4. Access to essential medicines
Access to essential medicines

4.1 Introduction

According to the WHO framework for health systems (1), a well-functioning health system ensures equitable access to essential medical products, vaccines and technologies of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use. To achieve these objectives, the following are needed:

• national policies, standards, guidelines and regulations that support policy;
• information on prices, the status of international trade agreements and the capacity to set and negotiate prices;
• reliable manufacturing practices when they exist in-country and quality assessment of priority products;
• procurement, supply and storage, and distribution systems that minimize leakage and other waste; and
• support for rational use of medicines, commodities and equipment, through guidelines and strategies to assure adherence, reduce resistance, maximize patient safety and training.

Monitoring access to essential medicines is closely intertwined with at least two other building blocks: service delivery and governance. Health service delivery is discussed in Section 1 of this handbook while issues related to governance are dealt with in Section 6.

This section of the handbook focuses on essential medicines, i.e. those that satisfy the priority health care needs of the population. Essential medicines are intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage, with assured quality, and at a price that individuals and the community can afford (2).

Access to medicines is included in the Millennium Development Goals under MDG 8, and specifically Target 8.E: In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries. 

Access has been defined as “having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour’s walk of the population” (3). Given its complexity, an overall picture of access to medicines can only be generated using a range of indicators that provide data on medicine availability and price, in both public and private sectors, in combination with key policy indicators. Recent United Nations reports, that assessed progress towards MDG target 8.E, found that low availability, high prices and poor affordability of medicines are key impediments to treatment access in low- and middle-income countries (4,5).

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4.2 Sources of information on access to essential medicines

Facility surveys

A general facility survey usually focuses on a wide range of key health services and collects information on facility infrastructure, equipment and supplies, support systems, management systems and providers’ adherence to standards. The collection of data on the availability of essential medicines and commodities and on the use of these medicines is an essential part of such surveys.

WHO and Health Action International (HAI) have developed a standardized methodology for facility-based surveys of medicine prices, availability, affordability and price components (6, 7). In the survey, data on the availability and price of approximately 50 medicines is collected through visits to medicines outlets in the public sector, private sector and any other sectors that serve as important medicine dispensing points (e.g. NGOs, mission hospitals). The list of survey medicines includes 14 medicines in use worldwide (Table 4.1) and 16 regionally specific medicines. In addition, countries are encouraged to collect data on a further 20 medicines of national importance. For each medicine, data are collected on the originator brand and the lowest-priced generic equivalent found at each medicine outlet. Government procurement prices are also collected, as are the add-on costs that are charged to medicines as they proceed through the supply and distribution chain. The survey is conducted by trained data collectors, following which data is double-entered into a pre-programmed Excel workbook that allows for standardized analysis. Treatment affordability is estimated by comparing medicine costs to the daily wage of the lowest-paid unskilled government worker.

Table 4.1 Global core list of medicines included in WHO/HAI surveys

<table>
<thead>
<tr>
<th>Indication</th>
<th>Medicine name</th>
<th>Strength</th>
<th>Dosage form</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Asthma</td>
<td>Salbutamol</td>
<td>0.1 mg/dose</td>
<td>inhaler</td>
</tr>
<tr>
<td>2 Diabetes</td>
<td>Glibenclamide</td>
<td>5 mg</td>
<td>capsule/tablet</td>
</tr>
<tr>
<td>3 Cardiovascular disease</td>
<td>Atenolol</td>
<td>50 mg</td>
<td>capsule/tablet</td>
</tr>
<tr>
<td>4 Cardiovascular disease</td>
<td>Captopril</td>
<td>25 mg</td>
<td>capsule/tablet</td>
</tr>
<tr>
<td>5 Cardiovascular disease</td>
<td>Simvastatin</td>
<td>20 mg</td>
<td>capsule/tablet</td>
</tr>
<tr>
<td>6 Depression</td>
<td>Amitriptyline</td>
<td>25 mg</td>
<td>capsule/tablet</td>
</tr>
<tr>
<td>7 Infectious disease</td>
<td>Ciprofloxacin</td>
<td>500 mg</td>
<td>capsule/tablet</td>
</tr>
<tr>
<td>8 Infectious disease</td>
<td>Co-trimoxazole</td>
<td>8+40 mg/ml</td>
<td>suspension</td>
</tr>
<tr>
<td>9 Infectious disease</td>
<td>Amoxicillin</td>
<td>500 mg</td>
<td>capsule/tablet</td>
</tr>
<tr>
<td>10 Infectious disease</td>
<td>Ceftriaxone</td>
<td>1 g/vial</td>
<td>injection</td>
</tr>
<tr>
<td>11 Central nervous system diseases</td>
<td>Diazepam</td>
<td>5 mg</td>
<td>capsule/tablet</td>
</tr>
<tr>
<td>12 Pain/inflammation</td>
<td>Diclofenac</td>
<td>50 mg</td>
<td>capsule/tablet</td>
</tr>
<tr>
<td>13 Pain/inflammation</td>
<td>Paracetamol</td>
<td>24 mg/ml</td>
<td>suspension</td>
</tr>
<tr>
<td>14 Ulcer</td>
<td>Omeprazole</td>
<td>20 mg/ml</td>
<td>capsule/tablet</td>
</tr>
</tbody>
</table>

*Medicine names may be spelt differently in different countries.

A detailed description of the methodology, as well as country-specific data and reports, can be found at http://www.haiweb.org/medicineprices/, accessed 23 May 2010.
Integration of a list of tracer medicines 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. A list of medicines has been proposed by various disease programmes in WHO for inclusion in the service availability and readiness assessment methodology (see Annex to this section) (8). It is recommended that all surveys collect, at a minimum, data on the global list of 14 medicines included in WHO/HAI surveys. The inclusion of additional medicines should be based on national treatment guidelines, local disease patterns and other priorities. Where possible, the use of the WHO/HAI methods of collecting, entering and analysing data are strongly encouraged.

In addition to the availability and price of medicines, it is also important to assess the quality of use aspects, such as appropriate prescription practices, rational medicine use and user adherence. This requires a more extensive assessment of practices in facilities, including record reviews, exit interviews and observation of patients and providers. There are three categories of indicators for which data are collected (9):

1. prescribing indicators (average number of medicines prescribed per encounter, percentage of medicines prescribed by a generic name, percentage of encounters with an antibiotic prescribed, percentage of encounters with an injection prescribed, percentage of medicines prescribed from essential medicines list);
2. patient care indicators (average consultation time, average dispensing time, percentage of medicines actually dispensed, percentage of medicines adequately labelled, the patient's knowledge of correct dosage);
3. facility indicators (availability of a copy of essential medicines list of formulary, availability of key medicines).

A recently conducted quantitative review of studies published between 1990 and 2007, (that reported common indicators of medicines use) reported on medicines use in developing and transitional countries, and on the impact of interventions undertaken to improve medicines use, by analysing data from 679 studies conducted in 97 countries (10).

To accompany the Questionnaire on structures and processes of country pharmaceutical situations, WHO has developed a set of facility-level indicators to measure key outcomes of these structures and processes in the areas of access, product quality and rational use (11, 12).

- Access is measured in terms of the availability and affordability of essential medicines.
- Quality is represented by the absence of expired stock on pharmacy shelves and adequate handling and conservation conditions.
- Rational use is measured by examining prescribing and dispensing practices and the implementation of strategies that have been shown to support rational use, such as standard treatment guidelines and the essential medicines list.

These indicators are measured with standardized collection instruments in public health facilities, private drug outlets and in warehouses supplying the public sector, through the Survey of Medicine Prices, Availability, Affordability and Price Components (6). Surveys of 30 public health facilities and their dispensaries gathered information about the availability of essential medicines, medicine prices, adequacy of conservation conditions, affordability, prescribing and dispensing habits, and presence of guidelines. A similar survey of five warehouses supplying the public sector also examined availability, stockout duration, and adequacy of conservation conditions. Surveys of 30 private pharmaceutical outlets assessed the availability, affordability and prices of medicines.
Key informant surveys

Surveys by experts with extensive knowledge about the medicines situation in a country can be used to generate information about pharmaceutical policies and practices related to regulation, selection of essential medicines, as well as procurement and use. While this method has a low cost and is relatively easy to implement, the disadvantage is its subjectivity, which introduces measurement errors and affects comparability both between countries and over time within the same country.

Data on national medicines policies and their components (including legislation and regulations, quality control of medicines, essential medicines lists, supply systems, financing, access to medicines, production, rational use, and protection of intellectual property rights) can be obtained from the WHO questionnaire on structures and processes of country pharmaceutical situations (8, 9). The questionnaire is a basic assessment tool that provides a rapid means of obtaining information on the existing infrastructure and key processes of each component of the pharmaceutical sector. Data are collected through a country data collection instrument that are used to generate a Pharmaceutical Country Profile. The national coordinator identifies responsible people, government agencies or groups who can provide responses and source documents related to the different pharmaceutical sections/areas in the data collection instrument.

4.3 Core indicators

The recommended core indicators to measure access to essential medicines are as follows.

**Recommended core indicator 1: Average availability of 14 selected essential medicines in public and private health facilities**

**Definition**
The average percentage of medicines outlets, where a selection of essential medicines are found on the day of the survey.

**Data collection methodology**
National surveys\(^3\) of medicine price and availability conducted using a standard methodology developed by WHO and Health Action International.\(^4\) Data on the availability of a specific list of medicines are collected from six geographic or administrative areas in a sample of medicine dispensing points.

**Periodicity of measurement**
In the absence of routine monitoring, it is recommended that a national survey of medicine prices and availability be conducted every three to five years using the WHO/HAI standard methodology.

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\(^3\) In large countries such as India and China, sub-national surveys have been conducted.

**Recommended core indicator 2: Median consumer price ratio of 14 selected essential medicines in public and private health facilities**

**Definition**

Consumer price ratios are calculated as the ratio between median unit prices (e.g. price per tablet or therapeutic unit) and Management Sciences for Health (MSH) median international reference prices for that exact product for the year preceding the survey.

**Data collection methodology**

National surveys of medicine price and availability conducted using a standard methodology developed by WHO and HAI. Data on the price of a specific list of medicines are collected in six geographic or administrative areas in a sample of medicine dispensing points.

**Periodicity of measurement**

In the absence of routine monitoring, it is recommended that a national survey of medicine prices and availability be conducted every three to five years using the WHO/HAI standard methodology.

**4.4 Additional indicators for a full pharmaceutical profile**

In addition to the core indicators, the following indicators are recommended should a country wish to undertake a full pharmaceutical profile. These are in line with the monitoring of progress towards MDG indicator 8.13 — the proportion of population with access to affordable essential medicines on a sustainable basis — that has been reported by the United Nations in 2008 (4) and 2009 (5) using a set of nine structural and process indicators proposed by WHO to quantify access (see summary in Table 4.2).

**Recommended indicator 1: Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation**

**Definition**

Whether or not access to essential medicines/technologies is recognized in the constitution or national legislation as part of the progressive realization of the right to health and/or as a specific entitlement of all citizens.

**Data collection methodology**

This indicator necessitates a review of the national constitution or legislation. At the international level, such a review was conducted by WHO in 2008.

**Periodicity of measurement**

The data are not likely to change frequently over time. Four-yearly national updates are envisaged as part of WHO's global pharmaceutical surveys.

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5 MSH international reference prices have been selected as a comparator as they are widely available, updated frequently, and relatively stable over time. They represent median prices of high quality multi-source medicines offered to developing and middle-income countries by different suppliers. The large majority of MSH prices are for multi-source products, and are usually ‘Ex-Works’ prices.
**Recommended indicator 2: Existence and year of last update of a published national medicines policy**

**Definition**
Existence of an official National Medicines Policy (NMP), expressed as a yes/no indicator, and updated within the past five years.

**Data collection methodology**
Key informant surveys with a standard tool, such as the WHO Questionnaire on structures and processes of country pharmaceutical situations.

**Periodicity of measurement**
Every four years.

**Recommended indicator 3: Existence and year of last update of a published national list of essential medicines**

**Definition**
Existence of an essential medicines list expressed as a yes/no indicator and updated within the past five years.

**Data collection methodology**
Key informant surveys with a standard tool, such as the WHO Questionnaire on structures and processes of country pharmaceutical situations.

**Periodicity of measurement**
Every four years.

**Recommended indicator 4: Legal provisions to allow/encourage generic substitution in the private sector**

**Definition**
Existence of legal provisions to allow generic substitution in the private sector, expressed as a yes/no indicator.

**Data collection methodology**
Key informant surveys with a standard tool, such as the WHO questionnaire on structures and processes of country pharmaceutical situations.

**Periodicity of measurement**
Every four years.
**Recommended indicator 5: Public and private per capita expenditure on medicines**

**Definition**
The reference indicator is total pharmaceutical expenditure (TPE). It may be defined as the total consumption of pharmaceuticals, regardless of the distribution mean, the place or condition of consumption or its type (prescription or over-the-counter). Per capita data are obtained from the whole population. As much as possible, this indicator is disaggregated into two components to reflect public and private sector financing. Public financing refers to social security, territorial governments, and extrabudgetary entities combined, while private financing includes out-of-pocket spending, finances related to private insurance, nongovernmental organizations, and corporations (excluding social security).

**Data collection methodology**
Data on medicines expenditures can be obtained from National Health Accounts (NHA), which is a systematic, comprehensive, and consistent monitoring of resource flows in a country’s health system for a given period. The NHA is designed to capture the full range of information contained in resource flows and reflects the main functions of health care financing, such as resource mobilization and allocation, pooling and insurance, purchasing of care, and the distribution of benefits. More information on NHA can be found in Section 5 of this toolkit, *health systems financing*. While the NHA has different tables with the same content from various approaches, TPE should be the basis of the estimation for this indicator.

**Periodicity of measurement**
Periodicity is dependant on collection of NHA data; annually for most countries.

**Recommended indicator 6: Percentage of population covered by health insurance**

**Definition**
*Numerator: *Number of people covered by health insurance.

*Denominator: *Total number of population.

**Data collection methodology**
Household survey. For example, data on insurance coverage has been reported using data from the World Health Survey 2004.

**Recommended core indicator 7: Percentage mark-up between manufacturers’ and consumer prices**

**Definition**
How much the final medicine price is greater, in percentage, above the manufacturer’s selling price or the cost, insurance and freight price.

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Data collection methodology

National surveys of medicines prices and availability conducted using a standard methodology developed by WHO and HAI. Data on the add-on costs that contribute to the final price of medicines are collected by tracking selected tracer medicines through the supply and distribution chain.

Periodicity of measurement

It is recommended that a national survey of medicines prices and availability be conducted every three to five years using the WHO/HAI standard methodology.

Table 4.2 Summary of indicators for a full pharmaceutical profile, including core indicators for access to essential medicines

<table>
<thead>
<tr>
<th>Indicators</th>
<th>Data collection method</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Structure</strong></td>
<td></td>
</tr>
<tr>
<td>1. Access to essential medicines/technologies as part of the fulfilment of the right to health, recognized in the constitution or national legislation.</td>
<td>Review of national constitution or legislation.</td>
</tr>
<tr>
<td>2. Existence and year of last update of a published national medicines policy.</td>
<td>Key-informant surveys using standard tool such as the WHO Questionnaire on structures and processes of country pharmaceutical situations.</td>
</tr>
<tr>
<td>3. Existence and year of last update of a published national list of essential medicines</td>
<td></td>
</tr>
<tr>
<td>4. Legal provisions to allow/encourage generic substitution in the private sector</td>
<td></td>
</tr>
<tr>
<td><strong>Process</strong></td>
<td></td>
</tr>
<tr>
<td>5. Public and private per capita expenditure on medicines</td>
<td>National Health Accounts</td>
</tr>
<tr>
<td>6. Percentage of population covered by health insurance</td>
<td>Household surveys</td>
</tr>
<tr>
<td>7. Average availability of 14 selected essential medicines in public and private health facilities*</td>
<td>National (or sub-national when necessary) surveys of medicine price and availability conducted using a standard methodology developed by WHO and Health Action International.</td>
</tr>
<tr>
<td>8. Median consumer price ratio of 14 selected essential medicines in public and private health facilities*</td>
<td></td>
</tr>
<tr>
<td>9. Percentage mark-up between manufacturers’ and consumer prices</td>
<td></td>
</tr>
</tbody>
</table>

* Core indicators to measure access to essential medicines.

Selected tools


This second edition includes updated versions of the survey manual, an automated data workbook, survey instruments and a CD ROM of survey tools and background materials, all of which have been refined based on the lessons learnt in the 50+ surveys conducted to date.


This operational package is a tool for researchers, policy-makers, planners and others who need to use standardized measurement tools to gather data and other information for monitoring and assessing country
pharmaceutical situations. Level I questionnaire can be used as a checklist to illustrate sectoral structures, strategies and approaches. Countries can also use selected forms from the Level II facility survey in their routine monitoring. The results can help focus their strategies, advocacy plans and information campaigns.

Note This package is being updated and a new version will be published in early 2011


This manual defines a limited number of objective measures that can describe the medicine use situation in a country, region or individual health facility. The medicine use indicators described are intended to measure specific aspects of the behaviour of health providers in health facilities in a reproducible manner.


This quantitative data collection instrument, developed by the USAID DELIVER project, helps assess health commodity logistics system performance and commodity availability at health facilities. A detailed user guide is included.


This qualitative data collection instrument provides a comprehensive system-level assessment of logistics system performance for any programme that manages a health commodity.

**Further reading**


**References**


Annex. Recommended list of medicines for inclusion in the WHO service availability and readiness assessment methodology

### Core medicines to be included in all surveys

- Amitriptyline 25 mg capsule/tablet
- Amoxicillin 500 mg capsule/tablet
- Atenolol 50 mg capsule/tablet
- Captopril 25 mg capsule/tablet
- Ceftriaxone 1 g/vial injection
- Ciprofloxacin 500 mg capsule/tablet
- Co-trimoxazole 8+40 mg/ml suspension
- Diazepam 5 mg capsule/tablet
- Diclofenac 50 mg capsule/tablet
- Glimeperazamide 5 mg capsule/tablet
- Omeprazole 20 mg capsule/tablet
- Paracetamol 24 mg/ml suspension
- Paracetamol 20 mg capsule/tablet
- Salbutamol 0.1 mg/dose inhaler
- Simvastatin 20 mg capsule/tablet

### Additional medicines to be considered for inclusion

#### Infectious diseases
1. Co-trimoxazole (capsule/tablet)
2. Fluconazole
3. Albendazole or Mebendazole (depending on country standards)
4. Metronidazole

#### Chronic diseases
1. Enalapril (depending on country standards)
2. Beclometasone (inhaler)
3. Metformin
4. Insulin (injection)

#### Other
1. Ibuprofen
2. Oral rehydration salts (sachets)
3. Measles vaccine

#### Reproductive health
1. Oral contraceptive pills (combined)
2. Injectable contraceptives (progestin-only)
3. Condoms (male)
4. Oxytocin (injection)
5. Magnesium sulphate (injection, eclampsia)
6. Diazepam (injection)

#### Malaria
1. ACT, Artemeter + Lumefantrine
2. SP, Sulphadoxine + Pyrimethamine
3. Quinine (oral or injectable)
4. Other antimalarial medicines (oral or injectable)

#### Tuberculosis
1. Ethambutol
2. Isoniazid
3. Pyrazinamide
4. Rifampicin
5. Streptomycin (injectable)
6. Isoniazid + Rifampicin (2FDC)
7. Isoniazid + Ethambutol (EH) (2FDC)
8. Isoniazid + Rifampicin + Pyrazinamide (RH) (3FDC)
9. Isoniazid + Rifampicin + Pyrazinamide + Ethambutol (4FDC)

#### 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
1. Atazanavir (ATV)
2. Indinavir (IDV)
3. Lopinavir/Ritonavir (LPV/RTV)
4. Nelfinavir (NFV)
5. Ritonavir (RTV)
6. Saquinavir (SQV)