

Viral Hepatitis Prevention Board  
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# Vaccine shortages: Definitions

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# Outline of the presentation

- Vaccine security: global context
- Terms systematic review: shortages/stockouts
- Core Definitions
- Causes of shortages
- Data & Gaps
- What's next?

# Securing access to quality vaccine supply: Essential to reaching immunization goals



## FIVE PRIORITY PROBLEMS

The Global Vaccine Action Plan is far off track. In response, the SAGE recommends that actions focus particularly on addressing five priority problems. Each problem is major, but each can be tackled, with a reasonable expectation that doing so will improve progress considerably

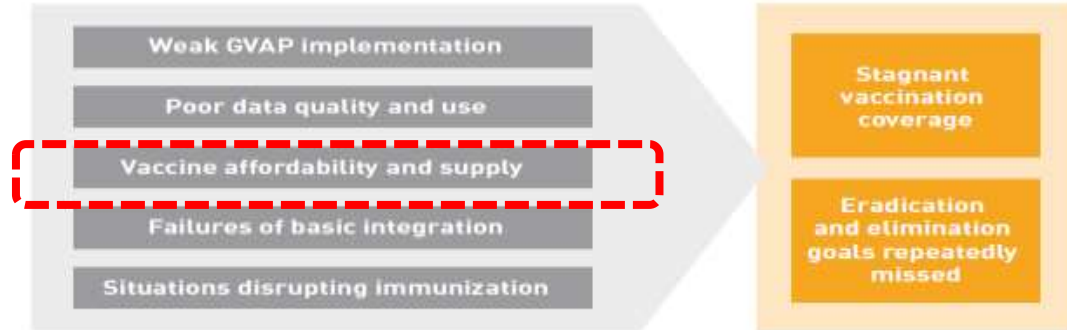
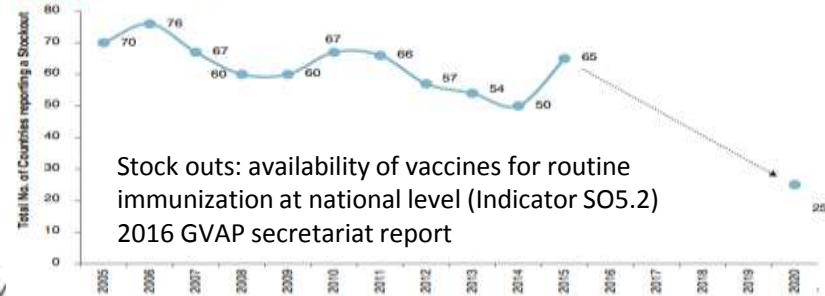


Figure 7.1: Trend towards the GVAP goal for vaccine stockouts



Stock outs: availability of vaccines for routine immunization at national level (Indicator SO5.2)  
2016 GVAP secretariat report

**Vaccine security:**  
“the sustained, uninterrupted supply of affordable vaccines of assured quality”<sup>1</sup>



# Securing access to vaccine supply: WHA resolutions and access strategies

## MEDICINES & VACCINES



### 69<sup>th</sup> World Health Assembly, May 2016

*URGES Member States to develop strategies to forecast, avert or reduce shortages/stockouts ...*

*CALLS upon manufacturers... to contribute to global efforts to address the challenges of medicines and vaccines shortages, including through participation in notification systems;*

*REQUESTS DG to “develop technical definitions, as needed, for medicines and vaccines shortages and stockouts assess the magnitude and nature of the problem of shortages & develop a global medicine shortage notification system....*

## VACCINES

### 68<sup>th</sup> World Health Assembly May 2015

*Obj. 5 Global Vaccine Action Plan,  
WHO Middle Income Country Strategy,  
SAGE April 2015*

*The establishment of effective and sustainable vaccine production, supply, procurement and delivery systems is essential to ensure access to all the necessary vaccines of assured quality at the right time*

*Creation of a global forum of exchange, communication and collaboration to address vaccine supply and demand issues between countries and manufacturers*

# Definitions in use: Terms systematic review

shortage

unavailability

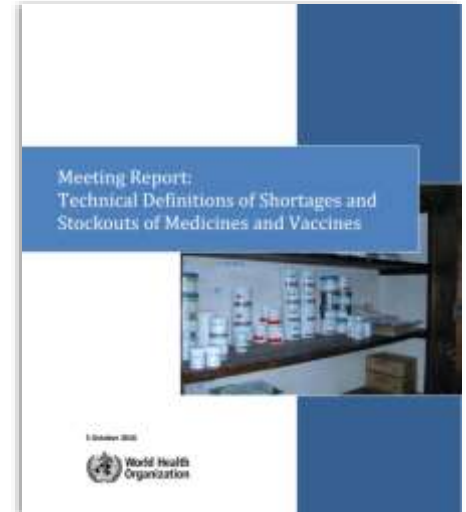
disruption of supply

interruption in supply

supply issue

rupture constatée

- Terms used interchangeably to mean different things
- Definitions vary by supply chain aspect: manufacturing /distribution / dispensing to patients;
- The definitions vary in their specificity;
- Frequently included references to timeframes or durations
- Many definitions - linked to contextual factors & sensitivities (i.e. “acceptable shelf life”, reporting vulnerabilities ....)
- Grouping: Supply side VS Demand side systems
- 26 definitions related to the demand side



Inter-Agency Supply Chain Group  
Industry,  
Member States  
Individual experts

Source: [http://www.who.int/medicines/areas/access/Meeting\\_report\\_October\\_Shortages.pdf](http://www.who.int/medicines/areas/access/Meeting_report_October_Shortages.pdf)

# Core Definitions: Shortages & Stockouts

## Shortage

### Supply side:

The supply of medicines, health products, and vaccines identified as essential by the health system is considered to be insufficient to meet public health and patient needs

### Demand side

demand exceeds supply at any point in the supply chain

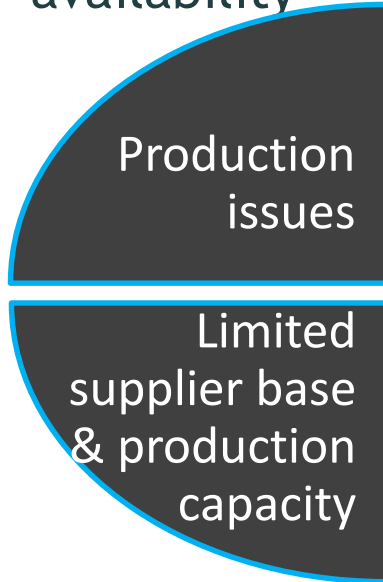


## Stockout

**The complete absence of the medicine, health product or vaccine at the point of service delivery to the patient**

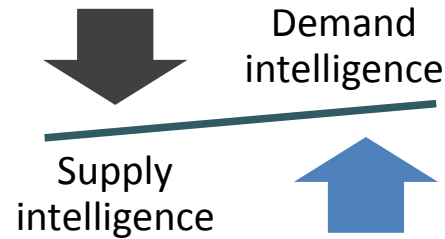
# There are various causes of shortages

**1**  
**SUPPLY**  
Factors limiting  
availability

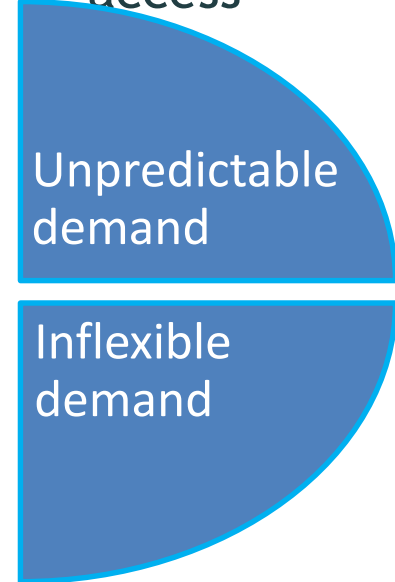


**3**  
**INCOMPLETE  
INFORMATION**

Limited communication  
between supply & demand



**2**  
**DEMAND**  
Factors limiting  
access





# Data & Gaps

## Reporting stockouts

Figure 7.3: Map of countries with national level stock-out event, 2015



Indicator: 'At least 1 stock-out event for at least 1 vaccine for at least 1 month at national level'

- Reporting mechanism through WHO/UNICEF JRF
- GVAP/EVAP monitoring indicator

Source: 2016 GVAP secretariat report

[https://www.technet-21.org/en/?option=com\\_content&view=article&id=5064&Itemid=1814](https://www.technet-21.org/en/?option=com_content&view=article&id=5064&Itemid=1814)

## Reporting Shortages

- NO routine global reporting (YET)
- NO established response mechanisms
- Supply side:
  - MA holders > to NRA (EU)
  - Limited data published/available
- Demand side:
  - Multiple actors
  - Variable & Fragmented data



# What's next?

## EB140/19

- Reviewed draft definitions and acknowledged the need for additional consultations

## EB 142/ 13 (January 2018)

- Reviewed the progress made in implementing resolution WHA69.25 , i.e.
  - Establishing a global mechanism to notify shortages of medicines & vaccines (limited to medicines included on the WHO Model List of Essential Medicines)
- Defined further areas of WHO work on shortages, i.e.
  - Continuation of WHO's normative work to specify standards and guidance for the development, regulation, production, selection, pricing, procurement, distribution, prescribing and use of medicines and vaccines
  - Supporting inter-organizational, regional and country collaboration, networking and training;

Source: Addressing the global shortage of, and access to medicines and vaccines

Report by the Director-General. [http://apps.who.int/gb/ebwha/pdf\\_files/EB142/B142\\_13-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/EB142/B142_13-en.pdf)



Thank you!