





Early-warning indicators to prevent stock-outs and overstocking of antiretroviral, antituberculosis and antimalaria medicines

















USAID DELIVER PROJECT









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#### WHO Library Cataloguing-in-Publication Data

Harmonized monitoring and evaluation indicators for procurement and supply management systems: early-warning indicators to prevent stock-outs and overstocking of antiretroviral, antituberculosis and antimalaria medicines.

"This document was prepared with the active involvement of many national and international institutions over the past 3 years." – Acknowledgements.

1.Anti-retroviral agents – supply and distribution. 2.Antitubercular agents – supply and distribution. 3.Antimalarials – supply and distribution. 4.Indicators. 5.Program evaluation. I.World Health Organization.

ISBN 978 92 4 150081 4

(NLM classification: QV 250)

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#### Designed by minimum graphics

Printed by the WHO Document Production Services, Geneva, Switzerland

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## Acknowledgements

This document was prepared with the active involvement of many national and international institutions over the past 3 years. We are grateful to the following participants of the WHO consultation on harmonization of monitoring and evaluation requirements for procurement and supply management systems for antiretroviral agents, held in Geneva, 10-11 October 2005: Hélène Degui and Alassane Ba (Centrale médico-humanitaire pharmaceutique, France), Luca Li Bassi and Steen Stottrup (Global Fund to Fight AIDS, Tuberculosis and Malaria), Xenophon Santas (United States President's Emergency Plan for AIDS Relief, Office of the Global AIDS Coordinator), Henk W.A. den Besten and Charles Chiedza Maponga (i+solutions, The Netherlands), Yasmin Chandani (John Snow Inc, USA), Douglas Keene (Management Sciences for Health, Rational Pharmaceutical Management Plus, USA), Bechir N'Daw (UNAIDS), Helene Moller (UNICEF), Bert Voetberg (World Bank), Wilbert Bannenberg (Consultant), Andrew Loke (Pharmaniaga Solutions, Malaysia), Ernest Rwagasana (Centrale d'Achat des Médicaments essentiels du Rwanda), Martin Olowo Oteba (Ministry of Health, Uganda), Nguyen Van Kinh (Ministry of Health, Viet Nam), Cao Thi Than Thuy (WHO Office, Viet Nam), Emma Nelson Msuya (National AIDS Control Programme, United Republic of Tanzania), Deus Bazira Mubangizi (Catholic Relief Services) Carole Presern (United Kingdom Mission in Geneva) and the following WHO staff: Teguest Guerma, Jos Perriëns, Mary Couper, George Loth, Amolo Okero, Vincent Habiyambere, Cyril Pervilhac, Helen Tata, Jeff Sinden and Marco Vitoria.

We would also like to thank the participants and facilitators of the i+solutions training workshops held in 2006, 2007 and 2008 on monitoring and evaluation of procurement and supply management systems for antiretroviral agents. They provided valuable input on the selection of the 12 core indicators. The participants and professionals were: Abdulmalik Hassen Ebro, Abiy Andargachew, Akaki Lochoshvili, Akondja Yandja, Albert Ntiringaniza, Alemu Shiferaw Damassa, Aminu Abubakar, Amjad Idries, Angela Taylor, Araia Berhane, Bamikale Feyisetan, Be El Hassan, Carl François, Cees Tuinenburg, Chiedza Maponga, Clarisse Morris, Clement Kouakou, Daniel Taddesse, Doris Tshabalala, Elfatih Elamin, Elina Sverdlova, Eric Nyiligira, Félicienne Trévant, Frederick Nicolaus Rubanga, Galina Bolshakova, Gashaw Shiferaw Mekonnen, Grace Waiharo, Habte Desbele, Hailu Tadeg, Hendro Supaat, Ishaya Dawha, Ivan Makumbi, Ivana Lohar, James Batuka, Jansen Susanna, Jean Claude Lundu Deka, Jean-François Saint-Sauveur, Jennie Lates, Jenny Jasmine, Jurgen Hulst, Karin Wiedenmayer, Kgosiemang Atamelang Sidney, Konan Jules Yao, Laurentiu Ionesii, Lerato Kholokholo, Liliana Caraulan, Loic Aubry, Ludmila Reutskaya, Marthe Everard, Masoko Nts'ekhe, Matebele Sefali, Mehamed Feleke Tessema, Michèle Razanamparany, Mohamed Motwaly, Mulusew Lijalem Belew, Naana Frempong, Nesrane Senbet Sahlemariam, Okumu Morris, Olivia du Moulin, Peter Graaff, Remi Olaitan, Rumen Andreev, Seyoum Temenit, Sharmini Khalikaprasad, Sookdeo Singh, Sushil Kumar Koirala, Tantely Rakotomalala, Tesfaselase Ghedel, Thomas Wushe, Tifenn Humbert, Vincent Habiyambere, Viviane Leu, Vladislav Volchkov, Yakubu Adamu and Yohannes Tsegay Berhe.

The members of the John Snow, Inc., Management Sciences for Health, Supply Chain Management System working group were: Dana Aronovich, Timothy Williams, Yasmin

Chandani, Youssouf Ouedraogo, Naomi Printz (John Snow, Inc.), Bannet Ndyanabangi, Helena Walkowiak, Laila Akhlaghi, Sameh Saleeb (Management Sciences for Health) and Gary Bettger, Jennifer Mboyane, Niall Shanbhag and Sarah Levine (Supply Chain Management System).

The following people, during adaptation of the French version, improved both the English and the French versions: Carinne Bruneton and Charles Rambert (Réseau Médicaments et Développment, France) and Caroline Damour (Groupement d'intérêt public Ensemble pour une Solidarité thérapeutique hospitalière en Réseau, France).

The following people used the preliminary procurement and supply management monitoring indicators in a survey of supply systems in sub-Saharan Africa in 2009: Eric Mercier (UNICEF), Jean-Marc Guimier (UNICEF Consultant), Tifenn Humbert (UNICEF), Caroline Damour (Ensemble pour une Solidarité thérapeutique hospitalière en Réseau), Magali Babaley (WHO), Helen Tata (WHO), Gilles Forte (WHO), Thomas Lapnet (WHO) and Desta Abaney (WHO).

We thank Volker Welter (UNDP), Guy Rino Meyers (UNDP), Jacqueline Pontré (UNDP), Helena Walkowiak (Management Sciences for Health, Strengthening Pharmaceutical Systems) and other people who contributed to various training procurement and supply management workshops and annual meetings of the partners of the AIDS Medicines and Diagnostics Service.

We are grateful for guidance received from Daisy Carandang (WHO), Dennis Ross-Degnan (Boston University, USA), Cyril Pervilhac (WHO), Yves Souteyrand (WHO), Chika Hayashi (WHO), Dongbao Yu (WHO), Boniface Dongmo Nguimfack (WHO), Jean-Michel Tassié (WHO) and several other people with expertise in the area, including Camellia Falcon, Loïc Aubry, Phillip Savio and Priya Emmart.

The following people made important contributions during field testing: Moussa Kabore (Burkina Faso), Rema Alphonse Ramdé (Burkina Faso), Nizigama Deogratias (Burundi), Albert Ntiringaniza (Burundi), Christophe Tchangou (Cameroon), Anne Tchiengang (Cameroon), Adou Kouakou Menzan (Côte d'Ivoire), Koné Fétégué (Côte d'Ivoire), Abdoulaye Tangaly Diallo (Guinea), Amadou Sadio Diallo (Guinea), Timóteo Moiouchene Jeremias (Mozambique), Obua Thomas Ocwa (Uganda), Anthony Ddamba (Uganda), Majaliwa Malasa Mtoroki (United Republic of Tanzania), Jerome Ngowi (United Republic of Tanzania), Forward Mudzimu (Zimbabwe), Misheck Ndlovu (Zimbabwe), Clarisse Morris (i+solutions, Netherlands), Vincent Habiyambere (WHO), Thomas Lapnet-Moustapha (WHO), Ouedraogo Karidja (WHO), Rochigneux Christophe (WHO) and Sillah Jackson (WHO).

We are grateful to the following people, who thoroughly reviewed the final version and made significant contributions to refining this manual: Silvia Bertagnolio (WHO), Megan Towle (Columbia University, USA), Ashley Smith (United States Agency for International Development Deliver Project), Carmit Keddem (United States Agency for International Development Deliver Project), Sarah Melendez (United States Agency for International Development Deliver Project), Dana Aronovich (United States Agency for International Development Deliver Project), Dana Aronovich (United States Agency for International Development Deliver Project), Ahmet Afsar (UNICEF), Ian Pett (UNICEF), Eric Mercier (UNICEF), Kaisamaija Valimaki-Erk (UNICEF), Paulo Meireles (UNITAID), Raquel Child (UNITAID), David Jamieson (United States President's Emergency Plan for AIDS Relief, Supply Chain Management System), Andrea de Lucia (Global Drug Facility, Stop TB Partnership), Thierry Cordier-Lassalle (Global Drug Facility, Stop TB Partnership), Thierry Cordier-Lassalle (Global Drug Facility, Stop TB Partnership), Thierry Cordier-Lassalle (Global Drug Facility, Stop TB Partnership), Caroline Bogren (Global Fund), Mariatou Tala Jallow (Global Fund), Marlon Banda (Global Fund), Luca Li Bassi (Global Fund), Serge Xueref (Global Fund), Clarisse Morris (i+solutions, Netherlands), Helena Walkowiak (Management Sciences for Health, Strengthening Phar-

maceutical Systems), Sameh Saleeb (Management Sciences for Health, Strengthening Pharmaceutical Systems), Douglas Keene (Management Sciences for Health, Strengthening Pharmaceutical Systems), Volker Welter (UNDP), Guy Rino Myers (UNDP), Jacqueline Pontré (UNDP), Jan van Erps (Roll Back Malaria), François Jouberton (Roll Back Malaria), Rima Shretta (Management Sciences for Health, Center for Pharmaceutical Management), Karl-Lorenz Dehne (UNAIDS), Gilles Forte (WHO), Christophe Rochigneux (WHO), Loic Aubry (WHO), Thomas Lapnet-Moustapha (WHO), Françoise Renaud-Thery (WHO), Boniface Dongmo Nguimfack (WHO) and Yves Souteyrand (WHO).

This document was written by Henk den Besten, Cees Tuinenburg, Michèle Razanamparany, Rino Meyers, Clarisse Morris, Jos Perriens, Peter Graaff and Vincent Habiyambere. The first version was tested in a pilot study, resulting in the 12 core indicators for monitoring national procurement and supply management systems and the identification of six earlywarning indicators to prevent stock-outs and overstocking of antiretroviral, tuberculosis and malaria medicines. It was thoroughly reviewed within the United States Agency for International Development Deliver project and all the institutions listed in the previous paragraph above, to which we extend our thanks.

Tracking key aspects of procurement and supply management (PSM) and taking the necessary corrective actions result in continuous improvement of the system's effectiveness. This document presents 12 core indicators for monitoring and evaluating PSM at national level. Six of the 12 indicators are defined as early-warning indicators<sup>1</sup> of stock-outs and overstocking of medicines, which, in this document, are antiretroviral agents (ARVs) and medicines to treat tuberculosis and malaria.<sup>2</sup> This manual is recommended for use in tracking the performance of national PSM systems and for preventing frequent stock-outs and overstocking, for regular use and interpretation of early-warning indicators in PSM. The indicators will also alert managers to areas in which technical support is required to strengthen the national PSM system. The manual will be disseminated to procurement and supply management managers for wider use and will be updated on the basis of experience gained from users.

Monitoring and evaluation are used to assess a system's strengths and weaknesses. Monitoring should cover all components of a PSM system, and monitoring and evaluation should trigger correction of all aspects that do not reach the target. Monitoring can therefore ensure continuous quality assurance of a national PSM system. Implementation of an effective monitoring and evaluation programme requires trained personnel and financial and other resources, which should be well planned.

The rationale for the 12 indicators includes the following:

- The performance of PSM systems must be monitored and evaluated regularly in a timely manner in order for corrective actions to be taken and to control quality.
- Core PSM indicators are needed that are relevant for all national drug programmes, donors and institutions. Harmonized indicators will highlight the most critical problems, avoid duplication of effort and complement monitoring and evaluation by multiple stakeholders. The 12 core indicators presented are common to all aspects of national PSM systems and are not specific to a donor or country programme. They are common to the multiple bodies within a country that are responsible for contributing data (e.g. partners and stakeholders involved in the national PSM system, ministries of health, the national AIDS programme and principal recipients).
- Valuable information about PSM systems is routinely collected and stored but is often not used to analyse a system's performance. The 12 indicators seek to make use of this information without an additional burden on already overwhelmed human resources.

Therefore, the aims of these indicators are to:

 provide information about the factors associated with stock-outs and overstocking (e.g. lead time, insufficient quantities procured);

<sup>&</sup>lt;sup>1</sup> In this document and the accompanying materials, early-warning indicators are identified with a red star (\*).

<sup>&</sup>lt;sup>2</sup> While the core indicators focus on antiretroviral agents and medicines for tuberculosis and malaria, we consider that they can be adapted to monitor other essential medicines and medical commodities.

- analyse routinely collected data to determine what is required to prevent stock-outs or overstocking;
- provide timely evidence to prevent stock-outs or overstocking and to measure the performance of national PSM systems (e.g. countries with positive results); and
- provide opportunities for:
  - enhancing collaboration among different levels in the national distribution system and among relevant sectors and stakeholders working in national programmes to supply ARVs and tuberculosis and malaria medicines;
  - strengthening data quality assurance and regular data reporting; Data on consumption and stocks should be analysed for real-time decision-making and further discussed in regular meetings with care providers and data managers; and
  - enhancing information-sharing and fostering partnerships among the various procurement stakeholders to achieve greater efficiency, problem-solving and synergy and thus improve the performance of national PSM systems.

## 2. Monitoring and evaluation

In order to guide the reader in the full use of the core indicators, it is useful to clarify the difference between monitoring and evaluation.

**Monitoring** is routine, timely tracking of the performance of continuous record-keeping, reporting or surveillance systems. Effective, frequent monitoring helps managers to make decisions in a timely manner. For example, the six earlywarning indicators presented in this document can help prevent stock-outs and overstocking if used in real time and not retrospectively.

**Evaluation** is episodic assessment of progress towards a programme's targets. The purpose of indicators is to establish whether a programme's inputs result in the desired outputs and outcomes (Figure 1). Evaluation helps managers to determine the added value of investments in the programme. Monitoring indicators often show the areas that require in-depth evaluation; evaluation is conducted at longer intervals and requires significant investment in a rigorous method.

#### Figure 1. Impact framework

**INPUTS** are the resources (e.g. money, staff, time, equipment) required to achieve results.

**PROCESSES** are the activities (e.g. training, supervision) of a programme with these resources.

**OUTPUTS** are the direct results of the programme (e.g. numbers of staff trained, supervision visits, increased number of treatment sites).

**OUTCOMES** are the programme's direct positive effects, as a result of outputs, such as behaviour change (e.g. appropriate prescribing, no stock-outs, no loss of medicines) that would ultimately have longterm effects on disease.

**IMPACTS** are long-term changes in a disease profile, such as a reduction in mortality, incidence of HIV infection, incidence of opportunistic infections or improved quality of life.

As a combined effort, monitoring and evaluation are used to evaluate programmes and results regularly, to determine whether progress is being made towards the targets and defined objectives. When monitoring and evaluation show that the programme is not meeting the targets, actions must be initiated to prevent or correct problems.

Thus, timely monitoring and evaluation can bring about rapid improvements in the quality of a PSM system. They also ensure regular reporting, accountability and transparency. Monitoring and evaluation are also used to inform donors, partners and beneficiaries about a programme's effectiveness and efficiency. Information on indicators is reported from operational to central levels, to donors or partners and back to operational levels.

Donors require information to justify how funds were spent and what targets were met. Usually, donors fund programmes with specific objectives, and measurement of performance requires a certain set of monitoring and evaluation indicators. National programmes might have to measure different indicators for different donors; this document presents harmonized indicators in an effort to minimize this burden. Other important considerations in planning monitoring and evaluation of PSM programmes include:

- the need for trained human resources and planned finances for effective monitoring and evaluation, which must be included in all public health programmes and be well budgeted;
- consistent, harmonious data indicators for reporting from operational to central levels and across programmes, to allow measurement of trends over time and across programmes, regions or countries for the purpose of making comparisons; and
- collection of monitoring indicators that are critical to decision-making by implementers and managers and not information that provides no added value for decisionmaking, thus saving scarce financial and human resources.

This document presents 12 core indicators for routine monitoring of the performance of national PSM systems, including early-warning indicators (designated with a red star\*) to prevent stock-outs and overstocking. The indicators are based on information that is collected routinely but is often stored and not used for monitoring in some countries. Facilities were not contacted to provide information, as only routinely reported data were used. The core indicators cover all components of the medicine supply cycle (Figure 2).

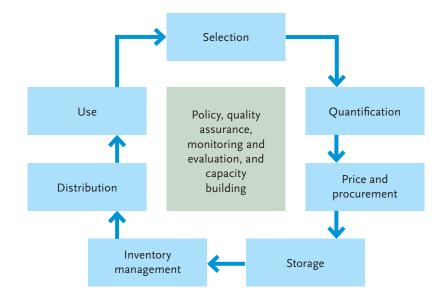


Figure 2. Procurement and supply management cycle

In 2004, at the request of national PSM managers participating in joint WHO–Global Fund PSM workshops, the AIDS Medicines and Diagnostics Partner Network and the AIDS Medicines and Diagnostics Service in the WHO HIV department concluded that donors providing funding for HIV/AIDS programmes should harmonize their requirements for reporting by countries, in order to increase the transparency, productivity and efficiency of programmes. The process by which indicators for reporting requirements were developed is described below.

#### **Desk review**

A desk review was conducted on reporting requirements, including monitoring and evaluation indicators for ARV PSM. The results were discussed at a meeting<sup>1</sup> on harmonizing indicators, and participants submitted indicators of components of PSM for further review.

#### **Compiling core indicators**

After the meeting, a working group<sup>2</sup> produced an initial list of 50 indicators that could be used for both continuous programme tracking and donor reporting. Guided by feedback at two monitoring and evaluation training workshops,<sup>3</sup> WHO finalized a list of 12 core indicators and designed an Excel tool and a method for data collection and analysis.

#### **Field-testing**

The indicators were field-tested in nine countries selected by the WHO Regional Office for Africa in collaboration with three inter-country support teams and WHO representatives. The countries were Burkina Faso, Burundi, Cameroon, Côte d'Ivoire, Guinea, Mozambique, Uganda, the United Republic of Tanzania and Zimbabwe. Field-testing was conducted in three phases. A training workshop was held in Harare, Zimbabwe, in November 2009 to review the indicators and the field-testing method to ensure good understanding of data collection and analysis. Participants in their own countries then conducted data collection, analysis and reporting to WHO with a standard reporting format. A workshop was held in Ouagadougou, Burkina Faso, in December 2009 to synthesize the results, validate the indicators and identify early-warning indicators.

<sup>&</sup>lt;sup>1</sup> The participants in the meeting in October 2005 included representatives from central medical stores, ministries of health, WHO regional offices and several international institutions, including the Committee for Medicinal Products for Human Use, the Global Fund, the United States President's Emergency Plan for AIDS Relief, Office of the Global AIDS Coordinator, i+solutions, John Snow, Inc., the United States Agency for International Development Deliver Project, Management Sciences for Health, Rational Pharmaceutical Management Plus, UNAIDS, UNICEF, the World Bank, Pharmaniaga Solutions, Catholic Relief Services and the United Kingdom Mission in Geneva.

<sup>&</sup>lt;sup>2</sup> The working group comprised representatives of John Snow, Inc, Management Sciences for Health and Supply Chain Management System.

<sup>&</sup>lt;sup>3</sup> The draft indicators were discussed during training workshops in June 2006 and March 2007, which were attended by national health staff involved in monitoring and evaluation and PSM for ARVs and tuberculosis and malaria medicines in low- and middle-income countries.

The objectives of field-testing were: to assess the clarity of the core indicators and their relevance for monitoring PSM performance; to assess the availability of the information necessary for the indicators in routine monitoring and evaluation and, if not available, to determine whether it could be collected without a survey; to determine which indicators should be retained for routine monitoring and evaluation of PSM, particularly for ARVs and tuberculosis and malaria medicines; and to identify early-warning indicators to prevent stock-outs and overstocking.

The results of the field test showed that all 12 indicators were relevant for monitoring the performance of national PSM systems, although some required minor amendments. Six indicators were identified that could provide early warnings to prevent stock-outs and overstocking.

The indicators presented in this document will be practical for staff involved in planning, managing, implementing, monitoring and reporting on national PSM systems, and for institutions and donors that wish to monitor the performance of PSM programmes for which they are providing technical or financial support.

It is essential to map and describe the distribution channels of ARVs and tuberculosis and malaria medicines and all the procurement partners and stakeholders in the national supply system. Major stakeholders in the national PSM system, i.e. partner organizations, should be identified, as should the medicines being procured and distributed. This exercise is critical for enhancing efficiency, collaboration and complementary efforts in various PSM areas.

Some partners support the distribution of ARVs and tuberculosis and malaria medicines through both the public and the private sector. In some countries, ARVs are distributed in the private sector in order to expand coverage; malaria medicines (e.g. artemisinin-based combination therapies) are also distributed in the private sector, for example, through the Affordable Medicines Facility for malaria.<sup>1</sup> Therefore, the core PSM indicators should cover, if relevant, both the public and the private sector, including nongovernmental organizations.

<sup>&</sup>lt;sup>1</sup> The Affordable Medicines Facility for malaria (AMFm) is an innovative financing mechanism designed to improve access to the most effective treatment for malaria, artemisinin-based combination therapies (ACTs). It is hosted and managed by the Global Fund, with financial support from UNITAID, the United Kingdom Department for International Development and other donors. Its aim is to enable countries to increase the provision of affordable ACTs through public and private sectors and nongovernmental organizations. This will save lives and reduce the use of less effective treatments, to which malaria parasites are becoming increasingly resistant. It will also reduce the use of artemisinin monotherapy, thereby delaying the onset of resistance to that drug and preserving its effectiveness. To achieve this aim, the Global Fund has negotiated with drug manufacturers to reduce the price of ACTs and to ensure the same sales prices for both public and private first-line buyers. The Global Fund pays most of this reduced price (a 'buyer co-payment') directly to manufacturers to further lower the cost to eligible first-line buyers, who pay only the rest of the sales price. First-line buyers are expected to pass on the highest possible proportion of this price benefit, so that patients can buy ACTs in the public, private, not-for-profit and for-profit sectors at prices that are lower than those of artemisinin monotherapies, chloroquine and sulfadoxine–pyrimethamine.

The purpose of the 12 core indicators described below is to monitor and evaluate the most critical components of the medicine supply chain (see Figure 2). The indicators are summarized in Table 1 and discussed in detail below. Indicators identified as early-warning indicators to prevent stock-outs or overstocking are labelled with a star ( $\star$ ). The others are performance indicators for measuring and monitoring the effectiveness of the PSM system. Some indicators are used for global reporting on universal access (Indicator 12) or used as early-warning indicators of HIV drug resistance (Indicators 2 and 12).

#### 5.1 Product selection

#### **Core indicator 1**

Percentage of medicine items received (procured plus donated) or planned to be received that are in the national standard treatment guidelines

#### What it measures

This indicator measures the extent to which the medicines received (retrospective) or planned to be received (prospective) are in line with those recommended in the national standard treatment guidelines (STG). If the country has no national STG, WHO standard treatment guidelines will be used.

#### Measurement period and frequency

There are two periods of measurement:

- once a year for items received during a defined retroactive period (e.g. 1 January-31 December of the past year); and
- any time for all orders planned or donations expected in the next year or two, depending on procurement cycle and donation commitments.

#### Rationale

It is recommended that professionals overseeing procurement and donations comply with policies such as national STG. The most recent versions of such documents should be available to health facilities, procurement agencies, partners and donors procuring or donating medicines. This indicator is easy to measure. While it may not be relevant in all countries, it highlights critical discrepancies between items received and national policies.

ARVs and tuberculosis and malaria medicines that are not in the national STG are still found in some countries, particularly where procurement activities are not integrated in the national system. This indicator measures products that are both procured and donated, as donations often do not comply with national policies, ignoring interagency guidelines for drug donations.

No.	PSM stage	Core indicator	Use
1	Product selection	Percentage of medicine items <sup>a</sup> received (procured plus donated) or planned to be received that are in the national standard treatment guidelines	To measure whether items received are in line with national standard treatment guidelines (target, 100%)
2	Prescribing and use	(A) Percentage of patients receiving ARVs and tuberculosis treatment in line with national standard treatment guidelines	To measure whether treatments (disaggregated by combination) are in line with national standard treatment guidelines (target, 100%)
		(B) Percentage of patients initiating ARV treatment on regimens in line with first-line treatments in national standard treatment guidelines (early-warning indicator for HIV drug resistance)	
3*	Forecasting	Proportion of quantities of products actually received (procured plus donated) during a defined period out of total quantities planned for the same period	To measure the extent to which the quantities received are consistent with the quantities planned to be received (target, 100%)
4*	Consumption	Percentage of quantities used out of total quantities available for consumption after deduction of buffer stock (opening balance plus quantities procured plus quantities donated minus buffer stock) during a defined period	To measure how much of the quantity available for consumption is actually consumed (target, 100%)
5	Procurement efficiency	Ratio between median price of products procured and the international median reference value	To measure the efficiency of procurement practices by comparing the median national price with the median international price (target, $\leq$ 1)
6*	Supplier performance and port clearance	(A★) Percentage of orders delivered in full and on time (as stated in the procurement agreement) per supplier in a defined period	<ul> <li>(A) To measure supplier's performance in complying with agreed delivery time and delivering all quantities ordered (target, 100%)</li> <li>(B) To measure port clearance performance (target for B1, 100%)</li> </ul>
		(B1★) Percentage of orders to be cleared from port that were cleared before the deadline	
		(B2) Average number of days between arrival at port and date of clearance from port	
7	Quality control	Percentage of product batches tested in past year that met national and international quality control standards	To measure product quality before release for consumption (target, 100%)
8*	Distribution	Percentage of treatment sites that received all orders in full and on time during a defined period	To measure reliability of national distribution system (target, 100%)
9*	Inventory control	Percentage of treatment sites that submitted complete inventory control reports on time, according to an established schedule, during a defined period	To measure regularity of reporting (target, 100%)
10	Loss	Percentage of quantities of each product lost per total quantities available for use (opening stock plus quantities received) in past year	To measure loss of products and causes (e.g. expiry, damage) (target, < 1%)
11*	Minimum stock level and inventory control	Percentage of treatment sites that placed orders during a defined period while the stock in hand of one or more items was below the minimum stock level	To measure effective use of inventory control: ordering to respect the minimum stock level to prevent stock-out (target, 0%)

#### Table 1. Summary of early-warning and performance indicators for procurement and supply management

<sup>a</sup> Antiretroviral agents (ARVs) and medicines against tuberculosis and malaria, unless otherwise specified.

No.	PSM stage	Core indicator	Use
12	Availability	Percentage of treatment sites that had a stock-out of one or more required medicines during a defined period (universal access and early-warning indicator for HIV drug resistance)	To assess the scale of stock-outs in all facilities (target, 0%)
		If target not reached:	
		(A1) Percentage of available items at each treatment site	(A) To assess the availability of products (target, 100%)
		(A2) Average percentage of items available at all treatment sites	
		(B) Percentage of treatment sites that had stock-out of a particular product during a defined period	(B) To measure stock-out per product (target, 0%)
		(C1) Average duration of stock-outs at each treatment site during a defined period	(C) To assess duration of stock-out (target, 0 days)
		(C2) Average duration of stock-outs at all treatment sites during a defined period (early-warning indicator for HIV drug resistance)	

### Table 1. Summary of early-warning and performance indicators for procurement and supply management (continued)

Treatment guidelines should be updated regularly, as new, more effective, safer medicines are developed and resistance and severe side-effects are found. WHO updates treatment guidelines regularly – every 2 years for ARVs. It is important that national programmes refer to updated WHO guidelines when revising their national STG in order to guarantee the best possible treatment. In addition, procurement is more efficient if programmes focus on obtaining sufficient quantities of nationally recommended items.

#### Data collection

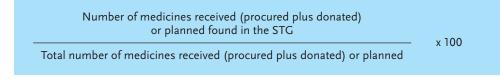
Measuring this indicator will require:

- the most recent national STG (or WHO STG if no national STG), to determine the recommended ARVs and tuberculosis and malaria medicines,
- a list of ARVs and tuberculosis and malaria medicines received by procurement or donation in the past year (period to be defined) and
- a list of items planned for receipt, including procurement orders prepared or placed and expected donations.

#### Data source

All this information is collected centrally, at the level at which procurement and donations of medicines are managed. The STG should be available to all procurement agencies, all partners and donors procuring or donating medicines and all treatment sites.

#### Calculation



#### Target

100%

#### Analysis

If the target is not reached, the reasons should be sought and corrective action taken. If some medicines planned for receipt are not in the STG, the immediate corrective action should be to revise planned procurement orders or anticipated donations.

If the drugs received are not consistent with national STG, the questions to be answered are:

- Are updated national STG for ARVs (tuberculosis and malaria medicines) available to all procurement agencies, procurement partners, donors and health facilities? These must be available and reinforced at all levels to ensure that ordering is in line with national policies.
- If the national STG have been updated, is the list of essential medicines synchronized with the latest STG? This list must be updated regularly and synchronized with the STG to ensure that the ARVs, tuberculosis and malaria medicines recommended in the STG are considered to be essential medicines, which are tax-free in several countries.

#### 5.2 Prescription and rational use

#### **Core indicator 2**

- 2A Percentage of patients receiving ARVs and tuberculosis treatment in line with national standard treatment guidelines
- 2B Percentage of patients initiating ARV treatment on regimens in line with first-line treatments in national standard treatment guidelines (early-warning indicator for HIV drug resistance)

#### What it measures

This indicator measures: (2A) the extent to which patients receive treatment regimens that are in line with the STG and (2B) the extent to which patients initiating ARV treatment are receiving first-line ARV regimens. If patients initiating ART start with second-line ARV regimens, further investigation is needed (e.g. irrational use, signs of drug resistance or a subtype of HIV that is naturally resistant to first-line ARV treatment, like HIV-2). This indicator is limited to HIV and tuberculosis programmes,<sup>1</sup> so that the quantities requested and used by treatment sites can be routinely reviewed.

<sup>&</sup>lt;sup>1</sup> Malaria is not included in this indicator, because, unlike for HIV infection and tuberculosis, no records (e.g. treatment patient cards) are available that provide information on the number of patients by treatment regimen. Malaria experts present at indicator field tests and review meetings reported that they conduct annual surveys of health facilities and households to assess current trends in patient treatment. Problems like malaria monotherapy, for example, are assessed by these means. In malaria programmes, requisitions are based on average monthly consumption, with the addition of quantities for security stocks. For example, in Guinea, health facilities are provisioned every 6 months: (average monthly consumption x 6 months) + 2 months x average monthly consumption.

#### Measurement period and frequency

Both indicators are measured every time a report is submitted as a cross-sectional snapshot of the previous month or previous quarter.<sup>1</sup>

#### Rationale

Use of medicines must be in line with the national STG, as noncompliance with the STG can result in:

- possible development of drug resistance, with the consequence of shifting procurement to more expensive ARVs; and
- irrational use, such as using the wrong quantity of an ARV or unjustified use of secondline treatment, which can distort planning and supply, increasing the risk for stockouts if consumption is disconnected from the quantities received and increasing the average cost of medicines.

#### Data collection

The tools required for data collection include the national STG (or WHO STG if there are no national STG) and requisition forms. When health facilities place orders for ARVs or tuberculosis medicines with central medical stores, the requisition forms should include the total number of patients by treatment regimen. This information is included for quantification and procurement purposes and makes it possible to measure the most commonly used ARV treatment combinations and tuberculosis treatment regimens. In some countries, the number of patients on the waiting list for ARV treatment is also reported in order to demonstrate the unmet demand.<sup>2</sup>

#### Data source

This information is collected centrally, where the requisition forms are submitted at district or health facility level.

From the information on the requisition forms, both indicators should be disaggregated by regimen:

- Indicator 2A should be disaggregated by gender and by treatment regimen to determine which treatment combinations have been used and the most commonly used treatment combination.
- Indicator 2B should be disaggregated by gender and by treatment regimen to determine which first-line ARV treatment combinations have been used and the first-line combination most commonly used in patients initiating treatment.

#### 2A. Calculation, target and analysis (cross-sectional assessment)

Number of patients on treatment regimens which are in line with national STG	x 100
Total number of patients on treatment	X 100

<sup>&</sup>lt;sup>1</sup> For example, if the indicator is calculated in mid-April 2011, the data for the previous month will be for 1–31 March 2011 and those for the previous quarter for 1 January–31 March 2011.

<sup>&</sup>lt;sup>2</sup> 'Demand' is represented by real data, whereas 'estimated need' is an estimate, which may not be reached in several countries in which the number of people tested for HIV is still low.

#### Target

100%

If the target is not met, some patients are on ARV or tuberculosis treatment regimens that are not approved in the STG. The corrective action to be taken is to examine which treatments (disaggregated) are being used and why they are being used, including whether the most recent STG are accessible in health facilities and whether care providers are trained in their use.

#### 2B. Calculation, target and analysis (cross-sectional assessment)

Number of patients initiating ARV treatment in line with first-line regimens in STG	— x 100
Total number of patients initiating ARV treatment	

#### Target

100%

If the target is not met, some patients are being initiated on ARV treatment regimens that are not approved as first-line treatment in the STG. The corrective action that should be taken is to examine which treatments (disaggregated) are being used and why they are being used, including whether the most recent STG are accessible in health facilities and whether care providers are trained in their use.

#### Additional indicators for prescription and rational use

Additional indicators can be used to examine rational medicine use. The first relates to prescription:

*Indicator:* Percentage of prescriptions for ARV (and tuberculosis medicines) that were dispensed in full at health facility level in the past 12 months

- Target: 100% of prescriptions dispensed in full.
- Measures: extent to which prescriptions for ARVs (and tuberculosis medicines) are dispensed in full. As all prescriptions should be dispensed in full, the target is 100%.
- Collection: A survey is required to collect data for this indicator, to investigate the reasons and to disaggregate the results into groups according to reason; the most frequent reason in developing countries is stock-out.
- Source: A survey in a health facility, involving dispensing staff, is the best way to collect such information. Otherwise, this indicator is difficult to measure, as the information required is not always available and is difficult to collect. There are many reasons for not filling a prescription.
- Rationale: If a prescription is not dispensed in full, adherence to treatment is affected and drug resistance may occur.

The second additional indicator is for adherence to treatment:

*Indicator:* Proportion of patients who take their treatment without interruption for 6, 12 or more months after they started ARV (or tuberculosis) treatment:

- **Target:** 100% of patients take their treatment without interruption at 6, 12 or more months.
- *Measure:* The extent to which patients adhere to treatment.

- Collection: Monitoring adherence to treatment requires a survey, which should be possible if dispensers (and prescribers) are involved in data collection, provided that the necessary information is recorded. Adherence can be monitored at facility level by recording patients who collect their refills according to schedule and by comparing the number of pills remaining to the expected number.
- Source: Individual dispensing forms or electronic dispensing software could be used to obtain the information and should be recommended in all treatment sites. Dispensing forms can also be used to measure, for instance, the percentage of patients who failed to collect their medication at the due date during the past 12 months.
- Further action: Adherence can be improved by informing patients about the importance of taking the correct dose at the correct frequency and following the schedule for medication re-supply.

#### 5.3 Quantification and forecasting

#### Core indicator 3\*

Proportion of quantities of products actually received (procured plus donated) during a defined period out of total quantities planned for the same period

#### What it measures

This indicator measures how closely the quantities of medicines received matched the expected quantities in a given period. The target is for the total quantities received to be as close as possible to those planned for procurement. Any variation should be explained, e.g. the planned quantities were not accurate, the budget for ordering the planned quantities was not available, or needs have changed since the previous forecasting exercise.

The indicator includes all products received (procured and donated). The field test showed that in some countries donations were available to cover all the forecasted need; therefore, there were no procurement activities. This indicator thus covers all sources (e.g. procured, donated, from nongovernmental organizations) of medicines to cover the country's needs. Procurement planning at national level should involve all relevant partners, including non-governmental organizations, development partners and international organizations that contribute ARV and tuberculosis and malaria medicines used in the country.

#### Measurement period and frequency

This indicator is measured each time a procurement is planned or for a defined period in the recent past, e.g. the past year or past quarter. It is a retroactive measurement.

#### Rationale

*Quantification* involves calculating the quantities of ARVs and tuberculosis and malaria medicines on the basis of the actual number of patients who need these medicines. Quantification is performed when a country is preparing to pass an order. It should involve all stakeholders, as above.

Quantification involves determining the actual number of packs of each medicine required at each level of the supply chain. It must take into account past consumption, current number of patients on treatment and number of patients expecting treatment, the results of past quantifications, pack sizes, stocks in hand, buffer stock required and stock-outs, if any, with their duration and anticipated losses.

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*Forecasting* involves planning demand for a longer period at national level on the basis of various assumptions, such as actual and estimated needs, the capacity of the health system, plans for scaling-up and the funds allocated. Updated forecasts ensure that quantification and procurement of medicines are based on accurate data, in order to reduce the risks for stock-out and overstocking.

*Stock-outs* disrupt treatment and can result in the development of resistance. *Overstocking* leads to expiration of product and wasted funds and should be prevented by taking into account the stock in hand and consumption data when calculating the quantities to be procured.

#### Data collection

This indicator requires:

- quantification exercises to specify the quantities to be procured in a defined period,
- the quantities of medicines procured (during the defined year or period) and
- the quantities of medicines donated (during the defined year or period).

#### Data source

The information is collected centrally, at the level at which forecasting and procurement planning are done.

#### Calculation

Quantities (no. of smallest units) of each product received during a defined period x 100 Quantities (no. of smallest units) planned for receipt in the same period

#### Target

As close as possible to 100%

#### Analysis

The aims of an analysis of this indicator are:

- to determine whether the proportion is > 100%, i.e. the quantities received exceeded the expected quantities and why procurement and donations exceeded those expected;
- if the proportion is < 100%, to investigate why the quantities received were less than those expected or planned; and
- if the quantities received did not match the quantities planned (either < 100% or > 100%) but there was no stock-out or overstocking, to determine whether the forecast was inaccurate and to examine this problem further, as described for Indicator 4.

#### Core indicator 4\*

Percentage of quantities used out of total quantities available for consumption after deduction of buffer stock (opening balance plus quantities procured plus quantities donated minus buffer stock) during a defined period

#### What it measures

This indicator measures whether the quantities of products received (procured and donated) were overestimated in relation to actual needs. Overestimation leads to overstocking, with a high risk for expired products, as observed in several countries.

The indicator should include all the quantities available for consumption, including stock in hand as the 'opening balance' plus products received (i.e. quantities procured plus quantities donated). The field test showed that in some countries the quantities consumed were considerably higher than those procured, because of significant donations of medicines. Therefore, all quantities available for consumption in a defined period are taken into account. This makes it possible to avoid overstocking and expired medicines, as procurement that ignores the quantities available and other sources of medicines may lead to overstocking.

#### Measurement period and frequency

This indicator is measured for a defined retroactive period, each time a procurement or a requisition is made.

#### Rationale

If it is assumed that the quantities received were consistent with those planned (Indicator 3), it is important to assess whether consumption was consistent with the quantities received. In general, health facilities order quantities according to the number of patients who need ARV treatment.

If the quantities procured by central medical stores are overestimated, or donated products are not counted as consumption, the rates of consumption will be much lower than the quantities received. This leads to overstocking, with a high risk for expired medicines. Similarly, if the quantities procured were underestimated at national level, the demand will be higher than the available products. This will result in stock-outs at treatment sites or long waiting lists of patients without treatment.

#### Data collection

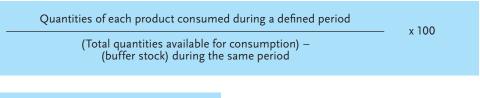
This indicator requires the following data, which can be found in various reports:

- the quantities of each product procured in a defined period;
- the quantities of each product donated in the same defined period;
- the opening balance of each product at the beginning of the defined period;
- the buffer stock requirements per product during the defined period; and
- the quantities of each product consumed during the same defined period, as reported by health facilities.

#### Data source

This information is collected centrally, at the level at which consumption and quantities available for consumption are recorded.

#### Calculation



#### Opening balance

- + procured quantities
- + donated quantities
- + other received quantities
- all expired and unusable quantities
- = quantities available for consumption

#### Target

100%

#### Analysis

- If the percentage is < 100%, the quantities consumed during the period were less than those available for consumption. This will result in overstocking and a high risk of expired medicines in stock.
- If the percentage is > 100%, more was consumed than the quantities available. This means that the buffer stock has been consumed, which may lead to stock-out.

Corrective action should be taken in either scenario. Two strategies used in countries are:

- frequent communication between treatment sites and procurement programmes, which can help to ensure that procurement is better tailored to meet real demand; and
- exchange of medicines between treatment sites with lower and higher consumption rates. The flexibility of medicine exchange between treatment sites can help prevent stock-outs at high-volume treatment sites (high consumption rates) and can also help prevent expiration of medicines at low-volume treatment sites (low consumption rates).

#### 5.4 Procurement efficiency

#### **Core indicator 5**

Ratio between median price of products procured and the international median reference value

#### What it measures

This indicator measures the efficiency of procurement practices by comparing the prices paid for medicines with international price standards.

#### Measurement period and frequency

This indicator refers to a defined period in the past, e.g. a calendar year, and should be measured at least once a year.

#### Rationale

Price is a key issue in procuring good-quality pharmaceuticals. The prices obtained for ARVs and tuberculosis and malaria medicines have a significant influence on the efficiency of PSM systems. The choice of procurement method (e.g. competitive bidding, direct procurement) affects the prices obtained. An efficient programme obtains best prices using reference price benchmarks, and reliable deliveries of good-quality pharmaceuticals from suppliers.

#### Data collection

This indicator requires:

- the international reference price: median price per unit per year from the WHO Global Price Reporting Mechanism,<sup>1</sup> Management Sciences for Health and others;
- purchase orders: the prices in all product orders placed during the defined period, including emergency orders and patented medicines, presented in Excel<sup>®</sup> to allow calculation of the median price per unit (e.g. tablet) from all suppliers; and
- if required, STG to establish the units of medicine required per day of treatment.

#### Data source

This information is collected centrally, at the level at which procurement is done.

#### Calculation

Median price paid for each medicine per unit per year of treatment

International median price for the same medicine per unit

#### Target ratio

≤1

#### Analysis

If the ratio is  $\leq$  1, the national prices are equal to or less than international prices. This suggests efficient procurement.

If the ratio is > 1, the national median price is higher than the international median price. This suggests that the country is paying too much for a medicine (e.g. if the ratio is 2, the country is paying twice the international price). Corrective action should be based on the answers to questions such as: Were several quotations sought for a product? Was international competitive bidding used as the main procurement method for multiple products? Were there many emergency orders, for which price negotiation is not an option?

<sup>1</sup> WHO's Global Price Reporting Mechanism provides an accessible database and summary reports: http://apps.who.int/hiv/amds/price/hdd/

#### Core indicator 6\*

- 6A\* Percentage of orders delivered in full and on time (as stated in the procurement agreement) per supplier in a defined period
- 6B1\* Percentage of orders to be cleared from port that were cleared before the deadline
- 6B2 Average number of days between arrival at port and date of clearance from port

#### What it measures

This indicator measures the supplier's compliance with the agreed quantities and agreed delivery time. It also measures the timely clearance of goods from the port.

#### Measurement period and frequency

This indicator is measured every time orders are received or in the recent past (e.g. past calendar year).

#### Rationale

If delivery times are delayed past the time agreed or if the delivered quantities do not match those ordered, shortages of supplies can occur or emergency ordering will be needed. Many delivery delays are due to delays in port clearance, which is sometimes the responsibility of national procurement agencies. Indicators 6B1 and 6B2 measure port clearance. The reasons for late deliveries must be identified in order to prevent the problem in future.

#### Data collection

Data required for this indicator include:

- a list of orders to each supplier during the defined period;
- port clearance forms during the defined period; and
- order receipt forms from the central medical store during the defined period, disaggregated by timeliness (late or on time) and quantity (in full or incomplete).

#### Data source

This information is collected both centrally, at the level at which procurement is done, and in central medical stores.

#### 6A. Calculation and target (performance of delivery of products)

Number of orders from each supplier delivered according to contract agreement (delivery time and quantities) in a defined period x 100

Total number of orders from the same supplier during the same period

#### Target

100%

#### Analysis

If a supplier does not meet the target:

- The reasons for late deliveries should be identified in order to prevent the problem for future deliveries.
- Contracts with suppliers must include penalties for non-compliance (e.g. if deliveries are late or if the full quantities are not delivered).
- 6B. Calculation and target (port clearance)
- 6B1. If the target deadline is known (e.g. to be cleared within 3 days of arrival):

Number of orders cleared from the port before the deadline	x 100
Total number of orders cleared	x 100

Target

100%

#### 6B2. If no target is defined:

Number of days to clear orders from the port

Total number of orders cleared

#### Target

As close as possible to 0; average days for clearance of all supplier orders

#### 5.5 Quality assurance

#### **Core indicator 7**

Percentage of the product batches tested in the past year that met national and international quality control standards

#### What it measures

This indicator measures the extent to which procured products meet quality requirements. Quality control is conducted in addition to other nationally or internationally defined standards used to assess the extent to which procured products are of good quality.

In countries where quality control tests are performed regularly on procured products before they are released for consumption, this indicator is easy to measure.<sup>1</sup> National and international quality standards, such as drug registration and WHO prequalification or approval by the United States Food and Drug Administration, will also apply.

#### Measurement period and frequency

This indicator is measured retroactively for a defined period, e.g. past calendar year, and should be measured at least once a year.

<sup>&</sup>lt;sup>1</sup> During a recent i+solutions monitoring and evaluation course, several countries reported that the quality of each ARV batch is tested before release for consumption.

#### Rationale

Medicines dispensed to patients should be effective, safe and of good quality. In order to ensure that procured products are safe and effective, certain quality standards should be met, including good manufacturing practice certification, WHO prequalification or United States Food and Drug Administration approval, national drug registration, correct packaging and labelling information, remaining shelf-life upon receipt and other quality standards defined in quality assurance policies. National drug regulatory authorities must set their own quality standards and filter out the products that do not meet them.

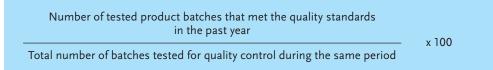
#### Data collection

This indicator will require reports of quality control tests performed during the defined period.

#### Data source

This information is collected at central level where quality standards are assessed by the national drug regulatory authority.

#### Calculation



#### Target

100%

#### Analysis

Products that failed quality testing – in particular those that failed quality control tests – should be sent back to the supplier or manufacturer or destroyed on site and replaced at the supplier's cost. This should be stipulated in the contractual agreement with the supplier.

In addition to the results of the quality control test, any observations about the product quality during inspection should be reported. These could include packaging, labelling and the shelf-life of received products.

#### 5.6 Distribution

#### Core indicator 8\*

Percentage of treatment sites that received all orders in full and on time during a defined period

#### What it measures

This indicator measures whether the distribution system is reliable. While this indicator is similar to Indicator 6, they measure different aspects: Indicator 6 measures supplier performance, while Indicator 8 measures the performance of the national distribution system.

#### Measurement period and frequency

This indicator is applied to a defined retroactive period, e.g. the past year or past quarter.

#### Rationale

Timely distribution is important, as it determines product availability and an uninterrupted supply of medicines to health facilities. This indicator applies to all levels of the supply and distribution system and to each sector in which medicines are distributed or dispensed (public, private, nongovernmental), as for other inventory control indicators. During the validation workshop, it was recommended that all levels of the supply chain be assessed.

#### Data collection

This indicator requires requisition forms from all treatment sites (HIV/AIDS, tuberculosis, malaria) during the defined period. Each order on these requisition forms should be disaggregated for timeliness (on time or late) and quantity (in full or incomplete).

#### Data source

This information is collected centrally, at the level at which health facilities submit their requisition forms.

#### Calculation

Number of health facilities that received all orders for ARVs (tuberculosis and malaria medicines) in full and on time during a defined period

x 100

Total number of health facilities that received orders for ARVs (tuberculosis and malaria medicines) during the same period

As orders are to be disaggregated by timeliness and completeness, additional aspects of distribution can be examined:

- percentage of health facilities that received all orders in full during a defined period and average completeness of orders and
- percentage of health facilities that received all orders on time during a defined period and average delay in receiving orders.

#### Target

100% of facilities receive 100% of orders in full and on time.

#### Analysis

This indicator is analysed in two ways:

1. Each facility is assessed for the extent to which it meets the target. For example, a facility receives 10 orders and 8 arrive on time and in full; therefore, 80% of orders are received on time and in full. This facility will miss the target of 100%. The data are also disaggregated into orders that were on time but not necessarily in full and those that were in full but not necessarily on time.

It is important to analyse why the facility did not receive all orders in full and on time, for example:

— What are the facility characteristics (e.g. remote area, poor roads)?

- Is there a seasonal trend in orders not arriving on time (e.g. due to rainy season)?
- When are orders being placed? Are they timely?

These questions, among others, will help in assessing whether late deliveries are due to the internal system (e.g. the order was received too late relative to the standard delivery schedule) or external issues (e.g. poor roads).

2. Calculation of the number of facilities by percentage of orders received in full and on time provides disaggregation by performance. Again, the target is 100%, i.e. that all facilities receive all orders in full and on time.

For example, a country has 10 facilities placing 10 orders each. Five of the facilities received all 10 orders (100%) in full and on time and thus met the target. Of the remaining five facilities, three received 8 of 10 orders in full and on time, or 80% of orders. The last two facilities received 5 of 10 orders in full and on time, or 50% of orders. The average and median of these data can be calculated and analysed.

#### 5.7 Inventory control (manual or computerized)

#### Core indicator 9\*

Percentage of treatment sites that submitted complete inventory control reports on time, according to an established schedule, during a defined period

#### What it measures

This indicator measures the reporting of health facilities on inventory control, whether facilities are submitting complete, timely reports according to an established schedule.

#### Measurement period and frequency

This indicator is applied to a defined retroactive period, e.g. the past year or past quarter.

#### Rationale

Inventory control reports on stock management are useful sources of information for monitoring the PSM system. It is important that inventory control reports be sent in a timely manner from all levels to the central level in order to facilitate real-time data analysis, reporting and decision-making. This indicator is easy to measure, as the information is available. Timely assessment of reporting systems is critical for strong PSM performance and for an effective monitoring and evaluation system.

Inventory control reports should include all the necessary information required to monitor PSM system performance: opening balance, quantities requested, quantities received, stock in hand, stock-out duration if any, quantities distributed or dispensed, number of patients on treatment by regimen, new patients, minimum and maximum stocks and losses for various reasons (e.g. expiry, theft, damage).

#### Data collection

The data required for this indicator include:

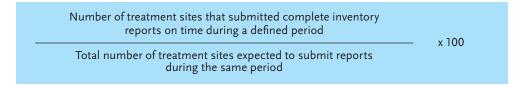
- a list of facilities dispensing antiretroviral, tuberculosis and malaria medicines and
- inventory control reports submitted by the facilities during the defined period.

Inventory control reports should be disaggregated by timeliness, according to the established reporting schedule, and by completeness. While the indicator evaluates reports that are complete and on time, disaggregation also allows calculation of the number of reports that are on time or complete.<sup>1</sup>

#### Data source

This information is collected centrally, at the level at which health facilities submit inventory control reports.

#### Calculation



Data should be entered separately for ARV and tuberculosis and malaria treatment sites. Each will have an Excel<sup>©</sup> data collection and analysis sheet.

#### Target

100% of facilities should submit all their PSM inventory control reports (100%), which should be complete and on time.

#### Analysis

This indicator is easy to measure, as the information is available. It measures a critical component of an effective monitoring and evaluation system.

This indicator should be analysed for:1

- completeness: percentage of facilities submitting complete reports,
- timeliness: percentage of facilities submitting reports on time and
- completeness and timeliness: percentage of facilities submitting complete reports on time.

The indicators measure the percentage of facilities that have achieved both completeness and timeliness, although completeness is the priority. A deeper analysis of facilities by the number of complete reports submitted on time will help managers to plan supervision to improve the situation.

When facilities do not meet the target, the following corrective actions are recommended:

- assessment of the characteristics of facilities that did not meet the target, especially those that missed the target by a wide margin, and identification of any further analysis required;
- Strengthened supervision to ensure that inventory control reports include all necessary information for monitoring the performance of the national PSM system.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Participants in the validation workshop suggested separate evaluations of completeness and timeliness, with priority given to completeness. These calculations are made on the Excel<sup>®</sup> data collection sheet.

<sup>&</sup>lt;sup>2</sup> Opening balance, quantities requested and quantities received, stock in hand, stock-out duration if any, quantities distributed or dispensed, number of patients on treatment by treatment regimen, new patients, minimum and maximum stock levels, losses due to various reasons (e.g. expiry, theft, damage)

#### Additional indicator for inventory control

It is important that the information submitted in the reports is consistent with the actual situation of the supply system. It is recommended that supervision be conducted randomly to assess the accuracy and validity of reported data. The following supplementary indicator would track data quality assurance:

### Percentage of products for which the physical counts and inventory records (stock cards or computerized data) match.

- What it measures: accuracy of inventory control and quality of reported data (i.e. whether inventory control data and actual physical stock data match)
- **Rationale:** It is important that the information registered in the system is consistent with the actual situation in the warehouse.
- Data collection: This indicator is not considered to be a core indicator as it is available only in countries where regular, systematic supervisory visits are conducted. The indicator is measured from supervisory reports, as the information is collected through physical counts during such visits, unless a survey is conducted on site in a facility.
- **Target: 100%**

#### **Core indicator 10**

Percentage of quantities of each product lost per total quantities available for use (opening stock plus quantities procured plus total quantities donated) in a defined period

#### What it measures

This indicator measures the quantity lost out of the total quantity available for use. The reasons for loss (e.g. expiry, damage, theft, diversion) should be determined by the manager.

#### Measurement period and frequency

This indicator is applied to a defined retroactive period, e.g. the past year or past quarter.

#### Rationale

In any efficient PSM programme, loss of medicines should be avoided. Medicines have both monetary and public health value. It is essential that loss be monitored in order to reduce the quantities lost. It is also important to examine the reasons for any loss in order to take corrective action.

#### Data collection

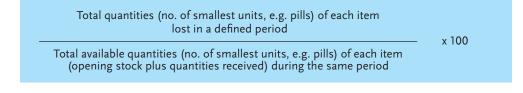
This indicator requires:

- reports from central medical stores on the quantities available;
- reports from central medical stores on the quantities lost, disaggregated by cause (e.g. expiry, damage, theft, diversion), as available;
- reports from all dispensing facilities on the quantities available (measured in Indicator 4); and
- reports from all facilities on the quantities lost, disaggregated by cause of loss.

#### Data source

This information is collected centrally, at the level at which reports on the quantities of medicine consumed and lost are submitted.

#### Calculation



#### Target

< 1% of quantities available<sup>1</sup>

#### Analysis

- percentage of quantities available that were lost, with corrective action and investigations if losses exceed 1%;
- causes of loss (e.g. expiry, damage, theft, diversion) and corrective action for each kind of loss;
- Ioss to expiry because of weak stock management, failure to use the 'first expiry, first out' principle or failure to apply average monthly consumption to the available quantities (For example, if a product has a 3-month shelf-life, but, on the basis of its average monthly consumption, all quantities are consumed within 2 months, the product available is safe. If the product has a shelf-life of 3 months and the average monthly consumption indicates that it will take 5 months to be consumed, it is advisable to redistribute some product to high-consumption treatment sites.); and
- Iosses in absolute value, in both quantities and monetary value, which can be calculated from the total value of the quantities available (For example, if the total value of the stock is US\$ 100 million and an estimated 1% was lost, the value of the lost quantities is US\$ 1 million.)

#### Core indicator 11\*

Percentage of treatment sites that placed orders during a defined period while the stock in hand of one or more items was below the minimum stock level

#### What it measures

This indicator measures the effective use of inventory control in decision-making. It is applicable at all levels of the distribution system – health facility, regional store and central medicines store.

#### Measurement period and frequency

This indicator is applied to a defined retroactive period, e.g. the past year or past quarter.

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<sup>&</sup>lt;sup>1</sup> Some institutional targets are lower; for example, UNDP seeks to minimize losses to < 0.2%.

#### Rationale

This indicator shows whether inventory control is being used effectively. Requests that are sent to the procurement department too late are a possible cause of stock-outs.

The 'minimum stock' required for this indicator is the level that represents a warning to place new order, taking into account the lead time and the average monthly consumption. It corresponds to the buffer stock plus the quantities required to cover the needs of patients during the lead time. If orders for ARVs and tuberculosis and malaria medicines are placed when the stock of an item is below the established minimum level, the risk for stock-out is high.

#### Data collection

This indicator requires the following information, which can be found on health facility requisition forms:

- opening balance,
- total quantities received,
- quantities of each item consumed,
- stock of each product in hand,
- minimum stock of each item,
- buffer stock of each product at each facility required,
- average monthly consumption of each product or consumption data during a defined period that can be used to calculate average monthly consumption and
- the standard frequency of ordering each product, e.g. monthly or quarterly.

#### Data source

The data source is the requisition form for each item from health facilities, showing the quantities requested, consumption and stock in hand. This information is collected centrally, where health facilities submit their requisition forms. It is essential that each stock card specify the minimum stock and the buffer stock of each pharmaceutical product.

#### Note on data collection

The objective of any PSM manager is to avoid stock-outs and overstocking. It is essential to monitor the stock in hand regularly and to place an order as soon as the minimum stock is reached.

Indicator 11 is crucial for assessing the risk for shortage, as it assumes regular monitoring of stocks. In order to determine which treatment sites ordered when their stocks were below the minimum, they must report the average monthly consumption and the stock in hand (in quantity and in months).

Average monthly consumption =	Total consumption during a defined period	
	Total number of months in the same period	

The period during which a stock-out was experienced should be taken into account by deducting the number of stock-out days from the denominator. The minimum stock varies between treatment centres and depends on the total number of patients on treatment and the delivery time; e.g. the longer the delivery time, the larger the quantities required for a minimum stock, and the more patients, the larger the quantities of medicines need-

ed. The minimum stock should be defined on the basis of the length of delivery for each treatment centre. It is advisable to monitor the stock in 'months' rather than 'quantities', because quantities vary with the average monthly consumption.

Stock in hand, in months =	Quantities of each item currently in stock
	Average monthly consumption of each item

The stock in hand should exclude all expired medicines. If the defined minimum stock is 2 months and the stock in hand is 1 month, the risk for stock-out is high, unless delivery is exceptionally accelerated. Having many months' worth of stock is not necessarily good either. For example, if 12 months of stock are in hand but the product will expire within 6 months, there is a high risk for loss due to expiration, and corrective action should be taken to redistribute quantities to treatment centres that need the medicines. For these reasons, it is essential to monitor the stock in hand continuously, not only in quantities but also in consumption months that these quantities will cover.

# Calculation

Number of facilities that placed an order when the stock in hand of an ARV (or tuberculosis or malaria medicine) was below the minimum during a defined period

Total number of health facilities that placed an order for ARVs (or tuberculosis or malaria medicines) during the same period

#### Target

0% of facilities ordering a product when its stock in hand is already below the minimum level to prevent stock-out

x 100

#### Analysis

This indicator must be analysed for corrective action at facility level.

- If the indicator is 0%, no facilities placed an order when the quantity of a product was below the minimum. This reaches the indicator target.
- If the indicator is > 0%, corrective action should be taken to examine why orders are being placed too late:
  - Are facilities properly calculating and using data for inventory control, such as the average monthly consumption, buffer stock, product lead time, maximum stocks and minimum stocks?
  - What tools, training, capacity or supervision are required to ensure that facilities use these calculations in order to time orders?
  - Do infrastructural issues (e.g. bad roads) complicate timely ordering?

#### 5.8 Availability of ARVs and tuberculosis and malaria medicines

#### Core indicator 12

Percentage of treatment sites that had a stock-out of one or more required medicines during a defined period (universal access indicator and early-warning indicator for HIV drug resistance)

#### What it measures

This indicator measures the effectiveness of the PSM system in terms of the availability of medicines. The consequences of stock-out – the scale of treatment interruption and risk for drug resistance – depend on the number of patients whose treatment will be disrupted because of product stock-out. During the validation workshop, it was suggested that stock-outs be assessed at all levels of the national supply chain: central medicines store, regional store and health facilities.

This indicator is easy to monitor, as the information is provided regularly to central medical stores in order to receive new ARV supplies. It is a useful indicator for assessing the performance of a PSM system. If this indicator misses the target, indicators 12A1, 12A2, 12B, 12C1 and 12C2 can be used to measure the severity of the stock-outs.

#### Measurement period and frequency

This indicator is applied to a defined retroactive period, e.g. the past year or past quarter. The additional indicators 12A1 and 12A2 measure cross-sectional availability. Indicators 12B, 12C1 and 12C2 are applicable for a defined period, e.g. previous calendar year or quarter.

#### Rationale

PSM managers are responsible for ensuring product availability and avoiding stock-outs. ARVs and tuberculosis and malaria medicines should always be available at health facility level to ensure that all prescriptions are filled when patients need treatment.

It is essential to monitor the risk for stock-out as close as possible to real time, to ensure that the stock in hand at a treatment centre never falls below the buffer stock.<sup>1</sup> If stock-out occurs, it is important to measure its severity (duration and number of products out of stock). The severity of stock-outs depends on the number of patients whose treatment contains the product that is out of stock.

#### Data collection

This indicator requires:

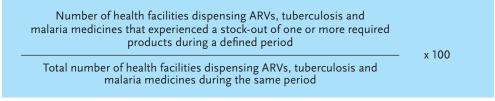
- stock inventory control reports from health facilities, also indicating the stock of each item;
- requisition forms submitted by facilities during a defined period (e.g. previous order period, previous quarter, past year) for ARVs and tuberculosis and malaria medicines; and
- a list of the medicines that each facility is expected to dispense, if these are not already included in the inventory control reports or requisition forms.

#### Data source

This information is collected centrally, at the level at which health facilities submit their inventory control reports or requisition forms for ARVs and tuberculosis and malaria medicines.

<sup>&</sup>lt;sup>1</sup> Ordering before the stock in hand falls to buffer stock (minimum stock) levels in Indicator 11.

#### Calculation



### Target

0% of facilities have a stock-out of one or more ARVs (tuberculosis or malaria products) during a defined period (100% of treatment sites have no stock-out during a defined period).

If the target has not been met, additional indicators can be used to measure the severity of the stock-out:

- 12A. Availability (cross-sectional analysis)
- 12A1 Percentage of available items at each treatment site
- 12A2 Average percentage of items available at all treatment sites

#### What it measures

Health facilities can report which ARVs (tuberculosis or malaria medicines) are out of stock in their periodic inventory reports. From this information, it is possible to calculate the percentage of products that are available per health facility and an overall average percentage for all treatment sites. It is also possible to assess which products are most often out of stock at all reporting treatment sites, i.e. the percentage of facilities experiencing a stock-out per product (Indicator 12B but in a cross-sectional analysis rather than a longitudinal one).

#### 12A1. Average percentage of available items at each treatment site

 Number of available ARVs, tuberculosis and malaria medicines
 x 100

 Total number of expected ARVs and tuberculosis and malaria medicines
 x 100

#### Target

100% of available products per health facility

**Example:** Health facility A is expected to have 10 ARVs available at all times. During the month of measurement, there was a stock-out of one product and only 9 of the 10 ARVs were available. Therefore, the facility had 90% of ARVs available.

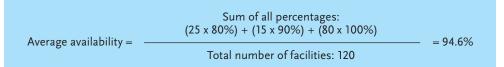
### 12A2. Average percentage of items available at all treatment sites

Average availability = Total number of facilities assessed

#### Target

100% of products

**Example:** Calculating the availability of products in each health facility will give the national average. There are 120 facilities, one of which is health facility A with 90% availability. There are 25 facilities with 80% availability, 15 facilities with 90% availability and 80 facilities with 100% availability:



# 12B. Percentage of treatment sites that had a stock-out of a particular product during a defined period

### What it measures

This indicator measures which products are most often out of stock, and investigations can be conducted to examine why. The percentage of treatment sites in a country that experienced a stock-out for each product can be calculated:

Number of health facilities dispensing ARVs and tuberculosis and malaria medicines that experienced one or more stock-outs of a particular product in the past year	x 100
Total number of health facilities dispensing the particular ARV or tuberculosis or malaria medicine in the past year	x 100

#### Target

0% of facilities

**Example:** Analysis of reports from 100 treatment sites shows that 15 health facilities had stock-outs of tenofovir and lopinavir/ritonavir, three facilities had a stock-out of efavirenz and two facilities had a stock-out of zidovudine. Therefore, 20 facilities experienced stock-outs of one or more ARVs.

This example shows that 20% of facilities (20 of 100) had stock-outs of ARVs. The stockout per product was 15% for lopinavir/ritonavir, 15% for tenofovir, 3% for efavirenz and 2% for zidovudine, which indicates which products were affected in most health facilities: lopinavir/ritonavir and tenofovir were out of stock in more health facilities. The reasons can be investigated specifically for these products, especially if the stock-out rates are severe.

12C.	Duration of stock-out
12C1	Average duration of stock-outs at each treatment site during a defined period
12C2	Average duration of stock-outs at all treatment sites during a defined period (early- warning indicator for HIV drug resistance)

### What it measures

This indicator examines the duration of stock outs; the longer the duration of stock-out, the more severe the situation. Given the importance of the duration of the stock-outs, it

is suggested that the number of days of stock-outs be recorded for each product for a defined period (e.g. the reporting period).<sup>1</sup>

While these indicators measure facility and country averages, it is also possible to sum all stock-out days per product registered in each health facility to determine which product was the longest out of stock. The data collection sheet allows calculation of the average duration per product.

## 12C1. Average duration of stock-outs at each treatment site during a defined period

Average stock-out duration in a health facility (days) =	Sum of stock-out days
	Total number of items

#### Target

0 days of stock-out

**Example:** Health facility A dispenses three ARVs: zidovudine + lamivudine, nevirapine and efavirenz. It reports 100 days of stock-out for zidovudine + lamivudine and 170 days of stock-out for efavirenz during the past year. With the formula above, the average duration of stock-out in this facility is:

90 days (average stock-out lasted 90 days, ranging from 0 days (nevirapine) =	_	Sum of stock-out days: 100 + 170 + 0
to 170 days (efavirenz))	_	Total number of items: 3
, (		Total Humber of items. 5

# 12C2. Average duration of stock-outs at all treatment sites during a defined period

Average number of stock-out days _	Sum of average stock-out duration in 12C1
at all health facilities in a country	Total number of health facilities

#### Target

#### 0 days of stock-out

In addition to 12C1 and 12C2, it is possible to measure the duration of stock-outs as a percentage of total days in the defined period. This is included in the data collection sheet. For instance, the example in 12C1 showed that the facility's average stock-out was 90 days and the defined period was 1 year, or 360 days. Therefore, the percentage of days during which there were stock-outs is 90/360 = 0.25, so that stock-out occurred during about 25% of the defined period.

# Analysis of Indicator 12

The ideal situation would be no stock-out of any ARV or medicine for tuberculosis or malaria in any target facility (public, private or nongovernmental) throughout the period. i.e. no stock-out of any item monitored during the defined period.

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<sup>&</sup>lt;sup>1</sup> During the validation workshop, malaria programme managers reported that the WHO Malaria Programme has an indicator to examine the duration of stock-outs and sets a maximum of 7 days of stock-out per quarter.

If a stock-out occurs, it is important to measure the availability or the percentage of available products (12A), the percentage of health facilities that experienced stock-out of a particular product (12B) and the duration (severity) of the stock-out (12C).

The objective of any PSM manager is to avoid stock-outs, which lead to treatment disruption with risk of drug resistance. It is therefore essential to monitor the stock in hand regularly. The stock at a treatment centre should never fall below the buffer stock (see core Indicator 11).

Any stock-out will require investigation if the targets are not met. The questions to be asked are:

- Why are certain products out of stock more frequently, for longer or more broadly than others? Is there an issue with suppliers? Is the buffer stock or average monthly consumption of these products not measured correctly? Were there unexpected changes in demand?
- Why do certain facilities experience more frequent or longer stock-outs? Is the facility staff equipped, trained and supervised in PSM management (e.g. inventory control, quantification, timely ordering)?

# 6. Conclusion and way forward for effective implementation

The goal of the PSM early-warning and performance indicators presented in this document is to provide a harmonized structure for monitoring and evaluation that will provide timely, critical information on PSM efficiency and stocks at different levels of the supply system, particularly at heath facility level.

Effective implementation of PSM monitoring systems requires supportive mechanisms. Participants in the workshop on validation of indicators identified the following elements:

- definition of partners and stakeholders in the national PSM system in order to better understand and define PSM actors in the country, areas for collaboration and complementary work and exchange of information on PSM;
- establishment of a national committee of relevant PSM partners and stakeholders to support data collection and reporting, use data for quantification, plan procurement and monitor the performance of the national PSM system, including the early-warning indicators;
- aggregation of data, especially in large countries with many health facilities. Data from primary and secondary facilities should be aggregated at intermediate levels (e.g. district, province, region) and then submitted to national level. This approach increases the involvement and commitment at various levels of the national health and supply system. Distribution channels and use of these indicators should be explained clearly at all levels of a decentralized system and in both the public and the private sectors to ensure synergy of all levels of distribution and sectors in order to minimize the risks for stock-out and overstocking.
- use of existing records already submitted by health facilities and aggregated at regional and central levels to measure the PSM early-warning indicators. It will be important to strengthen data quality assurance to ensure that the results of indicators and the decisions taken are based on valid, accurate information.
- regular supervision to assess the accuracy, timeliness and completeness of data submitted to central level. Oversight is essential to improving data quality.
- establishment of a mechanism for feedback to data providers and health service providers as a motivational factor, to show the importance of information-gathering, analysis and reporting. Provincial or national meetings should be held to discuss the results. Any recommended actions might enhance motivation and the relations between different levels of the national information system.
- assessment of the effect of monitoring on improving the PSM system, particularly if monitoring is regular. The PSM early-warning indicators are expected to help countries to prevent stock-outs and losses due to overstocking.

These supportive mechanisms will help PSM managers to fulfil their primary objective: to ensure an uninterrupted supply of essential products. PSM programmes must champion the recommendations listed above, integrate the 12 indicators into national PSM monitoring and allocate the necessary resources in the national plan to monitor the performance of national PSM systems and prevent stock-outs and overstocking.

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**Average monthly consumption:** How rapidly a product is usually consumed during the course of a month. It is calculated per product at each distribution point (health facility, intermediate or central level). Monthly consumption can be collated with data from daily use records, bin or stock cards or drug registers and is calculated from average consumption over a period (e.g. 6 months). The period during which a stock-out was experienced should be taken into account by deducting the number of stock-out days from the denominator.

Average monthly consumption = —	Total consumption during a defined period
	Number of months during that period

The average monthly consumption is a critical calculation for determining buffer and minimum stocks and avoiding stock-outs or overstocking. National PSM programmes must ensure that all facilities record the average monthly consumption of every product they dispense.

**Buffer stock** ('security stock', 'buffer inventory' or 'safety stock'): A defined level of stock maintained at a treatment site that is additional to the current forecasted demand. It is a defined stock for security purposes and varies with the size of the facility and the number of patients. The buffer stock is determined for every product, at every level of the supply chain (e.g. every treatment site and storage facility, like the central medical store). The buffer stock is used to ensure that, in exceptional circumstances – events or demand that are out of the ordinary, some stock is available to reduce the risk for stock-out.

**Forecasting:** Planning demand for a long period at national level on the basis of various assumptions, such as actual and estimated needs, the capacity of the health system, plans for scaling-up treatment coverage and the allocated funds. Frequently updated forecasts ensure that medicine quantification and procurement are based on accurate data, thus reducing the risks for stock-out and overstocking.

#### Lead time

**Delivery time:** The time between sending an order and delivery of supplies to a point in the supply chain (e.g. from the central medical stores to a treatment facility or a district medical store). Delivery time to stores can be further delayed by poor infrastructure (e.g. poor roads, especially during rainy seasons), poor condition of delivery vehicles, increased workload at the issuing store or non-availability of adequate resources at the central store.

**Supplier lead time:** The time between placing an order for a medicine item with a supplier (e.g. contract or purchase order is signed) and arrival of that order at the location agreed upon in the contract (e.g. port or central medical store). Lead time is usually measured in days, but the unit of measurement (e.g. days, weeks, months) should be clearly indi-

<sup>&</sup>lt;sup>1</sup> Based on this paper and *Management of drugs at health centre level – training manual*. Geneva, World Health Organization, 2004. http://apps.who.int/medicinedocs/en/d/]s7919e/7.4.html

cated. Lead time is a measure of the supplier's timeliness. In some cases, suppliers are contracted to deliver to a port; at other times, they are responsible for clearing items at the port and delivering them to the central warehouse, accounting for additional time for port clearance and in-country transport if required. Therefore, the supplier should be evaluated for the full cycle. The full purchase order cycle is from the time of quantification to the time supplies arrive at the central warehouse.<sup>1</sup>

**Maximum stock:** Upper limit of inventory (quantities), which should not be exceeded. The level is fixed per product for each facility on the basis of consumption rates, available storage space, risk for deterioration, buffer stock requirements and time between two consecutive orders. The maximum stock is the minimum level plus the quantities required to cover patients' needs between two consecutive orders. The longer the time between two consecutive orders, the higher the maximum stock. It is essential to monitor the stock in hand regularly to ensure that the required quantities are well quantified when making a new order, so that the stock does not exceed the maximum level, which would risk overstocking and expiry. The maximum stock is measured in months rather than quantities, because quantities vary by treatment site because of differences in average monthly consumption.

**Minimum stock:** Lower limit of the inventory, which gives an alert for ordering new quantities of health products to prevent the risk for stock-outs. The minimum stock is a warning level for placing a new order and corresponds to the buffer stock plus the quantities required to cover the needs of patients during the lead time.

The minimum stock of each product is determined at each facility on the basis of the lead time and average monthly consumption. If the order for ARVs and tuberculosis and malaria medicines is made when the stock of an item is below the established minimum level, the buffer stock will be consumed, and any delay may place the facility at high risk for stock-out. It is essential to monitor the stock in hand regularly to ensure that orders are placed in a timely fashion. A minimum stock is measured in months rather than quantities, because quantities vary by treatment site because of differences in average monthly consumption.

**Opening balance:** Stock in hand at the beginning of a defined time when new supplies are received.

**Overstocking:** Excess stocks of products, which exceed current demand at a given time. Overstocking can lead to product expiry and result in wasted supplies and funds. It should be prevented by taking into account the stock in hand and consumption data when calculating the quantities to be procured.

**Quantification:** Calculation of product quantities on the basis of the actual number of patients who need medicines. This exercise is carried out to minimize the risks for stockouts or overstocking. Quantification is undertaken when a country is preparing to place an order and should involve all stakeholders in the procurement and supply chain management.

Quantification involves determining the actual number of packs of each medicine required at each level of the supply chain. It must take into account past consumption, the current patient load, the number of new patients expecting treatment, pack sizes, stocks in hand, buffer stock required, stock-outs (if any, and their duration) and anticipated losses.

**Quantity:** Number of medicine items, defined in the smallest possible unit (e.g. pills, vials). The unit of measurement should always be specified for each medicinal product.

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See Measuring supply chain performance: guide to key performance indicators for public health. Washington DC, United States Agency for International Development Deliver Project, 2010. http://deliver.jsi.com/dlvr\_content/resources/allpubs/guidelines/MeasSCPerf.pdf

**Stock in hand:** Includes all quantities available for consumption at any stock control. The stock in hand excludes all expired medicines. If the defined minimum stock is 2 months and the stock in hand is for 1 month, the risk for stock-out is high, unless an emergency delivery is received.

Stock in hand (in months) = -	Current quantities of each item in stock
	Average monthly consumption of each item

Having many months of stock is not necessarily good. For example, if there are 12 months of stock in hand but the medicines will expire within 6 months, there is a high risk for loss due to expired products, and corrective action should be taken to redistribute quantities to other treatment centres that need them. For these reasons, it is essential to monitor the stock in hand continuously, not only in quantities but also in consumption months to be covered by these quantities. The expiry date of products should also be monitored, and the principle of 'first expiry, first out' should be applied.

**Stock-out:** Any time when, at a defined moment in a given inventory, a needed medicine item is not in stock and orders or prescriptions cannot be filled. Stock-outs of ARVs and tuberculosis and malaria medicines disrupt treatment, which can result in the development of drug resistance.

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