

Meeting Report: Technical Definitions of Shortages and Stockouts of Medicines and Vaccines



5 October 2016



**World Health
Organization**

WHO/EMP/IAU/2017.03 © World Health Organization 2017

All rights reserved. Publications of the World Health Organization are available on the WHO website (<http://www.who.int>) or can be purchased from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; email: bookorders@who.int).

Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press through the WHO website (http://www.who.int/about/licensing/copyright_form/en/index.html).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

For more information about this report, please contact:

Lisa Hedman
Innovation Access and Use
Essential Medicines and Health Products Department
WHO, Geneva
hedmanl@who.int

This publication contains the report of a WHO consultation and does not necessarily represent the decisions or policies of the World Health Organization.

Contents

- List of Acronyms 3
- Executive Summary 4
- Resolution WHA69.25 5
 - Discussion 5
- Findings of a systematic review 6
 - Discussion 7
 - Definitions identified in the systematic review 7
 - Using definitions based on context 7
 - Related definitions..... 8
 - Reporting and data 8
 - Challenges faced by participating agencies..... 8
- Draft definitions..... 9
 - Discussion 9
 - Text of draft definitions 10
 - Additional notes 10
- Conclusions..... 11
- Agenda..... 12
- List of participants 13
- Annex 1, Compiled list of definitions..... 0

List of Acronyms

API	Active Pharmaceutical Ingredient
EMA	European Medicines Agency
EML	WHO Model List of Essential Medicines
GDF	Global Drug Facility
GFTAM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GSK	GlaxoSmithKline
ISG	Inter-Agency Supply Chain Group
MSF	Médecins Sans Frontières
NEML	National List of Essential Medicines
NMRA	National Medicines Regulatory Authority
NDOH SA	National Department of Health of South Africa
PFSCM	Partnership for Supply Chain Management
RMNCH SCT	Reproductive Maternal Newborn and Child Health Strategy and Coordination Team
USAID	United States Agency for International Development
WHO	World Health Organization
WFP	World Food Programme

Executive Summary

In response to World Health Assembly resolution WHA69.25, “Addressing the Global Shortage of Medicines and Vaccines”, an informal consultation of experts was convened in Rome on 5 October 2016. The meeting took place at the World Food Programme offices and preceded a quarterly meeting of the Inter-Agency Supply Chain Group (ISG). Meeting participants were from the ISG, industry, Member States as well as individual experts.

The purpose of the meeting was to develop technical definitions of shortages and stockouts of medicines and vaccines, as requested in the resolution.

Meeting participants were given preliminary findings of a systematic review commissioned by WHO to analyze definitions of shortages and stockouts in the context of medicines and vaccines. The systematic review identified procedural, policy and programmatic documents, but few peer-reviewed publications relevant to the topic. The review also showed that terms used to describe shortages and stockouts were used interchangeably to mean different things.

The findings of the systematic review were discussed. Terms were mapped to different areas of the supply chain, from manufacturing to dispensing to patients, and then the mapped terms were grouped according to whether they were related to supply or demand. After further discussion, the group developed, by consensus, their own definitions and noted whether they were related to supply or demand.

This document summarizes the proceedings and conclusions of the meeting.

Resolution WHA69.25

Background information on the resolution was presented.

Member States in the 69th World Health Assembly in May of 2016 acknowledged the increasing number of shortages and stockouts of medicines and vaccines. Shortages can occur at many points in the supply chain owing to insufficient or non-existent manufacturing capacity of products; problems with active pharmaceutical ingredients (API); financial constraints; problems with forecasting; challenges with supply chain management; and serving areas that are difficult to reach. Financial constraints include limitations on national budgets as well as on patient out-of-pocket payments. In response to this problem, the WHO secretariat was asked:

*“to develop technical definitions, as needed, for medicines and vaccines shortages and stockouts, taking due account of access and affordability in consultation with Member State experts in keeping with WHO-established processes, and to submit a report on the definitions to the Seventieth World Health Assembly, through the Executive Board”.*¹

WHA69.25 also calls upon WHO to identify medicines at risk; estimate the magnitude of the problem; and consider reporting mechanisms that capture global and regional trends on medicines that are frequently in shortage or stockout.

Discussion

Participants noted that there have been significant successes in reducing supply chain shortages and stockouts in priority disease programmes such as HIV, malaria, tuberculosis, reproductive health and immunization. Promising practices are being developed, but recent reports of shortages of HIV medicines underscore that supply chain related shortages remain a challenge in many countries. Shortages related to manufacturing issues are increasing, but as of yet there are no comprehensive data on global trends. Increases in the frequency of global or regional shortages for cancer medicines, older antibiotics, paediatric dose forms and vaccines were cited as examples of shortages where the global nature and impact are clear. Examples were discussed where problems leading up to shortages were publicly reported on web sites of the United States Food and Drug Administration and the European Medicines Agency, but the shortages occurred nonetheless. The global medicines market is increasing as a result of population growth and other factors, which may compound the problem of shortages. Increases in demand may exacerbate other existing problems, for example, through additional pressures on supply chains and data systems.

¹ WHA29.65 Addressing the Global Shortages of Medicines and Vaccines
<http://apps.who.int/medicinedocs/documents/s22423en/s22423en.pdf>

Findings of a systematic review

The methodology and preliminary findings of a systematic review commissioned by WHO and were discussed, including a table of consolidated definitions (Annex 1).

The search used in the review included published scientific papers and “gray literature”. Search terms are shown in Table 1. The search was limited to English-language documents; however, some of the documents appeared to be translations from French language documents and included terms in French.

Table 1

Search terms for systematic review
1. Medicine, Vaccine, Product, Commodity, Active Pharmaceutical Ingredient, Medical Devices, Medical Diagnostics
2. Definitions, Define, Defin*
3. Stockout, Stock-out, Stockout, Shortages
4. Inventory, Stock Holding
5. Facility, Health Care Centre, Community Health Centre, Pharmacy, Warehouse, Central Stores, Depot, Sub-Depot, Distribution Centre, Stockroom
6. Harmonized

The literature review identified fifty-six definitions of shortages and stockouts. Although a number of papers were identified on the general topic of shortages and stockouts, many of these did not include definitions of these terms. Most of the definitions were found in policy, procedure, programmatic and operational guidance documents. Some papers described conditions or systems in which an action was required to address a shortage or stockout, in which case these descriptions were taken to be definitions.

General observations about the definitions identified included the following:

- Terms were frequently used interchangeably to mean different things. For example, shortage, unavailability, disruption of supply, interruption in supply, supply issue, and “rupture constatée” were frequently used but clearly meant different things;
- Definitions varied depending on what aspect of the supply chain they intended to address. For example, definitions that addressed problems at or related to the manufacturing level were different compared with those that addressed problems in distribution or in dispensing to patients;
- The definitions varied in their specificity;
- Definitions frequently included references to timeframes or durations, such as extended lead times for deliveries or inability to dispense to a patient within a certain time period;
- Many definitions were linked to contextual information. For example, one National Medicines Regulatory Authority (NMRA) defined the requirement to report shortages as a situation when a manufacturer or importer of a drug cannot meet actual or projected demand, including temporary

disruptions or permanent discontinuation of the production and supply of a drug. That definition goes on to use a time factor, indicating that as soon as a market authorization holder knows that it will take longer than 20 days to supply a drug to meet expected patient volumes on an ongoing basis, this would be reported as a shortage on a communications platform. Continuing this example, the inability of a patient to receive prescribed medicines at the first attempt to fill a prescription may not constitute a drug being in 'shortage,' as the drug may be available in other pharmacies or within the wholesale or distribution network (i.e. pharmacy supply chain), usually within a few days. (Health Canada, 2015)²

- The review identified 26 definitions related to the demand side of systems for medicines and vaccines. Of those, most were related to shortages occurring at health care facilities. These definitions often made reference to a maximum length of acceptable delay in dispensing or treating a patient;
- Fourteen of the demand-related definitions were from health programmes that have specific initiatives to monitor or report shortages and stockouts. Two examples include the Stop Stockout Programme in South Africa and the Médecins Sans Frontières Empty Shelves Programme.

Discussion

Definitions identified in the systematic review

The discussion of the systematic review included the question of how to categorize and work with the various published definitions. The definitions identified in the systematic review were mainly from programmatic, policy, procedure and operational guidance documents. The sources of information ranged from documents from NMRAs, informal wholesaler programmes, supply chain programmes, capacity development programmes and other sources, which vary in function and purpose. Thus, conflicting definitions and the interchangeable use of terms was not surprising. Some definitions were context dependent and could not be used without some form of guidance. It would be important to capture the sense and purpose of the various definitions in any consolidated technical definitions; otherwise, the result could be too narrow in scope.

The systematic review mapped the definitions according to the area of the overall supply chain that each one addressed, from manufacturing to dispensing to patients. Participants agreed to further group the definitions into those affecting supply side systems versus those affecting demand side systems.

Using definitions based on context

Definitions were often context dependent. As such, technical definitions would need to be accompanied by guidance on their use and applicability in different situations to avoid unintended consequences. One example

²Health Canada. (2015, February). *Drugs and Health Products*. Retrieved October 2016, from Health Canada: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/shortages-penuries/index-eng.php>

of a commonly recognized unintended consequence of reporting initiatives was that health care workers may be blamed and penalized for a stockout that they report, adversely affecting their motivation to make accurate reports of shortages and stockouts. Another example was reporting among wholesale pharmacy distributors that was intended to promote information sharing, but instead led to hoarding of products and price increases for items that appeared to be in shortage.

Related definitions

There are multiple definitions in supply chain management that could affect the application of a definition to a shortage or stockout. The example discussed was the definition of “acceptable shelf life”, which is commonly used as an acceptance criteria in procurement, i.e., if the medicine has less than a certain percentage of its original shelf life upon departure from the manufacturing facility (or on arrival at a given destination), the procurer has the right to reject the product. If products are frequently and unduly rejected under the acceptable shelf life definition, it could create a false impression of a shortage. Diagnostic kits that have a naturally short shelf life were an example of where this problem has occurred. Paediatric tuberculosis medicines that have only a two-year shelf life and medicines that have a limited shelf life when they are first introduced to the market were other examples. It was strongly suggested that guidance needs to be updated around acceptable shelf life to ensure alignment with the definitions of shortages and stockouts.

Reporting and data

The final discussion point was related to reporting and data. The quality of data from supply chains has historically been considered weak. Certain supply chain programmes have been able to stabilize data and reporting, but only for a small list of medicines that are supplied through specific programmes and mainly those with specific financial support from the donor community. A set of harmonized technical definitions will be useful in promoting interoperability of reporting and in the effectiveness of potential reporting mechanisms. Additional consideration as to how the definitions affect data collection and use will be needed, especially considering the importance of data in forecasting and other areas of monitoring and evaluation.

Challenges faced by participating agencies

The agencies represented in the meeting have experienced various challenges in avoiding shortages and stockouts of medicines across various initiatives. In some cases, the challenges are not a lack of availability, but are related to other issues. Specific challenges included the following:

- The European Medicines Agency represents multiple member states. The definition used for reporting a shortage or stockout might be different across these states and there is limited capacity to change the definition used by specific countries;

- Manufacturers and regulators have historically had differing opinions about how to implement against the requirements to report on shortages and stockouts of medicines;
- The Global Fund to Fight AIDS, Tuberculosis and Malaria discussed challenges in determining real versus perceived stockouts. Not being able to determine the root cause resulted in delays in identifying appropriate solutions for countries that receive support from GFATM. A key element will be to ensure that definitions accommodate rapid investigation of the root causes of specific shortages and stockouts to avoid inappropriate responses and the associated waste of resources;
- Multiple agencies, including WHO, have reported that shortages of common antibiotics are an increasingly serious issue. The case of Benzathine penicillin was discussed, including work commissioned by the Bill and Melinda Gates Foundation, activities at WHO as well as efforts by UNFPA and UNICEF to source this product.
- The Global Drug Facility specifically noted the challenges of alignment with other supply chain definitions. A specific suggestion was made to align the definitions of shortages and stockouts with guidance on acceptable shelf life for medicines.

Draft definitions

Participants worked in groups to develop draft definitions, taking into account the compiled definitions from the systematic review. The draft definitions were developed and discussed in plenary and are being reported to the WHO Executive Board as part of the progress on WHA69.25. Two definitions were developed, one focused on the supply side and the other on the demand side of the overall supply chain. The core elements of the definitions are included in the text and tables below.

Discussion

The following summary table as well as a compiled list of the definitions were provided to participants. The definitions that were drafted are also included below. These were discussed in plenary and agreed by consensus.

Table 2 Shortage Definition Framework

Core Definition of Shortage: 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				
Core Definition of Stockout: The complete absence of the medicine, health product or vaccine at the point of service delivery to the patient				
	Supply Chain	Measurement	Variables	Considerations
Level 1 National	Supply: <i>Manufacturing: e.g. Raw Materials, Active Pharmaceutical Ingredients, Final Products</i>	Amount of medicine delivered equals the amount ordered	Timeframe, Classification (VEN ³ , Impact), Alternatives, Patient Centric, Temporary/Permanent, Product Temperature, Infrastructure, Context, Developing vs Developed Member States, Economic Considerations, Quality Assurance, Data Availability and Data Quality	<ol style="list-style-type: none"> 1. Actors 2. Audience 3. Actions 4. Consequences
Level 1 National	Demand: <i>Channels to Patients: eg. Central Stores, Health Facilities, Distribution Affiliates, Strategic Buffer</i>	Inventory Metrics Service Delivery Metrics		

Text of draft definitions

On the supply side:

A “shortage” occurs when 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. This definition refers only to products that have already been approved and marketed, in order to avoid conflicts with research and development agendas.

On the demand side:

A “shortage” will occur when demand exceeds supply at any point in the supply chain and may ultimately create a “stockout” at the point of appropriate service delivery to the patient if the cause of the shortage cannot be resolved in a timely manner relative to the clinical needs of the patient.

Additional notes

Several criteria were identified as relevant in the future refinement of the definitions as noted below:

- Patient-centred definitions, including time-bound criteria for how long treatment is delayed;

³ VEN is a reference to Vital Essential and Necessary medicines which is an expression used by some countries to distinguish a subset of their national list of essential medicines.

- Public health impact;
- Ability to use in measurement / monitoring and evaluation;
- Responsible reporting, including avoidance of conflation or other forms of over-reporting;
- Focus on reporting that facilitates a response or other diagnostic is important, noting that facility stockout reporting can be useful in multiple types of assessments but alone does not take the place of other forms of reporting;
- Harmonization on units of measure will be needed to make data sharing practical and useful;
- Situational definitions, including durations ranging from temporary, long-term, and permanent will be needed;
- API or final product recalls and shortages caused by problems with quality;
- Markets are regional and global, implying that reporting of shortages and stockouts needs to involve sharing of information and harmonization of reporting;
- Quality of information will also require guidance on what, when and who should report on shortages and stockouts of medicines and vaccines, and to whom these should be reported.

Conclusions

The participants drafted definitions that will be used by the WHO secretariat to advance the work in this area. Responsible reporting, transparency, patient centred-approaches and the need for context-adapted definitions were among key points discussed and agreed. While definitions should be clear and sufficiently simple to implement, the context is often complex and definitions will need to also consider this. Where definitions already exist, there may be challenges in adapting to a new set of definitions. Definitions should also retain some level of correlation to the root cause of the shortage or stockout. An additional consultation is anticipated in 2017 to further this work.

Agenda
Expert consultation on definitions of Global Stockouts and Shortages
Pre-meeting of the Interagency Supply Chain Group (ISG)
Quarterly Meeting, October 6-7, 2016
World Food Programme, Rome, Italy

Draft Meeting Objectives

- Review definitions identified in a systematic review of definitions used in medicines supply chains and other relevant sectors
- Develop consensus responses and recommendations based on the systematic review

Wednesday, October 5 – 10:30 a.m. – 5:00 p.m.		
10 am	Introduction and Welcome	
10:30am	Administration process of expert consultations	WHO
11:00am	Review of the WHA69.25 resolution on Addressing the global shortage of medicines and vaccines and the purpose of a commonly shared definition http://apps.who.int/medicinedocs/documents/s22423en/s22423en.pdf http://apps.who.int/medicinedocs/en/d/Js22423en/	WHO
11:30am	Approach used to systematically identify definitions of medicines stockouts and shortages	TBD
12:00	Lunch	
1:00pm	Review of consolidated definitions based on the systematic review	TBD
1:30pm	Feedback from experts	ALL
3:00pm	Break	
3:30pm	Final review of proposed change and schedule for finalization of the definitions	WHO

List of participants

1. Jessica Burry – MSF
2. Patrick Costello – EMA
3. Lindabeth Doby – USAID
4. Bashier Enoos – PFSCM
5. Gilles Forte – WHO
6. Lisa Hedman – WHO
7. Hitesh Hurkchand – RMNCH SCT
8. Swathi Iyengar – WHO
9. Andrew Jackson - WFP
10. Sue King – GSK
11. Sophie Laroche – WHO
12. Sophie Logez – GFTAM
13. Ishmael Muchemenyi – PFSCM
14. Anban Pillay – NDOH SA
15. Brenda Waning – GDF

Annex 1, Compiled list of definitions

Definition	Category	Country/ Source	Variable 1: Time	Variable 2: Classification Typology	Variable 3: Alternatives	Variable 4: Patient
A drug is unavailable when enterprises which are responsible for the marketing of the drug are unable to deliver that drug for an uninterrupted period of four days to the community pharmacies, hospital pharmacies, or wholesalers in Belgium.	Manufacturing/ Production/Supply AND Facility/Demand	Belgium Law/Legislation	4days			
Holders of the market authorization should notify the Belgian FAMHP when a drug will be unavailable for a time period longer than 14 days.	Manufacturing/ Production/Supply	Belgian FAMHP	more than 14days			
The (temporally) not or inadequate supply of a registered pharmaceutical.	Manufacturing/ Production/Supply	Netherlands - Government Org				
All supply problems of drugs are reported if it is expected that the drug will be undeliverable for a time period longer than 14 days.	Manufacturing/ Production/Supply	Netherlands - Farmanco	more than 14days			

Definition	Category	Country/ Source	Variable 1: Time	Variable 2: Classification Typology	Variable 3: Alternatives	Variable 4: Patient
Undeliverable for a time period longer than 14 days.	Manufacturing/ Production/Supply	EMA - Government Org	more than 14days			
A situation in which the total supply of all clinical interchangeable versions of a FDA regulated drug is inadequate to meet the current or projected demand at the patient level .	Manufacturing/ Production/Supply	USA - FDA				X
A situation in which the total supply of all clinically interchangeable versions of an FDA-regulated medicine is inadequate to meet the current or projected demand at the user level .	Manufacturing/ Production/Supply	USA - FDA				X
Drug shortage is “a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug” .	Manufacturing/ Production/Supply	USA - FDA				
A drug shortage is a situation when a manufacturer or importer of a drug cannot meet actual or projected demand. Drug shortages can include temporary disruptions or permanent discontinuances in the production and supply of a drug.	Manufacturing/ Production/Supply	Canada Health				

Definition	Category	Country/ Source	Variable 1: Time	Variable 2: Classification Typology	Variable 3: Alternatives	Variable 4: Patient
As soon as a market authorization holder knows that it will take longer than 20 days to supply a drug to meet expected patient volumes on an ongoing basis, they will report this as a shortage on the communications platform. It is understood that the inability of a patient to receive their prescribed medicines at the first attempt to fill a prescription may not constitute a drug being in 'shortage,' as the drug may be available in other pharmacies or within the wholesale or distribution network (i.e., pharmacy supply chain), usually within a few days.	Manufacturing/ Production/Supply	Canadian Drug Shortage Databank	20days			x
A medicine shortage occurs when the supply of a medicine is not likely to meet the normal or projected consumer demand for the medicine within Australia for a period of time.	Manufacturing/ Production/Supply	Australia - Health	X			
When a medicinal product is not available or commercially unavailable all over the country and the market authorization holder does not assure appropriate and continued supply to meet the patients' needs.	Manufacturing/ Production/Supply	Italy - AIFA				X

Definition	Category	Country/ Source	Variable 1: Time	Variable 2: Classification Typology	Variable 3: Alternatives	Variable 4: Patient
Supply disruption may be due in particular to a shortage or a disruption in the supply chain: stock-out is defined as the inability to manufacture or use a drug; breaking in the drug distribution chain is defined as the non-supply of a pharmacy or a pharmacy for internal use in the absence of out of stock. The supply disruptions can have detrimental consequences for the patient, especially when they concern known of high therapeutic value medicines (MITM) .	Manufacturing/ Production/Supply	France				X
According to art 23a of the Directive 2001/83/EC the MA-holder shall notify the competent authority if the product ceases to be placed on the market of the Member State. Such notification shall, otherwise than in exceptional circumstances, be made no less than 2 months before the interruption/withdrawal either temporarily or permanently.	Manufacturing/ Production/Supply	Norway - Statens Legemideel verk	No Less than 2months			

Definition	Category	Country/ Source	Variable 1: Time	Variable 2: Classification Typology	Variable 3: Alternatives	Variable 4: Patient
Articles 23a and 81 of Directive 2001/83/EC (as amended) relate directly to the supply of medicines, and require marketing authorization holders – within the limits of their responsibilities – to maintain appropriate and continued supplies of their products, and to notify the Licensing Authority if a product is not going to be available, either temporarily or permanently. The legislation requires two months’ notice in all but exceptional circumstances. In addition to this requirement, companies should ensure that the Department of Health is notified as soon as possible of any potential shortages that are likely to have an impact on patient care.	Manufacturing/ Production/Supply	European Medicines Legislation	no less than 2months			X
Shortage is deemed to occur when a company at issue is unable to respond to any delivery requests.	Facility/Demand	Belgium	96hrs 4days			
We talk about drug supply disruption when a community pharmacy or a pharmacy for internal use (PUI) is unable to deliver a drug to a patient within 72 hours *. * Decree 28 / 09/2012. (A supply disruption is the inability for a dispensary pharmacy or internal use pharmacy dispensing a drug to a patient within 72 h or within a shorter time depending on the compatibility problems with the continued treatment of the patient.).	Facility/Demand	France - Law/Legislation	72hrs 3days			x

Definition	Category	Country/ Source	Variable 1: Time	Variable 2: Classification Typology	Variable 3: Alternatives	Variable 4: Patient
Stock-out is defined as “the inability for a pharmacy to deliver a drug to a patient within a delay of 72 hr”.	Facility/Demand	France	72hrs 3days			x
A shortage is construed as the inability of a pharmacy to dispense a medicine to a patient.	Facility/Demand	France	72hrs	If non-essential and alternatives available - then its not stockout		X
A disruption in supply of medicines, affecting the patient’s ability to access the required treatment within the appointed time-frame.	Facility/Demand	Europe	X			X
A situation in which the total supply of an approved (by an appropriate Health Authority) medicine is inadequate to meet the current projections or projected demand at the user level.	Facility/Demand	The International Society for Pharmaceutical Engineering				X
A potential drug shortage is defined as: the occurrence of internal or external situations (single or in a combination of both), which result in an interruption of supplies of a medicinal product, if not properly addressed and controlled.	Facility/Demand	European Federation of Pharmaceutical Industries and Associations				

Definition	Category	Country/ Source	Variable 1: Time	Variable 2: Classification Typology	Variable 3: Alternatives	Variable 4: Patient
Considers a drug shortage “when products used to prevent or treat serious or life threatening diseases or medical conditions for which no alternative product or drug exists.	Facility/Demand	FDA - urology editorial			X	
A drug shortage as “a supply issue that affects how the pharmacy prepares or dispenses a medicine product or influences patient care when prescribers must use an alternative agent”.	Facility/Demand	ASHP - American Society Health systems Pharmacists			X	X
Defines pharmaceutical shortage as a supply issue that affects how the pharmacy prepares or dispenses a drug product or how patient care is influenced when prescribers must use alternative products.	Facility/Demand	ASHP - American Society Health systems Pharmacists			X	X
ASHP operational definition of drug shortage includes situations where no product is available, most suppliers are out of product, or where ASHP received multiple reports for a shortage.	Facility/Demand	ASHP - operational definition				
Health care professionals define a drug shortage as a change in the drug supply that has the potential to compromise patient care. Changes in drug supply can alter the way medications are prepared in the pharmacy, the way they are administered to patients, and, in some cases, whether patients receive medications at all. When faced with a drug shortage,	Facility/Demand	ASHP - Healthcare Professionals			X	X

Definition	Category	Country/ Source	Variable 1: Time	Variable 2: Classification Typology	Variable 3: Alternatives	Variable 4: Patient
the ultimate goal is to avoid the situation in which the patient is told that the drug of choice is not available due to a shortage.						
A drug shortage happens when demand exceeds supply (that is, when a drug manufacturer or distributor cannot supply enough of a drug to fill prescriptions).	Facility/Demand	British Columbia				
An expectation that, under normal circumstances, pharmacies should receive medicines within 24 hours.	Facility/Demand	Pharmaceutical Services Negotiating Committee -UK				
Stockout indicates zero usable stock of the offered product or method at the location being assessed. (Usable stock refers to stock that is not expired or damaged.)	Facility/Demand	Reproductive Health Supplies Coalition (Relation to an indicator)				
The Universal Stockout Indicator is the percentage of facilities stocked out, by family planning product or method offered, on the day of the assessment (reporting day or day of visit). This point-in time stockout indicator is foundational. It is arguably the most reliable, feasible and easily understood	Facility/Demand	Reproductive Health Supplies Coalition/Take Stock/No empty Shelves				

Definition	Category	Country/ Source	Variable 1: Time	Variable 2: Classification Typology	Variable 3: Alternatives	Variable 4: Patient
Medicine shortages is defined as " a crisis situation caused by the inability of any Market Authorization Holder (MAH) to supply a medicine with a specific API to a market over an extended period of time resulting in the unavailability of this medication for patients".	Manufacturing/ Production/Supply AND Facility/Demand	European Federation of Pharmaceutical Industries and Associations	X			X
Drugs for which unavailability cause a risk for public health and have no therapeutic alternative.	Facility/Demand	ANSM (ANSM, 2014) - National Agency of the drug safety and health products			X	
A medicine shortage can be defined a drug supply issue requiring a change. It impacts patient care and requires the use of an alternative agent.	Facility/Demand	FIP			X	X
A situation in which the total supply of an authorized medicine or of a medicine used on a compassionate basis is inadequate to meet the current or projected demand at the patient level. The shortage may be local, national, European or international.	Facility/Demand	Common position paper (Charnay- Sonneketal.,2013)				X
Drug shortage as every delay in monthly drug supply.	Facility/Demand	Dragic, 2012	1 month			
A drug supply issue requiring a change that impacts patient care and requires the use of an alternative	Facility/Demand	Heiskanen et al., 2014			X	X

Definition	Category	Country/ Source	Variable 1: Time	Variable 2: Classification Typology	Variable 3: Alternatives	Variable 4: Patient
agent.						
A shortcoming in the supply of a medicinal product that affects the patient's ability to access the required treatment in due time.	Facility/Demand	Pauwels et al., 2015	X			X
A drug shortage can be defined as a shortcoming in the supply of a medicinal product that affects the patient's ability to access the required treatment in due time.	Facility/Demand	European Drug Shortages: A Survey of Hospital Pharmacists	X			X
A shortage occurs when a product is not commercially available in a sufficient quantity to meet the demand.	Facility/Demand	Mitigating the impact of drug shortages for a healthcare facility - EU Article				
Defined as an insufficient supply of drugs, result in changes in drug preparation methods by the pharmacy and/or the need to select a therapeutic alternative.	Facility/Demand	Clinical Management Strategies and Implications for Parenteral Nutrition Drug Shortages in Adult Patients			X	

Definition	Category	Country/ Source	Variable 1: Time	Variable 2: Classification Typology	Variable 3: Alternatives	Variable 4: Patient
Drug shortages can be defined as a shortcoming in the supply of a medicinal product which makes it impossible for suppliers to meet the demand for the product at patient level.	Facility/Demand	Drug Shortages in European Countries: Attractiveness and Cost Containment				X
Stock-outs occur when there are insufficient HIV drugs and supplies, resulting in interruption to treatment programmes.	Scenario Based/Articles	HIV Latin American article				X
Drug stock-out. Patients were retrospectively considered to be affected by a drug stock-out if: (i) it led to a combination ART (cART) regimen modification, defined as at least one drug substitution, or an discontinuation of at least one month (i.e.= prolonged discontinuation); (ii) the medical record stated that the cART modification or discontinuation had occurred due to a drug stock-out; and (iii) the cART modification or prolonged discontinuation occurred when there was a shortage of one of the patient's drugs, as reported by the study center pharmacy.	Scenario Based/Articles	HIV Ivory Coast Article	X		X	X
Shortage is defined as a fall in the stock level of antiretroviral drugs below the level needed to maintain patients on their monthly refill period.	Scenario Based/Articles	HIV Kinondoni District, Tanzania Article	X			X

Definition	Category	Country/ Source	Variable 1: Time	Variable 2: Classification Typology	Variable 3: Alternatives	Variable 4: Patient
Stock-out is defined as the complete absence of one or more of the antiretroviral drugs that constitute the ART regimens of the HIV/AIDS patients within the period of 12 months immediately preceding the survey.	Scenario Based/Articles	HIV Kinondoni District, Tanzania Article	X (12months preceding the survey)			
Stock-outs, also known as shortages or complete absence of a particular inventory, in public health facilities have become a hallmark in Uganda's health system making the notions of persistent doubt in access to healthcare - uncertainty, and doing more with less - 'improvisation', very pronounced.	Scenario Based/Articles	Northern Uganda Article				
In Uganda medication shortage is such a persistent phenomenon that in the healthcare circles it has been abbreviated as 'stock-out', also known as inadequate availability or complete absence of a particular inventory of supplies in health facilities (Omaswa 2002). While stock-out can refer to an inadequacy of medical supplies, in this paper we have used it to refer to a shortage or complete lack of human immunodeficiency virus (HIV) antiretroviral (ARV) drugs and other medicines (antibiotics, pain killers, and tuberculosis drugs) commonly used to treat opportunistic infections among HIV and acquired immunodeficiency syndrome (AIDS) patients.	Scenario Based/Articles	Northern Uganda Article				X

Definition	Category	Country/ Source	Variable 1: Time	Variable 2: Classification Typology	Variable 3: Alternatives	Variable 4: Patient
Drug stockout(s) were defined as the absence or lack of drug(s) at the health facility pharmacy store at the time of filling the prescription.	Scenario Based/Articles	Kenya - Diabetes - General Hospital				X
An inadequate supply of a drug alters how the pharmacy prepares or dispenses a drug product, and/or it can more directly affect patient care if an alternate drug must be used because of unavailability of the preferred drug.	Scenario Based/Articles	Drug Shortages in the Perioperative Setting				X
For the purposes of this survey, a stockout was defined as no medicine on the facility shelf. A stockout in the preceding 3 months was an event occurring during the 90 days before the day of the phone call and an ongoing stockout was an event occurring on the day of the phone call.	Scenario Based/Articles	Stop stockouts 2014	X			X
The SSP defines a stockout as the complete absence of a specific formulation and/or dosage of medicine at a given public health facility. The SSP's definition of stockouts includes those when patients are given alternatives or less medicine than intended resulting in patients receiving less optimal regimens, having higher pill burdens, and receiving incomplete or less optimal formulations (medium impact). Patients receiving medications or regimens that are more difficult to take or less well tolerated may incur higher chances of	Scenario Based/Articles	Stop stockouts 2015 (Long Definition - Same Timeline as above)	X	X	X	X

Definition	Category	Country/ Source	Variable 1: Time	Variable 2: Classification Typology	Variable 3: Alternatives	Variable 4: Patient
<p>treatment interruption. Receiving a smaller supply of medication requires patients to make more frequent visits to facilities for refills. The SSP also defines stockouts when patients are switched to a suitable alternative regimen or formulation, or the facility borrowed the medication that was out of stock, and it was given in full supply to the patient (low impact). These stockouts typically result in an acceptable outcome for the patient, but could require a facility to take measures to adjust stock levels of alternative regimens used.</p>						
<p>The WHO has defined a stockout as the complete absence of a required drug at a storage point or delivery point for at least one day. Stockouts are defined as absence of the medicines at health facility level. For those items out of stock, the duration of the stockout in days was determined by consulting the stock cards. Stockouts are defined as the absence of the medicines at health facility level.</p>	Scenario Based/Articles	MSF - Empty Shelves	X			

Definition	Category	Country/ Source	Variable 1: Time	Variable 2: Classification Typology	Variable 3: Alternatives	Variable 4: Patient
defined as occurring when the stock level is zero, or when the stock level reaches a certain minimum level (e.g., available remaining stock is expected to be sufficient for only three days projected consumption). Whether stockouts are assessed by a single product brand, product type (e.g., combined oral contraceptive), overall method (e.g., oral contraceptive), or across multiple products or methods	Scenario Based/Articles	Harmonizing Family Planning Stockout Indicators Project				
A stock-out is defined as the complete absence of a required ARV drug at a delivery point for at least one day. Health facilities include public and private facilities, health centres and clinics (including TB centres), as well as health facilities that are run by faith-based or nongovernmental organizations.	Scenario Based/Articles	Core Indicators for National AIDS programmes	1day			
The primary indicator of interest from this data source is "Percentage of facilities stocked out of SP", defined as having a zero closing balance of the product.	Scenario Based/Articles	Antimalarial Drugs -USAID Deliver - Malawi				