Toolkit on monitoring health systems strengthening

MEDICAL PRODUCTS, VACCINES AND TECHNOLOGIES

World Health Organization

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1. Introduction

A well-functioning health system ensures access to essential medical products, vaccines and technologies of assured quality, safety, efficacy and cost effectiveness. According to the WHO framework for health systems, this is one of the six building blocks of health systems and this requires:

- National policies, standards, guidelines and regulations that support policy. This includes evidence-based selection of medicines, vaccines, and technologies according to international standards.
- Information on prices, international trade agreements and capacity to set and negotiate prices.
- Reliable manufacturing practices and quality assessment of priority products.
- Procurement, supply and storage and distribution systems that minimize leakage and other waste.
- Support for rational use of essential medicines, commodities, and equipment, through guidelines, strategies to assure adherence, reduce resistance, maximize patient safety and training.

Monitoring of this building block is closely intertwined with at least two other building blocks: governance and service delivery. Issues related to policy and technologies are dealt with in the governance of this guide. For instance, the level of transparency and potential vulnerability to corruption can be assessed for pharmaceutical functions of registration of medicines, selection of essential medicines and procurement of medicines\(^1\).

This section primarily focuses on medicines. There is an MDG-related indicator specific to service delivery. MDG 8 – to develop a global partnership for development – aims "to provide access to affordable, essential drugs in developing countries". Hitherto, the indicator selected – proportion of population with access to affordable essential drugs on a sustainable basis – has not been monitored regularly due to lack of comparable data for the majority of countries.

Access to drugs is difficult to measure. A rough indication was obtained by WHO through a key information survey in which experts in each country provided an estimate of the proportion of the population who have access to a minimum list of 20 essential medicines which are continuously available and affordable at a health facility or medicines outlet, within one hour's walk from the patient's home (WHO, World Medicines Situation report, 2004). Key informant surveys, however, have substantial measurement error and can only provide a rough indication of trends.

2. Data sources

The data sources for medicines and vaccine availability are similar to those described under Service Delivery. For more details see the latter section of the guide.

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Facility reporting systems

Service data are generated at the facility level and include key outputs from the regular (mostly monthly) reporting systems include services and care offered and treatments administered. The problems associated with developing service coverage estimates from facility data are primarily related to completeness and accuracy of recording and reporting. Many countries use selected indicators about reporting medicine or commodity stock outs for the past one or three months.

Key informant survey

Surveys of experts with extensive knowledge about the medicines situation in a country are often used to generate information about the drug policies and practices related to regulation, selection of essential medicines and procurement. While these methods are low-cost and relatively easy to implement, the disadvantage is the subjectivity which introduces measurement error and affects comparability between countries and over time within the same country.

Facility survey

A general facility survey generally focuses on a wide range of key health services and collects information on facility infrastructure, equipment and supplies, support systems, management systems, providers' adherence to standards. The collection of data on the availability (and expiry dates) medicines is part and parcel of such surveys.

WHO and Health Action International have developed a methodology for medicine surveys, to collect data on the prices, availability, affordability and components of medicine prices in low and middle income countries (WHO and HAI, 2008). Data are collected from a stratified sample of facilities from public, private (including pharmacies) and other sectors (e.g. mission, NGO), on a core list of 30 medicines. This list is now structured to include 14 global medicines and 16 regionally specific medicines. In addition, countries are encouraged to collect data on a further 20 national complementary medicines. The affordability is evaluated by comparing medicine treatment costs to the days' wages of the lowest paid unskilled government worker. To integrate a list of tracer drugs in larger facility censuses or surveys would be desirable. This would allow more regular monitoring and integration with other data on health services such as infrastructure and human resources.

Apart from mere availability and drug expiry dates, the quality dimension is more difficult to assess: appropriate prescription practices, rational drug use, user compliance. This requires a more extensive assessment of practices in facilities including record reviews, exit interviews and observation of patient provider. There are three categories of indicators for which data are collected: prescribing indicators (average number of drugs per encounter, percent of drugs prescribed by generic name, percent of encounters with antibiotic prescribed etc.), patient care indicators (average consultation time, percent of drugs adequately labelled, patients' knowledge of correct dosage etc.), and facility indicators (availability of copy of essential drugs list of formulary, availability of key drugs).

WHO has collected information on the medicine supply system in over 100 countries in surveys in 1999, 2003 and 2007. This includes a facility and recently a household survey module has been pilot tested.

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3. Indicators

The MDG indicator on health service delivery - proportion of population with access to affordable essential drugs on a sustainable basis – has not been monitored regularly due to lack of comparable data. In general, there are still few systematic standardized efforts to measure drug access. WHO has decided to break down the MDG indicator into a structure and process component, which now includes nine indicators (see Box).

Measurement of access to drugs: different components and subindicators

<table>
<thead>
<tr>
<th>STRUCTURE:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>•  Access to essential medicines/technologies as part of the fulfillment</td>
<td>•  Access to essential medicines/technologies as part of the</td>
</tr>
<tr>
<td>of the right to health, recognized in the constitution or national</td>
<td>fulfillment of the right to health, recognized in the constitution</td>
</tr>
<tr>
<td>legislation (MTSP country progress indicator). Target: Yes</td>
<td>or national legislation (MTSP country progress indicator). Target:</td>
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<tr>
<td>•  Existence and year of last update of a published national medicines</td>
<td>Yes</td>
</tr>
<tr>
<td>policy (1). Target: Yes, and updated within the last ten years</td>
<td></td>
</tr>
<tr>
<td>•  Existence and year of last update of a published national list of</td>
<td>•  Existence and year of last update of a published national list</td>
</tr>
<tr>
<td>essential medicines (1) (MTSP indicator). Target: Yes, and updated</td>
<td>of essential medicines (1) (MTSP indicator). Target: Yes, and</td>
</tr>
<tr>
<td>within the last two years</td>
<td>updated within the last two years</td>
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<tr>
<td>•  Legal provisions to allow/encourage generic substitution in the private</td>
<td>•  Legal provisions to allow/encourage generic substitution in the</td>
</tr>
<tr>
<td>sector (1). Target: Yes</td>
<td>private sector (1). Target: Yes</td>
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<tr>
<th>PROCESS</th>
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<tbody>
<tr>
<td>•  Public and private per capita expenditure on medicines (1,2). Target:</td>
</tr>
<tr>
<td>country-specific $ value</td>
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<tr>
<td>•  Percentage of population covered by health insurance (1,2). Target:</td>
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<tr>
<td>country specific; ultimately 100%</td>
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<tr>
<td>•  Average availability of 30 selected essential medicines in public and</td>
</tr>
<tr>
<td>private health facilities (3) (MTSP country progress indicator). MTSP</td>
</tr>
<tr>
<td>target: 80%; probably needs country-specific targets</td>
</tr>
<tr>
<td>•  Median consumer price ratio of 30 selected essential medicines in</td>
</tr>
<tr>
<td>public and private health facilities (3) (MTSP country progress</td>
</tr>
<tr>
<td>indicator). MTSP target: below 4x world market reference price</td>
</tr>
<tr>
<td>•  Percentage mark-up between manufacturers’ and consumer price (3).</td>
</tr>
<tr>
<td>Target: country specific, but generally below 70% (target to be refired)</td>
</tr>
</tbody>
</table>

Explanatory notes:
(1) Standard WHO pharmaceutical survey indicator, collected every 4 years (last in 2007) from most countries
(2) Standard information, available from National Health Accounts, routinely collected from a large number of countries
(3) Standard WHO/HAI indicator from national medicine pricing surveys, currently available from 45 countries (2007)

Percent of facilities that have all tracer medicines and commodities in stock: on the day of visit, and in the last three months
Supplemented by: median proportion of tracer drugs that are in stock: on the day of visit, and in the last three months

Definition

- **Numerator**: the number of facilities with the selected tracer drugs in stock (present and non-expired) on the day of visit / during a specified reference period (last month or last 3 months).
- **Denominator**: the total number of facilities. The supplementary indicator gives the proportion of the 30 tracer drugs that are present in health facilities: Numerator: average number of tracer drugs present; denominator: total number of tracer drugs checked.
Data collection methods

- Facility visits are required using a standardized questionnaire to assess the availability of non-expired medicines and commodities on the day of visit and can also be used to assess stock-outs over the last month or last 3 months. Alternatively, facility reporting systems that are part of regular reporting systems such as the health management information system can generate the data required for this indicator.

Comparability issues

- The quality of data generated by facility visits is likely to be better than those based on reporting systems. Also, data on stockouts on the day of visit are more accurate than recalled data on stockouts in the months prior to the visit. The list of tracer items may vary between countries, or at least some elements and depending on the epidemiology (e.g. the presence of malaria or the type of AIDS epidemic). The components of the index (individual items) will have to be presented as well.

Periodicity

- The situation status at facilities should be monitored annually at the subnational level as a management tool. Sample facility surveys or routine reporting systems can provide national statistics.

Complementary dimensions

- Data on the medicines availability are used with data on other components of service capacity to assess the ability of facilities to provide specific services (see section on service delivery).

The proposed list of tracer medicines is shown in Box 1. In addition, more detail is obtained on the medicines for HIV/AIDS, tuberculosis, and malaria treatment.

More work is being done to obtain comparable data to monitor drug prices. A potentially useful indicator is the following:

**Ratio of median local medicine price to international reference price (median price ratio or MPR) for core list of drugs**

**Definition**

- **Numerator**: the median local price for a basket of tracer drugs.
- **Denominator**: the Management for Health Sciences International Drug Price Indicator Guide

**Data collection methods**

- Facility visits are required using a standardized questionnaire to assess the availability and price of non-expired medicines and commodities on the day of visit.

**Comparability issues**

- The core list of medicines tends to vary between countries and therefore results are often not comparable between countries. Also, the number of facilities (including pharmacies) is sometimes small leading to a large sampling error.
Periodicity

- Regular monitoring would be important (once every 2–3 years).

Complementary dimensions

- Data need to be presented by type of facility – public and private sector. In addition, public sector procurement price ratios can be used to monitor the situation.

An additional indicator focusing on affordability would be the number of days of the lowest paid government worker requires to purchase a course of a treatment. Such a treatment may be a pediatric respiratory infection treated with co-trimoxazole, a course of ciprofloxacin for gonorrhoea, one month course of glibenclamide treatment for diabetes, or salbutamol for asthma.
4. **List of medicines, commodities and vaccines**

**Infectious diseases**
1. Ciprofloxacin
2. Co-trimoxazole (suspension)
3. Co-trimoxazole (tabs)
4. Amoxicillin
5. Ceftriaxone (injection)
6. Other injectable antibiotic
7. Fluconazole
8. Albendazole or mebendazole (depending on country standards)
9. Metronidazole

**Chronic diseases**
10. Salbutamol inhaler (asthma)
11. Glibenclamide (diabetes)
12. Atenolol (cardiovascular diseases)
13. Captopril or enalapril (cardiovascular diseases) (depending on country standards)
14. Simvastatin (cardiovascular diseases)
15. Amitryptiline (depression)
16. Omeprazole (peptic ulcers and reflux)

**Other**
17. Diclofenac or Ibuprofen (pain)
18. Paracetamol (suspension)
19. Oral rehydration salts (sachets)
20. Oral contraceptive pills (combined)
21. Injectable contraceptives (progestin-only)
22. Condoms (male)
23. Oxytocin (injection)
24. Magnesium sulphate (eclampsia)
25. Measles vaccine

**Malaria**
1. Coartem (ACT, arteterm + lumefantrine)
2. Fansidar (SP, sulfadoxine + pyrimethamine)
3. Quinine (oral or injectable)
4. Other antimalarial drugs (oral or injectable)

**Tuberculosis**
1. Ethambutol

**Antiretrovirals**
1. Zidovudine (AZT, ZDV)
2. Abacavir (ABC)
3. Didanosine (DDI)
4. Efavirenz (EFZ)
5. Lamivudine (3TC)
6. Nevirapine (NVP)
7. Stavudine 40 or 30(d4T)
8. D4T + 3TC
9. D4T + 3TC + NVP
10. AZT + 3TC
11. AZT + 3TC + ABC
12. AZT + 3TC + NVP
13. Tenofovir + disoproxil fumarate (TDF/Viread)
14. TDF + Emtricitabine (FTC)
15. TDF + 3TC
16. TDF + 3TC + EFV
17. TDF + FTC + EFV

**Protease inhibitors**
18. Atazanavir (ATV)
19. Indinavir (IDV)
20. Lopinavir/ritonavir (LPV/RTV)
21. Nelfinavir (NFV)
22. Ritonavir (RTV)
23. Saquinavir (SQV)
Annex: selected tools and further reading


DELIVER project, John Snow Int. Arlington VA
http://deliver.jsi.com/dhome/topics/monitoring/monitoringpubs/meresources/metools

Logistics Indictors Assessment Tool (LIAT). 2006
A quantitative data collection instrument, developed by DELIVER, that assesses health commodity logistics system performance and commodity availability at health facilities. The User's Guide is included and provides detailed instructions on how to use the tool.

This document is a data gathering tool developed by the DELIVER project to assess laboratory services and logistics. The ATLAS is a diagnostic and monitoring tool that can be used as a baseline survey to complete an annual assessment or as an integral part of the work planning process. The ATLAS is primarily a quantitative tool with a small sample qualitative facility survey of available commodities and equipment. The information collected using the ATLAS is analyzed to identify issues and opportunities, and to outline further assessment and/or appropriate interventions.

Newly revised, this qualitative data collection instrument provides a comprehensive system-level assessment of logistics system performance for any program that manages a health commodity.