Introduction of Typhoid Vaccine : Cold Chain & Logistics Implications

D Chang Blanc, UNICEF EAPRO
IVI Meeting on Typhoid Vaccination
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Vaccine demand forecasting for typhoid vaccines: # of doses to be procured

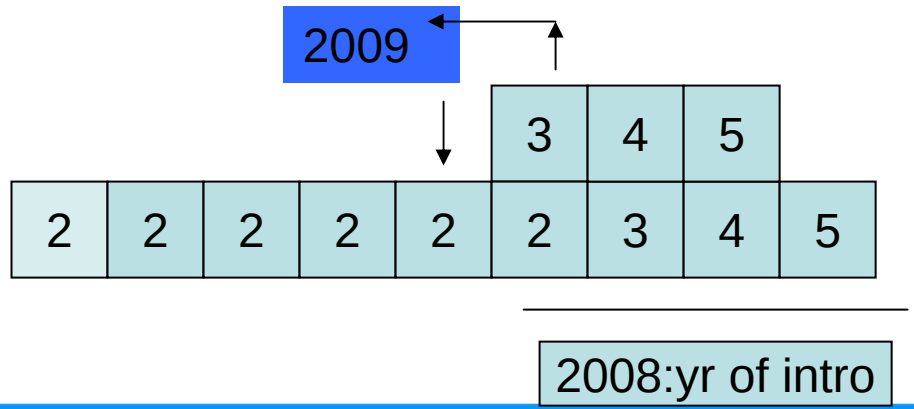
- Defining and estimation of eligible population—2-5 years or 5-10 years, all population>2 years
- Number of doses—one single dose in lifetime or multiple doses every 3 years
- To be provided through routine system or in a campaign approach covering broad age group every 3-5 years
- Or a combination approach—cover 2-5 years in first year of introduction; then cover 2 years old in following years
  - Estimate a fraction of older kids that may not come at 2 years of age

Calculation of # of doses required

- May become complicated if routine vaccination is done for broad age groups
- Difficult to make coverage assessments—what should be the denominator
- May run into overstock or under-stock situation

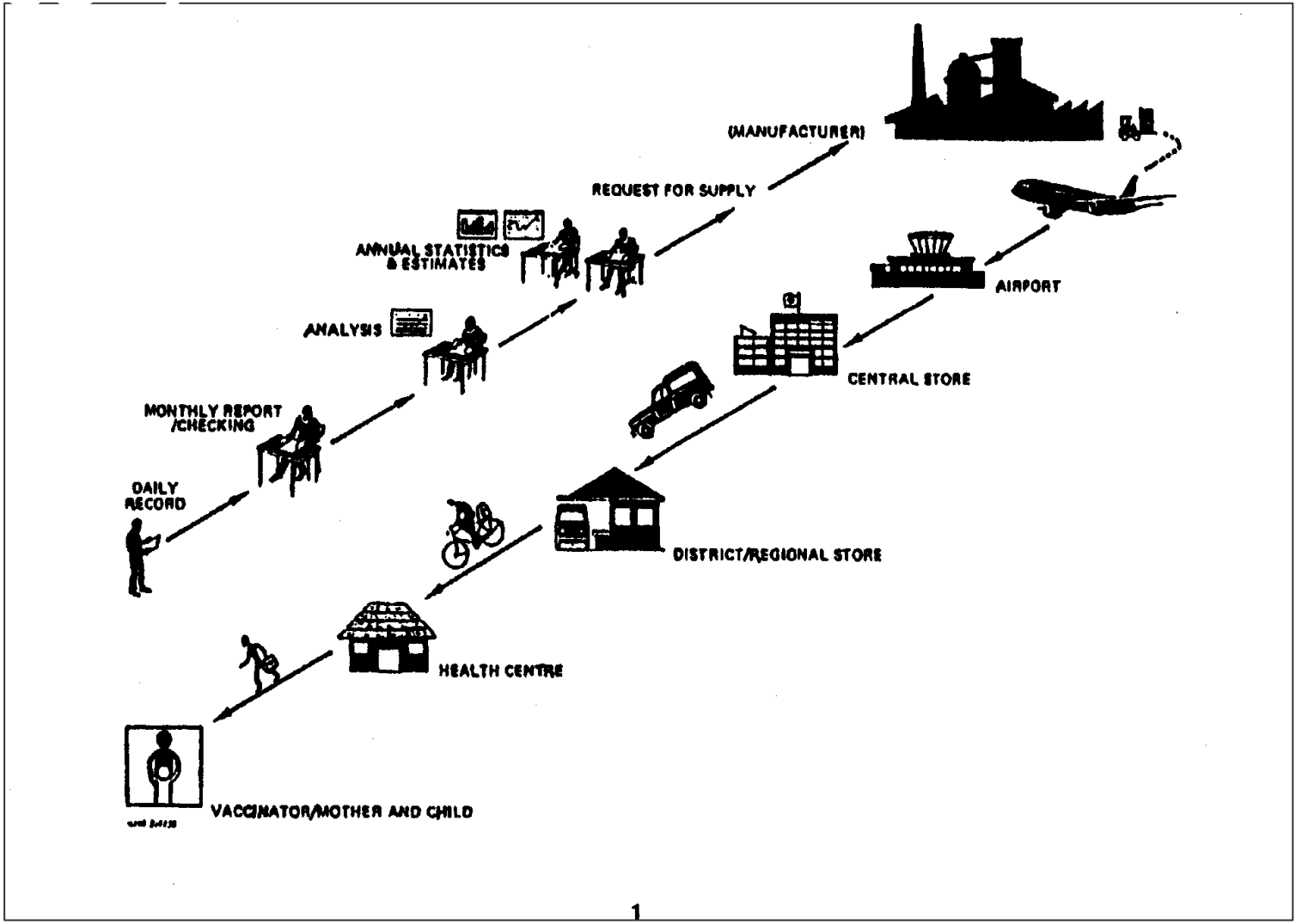
In 2008: Total 2-5 year old population: 350

In 2009: Total 2 year old population: 100+10% of 3-5 year old population



The vaccine cold chain

A complex system comprised of equipment and staff who ensure the proper storage and transport of vaccines at adequate temperatures, from the vaccine producer to the point of administration.



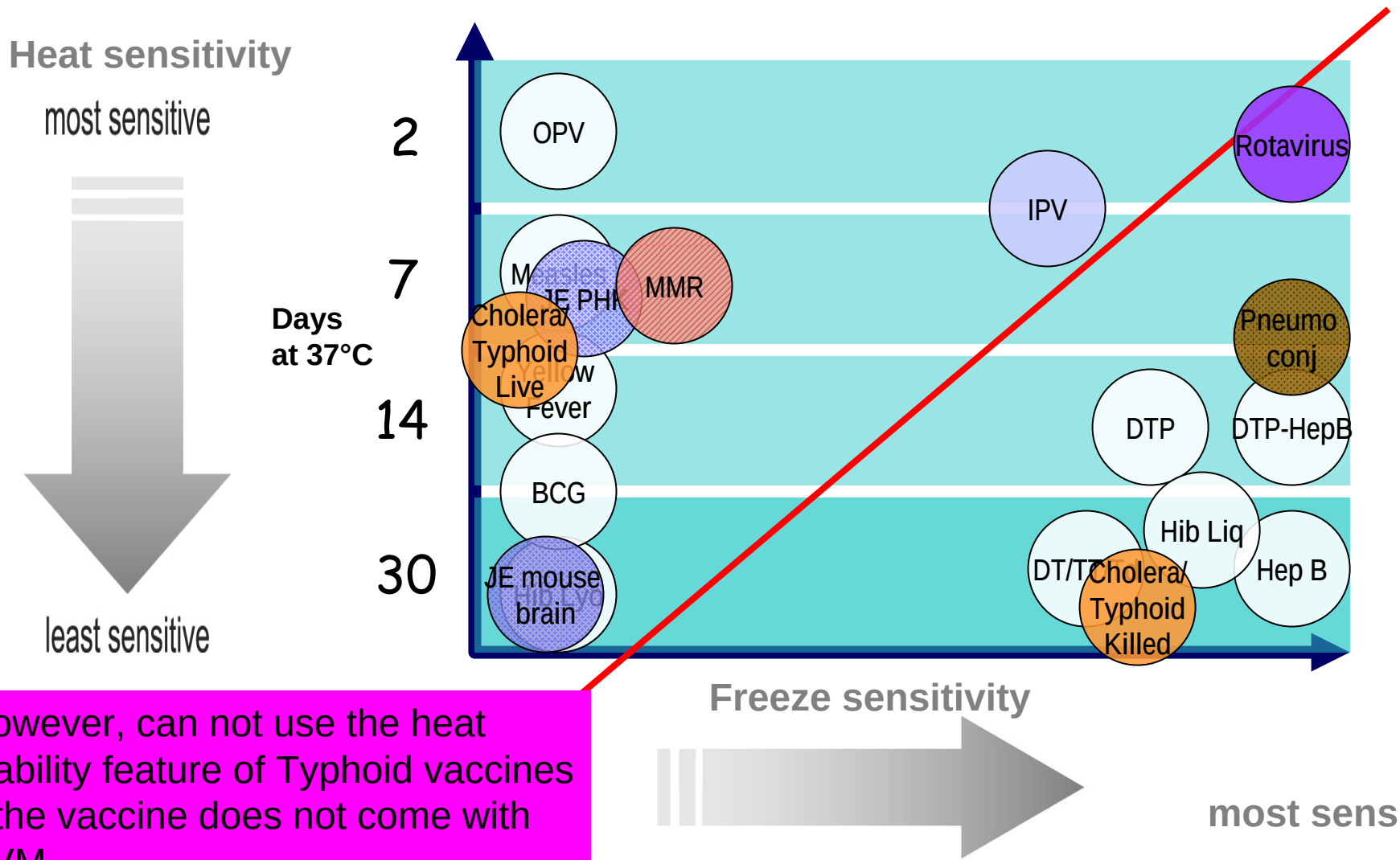
WHO recommended vaccine storage conditions

	Primary	Intermediate		Health Centre	Health Post
		Region	District		
OPV	-15°C to -25°C				
BCG	WHO no longer recommends that freeze-dried vaccines be stored at -20°C. Storing them at -20°C is not harmful but it is unnecessary. Instead, these vaccines should be kept in refrigeration and transported at +2°C to +8°C.				
Measles					
MMR					
MR					
Yellow Fever					
Hib freeze-dried					
HepB				+2°C to +8°C	
DTP-HepB					
DTP-Hib					
Hib liquid					
DTP					
DT					
TT					
Td					

All the currently available typhoid vaccines are recommended to be stored at this temperature as well

Diluent vials must NEVER be frozen. When the manufacturer supplies a freeze-dried vaccine packed together with its diluent, ALWAYS store the product at between +2°C and +8°C. Where space permits, diluents supplies separately from the vaccine may safely be stored in the cold chain at between +2°C to +8°C.

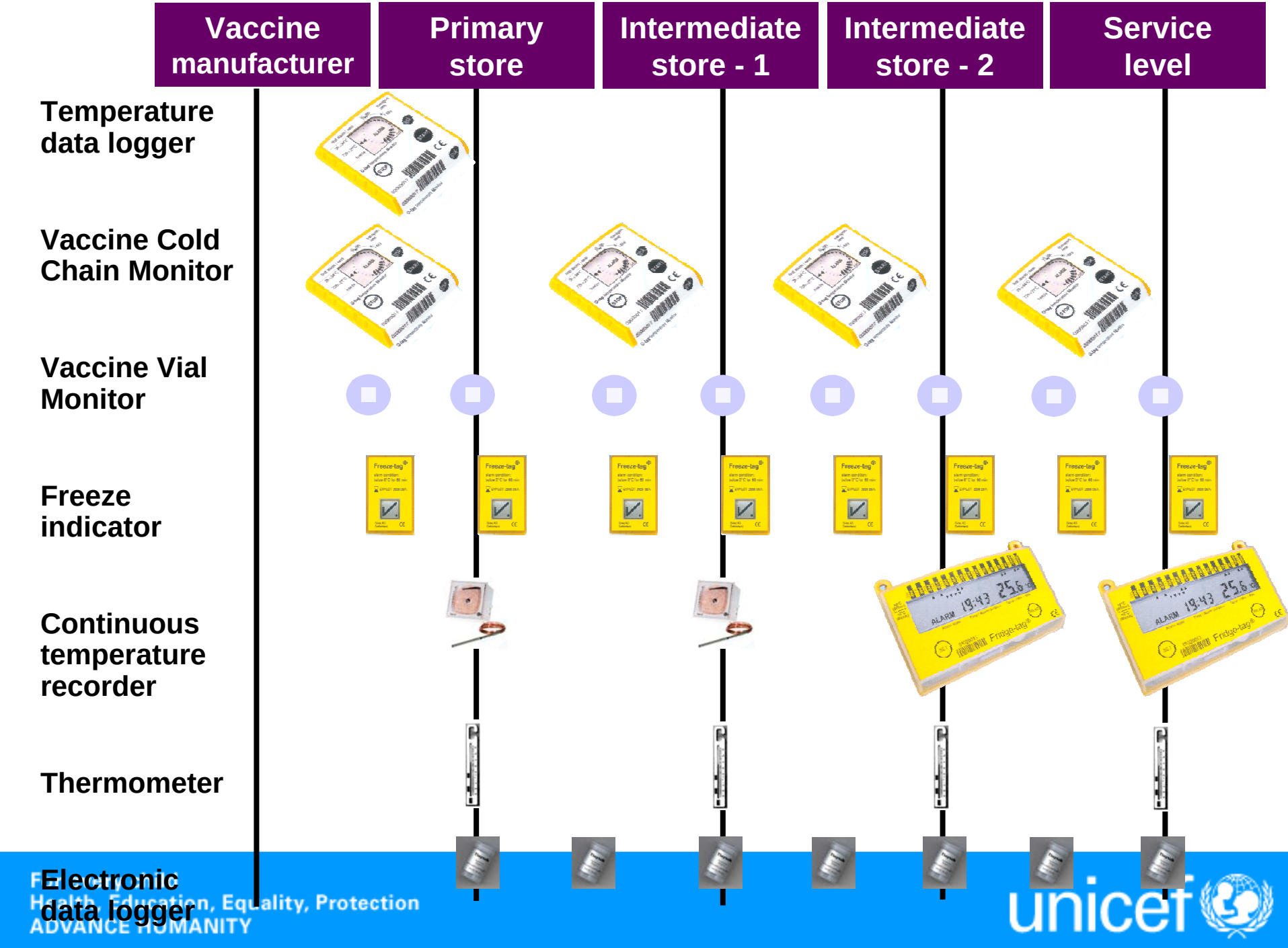
Vaccine Temperature Sensitivity



However, can not use the heat stability feature of Typhoid vaccines if the vaccine does not come with VVM

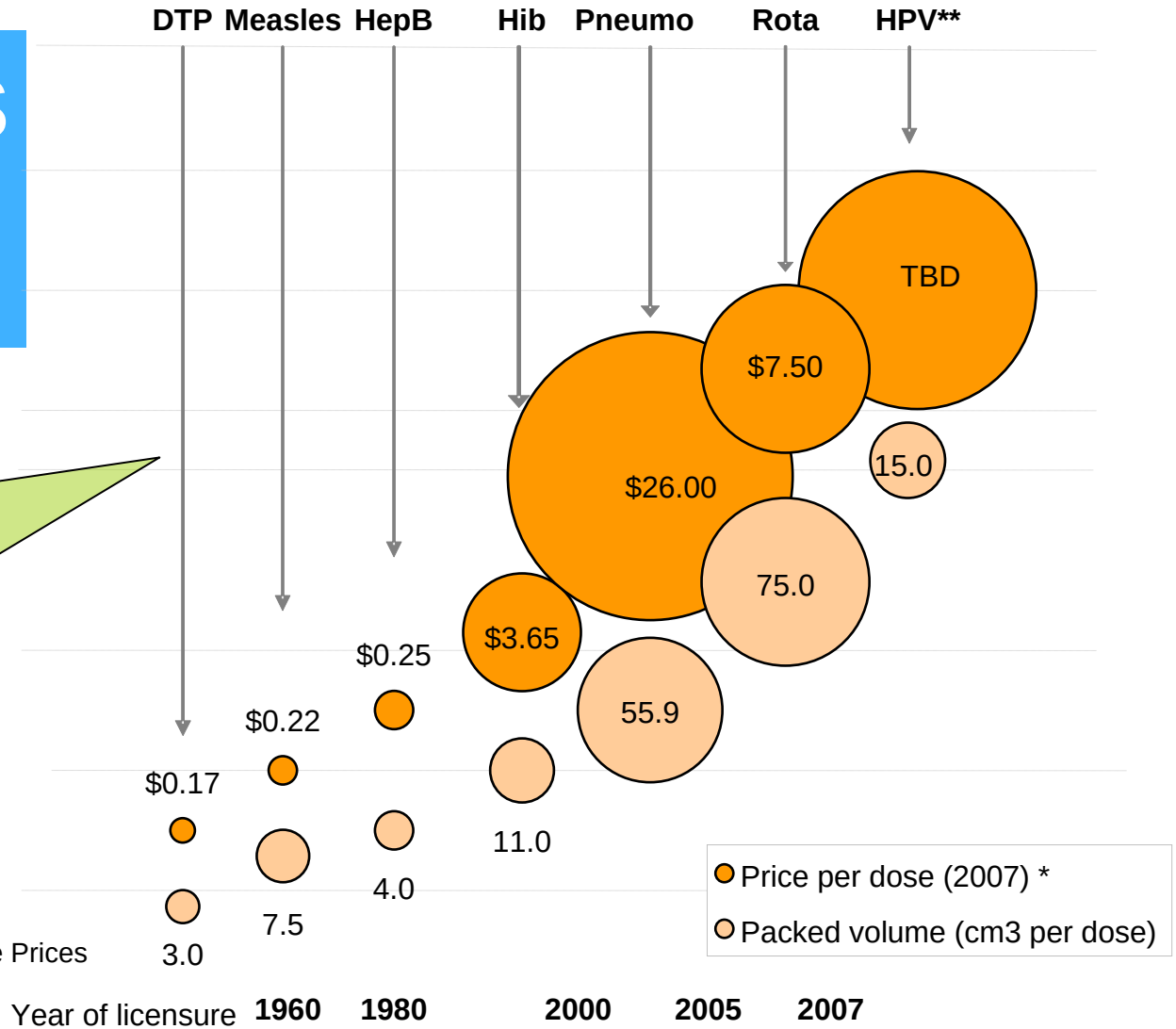
Cold chain equipment & devices

1. Storage & transportation equipment
   - Cold rooms (+2c to +8c degrees and -10c to -15c)
   - Freezers (OPV storage, production of frozen icepacks)
   - Refrigerators (storage of all types of vaccines)
   - Cold boxes and vaccine carriers (transport, vaccination sessions, outreach)
   - Refrigerated trucks
2. Systems and devices for temperature monitoring


Vaccine manufacturer
Primary store
Intermediate store - 1
Intermediate store - 2
Service level
Temperature data logger
Vaccine Cold Chain Monitor
Vaccine Vial Monitor
Freeze indicator
Continuous temperature recorder
Thermometer
Electronic data logger
Health, Education, Equality, Protection
ADVANCE HUMANITY
unicef

The stakes are higher

Newer vaccines are much bulkier and much more costly



* UNICEF and PAHO Revolving Fund Vaccine Prices

** GAVI Price Estimate (2008)

Example: Rotavirus vaccines

$635.50**

4100 doses
of Polio and Measles Vaccines
Rural hospital storage,
Mozambique

625 doses
of Rotavirus Vaccine
District vaccine store, Brazil

$4,687.50**

* Source: WHO. *Guidelines on the international packaging and shipping of vaccines*. 2002; WHO/V&B/01.05.

** Based on $7.50/dose for Rotarix and $0.155 per dose for polio and measles

Newer Vaccines: Added Volume

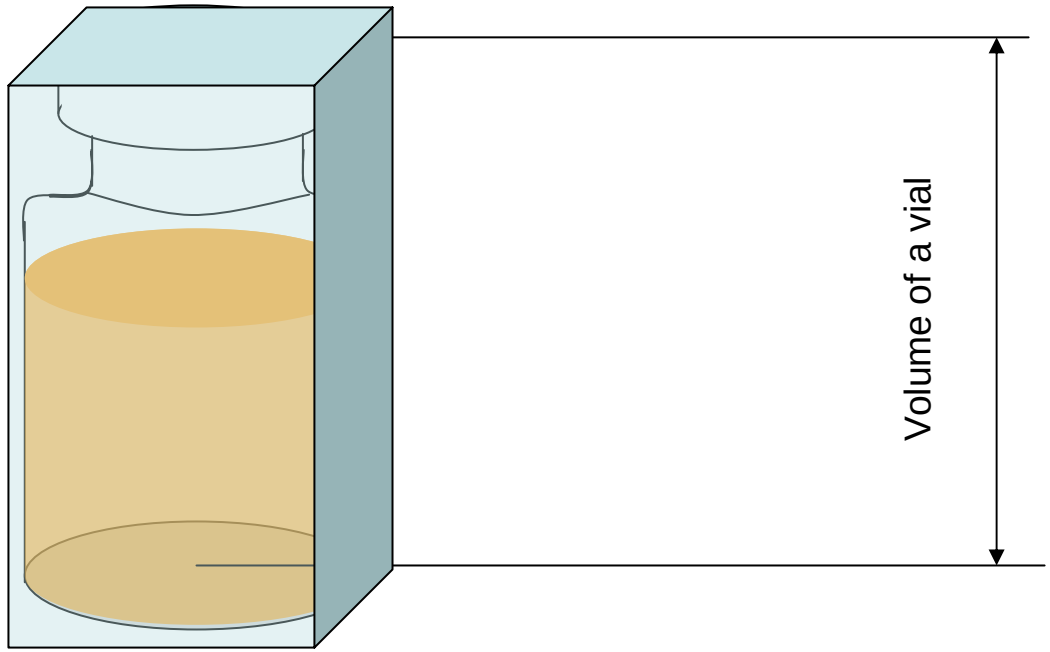
No!


Septran Tablets
Septran Tablets
PLEASE REPLACE AFTER USE
17 12:35

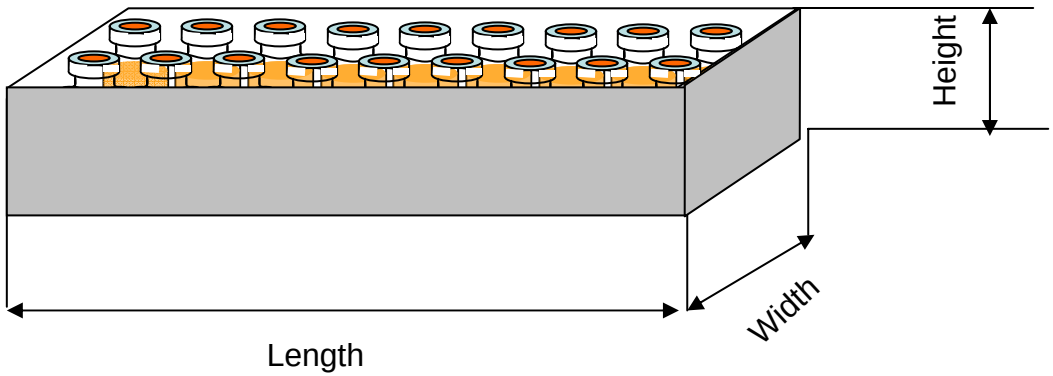
Yes!


2001.

Vaccine Volume



Volume of a packaged dose



Measurements:

Length of box: 15 cm

Width of box: 12 cm

Height of box: 7 cm

 # vials per box: 20 vials

# of doses per vial: 10 doses

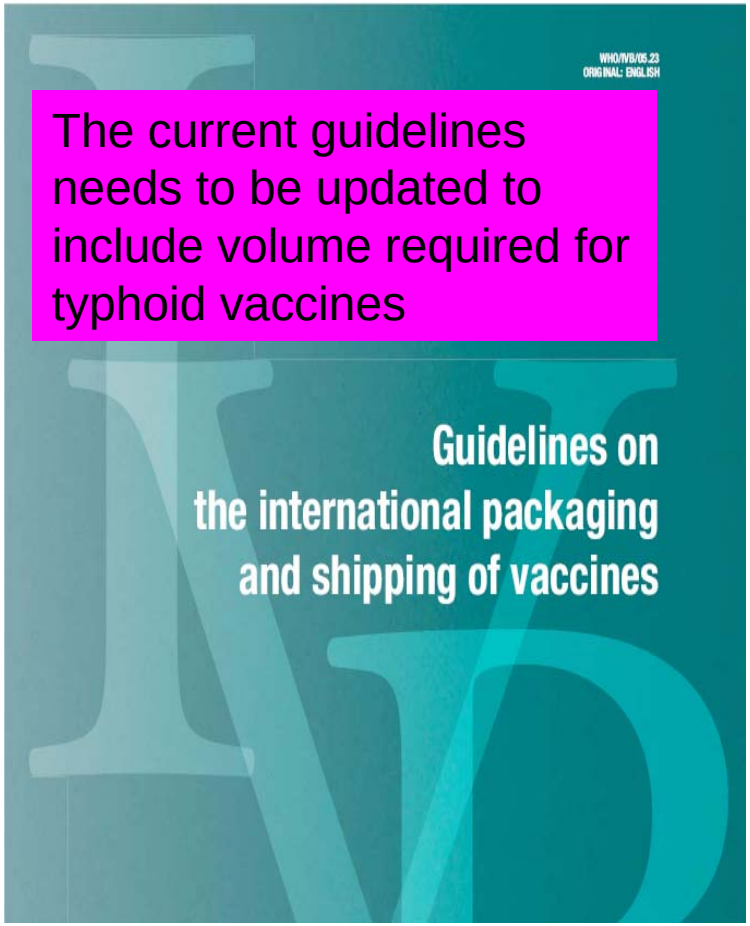
Volume per dose =

Length X Width X Height

---------- = 1260/200 cm3

Vials x Total doses per vial

The vaccine volume per dose varies according to vaccine type and across manufacturers



Vaccine	Doses per vial	Volume per dose in cm^3
BCG freeze dried	20 doses	1.2
DTP	10 doses	3.0
OPV	10 doses	2.5
	20 doses	1.5
Measles	10 doses	3.0
MR	10 doses	3.0
MMR	10 doses	3.0
	1 dose	19
TT	10 dos	2.5
	20 doses	3.0
Hep B	10 doses	3.8
	6 doses	3.0
	2 dose	17.5
	1 dose	35.0
	UNIJECT	24.6
DTP-HepB	10 doses	3.0
	2 doses	4.8
	1 dose	9.7
DTP-Hep-Hib	10 dose	5.3
	2 doses	9.7
	1 dose	19.4

New Vaccines: Current Presentations

Prevnar PCV-7 : One box contains 10 pre-filled syringes without needle

Storage volume per dose: 55.9cm^3

Rotarix: One box with 2 blisters of 5 syringes of diluents, 1 plastic bag with ten transfer adapter + 1 box with ten vials of vaccine

Storage volume per dose: 156.0cm^3

Typhim Vi:

One box of 1 pre-filled glass syringe vial of

Storage volume per dose: 91.3cm^3

Typhoid vaccines: current Presentations

- Vi Polysaccharide vaccine:
  - Prefilled single dose syringe (GSK vaccine Typherix™; Sanofi's Typhim Vi™) in singel box:
    - space requirements higher than current 7-valent pneumococcal vaccine- 91.3 cm3
  - 5-dose vials (by Bharat Biotech, India)
    - Space requirement similar to DPT vaccine (~5-6 cm3)
  - 20-dose vial (IVAC, Vietnam)

Application of multi-dose vial policy: ????

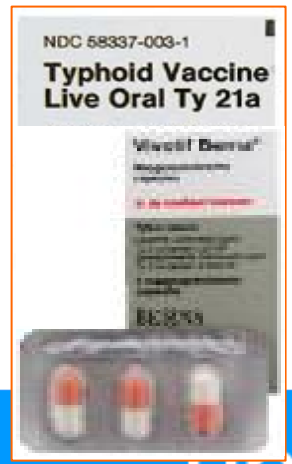
Live attenuated Ty21a vaccine

Licensed in 56 countries

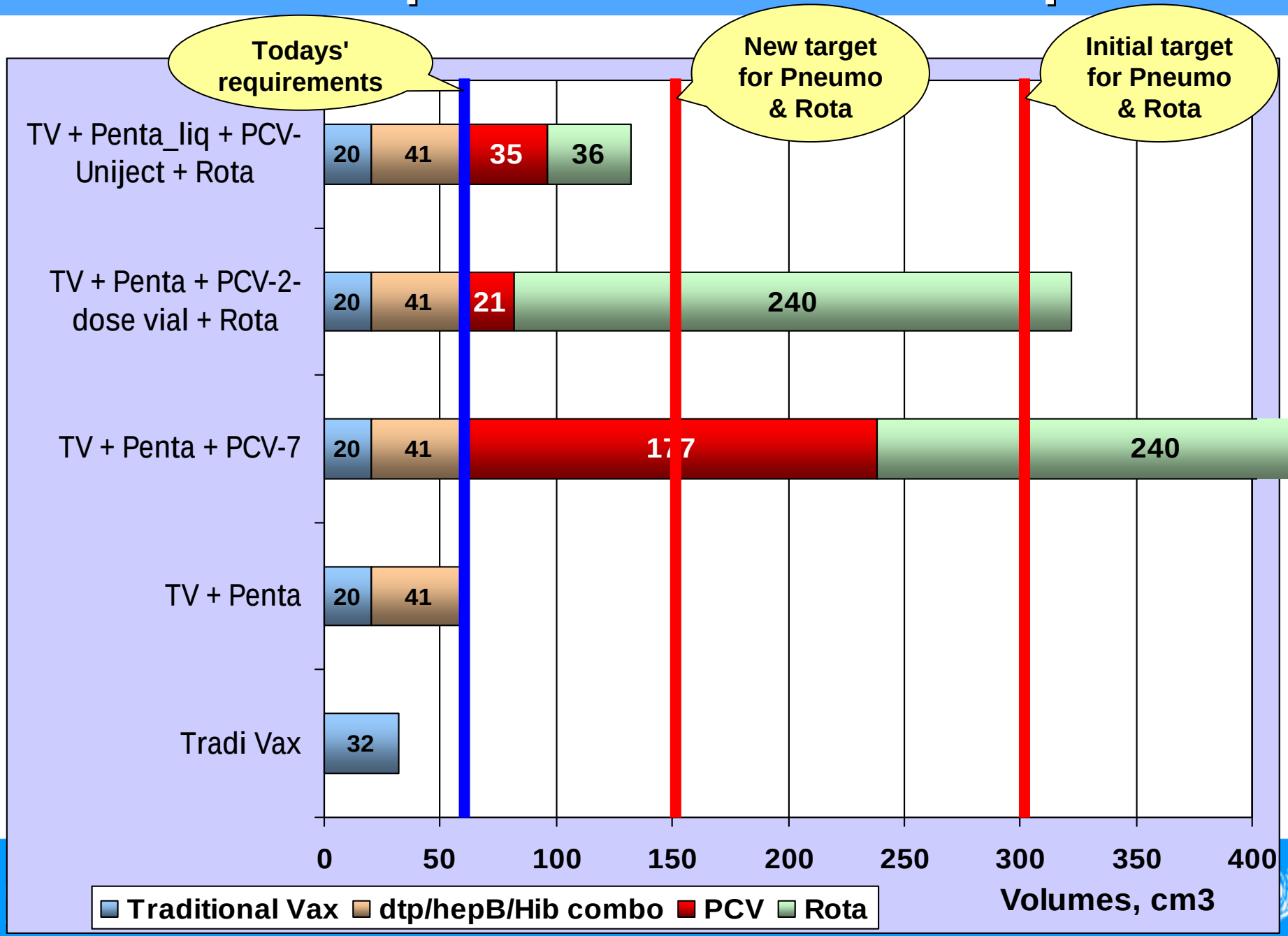
Produced by Berna Biotech – Switzerland

- Presented as phtallate-coated gelatin capsules
- A liquid formulation is also available (with sachet and buffer)
- Administered as three doses 2 days apart

- Cold chain space requirement: Needs to be calculated!



Current & anticipated vaccines volumes per FIC




ROTARIX
25 X 1 DOSIS

Lead Time Required

- Assessing the need → 3 months
  - Central & intermediate → 1-2 months
  - Intermediate & service → 2-3 months
- Preparing & ordering equipment → 6-9 months
- Receiving, installation, training → 3-6 months
- Can take at least 12 months to upgrade needed cold chain capacity for new vaccines introduction

Challenges Ahead

- Emerging vaccine products with non-standard characteristics
  - ✓ Challenging existing policies (MDVP, VVM)
  - ✓ Increased waste disposal
  - ✓ Service delivery strategies (expanded age groups)
- Increased volume of safe injection supplies stored at ambient temperatures
  - ✓ Adequate bundling and distribution of matched supplies
- Radical implication for training & supportive supervision:
  - ✓ Improved skills logistics managers at all levels
  - ✓ Health worker training and supportive supervision

Ongoing Efforts

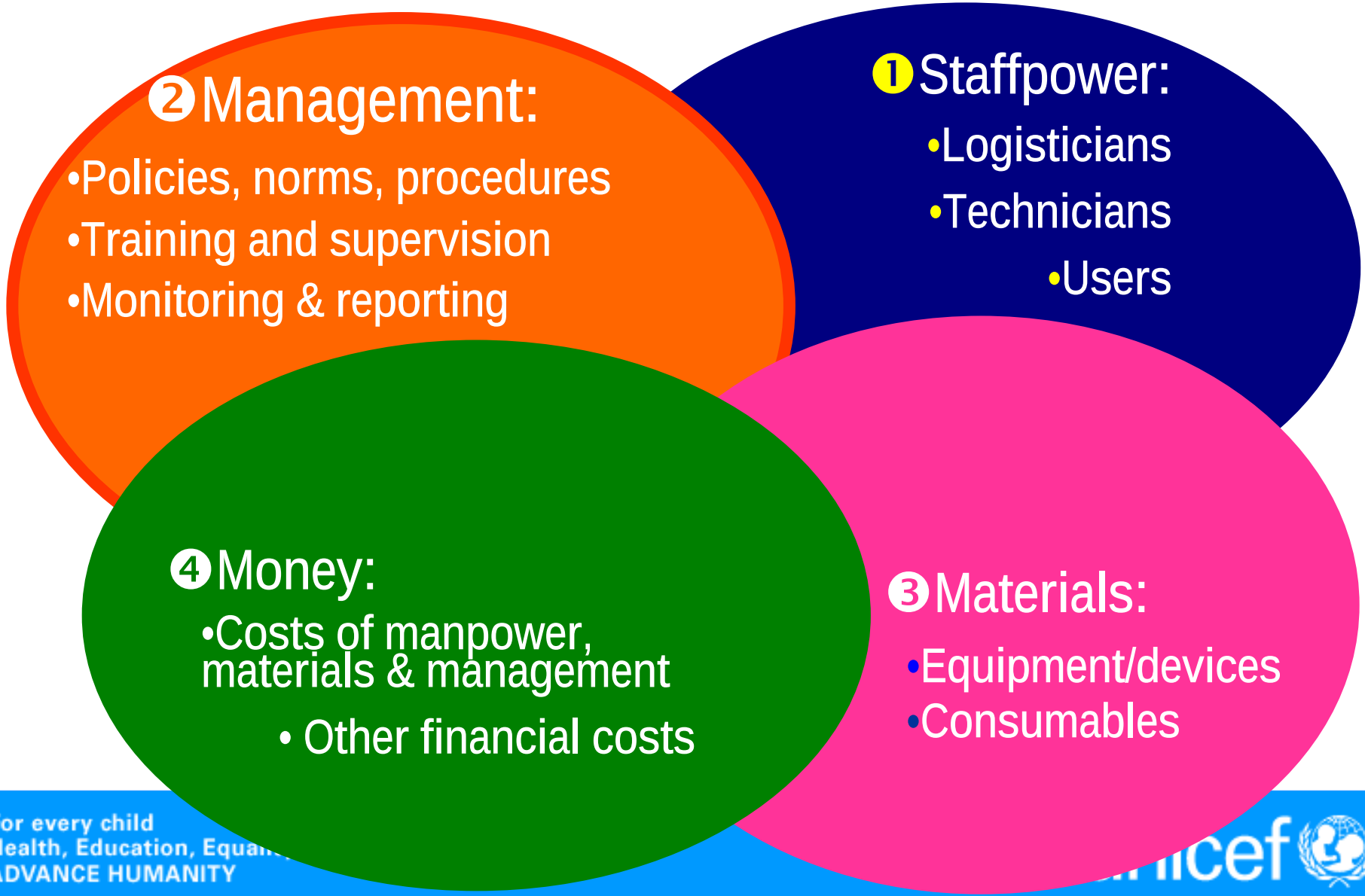
- **WHO Vaccine Presentation and Packaging Advisory Group** (VPPAG): Input to future presentation development

  [see http://sites.google.com/site/vppagp]

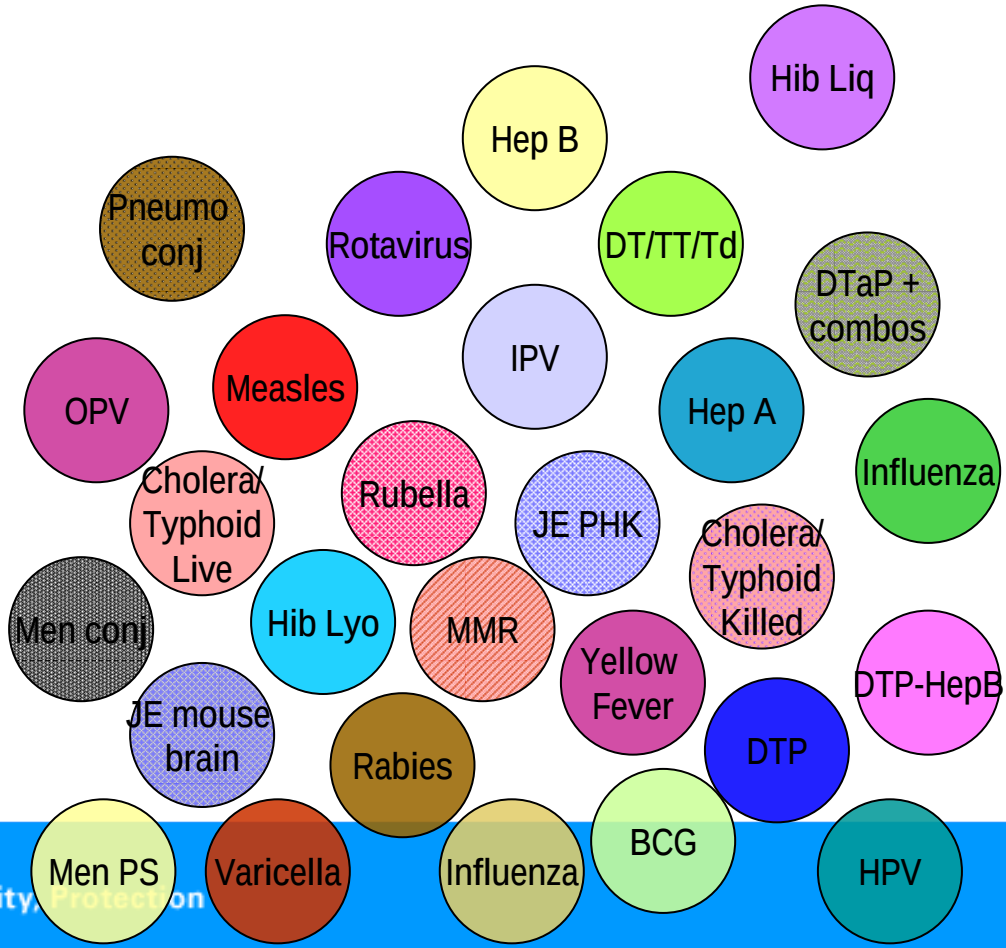
- WHO/PATH '**Optimise**' Project: Future of technologies and logistics

- Tools for country-decision-making and planning
  - ✓ Vaccine volume calculator
  - ✓ Stock management tool (Access and Excel Based)
  - ✓ Equipment inventory tools (Access and Excel Based)
  - ✓ EVSM and VMA assessment tools

The Logistics System

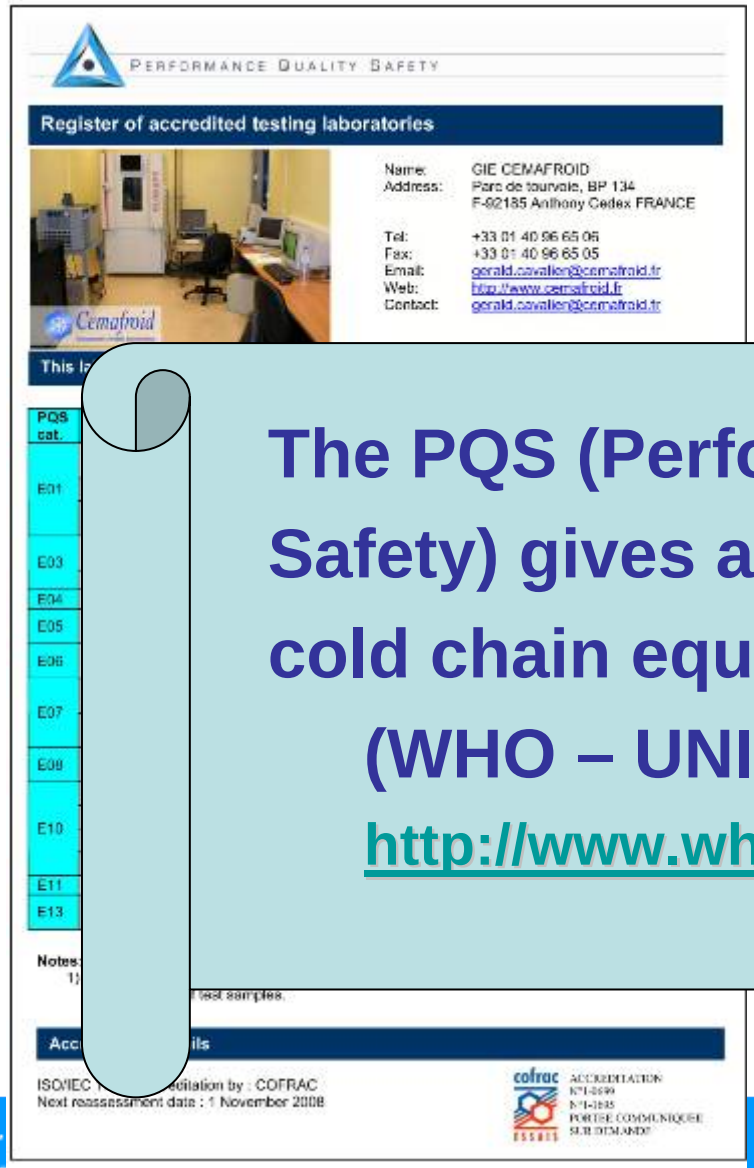


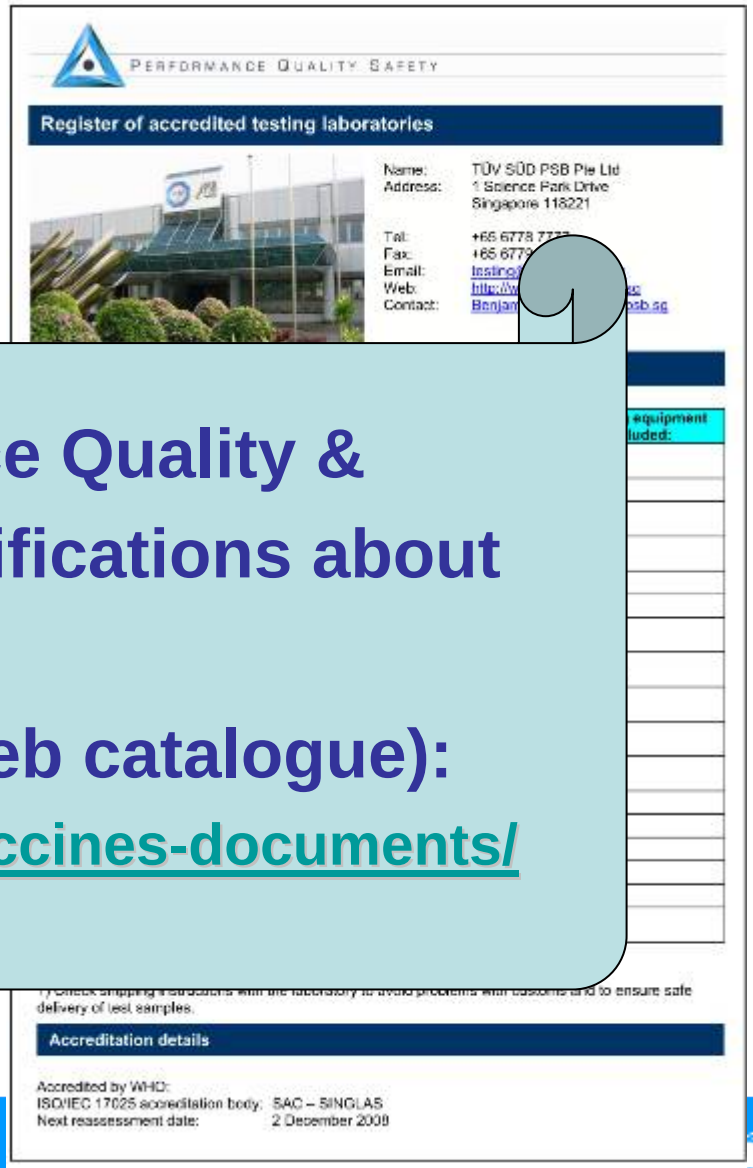
Khap Khun Kha!!



Extra Slides

PQS product verification





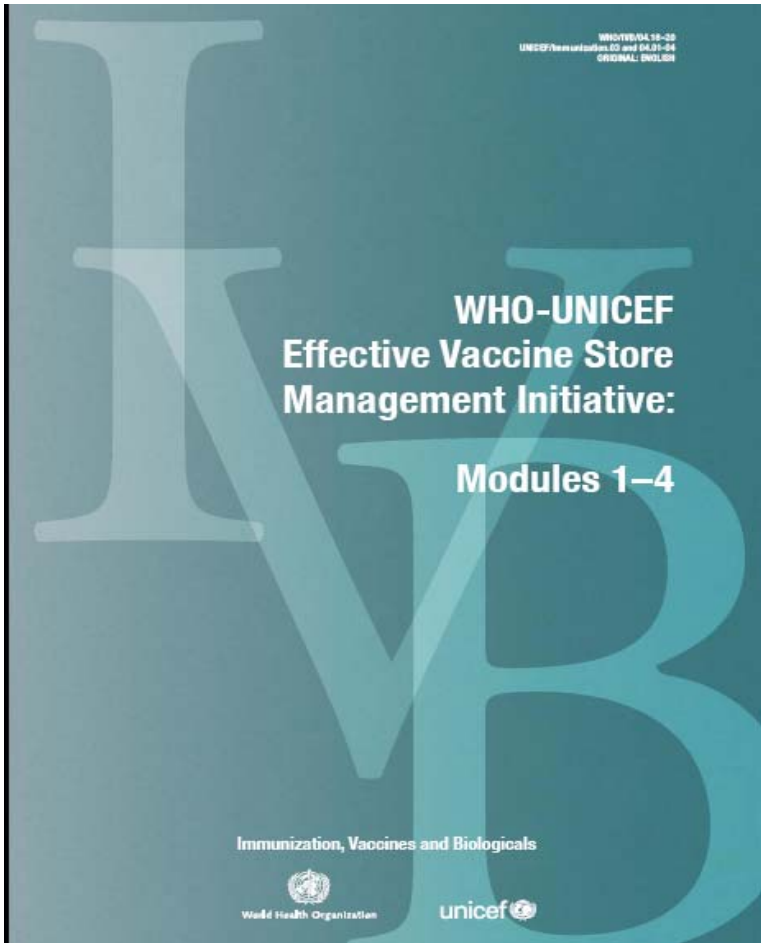
The PQS (Performance Quality & Safety) gives all specifications about cold chain equipment

(WHO – UNICEF web catalogue):

http://www.who.int/vaccines-documents/

WHO-UNICEF
EFFECTIVE
VACCINE STORE
MANAGEMENT
INITIATIVE

Assessment Tool



EVSM criteria at start of each worksheet

Critical indicators highlighted in colour

Enter results in these cells

Protected fields shaded grey

2. ***Over a period of 12 months, all vaccines have been stored within WHO recom… …ages.***

Note to assessors: There are a number of unforse… …g storage whic… …stem - for example, accidental damage during handling. To take account of such events, qu…

Ref	REQUIREMENTS	ASSESSMENT METHOD	RESULTS	SCORE
2.1	***Continuous temperature records are ava… …, and these records demonstrate that vaccine has been stored correctly in both permanent and temporary cold stores.***			
2.1.1	Store all vaccines and diluents at the correct temperature	**Method:** Interview staff, inspect training records		
		Q1: ***Critical indicator:*** Does the storekeeper know the correct storage temperature range for each of the vaccines on the schedule (see note 1)? [YES=1, NO=0]	1	5.00
		Q2: ***Critical indicator:*** Does the storekeeper know the freezing temperature of all the freeze-sensitive vaccines on the schedule (see note 2)? [YES=1, NO=0]	1	5.00
		Q3: Has the storekeeper received formal or on-the-job training in how to …	0	0.00
		Q4: Have all other staff who are responsible for looking after vaccines re…	0	0.00
		Commentary: Q3 & Q4: Interviews with staff suggest that training in vaccine manag…		
2.1.2	Use stock records to demonstrate that all vaccines and diluents have been stored in accordance with current WHO storage temperature recommendations.	**Method:** Inspect stock records		
		Q5: ***Critical indicator.*** Collect the following information to establish the percentage of doses that have been discarded as a consequence of incorrect storage conditions during the review period (note 3).		
		A. Record number of doses of all vaccines in stock at the start of the review period.	1,000,000	
		B. Record number of doses of all vaccines received during the review period.	1,000,000	
		C. Record number of doses issued during the review period.	0	
		D. Record number of doses of all vaccines discarded because of incorrect storage temperatures.	5,000	
		E. Record number of doses of all vaccines in stock at the end of the review period.	2,000,000	
		END BALANCE CHECK: Based on these figures, the end balance should be 1995000 doses. If it is not, query the stock records.		
		F. If the percentage discarded is greater than 1% score is set = 0. If equal to or less than 1%, score = 5.	0.25%	5.00
		Commentary: Discrepancy of 5000 doses could not be reconciled. Refer to Qs on stock management for further comments on this topic, showing weaknesses in this area of store management.		

Vaccine Volume Calculator

ANTIGENES	Nbre doses flacon	Volume par dose (cm3)	Nbre doses du calendrier	Facteur perte	Volume net de stockage in cm3 par Enfant Compl. Vacciné		
					à +4C	à -20C	Total
A	B	C	D	E	F	G	H
Pentavalent Lyo/liquid	2	9,7			-		-
Hib liquid	10	13,8			-		-
Hib liquid	1	32,3			-		-
Hib lyophilised	1	9,7			-		-
BCG	20	1,5	1	2	3,0	-	3,0
DPT	20	2,5			-		-
DPT	10	3,0	3	1,18	10,6		10,6
DT or Td	20	2,5			-		-
Measles	10	3,0	1	1,33		3,99	4,0
Polio	10	2,5	4	1,18		11,80	11,8
Polio	20	1,5			-	-	-
Yellow F.	10	3,0			-	-	-
Yellow F.	20	2,5	1	1,33	3,3	-	3,3
Tetanus toxoid (par ECV)	10	3,0	2	1,18	7,1	-	7,1
Tetanus toxoid (par ECV)	20	2,5			-		-
Volume net de stockage Cm3 par ECV					24,0	15,8	39,8