	3 to 5 years	Progra	ammability:	Remotely programmable	
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		Weigh	t per carton:	1.6kg	
		Incote	rma:	EXW	
Verification report:		Verific	ation laboratory:		
Current PQS status:	pre-qualified ; 03 Jul 2015		Valid until:	May, 2017	

http://apps.who.int/immunization standards/vaccine quality/pqs catalogue/



3.5 Monitoring in small subnational and district stores and health facilities

- Stores typically have one or more vaccine refrigerators and maybe a vaccine freezer
- Health facilities are often with a single vaccine refrigerator
- The table below sets out the options in order of preference

Option	Vaccine refrigerator	Vaccine freezer (if available)
Option A: Best practice	 30-day electronic temperature recorder [also referred to as 30 DTR] Stem thermometer backup Integrated digital thermometer or gas/ vapour pressure-dial thermometer Vaccine vial monitors (VVMs) 	 Stem thermometer Integrated digital thermometer or gas/ vapour pressure-dial thermometer VVMs
Option B	 Stem thermometer Electronic freeze indicator Integrated digital thermometer VVMs 	• Not applicable
Not recommended	 Stem thermometer or bimetallic dial thermometer alone VVMs 	Not applicable

Table 5. Temperature monitoring options in smaller stores and health facilities



3.5 Monitoring in small subnational and district stores and health facilities

30-day electronic temperature recorders (30 DTRs):

- These stand-alone devices are placed with the vaccine load in a vaccine refrigerator
- They log the refrigerator temperature at 10-minute intervals or less for 30 consecutive days on a rolling basis
- They also record and display a 30-day history of any heat and freeze alarm violations that have occurred
- Alarms are triggered if the temperature in the refrigerator drops to -0.5°C or below for 60 minutes or if it exceeds +8°C for a continuous period of 10 hours
- As long as the temperature has remained within the recommended range, the device displays OK or a tick symbol
- On newer models, data can also be downloaded to a computer via a USB (universal serial bus) interface.
- 30 DTRs are not designed to be used in vaccine freezers



Fridge-tag2™ with USB³⁰



Figure 7. 30-day electronic temperature recorders



LogTag® vaxtag³¹

3.5 Monitoring in small subnational and district stores and health facilities

Electronic freeze indicators

- These are small digital devices that are placed with freeze-sensitive vaccines during transport or storage
- The devices have a visual indicator that shows whether the vaccine has been exposed to freezing temperatures
- Once the alarm indicator is triggered, the device is no longer usable and should be discarded. Otherwise the device can be used until the built-in battery expires. These stand-alone devices are placed with the vaccine load in a vaccine refrigerator

Figure 8. Electronic freeze indicators



FreezeAlert™



Freeze-tag®





Q-Tag® Quad

3.6 Monitoring transport temperatures

Cold boxes and vaccine

carriers

Table 6. Temperature monitoring options during transport operations using cold boxes and vaccine carriers

	Cold boxes and vacc	ine carriers	
Option	With freeze-sensitive vaccines	Without freeze- sensitive vaccines	Comments
Option A: Best practice	Conditioned ice-packs • Freeze indicator • Vaccine vial monitors [VVMs] Cool-water packs • VVMs Warm-water packs • Freeze indicator • VVMs	All coolant-pack types • VVMs only	 The use of electronic freeze indicators depends on the type of coolant pack used and the type of vaccine being carried. These devices must be used whenever freeze-sensitive vaccine is transported with conditioned ice-packs or when warm- water packs are used to protect these vaccines from sub-zero ambient temperatures. They are not needed when freeze- sensitive vaccine is transported with cool-water packs, and they are not required if there are no freeze sensitive vaccines in the load.
Not recommended	Conditioned ice-packs • VVMs only	 Not applicable 	 If freeze-sensitive vaccines are transported with conditioned ice-packs, there is always a risk of freeze damage occurring because ice-packs may not have been conditioned correctly. For this reason it is essential to include an electronic freeze indicator.



Figure 10. Cab-mounted display and printer unit

3.6 Monitoring transport temperatures

Transport by refrigerated vehicle



Transcan Sentinel with thermal printer

Table 7. Temperature monitoring options for transport by refrigerated vehicles

Option	Refrigerated vehicle	Comments
Option A: Best practice	 Dashboard-mounted electronic temperature recorder with integrated printer VVMs 	 Mobile programmable electronic temperature and event logger systems³³ can be installed in refrigerated vehicles. These are equivalent to the event logger systems used for fixed storage locations and have similar functionality options, including multi-point temperature monitoring and a dashboard-mounted display and alarm system. The more sophisticated models can be integrated with Internet- or intranet-based vehicle tracking and remote monitoring, including SMS event alerts and local wireless area data retrieval.
Option B	 Data logger or electronic temperature recorder VVMs 	• One or more user programmable temperature loggers can be packed with the load, and the temperature history can be downloaded at the end of the trip. This option can provide a continuous temperature and alarm record for traceability purposes but cannot alert the driver if a temperature excursion occurs.
Option C	 Dashboard-mounted digital thermometer manually recorded hourly Freeze indicator VVMs 	 A dashboard-mounted digital thermometer does not provide a continuous temperature record for traceability purposes and the driver may not notice if a temperature excursion occurs. Moreover, the thermometer sensor only monitors temperatures at a single point in a compartment with a volume of many cubic metres. Traceability relies entirely on checking and recording the freeze indicator and VVM status at the point of delivery. Manually recording temperatures at regular intervals is a possibility; however, this can only be done in a safe and reliable manner if the driver is accompanied by a member of the EPI team.
Not recommended	Freeze indicator aloneVVMs	• The driver has no knowledge of the load temperatures over the course of the journey, and traceability relies entirely on checking and recording the freeze indicator and VVM status at the point of delivery.



5.1 Devices used for study purposes

User programmable temperature loggers

- The principal tool for conducting cold chain temperature monitoring studies, for transport route profiling and for temperature mapping in cold rooms, freezer rooms and refrigerated vehicles
- Currently pregualified models are affordable and user-friendly and can be used several times ٠
- The user can define alarm thresholds, set the frequency of temperature recordings and programme start ٠ and stop times
- At the end of the study, data can be downloaded to a computer for analysis ٠
- Most models have built-in batteries (when the battery expires the device is discarded); others have ٠ replaceable batteries and can be reused

Figure 11. User programmable temperature loggers

emi



Many resources available



► Temptime Improving Global HealthTM http://www.who.int/immunization/documents/IIP2015_Module2.pdf?ua=1 http://www.who.int/immunization/documents/financing/who_ivb_15.04/en/ http://apps.who.int/iris/bitstream/10665/183584/1/WHO_IVB_15.03_eng.pdf http://www.who.int/immunization/programmes_systems/supply_chain/evm/en/ http://epela.net/epela_web/evvm.htmJ http://epela.net/epela_web/introduction.htmJ http://apps.who.int/immunization_standards/vaccine_guality/pos_catalogue/



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Vaccine Arrival

Frequency and quantities are increasing



Storage Capacity More and new vaccines fill limited space

Improving Global Health[™]



Vaccine Arrival

Vaccine volume beginning to exceed management capacity



Temperature Control

Temperature monitoring essential but costly and not prioritized



Maintenance

Cold chain equipment requires regular maintenance



Distribution

Getting more vaccines to remote communities is difficult



Distribution

In-country transport is the weakest link in the supply chain



Infrastructure

Ancient and inefficient equipment is still used at health center level



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Human resources

The supply chain extends all the way to service delivery



Vaccine Management Use of expired and poorly stored vaccines is a concern



Vaccine Management Avoidable wastage is widespread



Waste Management More and more syringes to dispose of safely



Information Systems Point of service data could help improve forecasts





Growing concerns Accelerating pace of vaccine introductions



4

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Source: WHO

Concern

More storage space required for new vaccines







Concern Availability of existing vaccines



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Concern Basic vaccine management

EVM Assessment Findings in 70 Countries





Growing concerns New realities for today and the future

Immunization supply chains are having to manage



Immunization supply chain and logistics A Call to Action

The "Call to Action" Recommendations

Firstly for National Immunization Programmes

- 1. Measure, monitor, and evaluate the health of the iSCL system
 - Implement routine information systems to assess performance for availability, quality, and cost
 - Apply the *Effective Vaccine Management (EVM) tool and improvement process* to assess the state of supply systems and prioritize improvements

2. Plan and implement improvements

- Based on EVM assessments, and strengthened monitoring, prepare and implement costed improvement plans that address system weaknesses
- Introduce supply chain innovations that produce increased visibility and flexibility to manage future changes in iSCL systems

Immunization supply chain and logistics A Call to Action

The "Call to Action" Recommendations

Secondly for the Global Community of Partners

- 1. Increase awareness and investment
 - Call attention to the complexities of immunization supply chains, culminating in the need to support SC systems with increased funding to invest in the vital elements of EPI programmes: people and data as well as infrastructure

2. Address SC systems when formulating immunization recommendations

• Factor in the best available field evidence on implementation and ISCL system performance when formulating policy recommendations

3. Harmonize SC systems

- In the context of a broader Health System, take more deliberate advantage of new vaccination initiatives to build upon and strengthen an integrated SC systems
- Identify & resolve knowledge gaps to accelerate learning & adoption of new solutions
 - Need for further evidence on effectiveness of supply chain innovations. The global community of partners must highlight SC knowledge gaps, commission comparative studies of potential solutions, and accelerate the spread of proven approaches

Case study - Turkey

Immunization supply chain

Using Barcodes for Managing Vaccines Stocks

PUBLIC HEALTH INSTUTITE OF TURKEY DEPARTMENT OF VACCINES PREVENTABLE DISEASES

Dr. Ahmet Ozlu

Dr Osman Erkan Say

Technet 2013

1

Applied 2D barcodes - Examples

Each vials are in single dose presentations 34

2D barcode reading – who uses it?

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Vaccine Information System (Aşı-net)

Integrated Health Information System

Improving Global Health™

Impact & benefits of using 2D barcodes

- Patient safety and immunization surveillance
 - Prevent vaccine administration errors
 - Match individual immunization data & vaccine product information
 - Matching vaccine & the cold chain monitoring
 - Respond quickly to safety concerns
 - Locate persons vaccinated with a specific lot
 - Improved management of recalled lots.

Impact of 2D barcode in vaccines -II

- Stock management
 - Prevent stock management errors
 - Estimate needs and take appropriate actions
 - Prevent stock-outs
 - Expiry date warnings reduce/prevent wastage
 - Real time tracking of Stock at each level (Wastage, Stock Balance and Demands)
 - Stock level by lot and expiry date at each supply level
 - Optimize the cost of stocks
- Save the time on producing documents
- Improve reporting and statistics

18

ATS OVERVIEW (VTS-Vaccine Tracing System)

T.C. Sağlık Bakanlığı **Türkiye Halk Sağlığı Kurumu**

T.C. Sağlık Bakanlığı **Türkiye Halk Sağlığı Kurumu**

INCENTIVES

- •Evidence based assured vaccine quality
- Linkage vaccine information to child
- Linkage immunization information to Health-Net
 Preventive alert system- Flagging-documenting cold chain performance
- Reduce wastage
- Easy inventory and temperature monitoring
- Determine some topics to work on;
 - Optimization of logistics
 - Reducing costs
 - Feedback based optimization
 - Simulation modules;
 - disaster, outbreak, new vaccine implementation

T.C. Sağlık Bakanlığı **Türkiye Halk Sağlığı Kurumu**

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ATS – INVENTORY TRACKING

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CALL CENTER

- \rightarrow 7/24 functioning
- →Alarms sent to call center system
- → Risk assestment procsess (Written procedures under development),
- →Risk management: Direct advise & Additional expertise involved
- → response time 10 minutes "monitoring system-software module"
- →Multi level notification

SYSTEM MANAGEMENT

Administers, consultants and engineers gather at least once a week

- Discuss user habits, critics and suggestions, forthcoming issues
- Analysis the system by the automated reports
- Check the progress of the project
- Feedbacks from users and call center
- Refine the system
- Define time table for next levels
- Brain storm of new options

INCENTIVES

•Evidence based assured vaccine quality •Linkage vaccine information to child

Linkage immunization information to Health-Net
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Reduce wastage

Easy inventory and temperature monitoring

Determine some topics to work on;

Optimization of logistics

Reducing costs

Feedback based optimization

Simulation modules;

disaster, outbreak, new vaccine implementation

MAIN IMPACTS

- Awarness of importance about cold chain
- Vaccine store improvements
- Importance of SOPs (Standart Operating Procedures)
- Enhenced stock management

(expiration date based transportation & usage)

- Fixing & repairing vaccine stores/refrigirators
- Prevention of long term temperature tarcking device alarms
- Decision making algorithm
- Need of mathematical Modelling

UNICEF eLearning course

Developed jointly by UNICEF and WHO, the Immunization eLearning Initiative provides all immunization staff with access to training in areas deemed vital to the advancement of the Global Vaccine Action Plan and its vision that everyone live a life free from succine preventable disease.

This learning programme on "Immunization Supply Chain Management" provides all immunization staff with a better understanding of the role strong immunization supply chain systems play to achieve the global immunization mission. Enrolment Optione
This activity or course is open to
self-enrolment.
Join the activity

Translation assistance

🗿 Gelect Language 🔍

Provider Info

Through the improvement of a fictional country's immunization supply chain, you will acquire the skills and knowhow to identify problems and opportunities for improving the efficiency of the immunization supply chain, and plan for the introduction of new vaccines and campaigns.

Learning objectives At the end of this course, you will be able to:

- Specify the links between immunization supply chains and the EPI program and the positive effects that
 strengthening supply chains has on health system strength and immunization coverage and equity;
- Identify the appropriate procedures for forecasting and procuring the right products (vaccines and immunization supplies), in the right quantities, using the most appropriate forecasting and procurement mechanism based on of the health needs of a particular country/region;
- Assist the EPI program in assessing immunization supply chain requirements, procuring and allocating the most appropriate cold chain equipment and in establishing systems to monitor and control vaccine temperatures throughout the cold chain;
- Determine how many vaccines to ship, when they should be shipped, and how they should be shipped using information about the current stocks in a given facility, balancing trade-offs and efficiencies between frequency and volume of supplies while ensuring maximum quality;
- Use key performance indicators (KPIs), dashboards, and various supply information systems to determine
 whether a supply system is operating optimally and, if not, to identify which aspects of the system require
 remediation:
- Specify how new vaccine introductions and campaigns/SIAs impact the supply chain and specify ways of
 optimizing the supply chain to accommodate such events.

Audience

This eLearning course is for all national and international World Health Organization (WHO) and UNICEF professionals involved in immunization programs. It is also open to consultants and partners working in support of immunization.

It is recommended that immunization staff include the immunization elearning initiative courses as part of their professional development plan. Discuss with your supervisor to include this training curriculum as part of your 2016 goals.

Course Duration

It should take ±3 hours to complete this course. Each module should take 20-35 minutes to complete and must be completed in the order presented.

Methodology

This learning programme takes the learner through a mission to a fictional country to assist in improving various elements of its immunization supply chain. These experiential lessons consist of challenges where he or abe will meet different characters and address specific problems either a the national, regional or the district level.

Structure

This course is organized into one Introduction and 5 Challenges (modules):

Introduction: Mission preparation

UNICEF promotes the rights and wellbeing of every child in 190 countries and territories, with a special focus on reaching those in greatest need.

THANK YOU!!

