UNICEF Stockpiling Management
Lessons Learned & Way forward

Hans B. Christiansen
Contracts Manager, Vaccine Centre
UNICEF Supply Division

October 6th, 2017
UNICEF Vaccine Industry Consultation
Use of Vaccines for Emergency and Outbreak response

- **Measles and MR Vaccine**: LTAs with 3 components – Routine, Campaigns and buffer for outbreak response
- **Oral Cholera Vaccine**: LTA with 2 components: Pre-emptive/Humanitarian Campaigns and Outbreak response
- **Yellow Fever Vaccine**: LTA with 2 components: Routine and Emergency / Outbreak response
- **Meningococcal A, C and W containing vaccines**: LTA with 2 components: Routine and Emergency/Outbreak response
- **Oral Polio Vaccine**: – LTAs for Routine, SIAs and buffer for outbreak response
- **mOPV stockpile**: – LTAs for bulk and finished mOPV for eradicated polio viruses
- **IPV**: – LTAs for Routine and programmatic requirements
Use of Vaccines for Emergency and Outbreak response (size based on doses)
Vaccine Stockpiles

Why are they needed?

Access problems – not available in sufficient quantities in the spot market

Speed of deployment – very fast deployment

Timing of demand – difficult to foresee when an outbreak will occur

Quantity needed – lack of forecast, rarely know how much is needed

INSURANCE against supply failure to respond to outbreaks
<table>
<thead>
<tr>
<th><strong>Vaccine Stockpiles</strong></th>
<th><strong>Which modalities may be employed?</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Buffer</strong></td>
<td>Through close collaboration with suppliers, UNICEF is informed of stock inventory and is able to manage the stock available for outbreak response.</td>
</tr>
<tr>
<td><strong>Rotating</strong></td>
<td>Supplier rotates a minimum quantity available for outbreak response.</td>
</tr>
<tr>
<td><strong>Revolving</strong></td>
<td>As ‘Rotating’, but where the stockpile is replenished with new vaccines after every outbreak.</td>
</tr>
<tr>
<td><strong>Set Quantity</strong></td>
<td>UNICEF contracts a number of particular batches. Kept at supplier until an outbreak or until vaccines expire.</td>
</tr>
<tr>
<td><strong>Surge capacity</strong></td>
<td>In case there is risk of depleting the stockpile, UNICEF may have the opportunity to access additional vaccines kept in naked vials/bulk.</td>
</tr>
</tbody>
</table>
Vaccine Stockpiles

Which modality to employ?

Public Health Objectives
- Eradication / limit spread / increase coverage and protection

Risk of outbreak
- Forecasting demand / size of naïve populations / coverage

Epidemiology
- Disease conditions / rate of transmission

Vaccine Market
- Production capacity
- Production setup - ongoing / no production without stockpile contracting
Vaccine Stockpiles

What determines the stockpile size?

Potential campaign size and speed of immunization
Risk of urban outbreak

Epidemiology
Disease conditions / rate of transmission

Vaccine Market
Industry capacity / production speed / surge capacity
mOPV stockpile establishment

The removal of one serotype from the OPV and the risk of outbreak led to the need to establish a mOPV stockpile

Yellow Fever outbreak in Angola / DR Congo in 2016

Risk of urban outbreak leading to the requirement to replenish the stockpile as vaccines are deployed to outbreaks

Production capacity and availability of Cholera vaccine

Increased availability of Cholera vaccine has lead to increased demand for Humanitarian and pre-emptive campaigns and the enhance ability to rotate vaccines in stock at suppliers
In most vaccine markets, it is simple to establish a “stockpile”

- Alternative uses of vaccine
- Large production capacity
- UNICEF is a significant buyer
- Multiple vaccine sources
- Production method enables surge capacity

Under these circumstances, the risk of establishing a stockpile is limited and can be mitigated through the chosen stockpile modality. UNICEF experience is where there is good programmatic strategic direction and forecasting of requirements, the better opportunity there is for UNICEF with suppliers to secure supply availability at affordable price.
In a few vaccine markets there is low likelihood of vaccines being deployed/used:

- There are limited or no alternative uses of the vaccine through UNICEF
- The supplier has limited or no other markets for the vaccine
- Under these circumstances, there is risk associated with the establishment of a stockpile; risk for the buyer, risk for the supplier

**Options**

- Forecast accuracy improvements through use of outbreak demand modeling
- Establish programmatic requirements for prevention and control strategies that include vaccine (leading to possible innovation);
- Possible alternative uses for the vaccine secured in stockpiles (preventative campaigns, pre-positioning supplies)
- Pursue risk sharing arrangements with suppliers
Visibility on stockpile levels: vaccines in constrained supply

https://www.unicef.org/supply/index_94563.html
Publications on Products & Markets for key vaccine supplies

- **Market notes** available at: [http://www.unicef.org/supply/index_vaccines.html](http://www.unicef.org/supply/index_vaccines.html)

- **Format**
  - Market & Supply Updates
  - Product Specifications
  - Availability and Guidance

- **Aims**
  - Primary: To inform demand (e.g. from COs and Governments)
  - Secondary: To provide market signals

- **Content**
  - Analysis of UNICEF procurement data to illustrate market trends.
  - Narrative to articulate critical issues and improve situation

- Updated ~6 months or as needed
Information available on the UNICEF website

Supplies and Logistics

Immunization

Vaccines and micronutrient supplementation save millions of lives each year. Almost every child can be reached with vaccines and supplements, even under the most difficult circumstances. UNICEF is the leading agency for vaccine procurement. In 2013, UNICEF procured vaccines worth $1.296 billion. For more information please click here.

Latest

- Vaccine Industry Consultation 8th and 9th October 2014
- Measles-containing vaccines market update
- UNICEF presentation to India Vaccine Summit March 2014
- Current IPV Supply and Recent Tender Results
- Oral polio vaccine supply update
- Market update: Pneumococcal conjugate vaccine supply
- Developing Countries Vaccine Manufacturers Network (DCVWN)
- Cold Chain – Solar Direct Drive Refrigeration Systems Industry Consultation Meeting 1-2 Oct 2013
- ECO supply and demand update
- Refrigeration supply and demand update
Vaccine Stockpiles – VIC presentation outline

Why do we need vaccine stockpiles

- access problems
- speed of availability for deployment

*Insurance against not having (enough and fast) availability if a disease outbreak requires rapid vaccine response*

- use mOPV as example of insurance where we hope we’ll never use it, but when needed we’ll have availability for outbreak response.

What modalities of vaccine stockpiles do we manage

- Revolving - Measles/OPV/ future YFV
- Rotating - Measles/OPV/YFV/(OCV)
- Set quantity/Batch - Mening? mOPV

Modality of vaccine stockpile is determined by

- Public Health Objectives
- Risk of outbreak
- Size of potential outbreak
- Production size and set up
  - ongoing / by order / not existing without stockpile contracting

Size of vaccine stockpile – based on

- Programmatic requirement
  - Campaign size and speed of immunization
  - Epidemiology
- Industry capacity/production

Lessons Learned

- YFV 2016 let to the request to revolve the stockpile and request to establish surge capacity *(to have 6mds available always) – leading to change in how we manage this stockpile*
  - mOPV?
  - Cholera 2016/17 – increased capacity leads to increased demand
- Mening forecasting – inaccuracy and missing uptake is partly the cause of access problems

Way forward

- Improve risk mitigations to minimize financial risk at supplier and UNICEF
- Monitor the development in the epidemiology vaccines market to adapt vaccine stockpile modality and size
Managing high volume bOPV supply for routine, SIA calendar and a buffer for outbreak response

Outbreaks, production failures, market exits and regulatory issues have challenged supply in the past

- Forecast for 2013-2017 tender too conservative, with +65% increase in awards required post initial awards (4.9B to 7.7B)
- Market exit by one supplier, but new suppliers entering the market able to absorb
- Overall declining demand, with declared market exits from key suppliers

Risk mitigation in 2017, and moving forward

- 2017: Rolling buffer of finished product across all suppliers of up to 150Mds; 115Mds of bulk with manufacturer for immediate delivery with 3 months process time
- 2018 and beyond: i) Willingness to deliver 2Mds within 72 hours; ii) Capacity and willingness to store rolling buffer of OPV; iii) Willingness to secure bulk beyond awarded quantities; and iv) Willingness to extend contract beyond 2022
bOPV supply situation through to year end 2017 is sufficient to meet demand and 150Mds buffer

- Cumulative supply balance across all suppliers between 50-180Mds during 2017 to secure a buffer for outbreak response
Preparing for the global polio eradication requires establishing stockpiles for outbreak response

**mOPV2 stockpile a prerequisite for the global withdrawal of tOPV**

- Bulk stockpiles of mOPVs established following tender in 2009
- mOPV2 as finished product to respond to outbreaks after cessation secured 2015
- mOPV1 and mOPV3 to be secured for the future bOPV cessation
- Unique from other stockpiles as no other usage and production (challenges estimating requirements, production to order – long lead times, no ability to ‘freshen’)

**Delivery lead times to country in accordance with Protocol**

- Within 5-7 days from time of WHO Director General notification
- Countries accountable to initiate response within first 14 days

**Delivery lead times for freight forward pick up from purchase order**

- 3 working days for getting vaccines ready
Global stockpile of mOPV2 for immediate delivery to support country outbreak response against eradicated WPV2

- 80Mds delivered in 16 months
- 70Mds in stock, increasing to 100Mds in October
- 69Mds semi-finished – 20 weeks lead time

Unique challenge to ensure supply outside of a market context (long lead times, expiry, getting demand right)
Information available on the UNICEF website

We're building a new UNICEF.org
As we swap out old for new, pages will be in transition. Thanks for your patience – please keep coming back to see the improvements.

Supplies and Logistics

Supply home
About Supply
For suppliers and service providers
Procurement Services
Strengthening supply chains
Immunization
Emergency Vaccine Stockpiles
Vaccines Supply and Market Overview
Vaccine security
Vaccine Forecasting
Vaccine Price Data
Auto-Disable (AD)

Vaccine Price Data

UNICEF has a significant role within vaccine procurement for children. In recognition of this and to provide greater transparency, UNICEF is now publishing historic, current and future awarded prices for vaccines.

This overview has been prepared following consultations with vaccine suppliers to UNICEF on making pricing information more transparent.

The vaccine prices received by UNICEF from industry are based on the UNICEF mandate, UNICEF aggregated quantities, commercial terms, reliability of forecasts, payment terms and long standing relationship with industry.

Prices posted are based on CPT Incoterms for the period 2001 – 2003 and FCA nearest international airport Incoterms from 2004 and payment terms are 36 days net, unless otherwise specified.

For your reference, historical procurement data per vaccine in terms of quantities in doses and USD values is available here.

The below links provide an overview of prices contracted with suppliers by UNICEF per vaccine.


DONATE NOW

Children need your help

Children worldwide need your help right now. Please donate what you can today.
Emergency Preparedness: Supply Considerations
Outlines

- Vaccine Procurement Overview
- Emergency preparedness: supply considerations
- Vaccine in Emergencies
- General Resources on Immunization
UNICEF has a key role in vaccine procurement and procuring immunization supplies on behalf of around 100 countries annually.

**2016** Vaccines Supplies: US$ 1.64 billion

- **2.50 billion doses**
- **2,613 shipments**

**Immunization Supplies**

- **Vaccines**
  - BCG, DTP, TT/Td/DT, Measles containing, OPV, HepB, YF, DTP-HepB, DTP-HepB/Hib, DTP/Hib, Hib, MR, Meningitis, MMR, PCV, RV, IPV, HPV, etc.

- **Safe Injection equipment**

- **Cold Chain Equipment**

**Countries UNICEF procures on behalf of**

- **Full schedule**
- **Partial schedule**

Source: UNICEF Supply Division
The continuous changes in both supply and demand creates a dynamic market that requires continuous monitoring and management.

Systems are in place to monitor demand against supply and to report regularly both to manufacturers, countries and regional offices.

Internal coordination within Supply Division in the planning and procurement of vaccines, devices and cold chain for campaigns.

Strict guidelines and detailed coordination are applied to ensure the safe delivery of vaccines and the reporting of condition on arrival through the Vaccine Arrival Report.

UNICEF has the capacity to reallocate demand and supply between Countries and Suppliers, to avert crisis and level out demand fluctuations.

UNICEF’s Supply Management of Vaccines

- ~40 Vaccines from ~24 Suppliers
- ~14 Immunization devices from ~8 Suppliers
- To 80-100 countries
UNICEF’s Procurement is Focused on Achieving Vaccine Security

Vaccine Security: the sustained, uninterrupted supply of affordable, vaccines of assured quality

- To achieve value for money and access to vaccines for children in need
- Achieving healthy markets through the Vaccine Security approach (forecasting, funding and appropriate contracting) and specific vaccine procurement principles
- Vaccines as biological products – requiring a specific approach for vaccine procurement
- Quality of vaccines through prequalification by WHO – ensuring acceptability, in principle, as well as quality, safety and efficacy in target population of procured vaccines
UNICEF Vaccine Procurement Principles, implemented following the supply crisis in the traditional vaccine markets, are considered relevant for all vaccines to ensure healthy market

1. A **healthy industry** is vital to ensure uninterrupted and sustainable supply of vaccines

2. Procurement from **multiple suppliers** for each vaccine presentation

3. Procurement from manufacturers in **developing countries and industrialized countries**

4. Paying a price that is **affordable** to Governments and Donors and a price that reasonably covers manufacturers minimum requirements

5. UNICEF should provide manufacturers with **accurate and long-term forecasts**; Manufactures should provide UNICEF with accurate and long-term production plans

6. As a public buyer, providing grants to manufacturers is not the most effective method of obtaining capacity increases

7. The option to quote **tiered pricing** should be given to manufacturers.
Engagement with industry

UNICEF engagement with vaccine industry:

- Public solicitations (Tenders) to Vaccine Manufacturers
- Participation in Industry Associations Meetings (DCVMN / IPFMA)
- Regular visits to manufacturers
- Participation in Vaccine Congresses to monitor pipeline and new vaccine development
- Regular contact with awarded (regular TCs) to ensure production meets forecasted demand and shipment plans of countries
- Annual Vaccine Industry Consultation in UNICEF Supply Division in Copenhagen
  - [https://www.unicef.org/supply/index_92804.html](https://www.unicef.org/supply/index_92804.html)
- Ad Hoc Industry Consultations in UNICEF Supply Division in Copenhagen
  - May 2016 : ZIKA Diagnostics and Vaccines
Considerations to access vaccines in emergencies

**Availability of quality assured vaccines:**

- UNICEF procures WHO prequalified vaccine
- If there is limited or no supply of prequalified vaccine, UNICEF has established criteria to ensure the quality of the product including:
  - The manufacturer must be WHO pre-qualified for supply of at least one other vaccine.
  - The vaccine must be licensed by the NRA in the country of origin, and this NRA must be functional (as assessed by WHO/RSS)
  - The vaccine must be registered in at least two additional countries with functional NRAs (as assessed by WHO/RSS).
- In emergency situation where there are no options that meet the criteria, we will procure with the approval of the recipient country and WHO endorsement

**Product registration in country:**

- Approval is required by country to permit the vaccine into country if there are no other options available; we must respect the NRAs; support from WHO if/as needed
Considerations to access vaccines in emergencies

No available vaccine in the market:

- Limited supply/supply constrained vaccines are managed by the ICG; this is not the case with OPV/Measles
- Stockpiling vaccine to ensure there is timely availability of vaccines, taking into consideration global market for vaccine and lead-times for production

Timely Supply of vaccine to respond to outbreaks:

- Stockpiling vaccines or our long term arrangement (LTAs) improve the availability of vaccines required for timely response;
- Forecasting needs will assist us to develop contractual agreements with suppliers or terms sheets for donations of vaccines in support of emergency use)
- Forecasting accuracy and contracting help to achieve affordable prices for vaccines
Healthy Markets Framework

HMF represents a set of attributes that should be used to measure the health of a market and a process to evaluate each attribute that is vaccine specific.

Process

1. Common building blocks to consider in every procurement

2. Selection and prioritization of which building blocks apply to a specific market usually via product roadmaps

3. Selection of what market needs could or should be resolved with non-procurement intervention

4. Quantification of the trade-offs implied by various scenarios and decisions associated with each healthy market building block

Healthy Market Framework

- Total System Effectiveness
- Long Term Competition
- Product Innovation
- Buffer Capacity
- Individual Supplier Risk
- NRA Risk
- Accommodate Country Presentation Preference
- Supply of Antigen = Demand for Antigen
- Inadequate Supply

Developed in collaboration with BMGF and Gavi, the Vaccine Alliance
WHO has developed and published: *Emergency Use Assessment and Listing Procedure (EUAL) for candidate vaccines for use in the context of a public health emergency*

**Eligibility:**

- The disease for which the vaccine is intended declared by the WHO Director General to be a Public Health Emergency of International Concern (PHEIC).
- Based on the contingencies of the specific public health emergency, it is reasonable to consider the vaccine for EUAL assessment (e.g., there is no licensed vaccine for the indication or for a critical subpopulation, e.g. children, or there is a specific vaccine shortage).
- The vaccine is subject to oversight by a NRA that has been assessed as functional by WHO and is willing to provide oversight of batch release and other post-EUAL product safety and manufacturing quality assurance requirements.
- The vaccine is manufactured in compliance with current Good Manufacturing Practices (GMP).
- **The vaccine applicant** attests that it intends to complete the development of the product and apply for WHO prequalification.