SOLIDARITY

United in solidarity against filovirus threats
Building research readiness for a future filovirus outbreak

Emergency Clinical Trial Logistics

20-22 February 2024
Kampala, Uganda

WHE/WRE/SHO/OSL

World Health Organization

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Intro

In the midst of any pandemic, a single breakthrough in vaccine/therapeutic development offered a glimmer of hope to billions. Yet, the journey from laboratory to arm—a complex odyssey spanning thousands of miles, crossing international borders, and requiring precision at every step—presents an equally formidable challenge.

This story begins in a small lab, where after countless trials, a vaccine/therapeutics showing promise against the virus is finally developed. However, the real test lies ahead: delivering this beacon of hope to every corner of the globe, from bustling metropolises to remote villages, all while battling against time and the unforgiving decay of temperature-sensitive cargo.

It is all about emergency clinical trial logistics.

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The challenge

The logistics of clinical trials, especially during a pandemic, present a multifaceted set of challenges that demand innovative solutions and unwavering diligence.

The foremost challenge is the **rapid deployment of a trial**, a task that requires accelerated development and testing timelines without compromising safety or efficacy.

Timing / Temperature / Geographical / Resource availability / Monitoring

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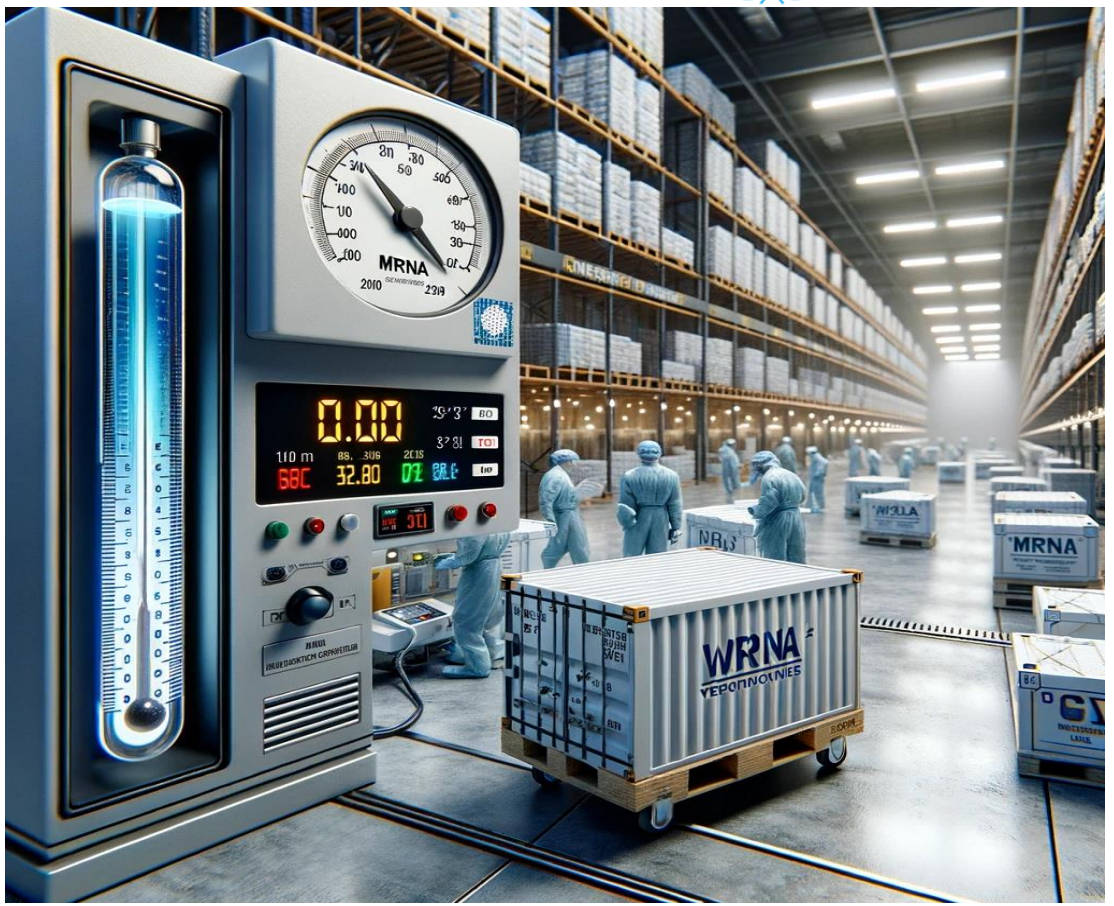
Maintaining the cold chain represents another significant hurdle. Vaccines, particularly those based on mRNA technology, require strict temperature controls throughout their journey from manufacturer to end-user. Any deviation, however slight, can compromise vaccine integrity, leading to wasted doses or, worse, ineffective vaccination efforts.

The following types of cold chains exist:

- **ULT storage (-80 °C to -60 °C);**
- **Refrigerated storage (-25 °C to -15 °C);**
- **Cold storage (+2 to +8 °C).**

Challenges that are out of logistics control (political situation, international/national regulations, etc.)



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Process visualization

The vaccination trial setup and logistics chain

Planning:	• Mapping the entire logistic plan and activities.
Product expedition:	• Vaccines and therapeutics (IP).
Storage and Handling:	• Store vaccines in cold storage facilities and refrigerators. • Implement temperature monitoring systems to ensure proper storage conditions.
Transportation:	• Transport vaccines from manufacturers to distribution centers and vaccination points. • Utilize trucks, planes, and specialized cold chain logistics providers for transportation.
Distribution Centers:	• Intermediate storage points for vaccines before distribution to vaccination points. • Manage inventory and ensure proper storage conditions.
Last-Mile Delivery:	• Deliver vaccines from distribution centers to vaccination points. • Use various transportation methods depending on the location, such as trucks or mobile units.
Vaccination Points:	• Locations where vaccines are administered to individuals, such as clinics, hospitals, or community centers. **The vaccination points should be located as close to patients as possible.**
Cold Chain Monitoring:	• Implement temperature monitoring and quality control measures throughout the supply chain to ensure vaccines remain within the required temperature range.

The process

Stage	Category	Airport	Central STOCK	Regional hub	Vaccination sites	Action	%
Country readiness level	HR	The team should be identified and trained on each level in advance.				Team should be trained and ready.	25
	SOPs	Reception of international shipment	Commissioning of UCC, Vaccine storage, Management of cold chain failure, Stock management, inventory, Decommissioning of UCC	Vaccine transport management, Cold chain failure	On site management of vaccine, Management of empty vials, Waste Management	SOPs should be designed and available on each level	25
	Infrastructure	Airport capacity, transport	Quantity of cold chain equipment (active/passive) should be identified and instoled/available, Transport, Electricity and it`s back up system, premices, etc.	Quantity of cold chain equipment (active/passive) should be identified and instoled/available, Transport, Electricity and it`s back up system, premices, etc.	Quantity of cold chain equipment (active/passive) should be identified and instoled/available, Electrisity and it`s back up system, premices, etc.	Analysis of a country level infrastructure should be performed and available. The constant development plan should be on.	25
	Min Stock capacity before outbreak		Cold chain equipment, Laboratory, PPE, Ancillaries, IT			Min stock should be calculated and available.	25
Country outbreak response	Since the official declaration of the pandemic, WHO has anticipated that within a **7-day** timeframe, a country would receive vaccines/therapeutics and accessories and be prepared for rapid distribution to the epicenter of the epidemic.						100

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The implementation process

Category	Airport	CentraL STOCK	Regional hub	Vaccination sites	Action	Needs	Timing
HR	Broker, freight forwarder	Log Project lead	Log manager	Site manager	Organigram should be adopted and approved/revised on the national level	Allocation budget for staff	1-2 months
		Team*	Team*	Team*			
SOPs					Log Project lead with the national log team should revise/update or design SOPs	Complex analisis of available SOPs	1-2 months
						Team should be trained by SOPs (budget allocation)	1 month
Infrastructure					Log Project lead with the national log team should revise/update	Complex analisis of available infrustructure and issuing conclusion.	1-2 months
						Allocation budget for infrastructure	2-3 mounth
Min Stock capacity before outbreak					Forcasting/ordering the min stock based on research team		1 month
Summary	Team* should be identified based on the trial size						
	All processes could be done simultaneously at the same time. In the active scenario, 3-4 months would be enough to prepare the Country's readiness level.						
	Team + time + trainings + SOPs + infrastructure + budget = SUCCESS						

WHO support

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Supporting the planning exercise: logistics requirement, supply plan

Supply of required commodities as appropriate: Cold chain (and UCC), dedicated laboratory items, ancillaries, team support equipment

Technical expertise: Health logistics and cold chain expertise

On site support: on demand deployment of health log expert

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