

Vaccine Procurement Practitioners Network

Managing vaccine supply with reduced shelf life: Impact of COVID-19 on vaccine security

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Panelists

Michaela Briedova, Contracts Specialist, Vaccine Centre, Supply Division, UNICEF Maricel de Quiroz-Castro, Technical Officer, Essential Programme on Immunization, Vaccine Supply and Logistics Team, WHO HQ

Key Respondents

Michelle Seidel, Senior Adviser Immunization, Programme Division Health, UNICEF Manuel E. Lavayen, Supply Chain Manager, Supply Chain Strengthening Centre, UNICEF

Moderators

Andrea Papan, VPPN, Community of Practice Manager, UNICEF Buya Jallow, Supply Officer, Supply Division, UNICEF

Key Learning Objectives:

- To strengthen the understanding of the implications of reduced vaccine shelf life on the whole supply chain system and its potential impact to vaccine supply security.
- To understand the role of manufacturers, UNICEF and countries and provide guidance on risk mitigation strategies in managing vaccine supply with reduced shelf life.
- To learn from countries about their barriers and challenges with supply of vaccines with reduced shelf life, and strategies applied to manage the situation.

Sharing Your Country Experience:

- In the Q&A, we ask you to please provide an example of a risk mitigation strategy you have applied. Briefly in 2-3 sentences, indicate:
 - Your name, title/organization, country
 - A bit about your experience (i.e. strategy taken, success/challenge/ lesson to share)
 - If you would like to speak about it or if it is for reading only
- From there, we ask all participants to read the contributions, and if there are many, please Upvote. Buya will contact speakers to share during the Q&A.
- Please kindly note, use the Q&A function; not the Chat function.



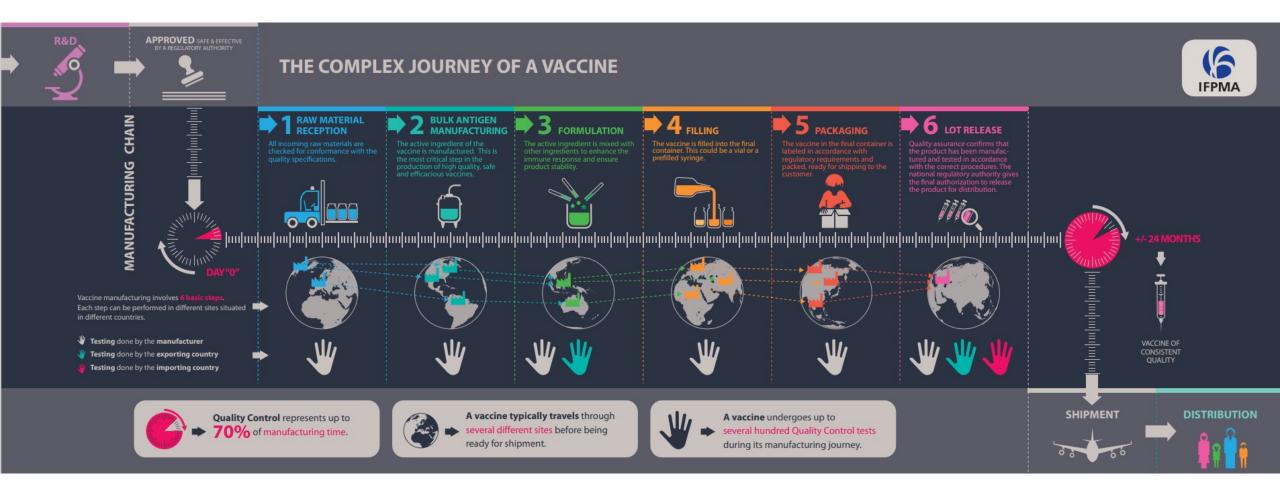
Agenda

TIME	AGENDA POINTS	RESPONSIBLE
9.30-9.35	Welcome/Introduction	Andrea
9.36-9.45	Interdependencies of Supply Chains Systems and Global Vaccine Security	Michaela
9.45-9.55	Risk Mitigation Strategies at Country-level	Maricel
9.55-10.00	Response from Key Respondents	Michelle and Manuel
10.00-10.24	Group Discussion and Q&A	All/Andrea
10.25-10.30	Reflections and Wrap Up	Buya

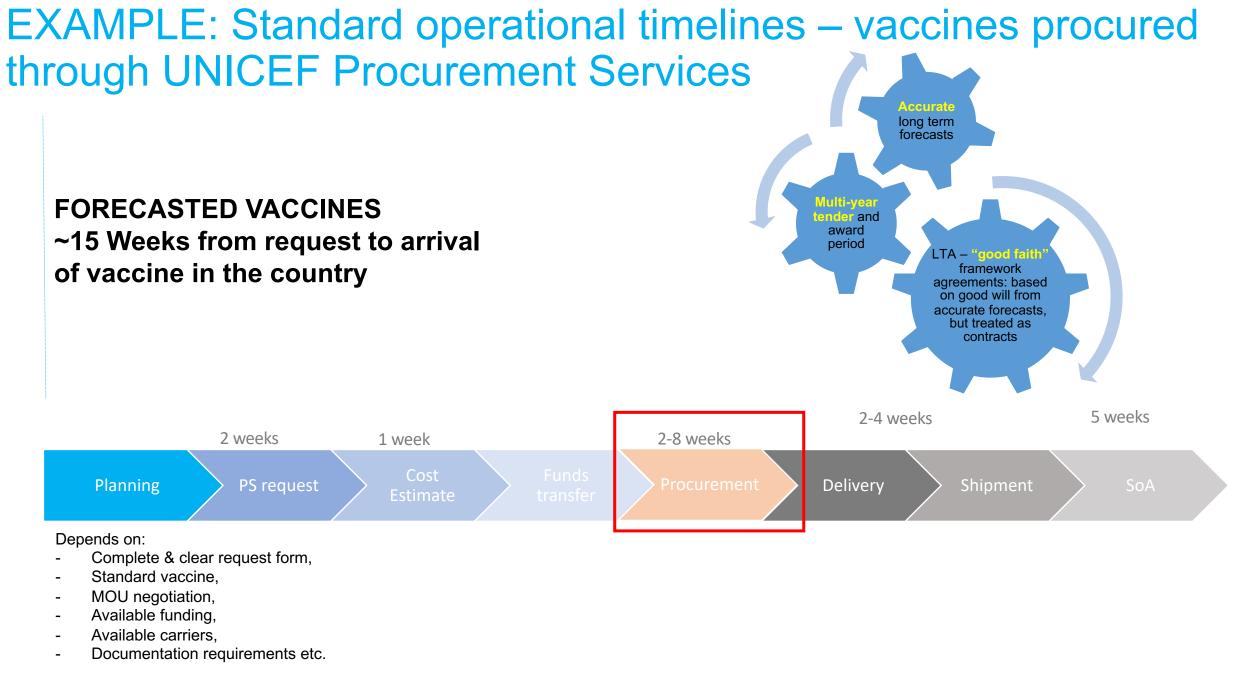
Interdependencies of Supply Chain Systems and Global Vaccine Security

Michaela Briedova, Contracts Specialist, Vaccine Centre, Supply Division, UNICEF Denmark

The complex journey of a vaccine

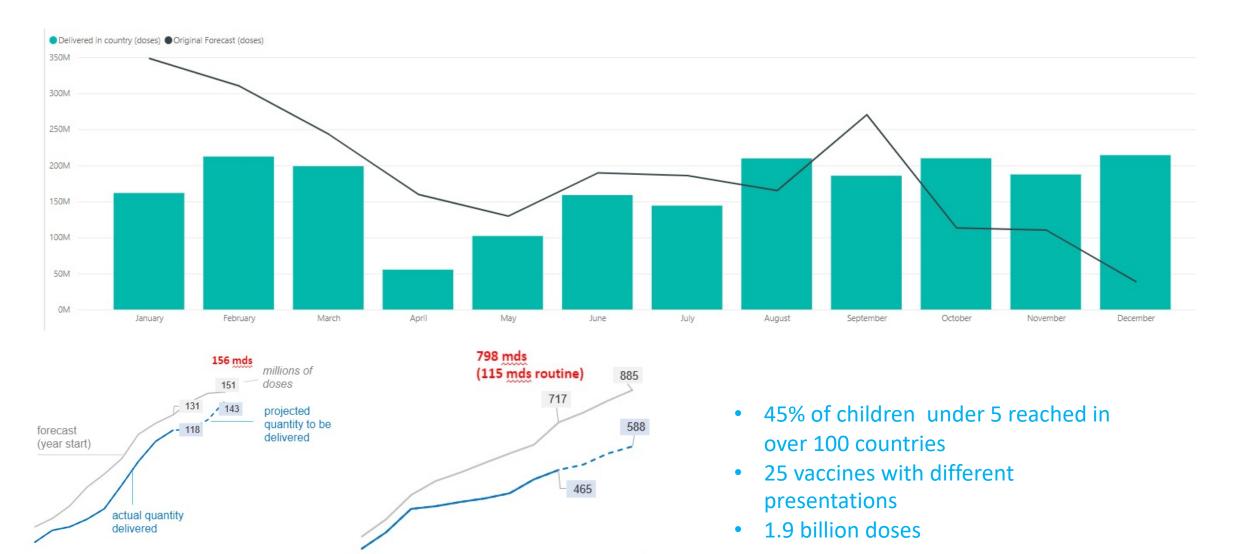


Source: International Federation of Pharmaceutical Manufacturers & Associations



Source: UNICEF Supply Division

UNICEF 2020 Vaccine Forecast Accuracy (volume)



Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec

Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec

bOPV

Penta

Source: UNICEF Supply Division

Achieving vaccine security to immunize every child



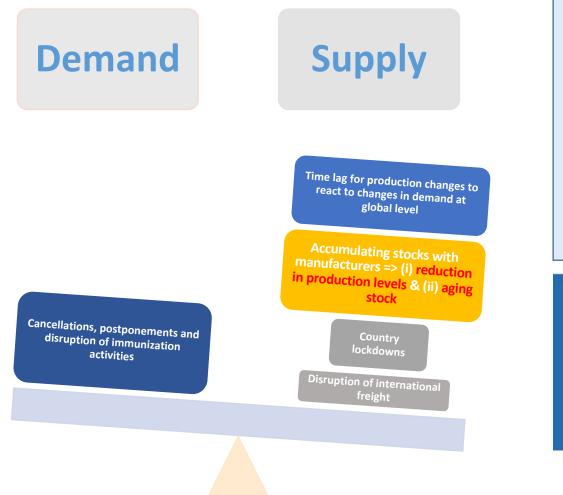
VACCINE SECURITY

The sustained, uninterrupted supply of affordable vaccines of assured quality through available funding,

- accurate forecasting & appropriate contracting.
- UNICEF implements a Vaccine Security approach:
- To achieve value for money & access to vaccines for children in need
 - To secure healthy markets
 - To ensure quality of vaccines



Even a temporary demand-supply imbalance can have long-term implications on vaccine security



The effect of this demand/supply imbalance, particularly any reduction in production levels and aging stocks along the supply chain puts global vaccine security - sustained, uninterrupted supply of affordable vaccines of assured quality at risk.

One of the measures mitigating this risk is to reduce the barriers to acceptance of vaccine with reduced shelf life through incorporation of risk mitigation strategies along supply chains to use vaccine with reduced shelf life

Acceptance of available traditional vaccine supply with reduced shelf-life

Interim guidance 1 March 2021

unicef @ for every child

World Health Organization

Available in English, French, Arabic, Russian on WHO's IRIS

Risk mitigation strategies – global perspective



IMPORTANT

Vaccine meets potency requirements through to the end of month indicated as expiry date, provided that:

- VVM does not indicate that vaccine needs to be discarded
- Label is intact
- Vial is not damaged
- Storage and transport conditions stipulated by the manufacturer should be followed

Risk mitigation strategies at global level

UNICEF SD

•Through ongoing dialogue with countries on funding availability, immunization plans, ensure communication on demand to manufacturers, to facilitate continued production for planned activities and timely replenishment of national stocks of vaccines for routine and supplementary immunization activities.

- •Consult countries on option of supply of mixture of reduced and full shelf life vaccine depending on needs, type of planned activity, utilization, wastage rates.
- •Acceleration of payment of invoices against receipt of standard documents, commitment to pay within 15d vs. 30d.

Countries

•Communicate any changes to required volumes to UNICEF (or manuf. or WHO's Mi4A team, if self procuring) as soon as possible.

•Consider longer timelines for international freight.

Risk Mitigation Strategies at Country-level

Maricel de Quiroz-Castro Technical Officer, Expanded Program on Immunization, WHO Philippines The decision to accept vaccines with reduced shelf life should be guided by:



Assessment of risks (and opportunities)



Country context



Resources

Key considerations when accepting vaccines with reduced shelf life



Product type





Inventory level

Projected lead times



Immunization schedule and planned campaigns



Frequency of vaccine deliveries

Co

Cold chain capacity

Suggested parameters for assessing risks:

- assessment of need
- type of product: criticality for vaccines products
- expiry date
- compliance with WHO guidelines on Good storage and distribution practices
- delivery time to storage facility
- delivery time from storage to end-user
- storage conditions

- stock rotation
- frequency of stock replenishment

 order frequency based on
 consumption
- assessment of the real needs
- emergency situation
- logistic setup (store locations, transportation means)
- Point of delivery
- activity specificities

Recommended minimum remaining shelf-life upon delivery

Total shelf-life (TSL)	RSL at the time of dispatch from manufacturer's premises	RSL at the time of delivery at port of entry of country	RSL at time of delivery at end-user level	
48 months $< TSL \le 60$ months	40 months	30 months	12 months	
36 months < TSL ≤ 48 months	30 months	24 months	12 months	
24 months < TSL ≤ 36 months	20 months	15 months	6 months	
$12 < TSL \le 24$ months	9 months	7 months	3 months	
$TSL \le 12$ months	Special arrangements and conditions apply			

https://www.who.int/publications/m/item/trs-1025-annex-8-shelf-life-medical-products-delivery

Options for risk mitigation strategies at country level

- Request for a temporary exception if national regulation limit the distribution of vaccine below a certain RSL
- Re-adjust distribution as needed
- Closely monitor vaccine utilization, wastage, RSL and VVM status at all levels
 - Carefully plan allocation and distribution
 - Follow FEFO principle
 - Monitoring is easier with electronic stock management system
- Consider accepting deliveries of smaller quantities, which can be used before expiry
- Closely monitor shipments/air freights and coordinate to prioritize vaccine delivery to prevent delay or off-loading

Options for risk mitigation strategies at country level

- Consider the following activities when accepting and using vaccines with RSL
 - Mass vaccination campaigns of short duration (e.g. outbreak response for measles/polio) – consider vaccinating wider cohort, with priority to missed/unvaccinated individuals
 - catch-up vaccination activities
 - vaccination in acute humanitarian emergencies with extra challenges, thus plan should be adjusted accordingly
- Sensitize health workers and build their confidence to implement best practices that will maximize vaccine potency and use within the RSL

Recommended minimum remaining shelf-life upon delivery

Shelf-life - the period of time, from the date of manufacture, that a product is expected to remain within its approved product specification while handled and stored under defined conditions.

Remaining shelf life - the period remaining, from the date upon delivery, to the expiry date, retest date, install by date or other use before date established by the manufacturer.

Upon delivery – refers to the date the medical product is delivered as specified (e.g. at the port, at the point in country after customs clearance, or at the end-user) and as defined in the agreement between relevant parties.

Key Respondents

Michelle Seidel, Senior Adviser Immunization, Programme Division Health, UNICEF

Manuel E. Lavayen, Supply Chain Manager, Supply Chain Strengthening Centre, UNICEF

GROUP DISCUSSION



Using the Q&A function please:

- Type in your question please identify which speaker you are addressing
- Upvote for other questions you would like to see prioritized
- Write in supplementary answers to questions with your own knowledge and expertise



Thank You



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