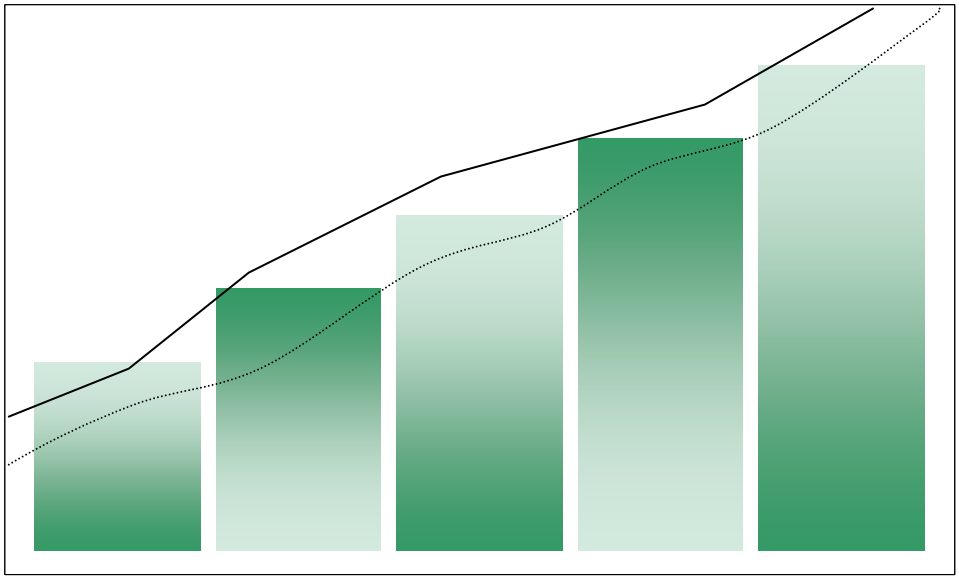
# WHO
# Operational Package for Monitoring and Assessing Country Pharmaceutical Situations



Working Draft June 2005

# Package Contents

## Introductory notes

## Technical manual

1. Manual for core indicators on country pharmaceutical situations

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2. Guide for coordinators and data collectors: Level II core indicators

## Packet containing:

3. Diskette
4. Loose copies for photocopying of:
   - Level II Survey Forms 1–15
   - Level II Summary Forms 1–4
   - Level I Questionnaire
   - Training Slides

***This version is a working draft and is still undergoing revision and editing. Please send comments as well as hard copy and/or electronic copy of completed summary forms, Level I Questionnaire, and any report resulting from this package to:***

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# Introductory notes

Monitoring and assessing the pharmaceutical sector is important to determine if the key pharmaceutical objectives are met: people have access to essential medicines, these medicines are safe, effective and of good quality, and these medicines are used properly. The pharmaceutical sector is a vital component of health systems. It is also complex because it involves many stakeholders and government agencies. A systematic method to assess and monitor the impact of strategies and activities will provide information on issues and gaps, all-important input in the development of health policies

The WHO process on pharmaceutical monitoring and assessment, uses a hierarchical approach with three groups of indicators: Level I, Level II and Level III. This provides a standard methodology to follow progress over time and to compare situations in different facilities, districts and countries.

Information gathered is useful to reassess strategies, prioritise and strengthen pharmaceutical system components, and to synchronise programmes and policies. Policy-makers and managers will have clear picture of national and institutional problems. International agencies and donors can focus on priority areas where best impact can be achieved. Professional groups and NGOs can focus advocacy and information campaigns. Information can be shared via database and web pages.

The *WHO Operational package for monitoring and assessing country pharmaceutical situations* was designed as a practical tool to monitor and assess pharmaceutical situations. This operational package is in three parts:

- *Manual for core indicators on country pharmaceutical situations* containing explanations of Level I and Level II indicators; survey and sampling design; and analysis and presentation templates.
- *Guide for coordinators and data collectors*: *Level II core indicators* detailing operational procedures to carry out the Level II indicator survey, step-by-step procedures on administrative preparation (budget, training plan and schedule) and technical requirements (training and field testing, surveying, analysis, and reporting). It includes training slides.
- Diskette and loose copies of the Level I questionnaire, Level II survey and summary forms and training slides for photocopying.

Since the year 2000, at least 20 countries have used the operational package. The current version has benefited considerably from the experiences in these countries. The indicators have also been used in international/regional courses and meetings to gather data from health facilities and pharmacies. Experiences have shown that the survey can be completed without investing large resources of time, people or money. Thus in the long run, regular monitoring is not difficult and can be done in a cost efficient manner. This experience encourages allotting a portion of country support budgets, project grants and MOH budget for monitoring and assessment.

# Manual for Core Indicators on Country Pharmaceutical Situations

*It is important to know…*

- *if people have access to essential medicines;*
- *if they are getting medicines that are safe, effective and of good quality; and*
- *if these medicines are being properly used.*

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# Pharmaceutical indicators for monitoring and assessment

## The need for pharmaceutical sector indicators

It is necessary to assess the pharmaceutical sector to know:

- if people have access to essential medicines[1];
- if people are getting medicines that are safe, effective and of good quality; and
- if these medicines are being used properly.

Since the pharmaceutical sector is complex, a systematic method of gathering data is very important for assessing access, quality, and rational use of medicines. There are multiple, cross cutting factors that can influence access and rational use of quality medicines and a variety of strategies countries can adopt and implement to improve their pharmaceutical situations.

A number of indicators have been developed for monitoring national medicines policies. These indicators enable systematic assessment, evaluation and monitoring of the formulation and implementation of pharmaceutical policies and programmes. These can be used to:

- Assess country capacity, such as available infrastructure, logistics and human resources to support the pharmaceutical sector and implement national medicines policies;
- Monitor the implementation of medicines policies;
- Measure the impact of implementation strategies; and
- Evaluate progress towards identified objectives.

## Who can use the result

All stakeholders in the pharmaceutical sector can use indicator-based assessment of the pharmaceutical situation to inform priorities and set targets. They can also use regular monitoring of the sector through indicator-based studies to assess strengths and weaknesses of strategies to improve the provision of pharmaceuticals.

Indicators provide policy-makers and managers with a clear picture of national and institutional problems. Policy makers and managers can refer to study results when developing strategies to strengthen the pharmaceutical sector. Results can also be used to synchronize policies. For instance:

- Low access as measured by availability and affordability of essential medicines could indicate that policies on health and medicines financing should be reviewed. Economic policies may be focused on joining the global economy

[1] The words "medicines" and "drugs" are used interchangeably in this text.

without adequate consideration of the implications on pricing, affordability and availability of important medicines.
- Presence on the market of a large number of substandard medicines products could indicate the need to assess various policies and systems, including licensing and inspection of manufacturers, quality assurance or product registration.

International agencies and donors can use the results of indicator-based studies to identify where their activities will achieve the greatest impact. Professional groups and non-governmental organizations (NGOs) can use the results to focus their advocacy and information campaigns.

Standard indicators allow informative comparisons among countries. For example an indicator based assessment in twelve countries revealed:[2]
- Most of the countries surveyed have relevant structures in place, however, "it is easier to create structure than to make it work".
- Most of the countries have a medicines regulatory authority with a mandate to register medicines and inspect manufacturer and retail outlets, however, the enforcement of regulations is often weak.
- In most of the countries, public financing for medicines is limited.

## Indicator-based monitoring strategies

Monitoring national medicines policies is a complex task. While important, it is difficult to establish a sustainable system of regular monitoring. Resources are not consistently allocated to this task and there is limited advocacy for a culture of monitoring. Further, many efforts to develop monitoring tools have been exhaustive, but impractical. In the past, most monitoring tools included indicators that were difficult to collect, especially if done regularly.

A number of indicator-based monitoring tools now exist. *Indicators for monitoring national drug policies*[3], a WHO manual, includes approximately 120 indicators covering structure, process and outcomes of various national medicines policy (NMP) components. Several countries have used it to monitor and evaluate their pharmaceutical situations. Another set of indicators, developed by Management Sciences for Health,[4] focuses on rapid assessment of strengths and weaknesses in the pharmaceutical sector. The WHO manual *How to investigate drug use in health facilities* has been used extensively in many countries. WHO is also developing indicators to assess medicines regulations and access to pharmaceuticals.

This package, *Core indicators for monitoring and assessing country pharmaceutical situations*, was developed to provide a practical indicator-based tool that can be regularly implemented without investing large amounts of human or financial resources. This package relies on a hierarchical approach to monitoring built around three groups of core indicators. The core indicators can be easily collected using standardized methodologies, small samples of data and simple survey techniques.

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[2] WHO, 1997. *Comparative analysis of national drug policies. Report of second workshop*. Geneva: DAP/97.6.
[3] Brudon P, Rainhorn JD, Reich M. 1994. *Indicators for monitoring national drug policies*.
[4] MSH, 1995. *Rapid pharmaceutical assessment – An indicator-based approach*. Washington DC: MSH.

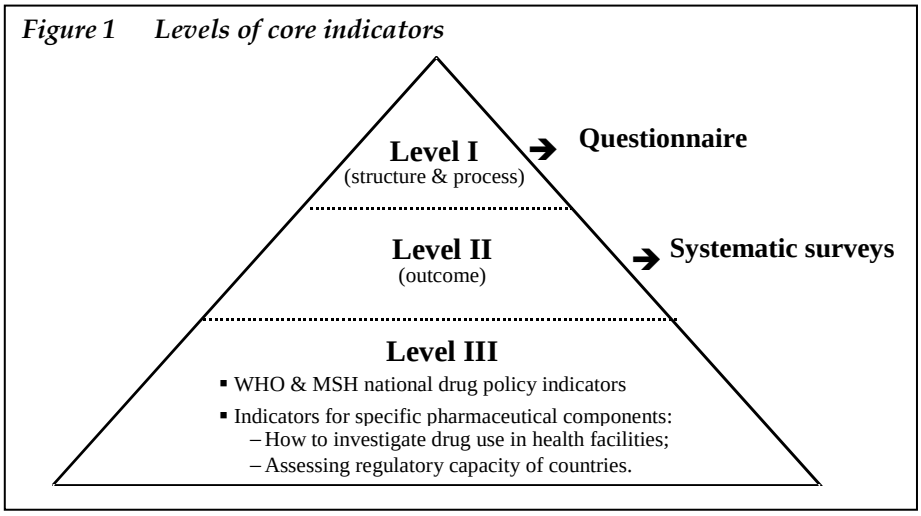
These core indicators measure systematically the most important information needed to gain a comprehensive picture of the pharmaceutical situation in a country.

## Levels of core indicators

Grouping monitoring indicators by level has the following advantages:

- It offers flexibility to those interested in information on the country pharmaceutical situation:
  - Rapid assessment of key pharmaceutical components;
  - Monitoring outcome and achievement of key objectives of the pharmaceutical policy; and
  - In-depth assessment of specific system components.
- It provides practical methods for regularly monitoring NMPs and their components.
- It encourages regular reporting and exchange of pharmaceutical information among facilities, districts, regions, government and non-governmental agencies as well as international organizations.

*Figure 1 Levels of core indicators*




**Level I** indicators provide a rapid means of obtaining information on the existing infrastructure and key processes of each component of the pharmaceutical sector. These indicators are assessed through a short questionnaire completed at the national level.

**Level II** indicators provide systematic data on access and rational use of quality medicines. Data on these indicators are collected through the systematic surveys contained in this package.

**Level III** indicators, such as those in the WHO manual *Indicators for monitoring national drug policies*, assess country NMP programmes and the implementation of each component in more detail. Countries implementing national medicines policies can use this as a baseline assessment and follow up studies can be conducted depending on needs and capabilities for extensive assessment. More information on these tools can be found on the WHO webpage http://www.who.int/medicines/strategy/policy/indicators_docs.shtml.

# Level I core indicators

The Level I core indicators are used to assess existing structures and processes in a national pharmaceutical system. They provide a method to rapidly assess the implementation of national medicines policies and their components.

For Level I indicators, a knowledgeable informant can coordinate the gathering of information. Most data will be available within the Ministry of Health, though data on intellectual property rights protection may require consultation with the responsible ministry. Data collection does not require field surveys and information can easily be updated periodically, for example every two years.

Data from Level I indicators can be used to array the achievements and weaknesses of individual pharmaceutical systems and to illustrate common sectoral strategies and approaches. Many WHO Member States have submitted data from the Level I questionnaire to EDM. The WHO MedNet can be consulted to compare results over time and among countries. Comparisons among countries can be particularly interesting and convincing for policy-makers. The questionnaire on Level I indicators is included as *Annex 1*. The indicators in this questionnaire are summarized below.

## Pharmaceutical components in level I indicators

**National medicines policy** An NMP document that covers the public and private sector, a written implementation plan and the integration of medicine and health policies provide a basic framework to organize and improve the pharmaceutical system. They also assist in coordinating the functions and strategies of each component as they are being implemented. Regular monitoring helps inform the NMP and its implementation.

**Legislation/regulations** on medicine manufacturing, sales and distribution must be in place. A medicines regulatory authority should be able to efficiently regulate these activities through registration of products, licensing and inspection of manufacturers, importers and pharmacies and monitoring of adverse drug reactions. Legislation directed at generic prescribing, dispensing and substitution can help increase access to essential medicines in both the private and public sectors.

**Quality control of pharmaceuticals** covers all activities to ensure patients receive safe, efficacious and high quality medicines. There should be a medicines quality control laboratory to test medicines prior to registration and from various points of the distribution system.

**Essential Medicines List (EML)** Both developed and developing countries have used EMLs to improve medicine supply management and use. The EML should be regularly updated.

**Medicines supply system** Access and availability of essential medicines, especially at public sector facilities, are affected by how medicines are purchased and distributed and how medicines are managed in the health system.

**Medicines financing** Access and availability are also affected by how much money the government can allocate to medicines, pricing policies, financing schemes (such as insurance programmes and user fees) and medicine donations.

**Access to essential medicines** includes physical access—distance to facilities and availability of medicines—as well as the affordability of these medicines.

**Production** activities from repackaging to formulation of products to developing new medicines are important in assessing the pharmaceutical sector.

**Rational use of medicines** Medicines policies can often have greater impact with effective use of strategies to improve the prescribing and dispensing practices of health workers. Key strategies include standard treatment guidelines, curricula and continuing education programs on essential medicines concepts, medicines information centers, and public education campaigns.

**Intellectual property rights protection and marketing authorization** Implementing TRIPS flexibilities in public health can increase access to medicines.

## Country progress indicators for the WHO medicines strategy[5]

WHO has identified key indicators to monitor its priority areas of work. Country progress indicators corresponding to target outcomes in the WHO Medicines Strategy were selected mostly from Level I indicators. WHO uses these to assess country, regional and global pharmaceutical situations and their progress. These indicators represent pharmaceutical components and strategies important in delivering effective health services.

The country progress indicators provide information on the structure, process and outcome of NMP implementation:

- *Structure: Does a country have the necessary structures and mechanisms in place for improving its pharmaceutical sector including:* a national medicines policy document, a national medicines policy implementation plan, a recently updated essential medicines list, computerized medicines registration, national guidelines on medicines donations, laws and regulations on herbal medicinal products, inclusion of traditional medicine in the national medicines policy and national health policy, and TRIPS compliant legislation using flexibilities to increase access to medicines?
- *Process: Has a country established the necessary procedures for implementing pharmaceutical strategies including:* continuing education programs on rational use of medicines, generic substitution at retail outlets, public health insurance that

[5] *WHO Medicines Strategy: Framework for action in essential drugs and medicines policy 2000-2003*

reimburses medicines costs, use of an essential medicines list and competitive tender for public procurement of medicines, participation in the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, and basic medicine regulation and quality assurance of medicines?

- *Outcome: Is a country achieving the pharmaceutical target outcomes set by WHO including:* improving the availability of essential medicines and increasing the percentage of the population with access to essential medicines?

For some indicators, several variables in the Level I questionnaire have been grouped together as minimum criteria necessary for ensuring implementation of a particular component of a pharmaceutical strategy or plan. These composite indicators are clearly more robust than indicators based on a single variable. *Box 1* provides examples.

***Box 1 Indicators with composite variables***

**Countries with public health insurance that covers medicines costs:** not only does a public health insurance system exist, but it also reimburses patients' medicines costs.

**Countries with a basic medicines regulation system:** including a law on medicines registration, a law on the manufacturing and importation of medicines, licensing based on inspection of retail outlets or manufacturers, registration of medicines by the medicines regulatory authority, and a list of registered medicines.

**Countries with basic quality assurance procedures:** including a request for proof of good manufacturing practices when an application for medicines registration is made, and sampling of medicines for regulatory purposes, and quality testing of medicines.

**Countries with a basic system for regulating pharmaceutical promotion:** including a law on promoting medicines which was established less than 10 years ago, regulation of the promotion of medicines by the government or co-regulation of by the government and the pharmaceutical industry, and regulation of medicines advertisements.

**Countries with a national medicines information centre able to provide independent information to prescribers and/or dispensers:** not only does such a centre exist, but it also actively provides information as requested by prescribers and/or dispensers.

**Countries with a medicines information service accessible to consumers:** not only does such a centre exist, but it also actively provides information as requested by consumers.

*WHO Medicines Strategy 2000-2003*

# Level II core indicators

The Level II core outcome indicators support the Level I structure and process indicators by providing specific data about important pharmaceutical outcomes. This set of indicators requires field surveys. For data to be collected accurately and reliably, attention must be paid to appropriate survey design, sampling, and data gathering techniques. In selecting the core outcome indicators, consideration was given to the need to obtain the most relevant information from as limited a data collection process as possible.

These indicators measure the degree of attainment of the strategic pharmaceutical objectives of improved access, quality and rational use. Access is measured in terms of the availability and affordability of essential medicines, especially to the poor and in the public sector. Measuring the actual quality of medicines by testing samples can be expensive. Instead, the presence of expired medicines on pharmacy shelves and the adequacy of handling and conservation conditions of medicines are used as indicators of quality. Finally, rational use is measured by examining prescribing and dispensing habits and the implementation of key strategies such as standard treatment guidelines (STG) and essential medicines lists (EML).

Level II indicators are measured in public health facilities, private drug outlets, and in warehouses supplying the public sector[6]. Surveys of 30 public health facilities and their dispensaries are used to gather information about availability of essential medicines, medicine prices, stockout duration, adequacy of conservation conditions, affordability, prescribing and dispensing habits, and presence of guidelines. A similar survey of 5 warehouses supplying the public sector also examines availability, stockout duration, and adequacy of conservation conditions. Surveys of 30 private drug outlets assess availability, affordability and medicines prices.

Survey Forms 1–15 have been developed to obtain data from survey sites. *Box 2* summarizes the Level II indicators and lists the corresponding survey forms. The indicators are described in more detail below. Information on data collection and calculation can also be found on the respective survey forms. *Part III* and *Part IV* outline the sampling framework and survey methodology. Summary Forms 1–4 provide a simple method of combining facility results to get national indicators.

***Box 2 Summary list of indicators and corresponding survey form used to collect the data***

| | Indicator | Survey Form |
|---|---|---|
| ***Accessibility*** | | |
| 1 | Availability of key medicines in public health facility dispensaries, private drug outlets and warehouses supplying the public sector | 1, 11, 13 |
| 2 | % of prescribed medicines dispensed or administered to patients at public health facility dispensaries | 6 |
| 3 | Average stockout duration in public health facility dispensaries and | 3, 14 |

[6] For the purposes of the Level II survey package, a private drug outlet is a permanent retailer selling medicines, whether a pharmacy, drug seller, drug store, or chemical seller, a warehouse is a central, regional, or district warehouse supplying the public sector, and a public health facility dispensary or public health facility pharmacy refers to the medicines dispensing area of the public health facility whether or not there is a pharmacist present.

| | | |
|---|---|---|
| | warehouses supplying the public sector | |
| 4 | Adequate record keeping in public health facility dispensaries and warehouses supplying the public sector | 3, 14 |
| 5 | Affordability of treatment for adults and children under 5 years of age at public health facility dispensaries and private drug outlets | 5, 10 |
| 6 | Price of key medicines in public health facility dispensaries and private drug outlets (under development) | 2, 12 |
| 7 | Average cost of medicines and related fees at public health facilities | 6 |
| ***Quality*** | | |
| 1 | % medicines expired in public health facility dispensaries, private drug outlets and warehouses supplying the public sector | 1, 11, 13 |
| 2 | Adequacy of conservation conditions and handling of medicines in public health facility dispensaries and warehouses supplying the public sector | 4, 15 |
| ***Rational use of medicines*** | | |
| 1 | % medicines adequately labelled at public health facility dispensaries | 6 |
| 2 | % patients know how to take medicines at public health facility dispensaries | 6 |
| 3 | Average number of medicines per prescription at public health facility dispensaries and public health facilities | 6, 7 |
| 4 | % patients prescribed antibiotics in public health facilities | 7 |
| 5 | % patients prescribed injections in public health facilities | 7 |
| 6 | % prescribed medicines on the essential medicines list at public health facilities | 7 |
| 7 | % medicines prescribed by generic name (INN) at public health facilities | 7 |
| 8 | Availability of standard treatment guidelines at public health facilities | 8 |
| 9 | Availability of essential medicines list at public health facilities | 8 |
| 10 | % tracer cases treated according to recommended treatment protocol/guide at public health facilities | 9 |

## Access

### 1. Availability of key medicines in public health facility dispensaries, private drug outlets and warehouses supplying the public sector (Survey Forms 1, 11 and 13)

*Purpose* To measure current availability of key medicines to treat common health problems in public health facility dispensaries, private drug outlets and warehouses. Essential medicines to treat common diseases should be available in all these facilities, especially in public sector facilities providing health services for the poor. Physical availability is a basic measure of access to essential medicines. See pages 29–30 for guidance on selecting key medicines for this study.

*Prerequisites* List of 15 key essential medicines to treat the most common health problems

*Source of data* Survey of 30 public health facility dispensaries, 30 private drug outlets, and 5 warehouses

*Process* Go through the shelves and identify which of the listed essential medicines are available at the facility at the time of the survey. Only count in stock medicines in the facility at the time of the visit

regardless of whether or not they are available at an offsite storage facility.

*Calculation* % of key medicines available in a facility = % in stock = number of key medicines available in a facility ÷ number of key medicines reviewed x 100

National average = sum of % of key medicines available for all facilities ÷ number of facilities sampled

**2. % of prescribed medicines dispensed or administered to patients at public health facility dispensaries (Survey Form 6)**

*Purpose* To measure the degree to which facilities are able to provide needed medicines

*Source of data* Sample of 30 prospective outpatient encounters at 30 public health facility dispensaries. See page 28 for sampling instructions.

*Process* Interview patients leaving the dispensing area or leaving the facility after they have been treated and received medicines. Patients can be interviewed consecutively or as convenient.

Count how many chemical entities were prescribed and dispensed.

*Calculation* % of medicines dispensed = number of medicine dispensed ÷ number of medicines prescribed x 100

National average = sum of % of medicine dispensed for all public health facility dispensaries ÷ number of public health facility dispensaries sampled

**3. Stockout duration at public health facility dispensaries and warehouses supplying the public sector (Survey Forms 3 and 14)**

*Purpose* To measure availability over the past 12 months of key medicines to treat common health problems. An adequate logistic system ensures that essential medicines remain in stock at all times.

*Prerequisite* List of 15 key essential medicines to treat the most common health problems

Adequate medicine stock recording system (able to access stock records for the previous 12 months)

*Source of data* Survey of 30 public health facility dispensaries and 5 warehouses

*Process* Using existing data on stock cards, record the number of days each key medicine is not available (when the stock is zero). A medicine is in stock if any dose of any equivalent product is available in either branded or generic form. Stockout should be measured based upon the chemical entity rather than any one brand or dosage form.

The review period should cover as much as possible one year and never less than six months.

*Calculation* Equivalent number of days per year each medicine is out of stock = number of days each medicine is out of stock x 365 ÷ number of days covered by the review for that medicine

Average stockout duration in each facility = average number of stockout days = sum of the equivalent number of days per year all medicines are out of stock ÷ number of key medicines reviewed

National average = sum of average stockout duration in all facilities ÷ number of facilities sampled

**4. % Adequate record keeping at public health facility dispensaries and warehouses supplying the public sector (Survey Forms 3 and 14)**

*Purpose* To determine the extent to which stock records are maintained. The presence of adequately maintained and accurate stock records contributes to proper management, estimation of needs and the reorder of medicines.

*Prerequisite* List of 15 key essential medicines to treat the most common health problems

*Source of data* Survey of 30 public health facility dispensaries and 5 warehouses

*Process* For each of the key medicines, examine the data on the stock card and identify those medicines for which there are records of quantities of receipt, issue and stock-on-hand for at least 6 months in the previous 12 months

*Calculation* % adequate stock records = number of incidences where there are adeqaute records for at least 6 months ÷ number of key medicines reviewed

National average = sum of % adequate stock records for all facilities ÷ number of facilities sampled

**5. Affordability of treatment for adults and children under 5 years of age at public health facility dispensaries and private drug outlets (Survey Forms 5 and 10)**

*Purpose* To measure affordability of basic pharmaceutical treatment as an indicator of access to essential medicines. In most developing countries, a majority of the population pays for treatment out-of-pocket. Affordability is expressed as the ratio of the cost of treating moderate pneumonia another condition to a standard unit of measure. For this survey, the lowest daily government salary is used. Countries may also identify an optional second unit of measure (e.g. poverty line, basket of food, etc.).

*Prerequisite* Lowest government daily wage or the lowest daily wage of any appropriate majority group

Standard treatment for moderate pneumonia and another condition (where no hospitalization is required) for adults and children

*Source of data* Survey of 30 public health facility dispensaries and 30 private drug outlets.

*Process* Identify the treatment of choice (medicine/generic name, dosage form and strength) for adults and children based on standard treatment guidelines

Identify the number of units needed to complete the treatment

Identify the unit price (the price charged to patients) for the lowest priced brand or generic equivalent medicine in each pharmacy, include any applicable charges that patients would pay to receive treatment such as dispensing fees and/or syringes. If there are flat charges paid for each medicine given to patients, then this amount should be recorded as the price of the medicine. Indicate "0" if medicines are given free of charge.

*Calculation*

Total cost of treatment = number of units needed to complete the treatment x unit price

Equivalent number of day's wages = total cost of treatment ÷ lowest daily government salary

Ratio of cost of treatment and optional standard unit of measure = total cost of treatment ÷ optional standard unit of measure

National average = sum of equivalent number of day's wages at all facilities ÷ number of facilities sampled

National average = sum of ratio of cost of treatment and optional standard unit of measure at all facilities ÷ number of facilities sampled

**6. Price of key medicines in public health facility dispensaries and private drug outlets (Survey Forms 2 and 12)**

UNDER DEVELOPMENT

**7. Average cost of medicines and related fees at public health facilities (Survey Form 6)**

*Purpose*

To measure average cost paid by patient for non-diagnostic fees at public health facilities as an indicator of access to essential medicines. In most developing countries, a majority of the population pays for treatment out-of-pocket.

*Source of data*

Sample of 30 prospective outpatient encounters at 30 public health facility pharmacies. See page 28 for sampling instructions.

*Process*

Interview patients leaving the dispensing area/pharmacy or leaving the facility after they have been treated and received medicines. Patients can be interviewed consecutively or as convenient.

Ask how much each patient paid out-of-pocket for the medicines received at the facility.

Ask how much each patient paid out-of-pocket in other non-diagnostic fees, such as visit or injections fees but not lab or x-ray fees.

*Calculation*

Average cost = (amount paid for medicines + amount paid in other non-diagnostic fees) ÷ number of patients reviewed

National average = average cost for all public health facility dispensaries ÷ number of public health facility dispensaries sampled

## Quality

**1. Presence of expired medicines in public health facility dispensaries, private drug outlets and warehouses supplying the public sector (Survey Forms 1, 11 and 13)**

*Purpose* To determine if expired medicines are being distributed or sold. In some countries, expired medicines are distributed or medicines are allowed to go out of date on pharmacy shelves. See page 29–30 for guidance on selecting key medicines for this study.

*Prerequisite* List of 15 essential medicines to treat the most common health problems

*Source of data* Survey of 30 public health facility dispensaries, 30 private drug outlets and 5 warehouses

*Process* Go through stock on shelves and check the expiry dates of all of the generic and branded forms of each of the essential medicines. If any of the strengths has an expiry problem, the answer for that medicine should be "yes". If expired medicines are listed and kept in a designated location in the store to be destroyed, availability of expiry should not be registered.

*Calculation* % of expired key medicines in stock = number of key medicines with any samples beyond expiry date ÷ number of key medicines in stock x 100

National average = sum of % of expired key medicines in stock at all facilities ÷ number of facilities sampled

**2. Adequacy of conservation conditions and handling of medicines in public health facility pharmacies/dispensaries and central/regional/district warehouses supplying the public sector (Survey Forms 4 and 15)**

*Purpose* To determine status of conservation conditions and handling of medicines in public sector facilities, both of which are factors that affect quality of medicines

*Prerequisite* Checklist of minimum criteria for adequate conservation conditions and handling of medicines at facilities

*Source of data* Survey of 30 public health facility dispensaries and 5 warehouses

*Process* Use the checklist to rate the conservation conditions and handling of medicines. Only indicate "true" if all conditions of the statement are true. If any condition of the statement is false, indicate "false".

*Calculation* Score = the total number of "true" responses to items on the checklist ÷ 8 x 100

National average = total score of all facilities ÷ number of facilities sampled

## Rational use of medicines

**1. % medicines adequately labelled at public health facility dispensaries (Survey Form 6)**

*Purpose* To assess quality of dispensing practice. If medicines are to be used properly, they should be labelled appropriately by the person dispensing them.

*Prerequisite* An adequate label includes the name of the medicine, how much to be taken and the frequency of administration.

*Source of data* Sample of 30 prospective outpatient encounters at 30 public health facility dispensaries. See page 28 for sampling instructions

*Process* Interview patients leaving the dispensing area or leaving the facility after they have been treated and received medicines. Patients can be interviewed consecutively or as convenient.

Check if each medicine label conforms to all requirements for adequate labelling. Count a medicine as adequately labelled only if all requirements are met.

*Calculation* % of medicines adequately labelled = total number of medicines adequately labelled ÷ total number of medicines dispensed x 100

National average = sum of % of medicines adequately labelled at all public health facility dispensaries ÷ number of facilities sampled

**2. % patients know how to take medicines at public health facility dispensaries (Survey Form 6)**

*Purpose* To assess if patients have adequate knowledge of how to take their medicines.

*Prerequisite* Adequate knowledge includes knowing the appropriate dosage and duration of each medicine.

*Source of data* Sample of 30 prospective outpatient encounters at 30 public health facility dispensaries. See page 28 for sampling instructions.

*Process* Interview patients leaving the dispensing area or leaving the facility after they have been treated and received medicines. Patients can be interviewed consecutively or as convenient.

Check if the patient knows both the appropriate dosage and duration of each medicine (i.e., how much, how often and for how long he or she should take each medicine). Count the patient as having adequate knowledge only if both criteria are met for all medicines dispensed to the patient.

*Calculation* % patients know how to take medicines = number of patients who know how to take medicines ÷ number of patients sampled x 100

National average = sum of % patients know how to take medicines at all public health facility dispensaries ÷ number of facilities sampled

**3. Average number of medicines prescribed in public health facilities (Survey Forms 6 and 7)**

*Purpose* To determine prevalence of polypharmacy, which is one measure of unnecessary prescribing

*Prerequisite* Outpatient treatment records covering the past 12 months or, if unavailable, current treatment records sufficient to randomly select 30 outpatient encounters

*Source of data* Sample of 30 outpatient encounters (retrospective or prospective) at 30 public health facilities. See pages 27–28 for sampling instructions.

*Process* SF6 Interview patients leaving the dispensing area or leaving the facility after they have been treated and received medicines. Patients can be interviewed consecutively or as convenient.

SF7 Request all available records for the past 12 months before beginning sampling. Consider only encounters for single disease, complaint, or symptom

List the number of medicines given per encounter. Combination products are counted as one medicine. The same product prescribed consecutively in different forms (i.e. injection and tablet) should be counted as one medicine, however if the same product is prescribed simultaneously in different forms, each form should be counted separately.

*Calculation* Average number of medicines per encounter = total number of medicines prescribed ÷ number of patient encounters reviewed

National average = sum of average number of medicines per encounter from all public health facilities ÷ number of facilities sampled

Note Survey Form 6 collects data from patient interviews and Survey Form 7 collects data from patient records. Results may therefore differ for Survey Forms 6 and 7 depending on how prescriptions are recorded at the facility.

**4. % patients prescribed antibiotics in public health facilities (Survey Form 7)**

*Purpose* To determine prevalence of antibiotic prescribing, since over-prescribing of antibiotics is one common type of inappropriate medicine use

*Prerequisite* Understanding of which medicines should be counted as antibiotics. Definitions of drugs considered as antibiotics must be agreed upon at the national level. Antimicrobial agents are not always classified in an identical way. Indicators for antibiotic use can be sensitive to certain drugs, especially in places with high incidence of parasitic infections, such as malaria or tuberculosis. Drugs such as antiprotozoals and antihelminthics are also usually placed in a different category of antibiotics. How to classify topical antibiotics widely used in areas where trachoma, bacterial conjunctivitis and bacterial skin infection are common will also need to be considered.

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*Source of data* Sample of 30 outpatient encounters (retrospective or prospective) at 30 public health facilities. See pages 27–28 for sampling instructions.

*Process* Request all available records for the past 12 months before beginning sampling.

Determine encounters where at least one antibiotic has been prescribed.

*Calculation* % of patients prescribed antibiotics = number of encounters in which one or more antibiotics is prescribed ÷ number of patient encounters reviewed x 100

National average = sum of % of patients prescribed antibiotics in all public health facilities ÷ number of facilities sampled

**5. % patients prescribed injections in public health facilities (Survey Form 7)**

*Purpose* To determine prevalence of injection use, since over-prescribing of injections is one common type of inappropriate medicine use

*Source of data* Sample of 30 outpatient encounters (retrospective or prospective) at 30 public health facilities. See pages 27–28 for sampling instructions.

*Process* Request all available records for the past 12 months before beginning sampling.

Determine encounters where an injection has been prescribed.

Do not count immunizations and injectable contraceptives.

*Calculation* % of patients prescribed injections = number of encounters in which one or more injection is prescribed ÷ number of patient encounters reviewed x 100

National average = sum of % of patients prescribed injections in all public health facilities ÷ number of facilities sampled

**6. % prescribed medicines on the essential medicines list at public health facilities (Survey Form 7)**

*Purpose* To measure the degree to which prescribing practice conforms to the national essential medicines list (EML). The essential medicines concept is one of the main strategies being promoted in medicines policy. More and more countries are formulating national EMLs. For most, this should be the basis for all public medicines procurement and prescribing.

*Prerequisite* A current national essential medicines list officially endorsed by the ministry of health. If there is no current officially endorsed EML, then this indicator should not be measured.

*Source of data* Sample of 30 outpatient encounters (retrospective or prospective) at 30 public health facilities. See pages 27–28 for sampling instructions.

*Process* If there is a current officially endorsed national EML, a copy should be provided to each survey team.

Request all available records for the past 12 months before beginning sampling.

Determine how many of the prescribed medicines are included on the EML, even if they are not prescribed under an internationally recognized name.

*Calculation* % prescribed medicines included on the EML = number of prescribed medicines included on the EML ÷ total number of medicines prescribed x 100

National average = sum of % prescribed medicines included on the EML at all public health facilities ÷ number of facilities sampled

**7. % medicines prescribed by generic name (INN) at public health facilities (Survey Form 7)**

*Purpose* To measure the degree to which prescribing practice conforms to the principles of generic prescribing.

*Prerequisite* A clear understanding of what is meant by the term generic medicine.

*Source of data* Sample of 30 outpatient encounters (retrospective or prospective) at 30 public health facilities. See pages 27–28 for sampling instructions.

*Process* Request all available records for the past 12 months before beginning sampling.

Determine the encounters where a generic medicine has been prescribed.

*Calculation* % medicines prescribed by generic name = number of medicines prescribed by generic name ÷ total number of medicines prescribed x 100

National average = sum of % medicines prescribed by generic name at all public health facilities ÷ number of facilities sampled

**8. Availability of standard treatment guidelines at public health facilities (Survey Form 8)**

*Purpose* To determine if prescribers have available to them the key source of therapeutic information they need in daily practice.

*Prerequisite* Identify STGs for pneumonia and another condition officially endorsed by the government, WHO or other international, academic or professional organisation. A copy should be provided to each survey team.

*Source of data* Survey of 30 public health facilities

*Process* Ask to see a copy of the relevant STGs. Only count a facility as having each STG if the facility is able to produce the current version. If the current version of the document is not physically available, mark "no".

*Calculation* National average = number of facilities with both STGs available ÷ number of facilities sampled

### 9. Availability of EML at public health facilities (Survey Form 8)

*Purpose* To determine if prescribers and/or dispensers have available to them the key source of pharmaceutical information that should be the basis for all medicine prescribing and dispensing.

*Prerequisite* A current essential medicines list officially endorsed by the ministry of health, region, district or health facility as appropriate.

*Source of data* Survey of 30 public health facilities

*Process* If there is a current officially endorsed national EML, a copy should be provided to each survey team.

Ask to see a copy of the current applicable EML for that facility. Only count a facility as having an EML, if the facility is able to produce the current version. If the current version of the document is not physically available or if it has been more than five years since the EML was last updated, mark "no".

*Calculation* National average = number of facilities with at least one current EML available ÷ number of facilities sampled

### 10. % tracer cases treated according to recommended treatment protocol/guide (Survey Form 9)

*Purpose* To measure quality of care for common conditions with clear recommended treatment protocols. Adherence to recommended protocols can be measured by checking if tracer diseases are treated appropriately. Such recommendations might include use of ORS for watery diarrhoea in children, use of the recommended antibiotic for mild pneumonia or non-use of antibiotics for simple ARI. The survey form has space for countries to track additional conditions, if desired.

*Prerequisite* Ability to sample cases retrospectively by diagnosis

Existing STG with clear treatment recommendation for any additional conditions evaluated

*Source of data* Sample of 10 outpatients under 5 years of age with non-bacterial diarrhoea, 10 outpatients under 5 years of age with mild/moderate pneumonia, and 10 outpatients of any age with non-pneumonia (non-bacterial) acute respiratory tract infection at 30 public health facilities. See page 27–28 for sampling instructions.

*Process* Request all available records for the past 12 months before beginning sampling.

Select encounters from outpatient records or under 5 ledgers. If possible choose only single diagnosis encounters.

Determine if patients received any of the treatments listed on the survey form.

*Calculation* % of cases prescribed each medicine = number of cases prescribed each medicine ÷ number of cases x 100

National average = sum of % of cases prescribed each medicine at all facilities ÷ number of facilities sampled

# Survey design and sampling

The Level II core outcome indicator surveys are designed to obtain relevant information from as simple a data collection process as possible.

Surveys of public health facilities, private drug outlets/pharmacies, and warehouses supplying the public sector are required. Small samples of data and simple survey techniques will be used to collect the quantitative and qualitative information needed for these indicators.

For data to be collected accurately and reliably, attention must be paid to appropriate sampling and data gathering techniques.

## Sampling

In order to estimate indicators accurately and reliably, it is important to follow specific procedures for drawing samples and gathering data. In this way, major types of selection bias are reduced and the study population is more representative of the reference population—in this case the national situation.

Larger samples are more costly but give more precise results. Sample size is therefore a balance between what is desirable and what is feasible. The best sample size will be the smallest one that will result in estimates with the desired degree of precision.

Experience with similar methodologies[7] has shown that individual health providers tend to have consistent practices over time. Therefore a sample drawn at one point in time will provide roughly similar results as a sample that covers a longer period. However since data will generally be collected over a short period, they may suffer from bias due to seasons, variations in staffing, inconsistencies in the supply cycle etc. Where possible, the survey should use records to sample retrospectively over the previous 12 month period rather than sampling cases only on the day of the data collection.

Because the treatment practices of individual providers are consistent and similar amongst providers within the same facility (i.e., correlated), within-facility variation tends to be reduced. Because of this, after a certain point, adding prescriptions to a sample within a facility adds little new information. The principal source of variation in the country situation will tend to be differences in practices between health facilities. Increasing the number of facilities in a sample is the best way to improve accuracy. It is generally unwise to generalise about a group of facilities if that sample includes fewer than 20 facilities.

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7 *How to investigate drug use in health facilities*, WHO/DAP/93.1.

If resources allow, increasing the number of geographic areas and facilities/outlets above the minimum numbers quoted will increase the accuracy of the survey, however the sample sizes recommended have been shown to be sufficiently accurate and balance accuracy and investment of funds and time to carry out the survey.

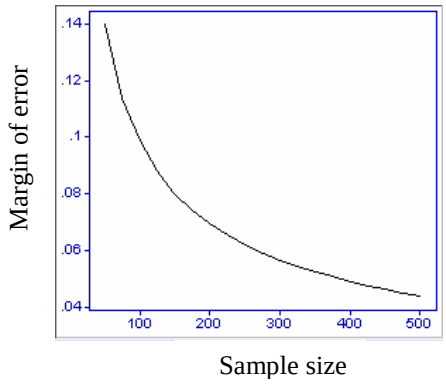
Experience with measuring prescribing indicators in similar types of health facilities has shown that samples similar to those recommended in this survey result in estimates that are accurate 95% of the time within a range of plus or minus 7–9% in the worst case. Facility-specific indicators, such as estimates of availability of medicines, have a sample size equal to the number of health facilities or pharmacies, so they will tend to have a somewhat wider range of error.

***Box 3 Error in sampling***

*Error due to simple random sampling*

As shown in the figure to the right, the margin of error around an estimate from a simple random sample gets smaller as sample size increases. A percentage estimated as 50% in a sample of 100 units has a 95% confidence interval of +/- 10%, which means that 95 random samples out of 100 drawn from the same population would yield estimates between 40% and 60%. If the sample size were increased to 300, the margin of error around the same estimate of 50% would be +/- 6%. An estimate of 50% is the worst case; percentages greater or smaller than 50% have somewhat narrower margins of error.

***Margin of error (half of 95% confidence interval) around a proportion of 0.5 (worst case) estimated from sample sizes ranging from 50 to 500***




*Error due to clustering within a sample*

When sample units (e.g., households, patients in a clinic) are drawn in clusters, as most large samples are, the calculation of the margin of error around a sample estimate is more difficult. Units within a cluster (e.g. households in the same village, patients treated at the same health facility) are often more alike than units drawn randomly from other clusters. In this case, the characteristics or behaviors of these units are said to be correlated. Examples of correlated behaviors might be where people in a village purchase their medicines, or which patients in the same facility receive for a particular diagnosis. In the worst case, where the behaviors are perfectly correlated, knowing the value from one unit allows you to predict the value for other units in the cluster, so sampling additional units yields no new information.

The effect of within-cluster correlation is to reduce the effective sample size below the actual number of units sampled. To know how much the effective sample size is reduced requires knowing the value of the within-cluster correlation for a particular characteristic to be estimated; this is rarely known in advance. All in all, increasing the number of clusters and reducing the number of units within each cluster is the best way to increase the reliability of estimates. However, sample design will often be a balance between adding more clusters (which increases logistic complexity and cost) and getting a convenient number of units per cluster (to allow for work to be carried out in multiples of an entire day).

For the types of indicators measured in medicines use surveys, it is not unusual for the effective sample size to be reduced by half, depending on the actual within-cluster correlation and the cluster size. Using the figure above, this would mean that for a sample size of 300 (drawn as 20 clusters of 15 units), the effective sample size might actually be 150, and the margin of error (95% confidence interval) roughly +/- 7–9%. This is a conservative estimate of the margin of error for most of the patient indicators in the Level II survey.

## Selecting geographic areas

The survey should be conducted in five geographic areas (regions, districts, municipalities, provinces) where acceptable sample units can be drawn. If appropriate data is available, select the largest or capital city, the most rural or lowest income generating area, and randomly select three other geographical areas from the remaining regions. If data is not available, select the capital city and randomly select four other areas from the remaining regions.

***Box 3 Selecting 5 geographic areas***

1. The largest or capital city
2. One of the lowest income generating areas
3. Three other randomly selected areas

In selecting the 5 geographic areas, the urban/rural population split can be taken into consideration at this level of sampling or at the next level (facility sampling) depending upon the size and make-up of the geographic areas. In some countries, geographic areas may be predominantly urban, predominantly rural, or they may be mixed depending upon the size of the geographic area sample unit. Most countries have official statistics on the degree of urbanisation. It however may be more practical to take the urban/rural split into consideration when sampling facilities within a geographic area.

In a number of countries major logistical constraints such as transport, time, budget, and security concerns necessitate excluding some parts of the country from the data collection process. When reporting results of the study, it is important to explicitly state any parts of the country that were excluded from the sampling to acknowledge possible bias.

There may be also difficulties in countries with large nomadic or mobile populations where there are very few fixed facilities that are operational or utilised throughout the year. Often in such areas facilities only function in some seasons or there are mobile facilities. Effort should be taken to include such regions if possible.. Excluding them may exclude a portion of the population whose access to health care is difficult. The degree of importance to the national picture will depend upon the proportion of the population that such groups represent. Any access difficulties of this group cannot be identified separately unless they represent the whole geographic area.

## Issues to address in identifying sectors (public/private) to include in the sampling

Level II indicators measure selected aspects of the delivery of pharmaceutical services for routine outpatient primary health care. Prior to sampling, careful consideration needs to be given to where patients access the pharmaceutical sector for routine outpatient care. This will ensure a study population representative of the reference population—which is the national population.

Consideration also needs to be given to the structure of the pharmaceutical sector in order not to exclude parts of the sector from the sampling process. In particular, is

publicly-supported health care provided only in public facilities or also in the not-for-profit or private sectors, where is primary health care delivered, and which warehouses supply the public sector.

Amongst the main considerations in drawing the sample of facilities are:

- Is publicly-supported health care provided only in public facilities or also in the not-for-profit or private sector?
- Is Primary Health Care delivered in general outpatient clinics of hospitals?
- Are public sector supplies obtained from public or private warehouses?
- Are medicines purchased from private pharmacies and drug outlets?
- Are medicines sold in the formal and informal sectors?

These issues will be discussed further below. As a rule of thumb, if non-public sector sources represent greater than 25% of publicly-funded service delivery, then they should be included in the survey.

- *Is publicly supported health care provided by in the not-for-profit or private sectors?*
  The survey is primarily looking at the delivery of pharmaceutical services in the public sector and alternative points of access to pharmaceuticals in the private sector.

  The "public sector" indicators are intended to measure issues around access, quality and rational drug of medicines that patients obtain from the public sector. The delivery of public sector services may vary from country to country. Sometimes a significant portion of publicly supported care may either officially or in practice be delivered by not-for-profit, NGO, or mission providers or even in the private sector. In such a country, these sectors should be sampled to represent the proportion of care they provide.

- *Is Primary Health Care delivered in general outpatient clinics of hospitals?*
  Primary health care is delivered in health centres and clinics, but hospitals may also have large primary care clinics, especially in urban areas. For this reason, 5 hospitals (1 per geographic area) have been included in the general survey methodology. The hospital-based survey must be the department(s) serving general outpatients and not specialist clinics; this should apply not only to patient interviews, but also to the retrospective and prospective surveys of patient records and prescriptions.

  Patient samples should be restricted to general illness encounters, representing a mix of health problems and ages. These indicators have limitations when applied to well-child visits, pre- and post-natal visits, specialist consultations, or even separate clinics for adults and paediatric cases because treatment practices are different and results may be difficult to interpret.

  If general primary health care services are delivered primarily in hospitals in a given country, the proportion of hospitals in the survey might need to be increased. Alternatively, the proportion may need to be reduced if hospitals provide an insignificant proportion of primary health care service.

- *Are public sector supplies obtained from public or private warehouses?*
  The survey requires collection of data from 5 public sector central/regional/district warehouses. The intention is to measure the availability of medicines in the supply

chain at the level(s) above the health facility regardless of whether these warehouses are managed and owned by the public sector, private sector, or a public-private partnership. The sample should be drawn from the locations from where the public sector facilities obtain their medicine supply.

## Selecting public health facilities

To collect most of the indicators for access, quality and rational use, a total of 30 public health facilities need to be selected from the five geographic areas identified (see *Box 4*). These public health facilities should cater to general outpatients and they should have a pharmacy or a medicine-dispensing area. Within each geographic area, choose six public health facilities providing outpatient services. One of the selected public health facilities should be the main (biggest) public hospital in the area. Of the other five facilities, at least one should be a primary/rural health center or lowest level public health facility. The remaining ones should be chosen randomly from all middle level public health facilities, i.e. excluding primary/rural health units and hospitals. The names and affiliations of all facilities in a region can usually be determined at the central level, so this sampling can be done centrally. A number of facilities can be identified as replacements if the facility selected in sampling is not available, has too few patients, or has totally inadequate records. If replacement facilities are used, data collectors should note the reason for not surveying the first selected facility.

***Box 4 Selecting facilities from 5 geographic areas***

**Public health facilities**

Total for country: 30 public health facilities

Per geographic area: 6 public health facilities

1. The main or biggest public hospital in the area
2. One primary/rural health center or lowest level public health facility
3. Four middle level public health facilities, i.e. excluding primary/rural health units and hospitals

Each facility should cater to general outpatients and have a medicine-dispensing area.

**Private drug outlets**

Total for country: 30 private drug outlets

Per geographic area: 6 private drug outlets

1. Select the private drug outlet closest to each public health facility included in the survey

**Central/regional/district warehouses**

Total for country: 5 warehouses

Per geographic area: 1 warehouse

1. Select one warehouse in each geographic area

If resources allow, countries may choose to add surveys of private, non-governmental or mission health facilities to the core package. This is particularly important if any of these sectors represent more than 25% of service delivery. The public health facility survey forms can be adapted for use at these facilities. Any surveys done at other facilities should be in addition to the surveys carried out at public health facilities.

## Making random selections

*Box 5* provides an example illustrating the process of randomly selecting public health facilities from the capital city. The same process is used to select public health facilities in each of the five geographic areas included in the survey.

***Box 5 Randomly selecting public health facilities from the capital city***

**Step 1: Select the first facility.** From a list of all public health facilities in the capital city, select out the main or biggest public hospital.

**Step 2: Select the second facility.** Identify all of the primary health centers or lowest level public health facilities and randomly select one.

**Step 3: Number the remaining health facilities that are not hospitals or lowest level public health facilities**

**Step 4: Calculate the sampling interval.** For example, if there are 303 medium level public health facilities in the capital city and 4 are to be chosen. The sampling interval is calculated by dividing the total number of facilities by the number to be selected: 303 ÷ 4 = 75.75

**Step 5: Identify the third, fourth, fifth, and sixth facilities**

- Choose a random whole number between 1 and 75.75, for instance 35.
- The third facility to be chosen will be the one numbered 35.
- Add the sampling interval to the randomly chosen number: 75.75 + 35 = 110.75 = 111 (always round up). The fourth facility is the one numbered 111.
- Continue until all 6 facilities from the capital city have been chosen, i.e. the fifth facility is: 75.75 + 110.75 = 186.5 = 187; the sixth facility is: 75.75 + 186.5 = 262.25 = 263

## Selecting private drug outlets

Select the closest private drug outlet to each public health facility surveyed (see *Box 5*). It may be possible to do this selection centrally from data from the ministry/department of health, the chief pharmacist and/or the national pharmacy association/council. However, information may be outdated and you may find that the "map and terrain" do not match. The data collectors may need to select the private drug outlets to be surveyed after arriving in the field.

Depending on the country situation, other types of drug outlets may be surveyed as well. If another sector of drug outlets (other than private drug outlets and dispensaries/pharmacies connected to public health facilities) provide at least 25% of primary health care medicines, the private pharmacy/drug outlet forms can be adapted for use in these drug outlets. Surveys of other drug outlets should be done in addition to the surveys completed at public health facility pharmacies/dispensaries and private drug outlets.

## Selecting warehouses

Select one central/regional/district warehouse in each geographical area for inclusion in the survey (see *Box 5*).

## Sampling patients for data collection

To measure the rational medicine use indicators, general outpatient encounters from health facilities should be used. The patients to be sampled should be restricted to general illness encounters, representing a mix of health problems and ages. These indicators have limitations when applied to well-child visits, pre- and post-natal visits, specialist consultations, or even separate clinics for adults and paediatric cases because treatment practices are different and results may be difficult to interpret.

As discussed above, the survey will include both retrospective and prospective sampling. In some cases only one approach will be possible, but elsewhere, there will be a choice. Prospective sampling can introduce bias due to seasons, variations in staffing, inconsistencies in the supply cycle etc. Therefore where there is a choice of sampling methods, the survey should retrospectively sample the previous 12-month period rather than only sampling patients on the day of the data collection.

### Retrospective sampling

(Survey Forms 7 and 9)

- *Confirm the availability and accessibility of medical records.* Possible sources of retrospective prescribing data include clinic registers, treatment logbooks, patient/family files, and retained prescription forms. The data collector must know where to locate these records in the facilities and how to use them.
- *Identify the study period to be covered.* Because of seasonal differences, variations in staffing, inconsistencies in the supply cycle etc., the survey should, as much as possible, cover the 12-month period prior to the date of data collection. If records during this period cannot be found or do not meet the sampling requirements, the study period can be shortened, making sure that there are no missing records during the period covered. This can be done by checking that all the months and days are represented in the record.
- *Select patient encounters and extract data*

*Survey Form 7* From general outpatient treatment records, select 30 patients with any diagnosis seen during the last 12 months. Use either the chronological or alternative sampling method described in *Box 6*. If records are not available, 30 patients may be selected from current treatment records provided there are sufficient records to randomly select the patients. Prospective sampling can also be used.

*Survey Form 9* From general outpatient records or under 5 ledgers, select:
- 10 patients under 5 years of age seen during the last 12 months for diarrhoea,
- 10 patients under 5 years of age seen during the last 12 months for pneumonia, and
- 10 patients of any age seen during the last 12 months for ARI.

Following the chronological sampling method described in *Box 6*, select 30 days and one patient encounter each day. If the selected patient encounter does not meet the inclusion criteria (i.e. does not have the appropriate diagnosis) select the next patient on the list who does. Alternate between the three diagnoses. If it is possible to determine all the patients in the past 12 months with each diagnosis, the alternative sampling method described in *Box 6* may be used.

*Box 6 Retrospective sampling: Selecting 30 patients from general outpatient records covering 12 months (365 days)*

**A. Chronological sampling method**

- Calculate the sampling interval by dividing the number of days covered by the outpatient list by the number of patients to be selected: 365 ÷ 30 = 12.2 days
- Number each day covered by the outpatient list.
- Select one patient encounter from the day numbered 1 on the list.
- Each subsequent encounter is selected by adding the sampling interval (12.2) to the previous total and rounding up. In other words, select one patient encounter from day 1, skip the sampling interval, and select one patient from day 14 (1 + 12.2 = 13.2 = 14 always round up).
  - Third encounter = 13.2 + 12.2 = 25.4 = 26th day
  - Fourth encounter = 25.4 + 12.2 = 37.6 = 38th day
  - Fifth encounter = 37.6 + 12.2 = 49.8 = 50th day
- To choose a patient encounter from the patient list for each selected day, pick a random number between 0.0 and 1.0, multiply this number times the number of patient encounters on the list, and round upwards. For example, if you choose 0.4 and there are 18 patients on the list for the selected day: 0.4 x 18 = 7.2 = 8 (always round up). Review the 8th patient encounter when completing the survey forms provided the patient meets the inclusion criteria. If the patient does not meet the inclusion criteria, select the next patient on the list who does. Repeat this process, selecting one patient encounter from each selected day until 30 patient encounters have been reviewed.

**B. Alternative sampling method**

- Calculate the sampling interval by dividing the total number of patient encounters on the general outpatient list for the year by the number of patients to be selected. For example, if there are 5000 patient encounters on the general outpatient list covering the previous 12 months and 30 patient encounters are to be selected: 5000 ÷ 30 = 166.6. Select every 167th patient encounter from the list or the next one thereafter who meets the inclusion criteria.

## Prospective sampling[8]

(Survey Form 6)

Interview 30 patients leaving the dispensing area/pharmacy or leaving the facility after they have been treated and received medicines to see how many of the prescribed medicines were dispensed, if the medicines are adequately labeled (label should contain the medicine name and how it should be taken), if the patients know how to take their medicines (patient knows dosage and duration of all dispensed medicines), and how much the patient paid out-of-pocket for medicines and in non-diagnostic fees. Patients may be interviewed consecutively or as convenient.

It is important to know how to identify the patients to be included and to construct a system that will allow patients to be interviewed without disrupting the normal activities of the facility.

Planning the data collection is also important. Throughout the day, facilities tend to have peak times when collecting enough interviews will be easy and low times when there will not be enough patients to effectively carry out the surveys.

[8] *How to investigate drug use in health facilities.* Prospective methods for sampling encounters (pp. 63-65).

## Tailoring the survey forms to country situation through choosing key medicines, selecting tracer conditions, and identifying treatment protocols

In addition to selecting geographic areas and facilities to be included in the survey, there are a number of items on the survey forms —such as basket of key medicines, treatment protocols, and tracer conditions—that need to be identified at the national level. These items tailor the forms to specific country situations. There are also several places on the forms where countries can indicate additional data to be collected without affecting the indicator outcomes.

### Selecting basket of key medicines

(Survey Forms 1, 2, 3, 11, 12, 13 and 14)

A list of 15 key medicines used to treat common health problems must be selected to measure availability, presence of expired medicines, medicine price and stockout duration. It is important to select key medicines that are basic requirements in all levels of health care. When selecting the medicines, list the 15 most common conditions treated at the primary health care level and choose medicines used to treat these conditions. The chosen medicines must be:

- On the national essential medicines list
- The most important therapeutically and based on national treatment guidelines or at least on the consensus of experts
- The most widely used of the medicines meeting the above criteria
- Medicines expected to be available at all primary health care facilities at all times

The basket of key medicines can be selected systematically applying the above principles by referring to official morbidity data for adults and children and following this step-by-step guide:

1st List the top 15–20 morbidity's for adults and children

2nd Remove from that list conditions that would not be treated as general outpatient cases at primary health care services

3rd For each remaining morbidity, assign the most important medicine that corresponds to the applicable standard treatment guideline. Be sure to include medicines for both adults and children. For Survey Forms 2 and 12, formulations and strengths need to be defined. Again, include both adult and paediatric formulations and strengths on the list.

4th The resulting list will probably be longer than 15 medicines, prioritize and reduce the list of key medicines to reflect the principles listed above.

5th Revisit the list and ensure that important medicines used for the alleviation of common symptoms and important preventative medicines have not been excluded. If they have, make appropriate substitutions so as to have a list of 15 medicines.

Drugs that are known to be problematic should not be included in the basket of drugs merely because they are problematic, as this will disproportionately reduce the value of this indicator. Instead, such drugs can be monitored separately as "optional additional drugs". Likewise, other drugs that may be of interest, but do not meet all the above principles could be included on the optional list. This enables additional data to be collected with very little effort and without adversely affecting the results.

A model list of key medicines is presented in *Table 1*. This list can be modified based on important health problems in the country. Once the medicines have been selected, pre-print them on the survey forms. For medicines without a universal name, note on the form that a brand name is being used.

| ***Table 1 Model list of key medicines*** | |
|---|---|
| diarrhoea | Oral rehydration salts(ORS) , cotrimoxazole tablets |
| acute respiratory tract infection | amoxycillin, cotrimoxazole tablets, procaine penicillin injection, paediatric paracetamol tablets |
| malaria | chloroquine tablets |
| anaemia | ferrous salt + folic acid tablets |
| worm infestations | mebendazole tablets |
| conjunctivitis | tetracycline eye ointment |
| skin infection | iodine, gentian violet or local alternative |
| fungal skin infection | benzoic acid + salicylic acid ointment |
| pain | acetylsalicylic acid or paracetamol tablets |
| prophylactic | retinol (vit A) ferrous salt + folic acid tablets |

### Identifying medicines of choice to treat outpatient adults and children

(Survey Forms 5 and 10)

One indicator of medicine affordability uses the price of treatment. The STG to treat moderate pneumonia and another condition in adults and children who are not hospitalized should be identified. The standard treatment guidelines to be used must be produced by an unbiased organisation. Ideally these should be officially endorsed and used by the ministry/department of health.

For adults and children, identify the medicine of choice and the recommended dosage preparation based on the guidelines. For example, from the WHO guidelines[9] and essential medicines list[10] the following medicines and dosage preparations are recommended for pneumonia (other dosage preparations can be chosen if these are not available on the market):

Adults: Procaine penicillin 1g 1 mill IU
Children: Amoxycillin 25mg/ml (syrup or suspension)

The medicines of choice, their preparations, and the number of units needed to complete treatment should be preprinted on the survey forms.

## Identifying prices of medicines for data collection

### Identifying unit price of medicines to treat outpatient adults and children

(Survey Forms 5 and 10)

The unit price of each medicine at the facility or the price charged to patients should be recorded, including the price of a syringe, if applicable. The lowest priced brand or

[9] WHO, 2000. *Management of the child with a serious infection or severe malnutrition* Geneva: WHO/FCH/CAH/00.1.

[10] WHO, 2000 *The use of essential drugs*, WHO technical report series 895

generic equivalent medicine should be used. If there are flat charges paid for each medicine given to patients, then this amount should be recorded as the price of the medicine. Indicate if medicines are given free.

### Identifying price paid by facility and patient for key medicines

(Survey Forms 2 and 12)

UNDER DEVELOPMENT

## Summary of Level II indicators measured by facility

*Table 2* gives the bird's-eye view of the facilities to be visited and indicators to be measured during the Level II survey (see *Annex 2* for corresponding survey forms).

*Table 2 Study facilities and indicators and forms*

| Indicators | Public health facilities (n=30) | Private drug outlets (n=30) | Warehouses (n=5) |
|---|---|---|---|
| **Access** | | | |
| Availability of key medicines | Check availability of 15 medicines (P)* SF 1 | Check availability of 15 medicines (P)* SF 11 | Check availability of 15 medicines (P)* SF 13 |
| Average stock-out duration | Review stock cards of 15 medicines (R) SF 3 | | Review stock cards of 15 medicines (R) SF 14 |
| Adequate record keeping | Review stock cards of 15 medicines (R) SF 3 | | Review stock cards of 15 medicines (R) SF 14 |
| Affordability of treatment | Check price of medicines to treat pneumonia and another condition (P) SF 5 | Check price of medicines to treat pneumonia and another condition (P) SF 10 | |
| % medicines dispensed or administered | Exit interview 30 patients SF 6 | | |
| Price of key medicines | Check price of 15 medicines (P) SF 2 | Check price of 15 medicines (P) SF12 | |
| Average cost of medicines and related fees | Exit interview 30 patients SF 6 | | |
| **Quality** | | | |
| % medicines expired | Check if there are expired medicines (P) SF 1 | Check if there are expired medicines (P) SF 11 | Check if there are expired medicines (P) SF 13 |
| Adequate conservation conditions and handling of medicines | Check conditions using checklist (P) SF 4 | | Check conditions using checklist (P) SF 15 |
| **Rational Use of Medicines** | | | |
| % medicines adequately labelled | Exit interview 30 patients (P) SF 6 | | |
| % patients know how to take medicines | Exit interview 30 patients (P) SF 6 | | |
| Average number of medicines per prescription | 30 patient records (R) SF 6 & 7 | | |
| % patients prescribed | 30 patient records (R) | | |

| | | | |
|---|---|---|---|
| antibiotics | SF 7 | | |
| % patients prescribed injections | 30 patient records (R) SF 7 | | |
| % medicines prescribed by generic name (INN) | 30 patient records (R) SF 7 | | |
| % of prescribed medicines on EML | 30 patient records (R) SF 7 | | |
| Availability of STGs | Check at 30 facilities (P) SF 8 | | |
| Availability of EMLs | Check at 30 facilities (P) SF 8 | | |
| % tracer cases treated according to recommended treatment protocol/guide | 30 cases (10 each of diarrhoea, pneumonia and ARI) (R) SF 9 | | |
| * (R): retrospective review; (P): prospective review, see pages 27–28. | | | |

# Data processing, analysis and reporting

## Computation and processing of Level I and Level II indicators

Data processing should be carefully planned. Even before data collection begins, the necessary resources and a person to encode/tabulate the data and do the computations must be identified.

The data filled on the survey forms should be totaled and calculations made. The completed results per facility/outlet should then be transferred onto the applicable summary form. When reporting the indicator level at the national or geographic region level, the median value (rather than the mean or average value) should be used. The median value is a better measure of central tendency than the average in small sample surveys as it prevents excessive skewing by outliers.

All the calculations can easily be done manually or on the computerized spreadsheets. For Level II indicators, Summary Forms 1–4 (public health facility dispensaries, public health facilities, private drug outlets, and warehouses) can be used to calculate and analyze data, make graphs and tables, and prepare reports. Summary Forms 1–4 are attached as *Annex 3*. Several graphs will also be automatically generated if the comperterized summary forms included in the package are used. Comparisons can be made with similar studies done in the past and with results from studies done in other countries.

The results and information from Level II core indicators should be correlated to information on processes and structures obtained from the Level I questionnaire. Presentations and reports should be prepared in a clear and visually attractive manner.

## Limitations of the survey

The survey has been designed to provide a picture of the national pharmaceutical situation in a country. The regions and facilities selected cumulatively represent the national situation.

The sample sizes used are statistically not large enough to make inter-facility comparisons. For patient care indicators, for example, a minimum sample size of 100 would be necessary in order to make comparisons between facilities. This survey uses a sample size of 30. However, providing that majority of the data is collected and the results are statistically different, comparisons between geographic regions can be made. Regional comparisons may be of interest where there is especially wide variation or contrasts, particularly with a group of related indicators. Regional comparisons should be done sparingly as not all geographic regions are represented

and over-emphasizing the five regions included in the study will detract from the study's significance as a national survey.

## Quality of data and information

The quality of the information that can be generated depends on the quality of data. The data must be checked during the field survey and missing information completed. The data must be checked again for completeness and consistency before the final calculation and analysis. Inconsistent data that cannot be corrected must be excluded. How the data have been coded and subsequently entered must also be checked when entering it into the summary forms.

Reporting biased data can also happen. Those involved in the survey or those providing information on Level I indicators may either be motivated to report only on the success of a programme or only the negative picture of the existing situation. Those involved in collecting, analyzing or presenting the data should bear in mind that the purpose of the exercise is to measure what is really going on in order to improve the situation.

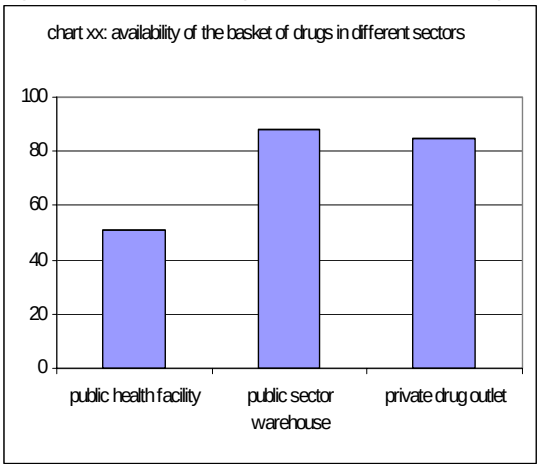
## Presentation of results

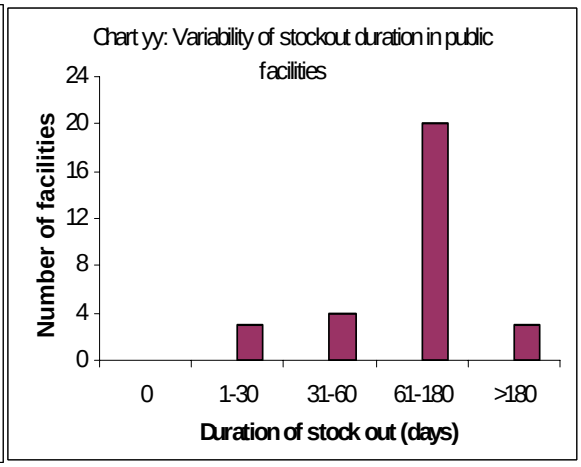
Reports always have greater impact when results are presented clearly. Tables and graphs should complement narrative description. On first examination, it might appear that there are limited ways of graphically presenting results at the national level for a single country. However, there are a number of ways of presenting interesting and meaningful graphs.

The following approaches can be taken (see *Figure 2*):

- Bar charts comparing the same indicator in different sectors, e.g. availability of the basket of medicines in public facilities, private drug outlets, and warehouses
- Bar charts showing variability of facilities, e.g. variability of stockout duration in public facilities.
- Comparison of similar indicators, e.g. comparison of rational medicine use indicators: % patient prescribed antibiotics, % patients prescribed injections and % medicines prescribed on the essential medicines list.
- Presentation of results of similar indicators in a table, e.g. prescribing of various medicines.

*Figure 2 Presenting national level data graphically*



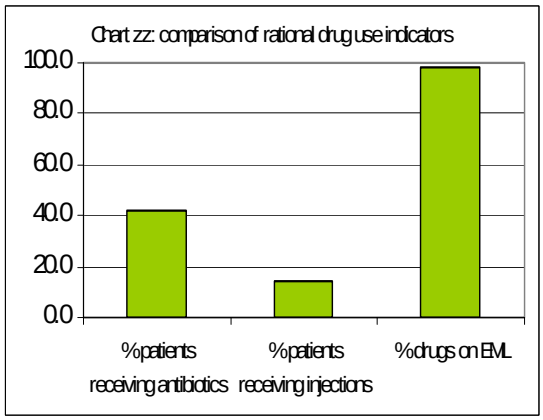




Chart ww: prescribing of drugs by diagnosis

| % prescribing of | Diagnosis: Diarrhoea | Diagnosis: Pneumonia | Diagnosis: Respiratory Tract Infections |
|---|---|---|---|
| Oral rehydration salts (ORS) | 76.1 | | |
| Antibiotics | 50.24 | 55.6 | 75.5 |
| Antidiarrheal | 4.76 | | |

## Analysis and writing the report

After all data have been processed and all indicators calculated, the information should be analyzed. Analysis can be done systematically by looking at each group of indicators and correlating the structures, processes and outcomes. Some examples are given in two key reference documents, *Indicators for monitoring national drug policies*[11] and *How to investigate drug use in health facilities*.[12]

The core indicators represent general measures of the current pharmaceutical situation. Reasons for improvements, deterioration or stagnation in implementation of the NMP can be deduced from the results. This will help to identify the inputs that have had a real impact and to focus attention, resources and efforts on areas that need improvement. More detailed investigation and further analysis of a particular pharmaceutical component can be done if needed.

[11] WHO/EDM/PAR/99.3; Brudon P, Rainhorn JD, Reich M, *Indicators for monitoring national drug policies,* Second Edition; Chapter 5 pages 46-47.

[12] WHO/DAP/93.1; *How to investigate drug use in health facilities, Selected drug use indicators.* Chapter 4 pages 37-43.

The data and results themselves do not suggest the implementation of specific interventions, but can be used as a good take off point to discuss problems in more detail so that a focused strategy can be identified. This can also direct the responsible group to identify follow up activities that can be done.

A report to communicate the information obtained should be prepared by the monitoring unit. This report is an important source of information and a basis for decisions on medicine policy and strategies. It should be persuasive and well prepared. The results must be discussed in a comprehensive and systematic manner, taking into account the objectives and strategies of the medicine policy. The report can also be published.

Depending on country situation, needs, and the chosen reporting style, the written report should be around 30 pages in length, not including annexes. The results should be presented in a logical order with a logical link between findings, analysis, and recommendations. Data included in the report should name the source of information, i.e. exit interview of patients, retrospective sampling of records, household interview, etc. While not necessary to include in the report, raw data should be kept for reference. See *Table 3* for a suggested outline.

*Table 3 Suggested report outline*

| Section | Notes |
|---|---|
| **1. Table of contents** | ▪ Include list of graphs and tables |
| **2. Acknowledgements** | |
| **3. List of abbreviations** | ▪ Sort alphabetically |
| **4. Executive summary** | ▪ Summarize survey findings and recommendations |
| **5. Introduction** | |
| Country profile | ▪ Basic geography (regions, provinces, districts)<br>▪ Data on population<br>▪ Basic economic indicators (presented in a table) |
| Structure of health and pharmaceutical systems (results from Level I can be used here) | ▪ Brief overview of the health situation including key health indicators (presented in a table) the structure of the health system and how the basic mechanisms of medicine distribution, financing, etc. operate.<br>▪ Description of all pharmaceutical sectors: public, private, not-for-profit, NGO, informal.<br>▪ Total size (or best estimate) of the pharmaceutical market split by public and private sectors<br>▪ Inventory and overview of any previous pharmaceutical sector surveys<br>▪ Brief overview of the NMP (when approved, summary of content, achievements/constraints) |
| **6. Study design and methodology** | ▪ Brief summary including any country specific considerations and a reference to this manual |
| Study purpose and indicators | ▪ Clear and realistic within the limitations of the design of the survey package |
| Scope and limitations of the data | ▪ General scope and limitations of the package and any additional limitations that have been introduced at the implementation level |
| Sampling procedure | ▪ Concise, to the point description of the process, including any exclusions from the sampling process that might limit the interpretation of the results (e.g. exclusion of a region in the |

| | |
|---|---|
| | sampling due to security reasons or difficulty of travel; exclusion of the not-for-profit sector) |
| Problems experienced | ▪ In the carrying out of the survey especially those which might have affected the data collection and put limitations on the interpretation of the results. Include general problems identified in carrying out the survey at the national level and reports from the data collectors (e.g. difficulties in finding sufficient patients for the exit interviews; refused access to private drug outlets) |
| **7. Results and analysis** (any findings from Level I not already presented and results from Level II)<br>▪ Policy<br>▪ Access<br>▪ Quality and safety<br>▪ Rational use | ▪ Report results concisely and clearly<br>▪ Use tables and graphs<br>▪ Use headings and appropriate lead sentences to enable the reader to quickly find information, e.g. "62% of the 15 key medicines were found to be available in the public health facilities". More description and discussion can then follow.<br>▪ The survey is primarily designed as a survey of the national situation and the report should reflect this. The report should not focus on reporting differences between the 5 geographic areas. Comparisons between the 5 areas should only be used where they are particularly interesting. Any geographic comparison should also include the national median.<br>▪ See *Analysis* above for examples of how to graphically present national results |
| **8. Interpretation of the results** | ▪ Make logical inferences based on the results of the survey and taking into account its limitations.<br>▪ Link appropriate access, quality and rational drug use indicators |
| **9. Conclusions and recommended interventions and/or next steps** | ▪ Conclusions should be focused and clear<br>▪ Recommendations and interventions should be realistic, limited and focus on those areas where greatest impact can be achieved. They should identify the problem to be addressed and the proposed activity to address the problem.<br>▪ Next steps should be as specific as possible listing:<br>▪ Expected outcome<br>▪ Timeline<br>▪ Necessary (policy) decisions required and by whom<br>▪ Whom is responsible and whom will carry out the recommendation<br>▪ Necessary budget and other resources<br>▪ Recommendations and next steps should reflect consultation with the Ministry of Health and input from the stakeholder workshop where possible |
| **10. Annexes** | |
| Completed level 1 questionnaire | |
| Summary forms | ▪ Facilities names should not be reported as the survey was not designed for interpretation of results by facility<br>▪ Original survey forms should be retained for archiving purposes. Interpretation of the coding should be retained with the forms |
| Sampling and country-specific items | ▪ Lists of geographic areas, facilities (without coding), key medicines, definitions of adequate labelling, adequate knowledge, and other specifications to the survey forms made at the national level |

**General notes**

- The report should be as concise as possible presenting the information in a way that is understandable to a moderately informed reader. It should be easy to quickly locate the methodology, key findings and recommendations
- Tables and graphs should be used to avoid long complicated narrative descriptions
- General country, health and pharmaceutical data should be as up-to-date as possible. Data older than 5 years is generally not very informative unless part of a time-trend where more up-to-date data is also presented.

## Presentation and discussion of results and related issues

The monitoring and assessment report should be presented to all parties involved in formulating policies and implementing pharmaceutical strategies. The discussion should be non-judgmental, pointing out both the positive and negative findings and recommendations. The presentation focus must be suited to the type of audience.

It is advisable to present the report separately to national, district/regional managers, and health facility levels. When presenting to a specific audience with a specific area of interest, provide a brief general summary of the overall results so the audience will know the entire picture and relate how a problem in one component can affect the other. The majority of the presentation, however, should be limited to issues that will be of interest and relevant to the specific audience. The presentation should:

- Present the issues clearly
- Recognize what is well done and encourage further improvement in performance
- Focus on the part the audience is responsible for, can influence or is directly concerned with so the discussion, consensus and recommendations are directed to specific actions, activities and strategies
- Give enough time to discuss what did not work and potential changes that need to be implemented

Health workers should be presented with the findings and given specific feedback on how they are performing and how/where they can make improvements. They must be encouraged to participate in the discussion and give their comments.

Policy-makers at the national level can use the results to emphasize issues that can be addressed by a national strategy, to update current strategies, to define new ones, to reallocate resources or to adjust plans and targets. The discussion can also lead to decisions to put appropriate structures in place, to strengthen enforcement of policies and laws and to motivate/direct different levels and agencies of the health care system to take action or to improve performance.

A meeting with key managers in the district, regional and administrative areas should also be held.

Wide dissemination of the results is important to create awareness at different levels. The results can also be discussed with other stakeholders—civil society, professional organizations and academia—who can help in revising or selecting appropriate pharmaceutical strategies and who can contribute to effective implementation plans.

# List of annexes

| | | |
|---|---|---|
| | ____ | |
| Establishment of regulatory authority: | **Yes/No/Don't Know** **Year** ____ | |
| Marketing authorisation of pharmaceuticals: | **Yes/No/Don't Know** **Year** ____ | |
| Manufacturing of medicines: | **Yes/No/Don't Know** **Year** ____ | |
| Distribution of medicines: | **Yes/No/Don't Know** **Year** ____ | |
| Promotion & advertising of medicines: | **Yes/No/Don't Know** **Year** ____ | |
| Importation of medicines: | **Yes/No/Don't Know** **Year** ____ | |
| Exportation of medicines: | **Yes/No/Don't Know** **Year** ____ | |
| Licensing & practice of prescribers: | **Yes/No/Don't Know** **Year** ____ | |
| Licensing & practice of pharmacy: | **Yes/No/Don't Know** **Year** ____ | |
| Herbal medicines *(See glossary for definition)*: | **Yes/No/Don't Know** **Year** ____ | |
| Empowers inspectors to enter premises and collect samples and documentation: | **Yes/No/Don't Know** **Year** ____ | |
| Requires transparency, accountability and code of conduct in regulatory work: | **Yes/No/Don't Know** **Year** ____ | |
| 2.2 System and operation of medicines registration: | | |
| a) Is marketing authorisation required for medicines to be sold? If yes, how many medicinal products have been approved to be marketed? *(express as number of dosage forms & strengths)* | **Yes/No/Don't Know**<br>**Total**_____ | |
| Is marketing authorisation required for herbal medicines to be sold? If yes, how many herbal medicinal products have been approved to be marketed? *(express as number of dosage forms & strengths) (See glossary for a definition of herbal medicines)* | **Yes/No/Don't Know**<br>**Total**_____ | |
| b) Are there detailed written guidelines, including reference guidelines and criteria, for submitting applications for the registration of medicinal products? Are there guidelines covering the registration of herbal medicines? | **Yes/No/Don't Know**<br>**Yes/No/Don't Know** | |
| c) Is the WHO Certification Scheme certificate required as part of the marketing authorisation process? | **Yes/No/Don't Know** | |
| d) Is INN used in the registration of medicines? | **Yes/No/Don't Know** | |
| e) Is a list of all registered products publicly accessible? *(Registered product is defined in the glossary.)* | **Yes/No/Don't Know** | |

| | | |
|---|---|---|
| 2.3 Is there a computerised registration system that facilitates retrieval of information on registered products? *(Registration system is defined in the glossary.)* | **Yes/No/Don't Know** | |
| Is there a medicines regulatory authority website providing publicly accessible information on any of the following: legislation, regulatory procedures, prescribing information (such as indications, counterindications, side effects, etc.), authorised companies, and/or approved medicines? | **Yes/No/Don't Know** | |
| 2.4 Is licensing a requirement? *(Licensing is defined in the glossary.)* If yes, is it based on site inspection of: | **Yes/No/Don't Know** | |
| Manufacturers: | **Yes/No/Don't Know** | |
| Importers/wholesalers: | **Yes/No/Don't Know** | |
| Retail distributors/pharmacies: | **Yes/No/Don't Know** | |
| 2.5 Are there written national guidelines/codes/checklists for the inspection of: | | |
| Manufacturers: | **Yes/No/Don't Know** | |
| Importers/wholesalers: | **Yes/No/Don't Know** | |
| Retail distributors/pharmacies: | **Yes/No/Don't Know** | |
| 2.6 Is prescribing by generic name obligatory in the: | | |
| Public sector: | **Yes/No/Don't Know** | |
| Private sector: | **Yes/No/Don't Know** | |
| Is generic substitution permitted at: *(Generic substitution is defined in the glossary.)* | | |
| Public pharmacies: | **Yes/No/Don't Know** | |
| Private pharmacies: | **Yes/No/Don't Know** | |
| 2.7 Is promotion/advertisement of medicines regulated by: | | |
| Company self-regulation: | **Yes/No/Don't Know** | |
| Government agency or medicines regulatory authority: | **Yes/No/Don't Know** | |
| Are civil society/non-governmental organisations involved in review, assessment, or surveillance of promotion/ advertisement of medicines? | **Yes/No/Don't Know** | |
| Do regulations on promotion/advertisement of medicines include: *(See glossary for the distinction between promotion and advertisement.)* | | |
| Published ethical criteria for medicines promotion: | **Yes/No/Don't Know** | |
| Pre-approval for promotional materials: | **Yes/No/Don't Know** | |
| Pre-approval for advertisement materials: | **Yes/No/Don't Know** | |
| Explicit prohibition on advertising prescription medicines: | **Yes/No/Don't Know** | |
| Detailed restrictions on advertising non-prescription medicines: | **Yes/No/Don't Know** | |
| 2.8 Are adverse drug reactions (ADR) monitored? If yes, what is the total number of each of the following for the most recent year for which data is available? | **Yes/No/Don't Know** | |
| Total number of validated ADR reports received: | ____ ____ (**Year** ____) **DK** ☐ | |
| Total number of reporting physicians: | ____ ____ (**Year** ____) **DK** ☐ | |
| Total number of physicians in country: | ____ ____ (**Year** ____) **DK** ☐ | |
| Are ADR of herbal medicines monitored? | **Yes/No/Don't Know** | |
| **3. QUALITY CONTROL OF PHARMACEUTICALS** | | |
| 3.1 Testing of medicines samples collected last year for regulatory purposes (i.e. including drug registration and post-marketing surveillance, but excluding testing done in conjunction with procurement activities): | ***Total number of samples*** | |
| Total number of samples collected: | ____ ____ | **Don't Know** ☐ |
| Total number of samples tested: | ____ ____ | **Don't Know** ☐ |
| Total number of samples that failed identity or assay: | ____ ____ | **Don't Know** ☐ |
| 3.2 Where have the above samples *(see 3.1)* been tested: | ***Percentage of total samples tested*** | |
| Government quality control laboratory: | ____**%** | **Don't Know** ☐ |
| Local academic institutions: | ____**%** | **Don't Know** ☐ |
| Quality control laboratory in another country: | ____**%** | **Don't Know** ☐ |
| Private quality control laboratory: | ____**%** | **Don't Know** ☐ |

| | | | |
|---|---|---|---|
| **4. ESSENTIAL MEDICINES LIST (EML)** | | | |
| 4.1 Are there Essential Medicines Lists (EML)? *(An Essential Medicines List is a government-approved selective list of medicines or national reimbursement list)* | | ***Total number of medicines*** | ***Year of last update*** |
| National EML: | **Yes/No/DK** | _____ | ____ |
| State or provincial list: | **Yes/No/DK** | _____ | ____ |
| List for primary health care: | **Yes/No/DK** | _____ | ____ |
| 4.2 Are EMLs being used in: Public sector procurement: | **Yes/No/Don't Know** | | |
| Public insurance reimbursement: | **Yes/No/Don't Know** | | |
| Private insurance reimbursement: | **Yes/No/Don't Know** | | |
| 4.3 Are local herbal medicines included on the national EML? | **Yes/No/Don't Know** | | |
| **5. MEDICINES SUPPLY SYSTEM** | | | |
| 5.1 Who is responsible for public sector drug procurement and distribution? What percentage of the total cost is each responsible for? | ***Procurement*** | ***Distribution*** | |
| Ministry/Department of Health: | **Yes/No/DK ____%** | **Yes/No/DK ____%** | |
| Non-governmental organisation (NGO): | **Yes/No/DK ____%** | **Yes/No/DK ____%** | |
| Private institution contracted by the government: | **Yes/No/DK ____%** | **Yes/No/DK ____%** | |
| Individual health institutions: | **Yes/No/DK ____%** | **Yes/No/DK ____%** | |
| 5.2 Is government procurement limited to medicines on the EML? | **Yes/No/Don't Know** | | |
| If no, is a percentage of the budget set aside for non-EML items? | **Yes/No/Don't Know** | | |
| What is the percentage? | **____%** | | |
| 5.3 Type of tender and percentage of the total cost for each: *(Tender is the process by which competing bids are entered for a particular contract.)* | | ***Percentage of total cost*** | |
| National competitive tender: | **Yes/No/DK** | **____%** | |
| International competitive tender: | **Yes/No/DK** | **____%** | |
| Negotiation/direct purchasing: | **Yes/No/DK** | **____%** | |
| 5.4 Is drug registration a prerequisite for government purchases? | **Yes/No/Don't Know** | | |
| **6. MEDICINES FINANCING** | | | |
| 6.1 What is the total public or government budget for medicines in US$ for the most recent year for which data is available? | **$_____, Year ____** | | |
| 6.2 Are there guidelines on medicines donations that cover the public sector, the private sector, or non-governmental organisations (NGO)? | ***Public Sector*** | ***Private Sector*** | ***NGO*** |
| | **Yes/No/DK** | **Yes/No/DK** | **Yes/No/DK** |
| 6.3 Which medicines are free at primary public health facilities: | | | |
| All medicines are free of charge: | **Yes/No/Don't Know** | | |
| Malaria medicines are free: | **Yes/No/Don't Know** | | |
| Tuberculosis medicines are free: | **Yes/No/Don't Know** | | |
| Sexually transmitted diseases medicines are free: | **Yes/No/Don't Know** | | |
| HIV/AIDS-related medicines are free: | **Yes/No/Don't Know** | | |
| Medicines are free to those who cannot afford them: | **Yes/No/Don't Know** | | |
| Medicines are free for children under 5 years of age: | **Yes/No/Don't Know** | | |
| Medicines are free for pregnant women: | **Yes/No/Don't Know** | | |
| Medicines are free for elderly persons: | **Yes/No/Don't Know** | | |
| No medicines are free of charge: | | | |
| 6.4 Which fees are charged in public health facilities: | | | |
| Registration/Consultation fees: | **Yes/No/Don't Know** | | |
| Dispensing fees: | **Yes/No/Don't Know** | | |
| Flat fees for medicines: | **Yes/No/Don't Know** | | |
| Flat rate copayments: | **Yes/No/Don't Know** | | |
| Percentage copayments: | **Yes/No/Don't Know** | | |
| *(Co-payments cover part of the cost of medicines, the other part being paid by an insurer or government.)* | | | |
| 6.5 Is revenue from fees or drug sales used to pay the salaries of public health personnel in the same facility? | **Always/Frequently/Occasionally/Never/DK** | | |
| 6.6 Health insurance: *(Health insurance is any prepayment scheme for health care costs additional to but excluding subsidies funded through the Ministry of Health budget.)* | ***Public*** | ***Private*** | |
| What percentage of the population has health insurance? | **All/Some/None/DK** | **All/Some/None/DK** | |
| Are medicines covered by health insurance? | **All/Some/None/DK** | **All/Some/None/DK** | |
| Of the covered medicines, what percentage of the cost is covered: | **____%** | **____%** | |

| | | | |
|---|---|---|---|
| 6.7 Is there a pricing policy on medicines that covers the public sector, the private sector, or non-governmental organisations? | ***Public sector*** | ***Private sector*** | ***NGO*** |
| If yes, does it apply to: | **Yes/No/DK** | **Yes/No/DK** | **Yes/No/DK** |
| All medicines, some or none: | **All/Some/None/DK** | **All/Some/None/DK** | **All/Some/None/DK** |
| Is maximum wholesale mark up established in laws/regulations: | **Yes/No/DK** | **Yes/No/DK** | **Yes/No/DK** |
| If yes, amount: | **____%** | **____%** | **____%** |
| Maximum retail mark up established in laws/regulations: | **Yes/No/DK** | **Yes/No/DK** | **Yes/No/DK** |
| If yes, amount: | **____%** | **____%** | **____%** |
| Duty on imported raw pharmaceutical materials: | **Yes/No/DK** | **Yes/No/DK** | **Yes/No/DK** |
| Duty on imported finished pharmaceutical products: | **Yes/No/DK** | **Yes/No/DK** | **Yes/No/DK** |

## 7. ACCESS TO ESSENTIAL MEDICINES

| | |
|---|---|
| 7.1 In your opinion, what percentage of the population has regular access to essential medicines (i.e. minimum of 20 most essential medicines available and affordable at public and private facilities within a one-hour walking distance)? | **____%** |

| 7.2 What percentage of: | ***Public health facility*** | ***Private health facility*** | ***Public or private retail drug outlet*** |
|---|---|---|---|
| The population is within one-hour walking distance to: | **____%** | **____%** | **____%** |
| Facilities have essential medicines available: | **____%** | **____%** | **____%** |
| The population can afford essential medicines at: | **____%** | **____%** | **____%** |

## 8. PRODUCTION

| | |
|---|---|
| 8.1 What is the medicines production capability in the country? | |
| Research and development of new active substances: | **Yes/No/Don't Know** |
| Production of pharmaceutical active starting materials: | **Yes/No/Don't Know** |
| Formulation from pharmaceutical starting materials: | **Yes/No/Don't Know** |
| Repackaging of finished dosage forms: | **Yes/No/Don't Know** |

| 8.2 For each of the following types of local production, indicate number of factories and total annual sales in US$ for the most recent year for which data is available: | ***Number of factories*** | ***Sales in US$*** | ***Year*** | ***Don't know*** |
|---|---|---|---|---|
| Starting materials: | **____** | **$____** | **____** | **DK☐** |
| Finished products: | **____** | **$____** | **____** | **DK☐** |
| Products containing active substances developed/marketed for the first time during the last 5 years: | **____** | **$____** | **____** | **DK☐** |

| | |
|---|---|
| 8.3 What is the total volume and US$ value of the medicines market? Generic medicines compose what percentage of market volume and value? | **Volume _____, Value $_____**<br>**Volume _____%, Value _____%** |

## 9. RATIONAL USE OF MEDICINES

| 9.1 Are there standard treatment guidelines (STGs) produced by the health ministry/department for major conditions? *(STGs are recommendations about how to treat a clinical condition.)* | | ***Number of conditions/ diseases*** | ***Year of publication or review*** |
|---|---|---|---|
| National STG: | **Yes/No/DK** | **____** | **____** |
| STG for hospital level: | **Yes/No/DK** | **____** | **____** |
| STG for primary health care level: | **Yes/No/DK** | **____** | **____** |

| | |
|---|---|
| 9.2 Is there a National Medicines Formulary manual? *(A formulary manual contains summary drug information.)* If yes, does it cover only medicines on the Essential Medicines List? | **Yes/No/Don't Know**<br>**Yes/No/Don't Know** |
| What year was it last published/reviewed: | **Year ____** |

| 9.3 Are any of the following aspects of the essential medicines concept generally part of the basic curricula in most health training institutions/universities for: *(Essential medicines are those that satisfy the priority health care needs of the population. See glossary for a definition of problem-based pharmacotherapy.)* | ***Essential Medicines List*** | ***Standard Treatment Guidelines*** | ***Problem-based pharmaco-therapy*** | ***Rational prescribing*** |
|---|---|---|---|---|
| Doctors: | **Yes/No/DK** | **Yes/No/DK** | **Yes/No/DK** | **Yes/No/DK** |
| Nurses: | **Yes/No/DK** | **Yes/No/DK** | **Yes/No/DK** | **Yes/No/DK** |
| Pharmacists: | **Yes/No/DK** | **Yes/No/DK** | **Yes/No/DK** | **Yes/No/DK** |
| Pharmacy assistants: | **Yes/No/DK** | **Yes/No/DK** | **Yes/No/DK** | **Yes/No/DK** |
| Paramedical staff: | **Yes/No/DK** | **Yes/No/DK** | **Yes/No/DK** | **Yes/No/DK** |

| | |
|---|---|
| 9.4 Are there independent publicly or non-commercially funded obligatory continuing education programs which include use of medicines for: Doctors: | **Yes/No/Don't Know** |
| Nurses/midwives/paramedical staff: | **Yes/No/Don't Know** |
| Pharmacists: | **Yes/No/Don't Know** |
| Pharmacy aides/assistants: | **Yes/No/Don't Know** |

| | | | |
|---|---|---|---|
| 9.5 Is there a public or independently funded nationally accessible (e.g. by phone) medicines information centre or service co-ordinated by the Ministry of Health, academia, and/or a non-commercial non-governmental organisation that provides information on demand to: Prescribers:<br>Dispensers:<br>Consumers: | **Yes/No/Don't Know**<br>**Yes/No/Don't Know**<br>**Yes/No/Don't Know** | | |
| 9.6 Has there been any public education campaign concerning rational medicines use in the previous two years conducted by Ministry of Health/non-governmental organisation/academia on the following topics: Use of antibiotics:<br>Use of injections:<br>Other topics/issues: | **Yes/No/Don't Know**<br>**Yes/No/Don't Know**<br>**Yes/No/Don't Know** | | |
| 9.7 How often do the following personnel prescribe at the primary health care level in the public sector? Doctors:<br>Nurses/midwives/paramedical staff:<br>Pharmacists:<br>Pharmacy aides/assistants:<br>Personnel with less than one month formal health training: | **Always/Frequently/Occasionally/Never/DK**<br>**Always/Frequently/Occasionally/Never/DK**<br>**Always/Frequently/Occasionally/Never/DK**<br>**Always/Frequently/Occasionally/Never/DK**<br>**Always/Frequently/Occasionally/Never/DK** | | |
| 9.8 Is there a government department with a specific mandate to promote the rational use of medicines and co-ordinate medicines use policies? | **Yes/No/Don't Know** | | |
| 9.9 What proportion of facilities have a drugs and therapeutics committee? (A drugs and therapeutics committee promotes the safe and effective use of medicines in the facility or area under its jurisdiction) Referral hospitals:<br>General hospitals:<br>Regions/provinces: | **All/Most/Half/Few/None/Don't Know**<br>**All/Most/Half/Few/None/Don't Know**<br>**All/Most/Half/Few/None/Don't Know** | | |
| Is there a mandate for drugs and therapeutics committees in the national medicines policy? | **Yes/No/Don't Know** | | |
| 9.10 Is there a national strategy to contain antimicrobial resistance? | **Yes/No/Don't Know** | | |
| Is there a national reference laboratory to coordinate epidemiological surveillance of antimicrobial resistance? | **Yes/No/Don't Know** | | |
| Is there a funded national intersectoral task force to coordinate the implementation of interventions to promote appropriate use of antimicrobials and prevent the spread of infection? | **Yes/No/Don't Know** | | |
| 9.11 Are the following medicines sold over the counter without any prescription? Antibiotics:<br>Injections: | **Always/Frequently/Occasionally/Never/DK**<br>**Always/Frequently/Occasionally/Never/DK** | | |
| **10. INTELLECTUAL PROPERTY RIGHTS PROTECTION AND MARKETING AUTHORIZATION** ***(See glossary for definitions of terms used in this section.)*** | | | |
| 10.1 Is patent protection legally provided for pharmaceutical products? If yes, indicate*:*<br>Year introduced:<br>Type:<br>Duration of patent validity: | **Yes/No/Don't Know**<br>____<br>**Process/Product/Both/Don't Know**<br>____ | | |
| 10.2 Which intellectual property right protection regime/activities are provided for traditional medical knowledge? | | ***Year introduced*** | ***Duration of data protection*** |
| TRIPS:<br>Sui generis regimes:<br>Digital library:<br>National inventory of medicinal plants:<br>Others:<br>None: | **Yes/No/DK**<br>**Yes/No/DK**<br>**Yes/No/DK**<br>**Yes/No/DK**<br>**Yes/No/DK**<br>☐ **(DK☐)** | ____<br>____<br>____<br>____<br>____ | ____<br>____<br>____<br>____<br>____ |

| | | |
|---|---|---|
| 10.3 TRIPS Agreement (Agreement on Trade Related Aspects of Intellectual Property Rights): | | |
| a) Is your country a World Trade Organization Member? *If no, skip to 10.4* | **Yes/No/Don't Know** | |
| b) Has national legislation been modified to implement the TRIPS Agreement? If yes, what year did it go into effect? | **Yes/No/Don't Know Year ____** | |
| c) Is your country availing itself of the transitional period provided by Article 65 of the TRIPS Agreement? | **Yes/No/Don't Know** | |
| d) If your country is a least-developing country (LDC), has it availed itself of the transitional period accorded to LDCs in Article 66 of the TRIPS Agreement? | **Yes/No/DK/Country not an LDC** | |
| 10.4 Have parallel importing provisions on pharmaceuticals been incorporated into national legislation? If yes, have these provisions been applied? | **Yes/No/DK/Currently being discussed**<br>**Yes/No/DK/Currently being discussed** | |
| 10.5 Have compulsory licensing provisions for pharmaceuticals been incorporated into national legislation? If yes, under what conditions? | **Yes/No/DK/Currently being discussed** | |
| National emergency: | **Yes/No/Don't Know** | |
| Public non-commercial use: | **Yes/No/Don't Know** | |
| Remedying anti-competitive practices: | **Yes/No/Don't Know** | |
| Other: | **Yes/No/Don't Know** | |
| 10.6 Are generic pharmaceutical manufacturers allowed to use patented inventions for the purpose of obtaining marketing approval prior to patent expiration? | **Yes/No/DK/Currently being discussed** | |

**COMMENTS ABOUT INDICATORS AND VALUES**

| Item Number | Comment |
|---|---|
| | |
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# Questionnaire on structures and processes of country pharmaceutical situation

## Glossary of Terms:

**Advertisement:** A set of activities undertaken to advertise medicines. It is usually targeted to the general public and it is usually limited to over-the-counter medicines.

**Compulsory licensing:** This term is used when the judicial or administrative authority is allowed by law to grant a license, without permission from the holder, on various grounds of general interest (absence of working, public health, economic development, and national defence). "Working" of a patent is the execution of the invention in the country of registration.

**Co-payments:** Co-payments cover part of the cost of medicines, the other part being paid by an insurer or government.

**Drugs and therapeutics committee:** A drugs and therapeutics committee promotes the safe and effective use of medicines in the facility or area under its jurisdiction.

**Essential Medicines List:** An Essential Medicines List is a government-approved selective list of medicines or national reimbursement list.

**Essential medicines:** Essential medicines are those that satisfy the priority health care needs of the population.

**Generic substitution:** The practice of substituting a product, whether marketed under a trade name or generic name, by an equivalent product, usually a cheaper one, containing the same active ingredient(s).

**Health insurance:** Health insurance is any prepayment scheme for health care costs additional to but excluding subsidies funded through the Ministry of Health budget. The purpose of question 6.6 is to identify how much protection the population has against exposure to the cost of medicines at the time people are sick. Prepaid financing is the usual method for providing such protection. Public funding through the (prepaid) Ministry of Health budget is the most widespread form of prepayment. Question 6.5 attempts to identify additional prepayment protection (percentage of the population covered and degree of protection against medicine costs) such as private or employer-based health insurance, community prepayments schemes, social health insurance (health care funded through social security systems), etc.

**Herbal Medicines:** Herbal medicines are plant-derived material or preparations with therapeutic or other human health benefits, which contain either raw or processed ingredients from one or more plants. Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products, which are classified in the medicines category according to a national regulatory framework. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients, however, finished products or mixture products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal. In some countries, herbal medicines may also contain, by tradition, natural organic or inorganic active ingredients which are not of plant origin.

**Licensing:** Licensing is a system that subjects all premises to evaluation against a set of requirements before a specific activity (e.g. manufacturing, storage etc.) is authorised to take place.

**Medicines formulary manual:** A formulary manual contains summary drug information.

**National medicines (drug) policy (NMP):** A national medicines policies is an expression of the government's goals and priorities for the medium to long term for the pharmaceutical sector. It also identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and private sectors, and involves all the main actors in the pharmaceutical field.

**Parallel importing:** Parallel importation is importation, without the consent of the patent-holder, of a patented product marketed in another country either by the patent-holder or with the patent-holder's consent. Parallel importation enables promotion of competition for the patented product by allowing importation of equivalent patented products marketed at lower prices in other countries.

**Problem-based pharmacotherapy:** Problem-based pharmacotherapy is a problem-based practical approach to teaching prescribing.

**Promotion:** A set of activities undertaken to promote prescription of prescription-only medicines. It is usually targeted to health providers only and it is usually forbidden to target the general public.

**Registered products:** Products that have been evaluated for quality, safety and efficacy and thence authorised for marketing.

**Registration system:** A system that subjects all products to evaluation of quality, safety and efficacy before they are authorised for marketing.

**Standard Treatment Guidelines (STG):** STGs are recommendations about how to treat a clinical condition.

**Tender:** Tender is the process by which competing bids are entered for a particular contract.

**Traditional medical knowledge:** Knowledge related to traditional medicine (see definition of *Traditional medicine and complementary/alternative medicine*).

**Traditional medicine and complementary/alternative medicine (TM/CAM):** Traditional medicine is the sum total of the knowledge, skills, and practices based on theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in prevention, diagnosis, improvement or treatment of physical and mental illnesses. The terms "complementary medicine" and "alternative medicine" can be used interchangeably with "traditional medicine" in some countries. The term "complementary and alternative medicine" can also be used to refer to a broad set of health care practices that are not part of the country's own tradition and are not integrated into the dominant health care system.

**Transitional period:** TRIPS provides transitional periods during which countries are required to bring their national legislation and practices into conformity with its provisions. The latest dates for WTO Members were/are: 1996 for developed countries; 2000 for developing countries (as a general rule); 2005 for developing countries who had not introduced patents before joining the WTO; and 2006 for least-developed countries (extended to 2016 by the Doha Declaration). The TRIPS Agreement specifically recognizes the economic, financial, administrative and technological constraints of the least-developed countries. It therefore provides the possibility for further extension of the transitional period.

**TRIPS Agreement (Agreement on Trade Related Aspects of Intellectual Property Rights)**
**Article 65: Transitional Arrangements**
1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date[Ξ] of entry into force of the WTO Agreement.
2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.
3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.
4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.
5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.
**Article 66: Least-Developed Country Members**
1. In view of the special needs an requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other that Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.
2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

[Ξ] [WIPO note] January 1, 1995

# Guide for Coordinators and Data Collectors

## Level II Core Indicators

*It is important to know…*

- *if people have access to essential medicines;*
- *if they are getting medicines that are safe, effective and of good quality; and*
- *if these medicines are being properly used.*

Working Draft June 2003

# Table of Contents



*List of boxes*

# Introduction for coordinators and users

Monitoring and assessing the pharmaceutical situation is important. It should not be regarded as a complex, time consuming and expensive activity. Rather, it can be done using a simple set of tools. This guide provides a practical approach to monitoring based on efficient use of resources—time, people and money. It also provides step-by-step administrative and technical procedures to assist the survey coordinator in planning for the Level II survey of the national pharmaceutical situation:

*Administrative preparation:*

- Coordinating with WHO, ministry/department of health, public health facilities, private drug[1] outlets, warehouses
- Making logistic arrangements and budget allocations

*Technical requirements:*

- Selecting geographic areas and facilities
- Identifying country-specific items of the survey forms, e.g. key basket of medicines, treatment guidelines, etc.
- Training data collectors to carry out the survey and use the survey and summary forms
- Analysing and computing the data
- Preparing a report
- Using the results

All information and tools to assist countries and other groups interested in assessing, evaluating and monitoring pharmaceutical situations—such as training slides, a manual, and a complete set of survey forms and summary forms—are included.

Some portions of the *Manual for core indicators on country pharmaceutical situations* have been summarised below to keep this is an easy guide to training and survey preparation.

## Coordination

A national coordinator is needed to prepare for the Level II survey and oversee the survey process, data analysis, reporting and presentation of results. The coordinator should be a person knowledgeable of the pharmaceutical sector as well as experienced in conducting surveys. A thorough working knowledge of the pharmaceutical sector will help ensure important aspects of the sector are not overlooked in planning for the Level II survey. The results of the Level I questionnaire will also inform the planning process.

Any group within a health ministry/department involved in pharmaceutical activities, such as a pharmaceutical service management group, medicines regulatory authority, or national medicines policy office can coordinate the Level II survey activity. It is also

[1] The words "medicines" and "drugs" are used interchangeably in this text.

possible for other groups such as NGOs, professional groups and academia to initiate the activity. WHO, through the country and regional offices and EDM/HQ, and other donor agencies may be able to provide assistance. A complete coordinator checklist is provided in *Annex 1.* The roles and functions of the coordinator include:

- Communicate with government officials and other local agencies to gain approval for the survey and to request personnel who will do the survey
- Select geographic areas and identify facilities to be surveyed
- Allocate budget and, if necessary, request financial and technical support (*Box 1*)
- Coordinate and identify sources of information for *Level I questionnaire on structures and processes of country pharmaceutical situation*
- Identify country-specific items of the survey forms, e.g. key basket of medicines, treatment guidelines, etc.
- Prepare all the necessary materials for training, field test, and survey of Level II indicators
- Provide training and arrange field test exercise for Level II data collectors
- Supervise the actual survey of Level II indicators
- Check that are survey forms are completed correctly and in full
- Check the computations on the survey forms
- Coordinate completion of summary forms, analysis of results, writing of report, and presentation/feedback of results to appropriate groups.

***Box 1 Example of budget allocation***

| **Item** | **Cost (US$)** |
|---|---|
| Training to do the survey (10 people at US$10.00 each for 2 days' snacks) | 100.00 |
| Field test allowance (10 people at US$15.00 each) | 150.00 |
| Actual survey (US$35.00 per day per diem for 10 people for 6 days each) | 3900.00 |
| Transportation and communication | 600.00 |
| Materials (printing costs, paper, pens, calculator, etc) | 500.00 |
| Analysis and computation | 600.00 |
| Other expenses and fees** | 1650.00 |
| **TOTAL** | **7500.00** |

* For the actual survey, the rates should be computed based on the sites to be visited bearing in mind the need to provide expenses for board, lodging and transportation

**Include professional and coordinator fees and other services that may be needed

# Preparing the survey

The survey of Level II indicators is a very important part of monitoring the pharmaceutical sector because these indicators measure the outcome and impact of pharmaceutical programs in a country. Adequate preparation is needed and those who will gather the data must be trained. Key pointers are discussed below. More detail can be found in *Manual for core indicators on country pharmaceutical situations.*

## Selecting the survey areas and facilities

Five geographic areas will be included in the survey. A geographic area can be a district, municipality, or province. From these five geographic areas, a total of 30 public health facilities catering to outpatients and with pharmacies/drug dispensing units, 30 private drug outlets, and 5 central/district warehouses[2] will be selected, see *Box 2*. Selection can occur before the training or during the training with the participation of the data collectors.

***Box 2 Summary of survey areas and sites***

- Identify five geographic areas
  - 1 should be the largest or capital city
  - 1 should be among the lowest income generating areas
  - 3 others should be randomly selected
- From the five geographic areas select
  - 30 public health facilities treating general outpatients and with a medicines dispensing units. Six public health facilities should be selected from each area:
    - 1 public hospital (should be the largest facility with general public outpatient services in the area)
    - 1 primary/rural health centre or lowest level public health facility
    - 4 health facilities randomly selected from all middle level public health facilities, i.e. excluding primary/rural health units and hospitals
  - 30 private drug outlets (6 from each geographic area)
  - 5 warehouses (1 from each geographic area)

If the country situation is such that at least 25% of primary health care is delivered by facilities other than public health facilities – such as missions, NGO, social security, etc.– the public health facility forms can be adapted for use at these facilities as well. Any surveys done at other facilities should be in addition to the surveys carried out at public health facilities. Likewise, drug outlets in addition to private drug outlets and pharmacies/dispensaries connected to public health facilities can be included in the survey if they provide at least 25% of primary health care medicines. The private pharmacy/drug outlet survey forms can be adapted for use in these drug outlets.

[2] For the purposes of the Level II survey package, a private drug outlet is a permanent retailer selling medicines, whether a pharmacy, drug seller, drug store, or chemical seller, a warehouse is a central, regional, or district warehouse supplying the public sector, and a public health facility dispensary or public health facility pharmacy refers to the medicines dispensing area of the public health facility whether or not there is a pharmacist present.

## Tailoring the survey forms to country situation through choosing key medicines, selecting tracer conditions, and identifying treatment protocols

The survey forms used to collect data on Level II indicators are designed to be tailored to country situations. Tailoring must be done at the national level and country specific features pre-printed on the survey forms and discussed with data collectors during training (see *Box 3*). The survey forms also have several places where countries can indicate additional data to be collected without affecting the indicator outcomes.

***Box 3 Items on survey forms to predefine at national level***

| Survey Form | Item |
|---|---|
| 1, 3, 11, 13, 14 | Identify key medicines and any optional medicines |
| 2, 12 | Identify dosage forms and strengths of key medicines and any optional medicines |
| 4, 15 | Review language so fits with normal terminology. During training ensure data collectors are using uniform criteria for evaluating items on the checklists. |
| 5, 10 | Identify additional condition and treatment of choice for pneumonia and additional condition |
| 6 | Define the requirements for adequate labelling and patient knowledge if different from those listed<br>Define what will be considered as an antibiotic |
| 7 | Develop guidelines for data collectors on categorizing generic versus brand medicines |
| 8 | Identify the acceptable guidelines and medicines lists; obtain 1 copy of each for each survey team |
| 9 | Define 1st line antibiotics for mild/moderate pneumonia and identify any optional conditions and medicines that will be used to measure recommended or non-recommended practices |

### Identifying basket of key medicines

(Survey Forms 1, 2, 3, 11, 12, 13 and 14)

To select the basket of medicines, list the 15–20 most common conditions treated at the primary health care level and choose 15 of the most important medicines used to treat these conditions. The chosen medicines must be:

- On the national essential medicines list
- The most important therapeutically and based on national treatment guidelines or at least on the consensus of experts
- The most widely used of the medicines meeting the above criteria
- Medicines expected to be available at all primary health care facilities at all times

Appropriate persons must be consulted in drawing the list of key medicines to be included in this survey. *Box 4* provides a model list based on common disease conditions seen at outpatient facilities.

| *Box 4 Model list of key medicines* | |
|---|---|
| diarrhoea | Oral rehydration salts (ORS), cotrimoxazole tablets |
| acute respiratory tract infection | amoxycillin, cotrimoxazole tablets, procaine penicillin injection, paediatric paracetamol tablets |
| malaria | chloroquine tablets |
| anaemia | ferrous salt + folic acid tablets |
| worm infestations | mebendazole tablets |
| conjunctivitis | tetracycline eye ointment |
| skin infection | iodine, gentian violet or local alternative |
| fungal skin infection | benzoic acid + salicylic acid ointment |
| pain | acetylsalicylic acid or paracetamol tablets |
| prophylactic | retinol (vit A) ferrous salt + folic acid tablets |

### Identifying standard treatment guidelines for pneumonia and another condition

(Survey Forms 5 and 10)

If the WHO recommended guidelines will not be used, the treatment guidelines for pneumonia and another condition must be carefully specified with input from national experts. Selected treatment guidelines must be developed by an independent group and not influenced by pharmaceutical promotion.

## Selecting data collectors

Based on experience the most effective data collectors are persons with clinical experience such as physicians, nurses, pharmacists or paramedical staff. Health ministry/department staff and temporary employees with some health related background and experience are possible candidates. It can also be useful to select data collectors from different parts of the country to reflect language differences and enable a more diverse sampling of geographic areas—this could also resolve any concerns data collectors may have about travelling to unfamiliar areas. In all, ten data collectors will be needed—one team of two data collectors for each geographic area

# Training data collectors

Data collection is the most crucial part of the monitoring process. For accuracy and reliability of information and indicator measurement, the data collectors must be well trained. Training should focus on ensuring data collectors have a common understanding of the required information and know how to gather the data and complete the survey forms in a standardized fashion.

This training guide will help the coordinator introduce the survey process to those who will do the data gathering. The training will be in three parts (*Box 5*).

| ***Box 5*** | ***Sample training schedule*** | |
|---|---|---|
| Part I: | 4 hours briefing on survey forms and patient sampling | (1st day) |
| Part II: | Field test | (2nd day) |
| Part III: | 3 hours of debriefing and calculation | (3rd day) |
| Note: All data collectors should be trained together | | |

## Training components

- How to use Survey Forms 1–15. Copies of these forms must be available for discussion and use during training.
- Sampling exercises using copies of actual general outpatient lists and patient records. These can be obtained from nearby facilities. It is advisable to keep all the records and materials used in training for future use.
- Field tests in public health facilities and private drug outlets to familiarise data collectors with the procedures they will use in the field.

Note that facilities visited during the field test and those that will be included in the actual survey should be contacted and permission of the facilities and appropriate officials sought in advance. Data collectors will need to be properly introduced to the facilities by an endorsement letter from an appropriate authority, e.g. the health ministry/department.

## Training tools included in this package

- Slides 1–17, explained below and provided as *Annex 2*
- Survey Forms 1–15 (Data collectors will need copies for discussion during training, for practice during the field test, and for carrying out the actual survey.)
- Summary Forms 1–4 (Data collectors will need copies for discussion during training and use during the field test. For the actual survey, a data analyser will complete the forms.)
- *Manual for core indicators on country pharmaceutical situations* provides more information on the indicators and the survey process. Sampling methods crucial in getting valid and accurate data are also described in more detail in *The Manual*.

# Part I Training to introduce the Level II survey and how to conduct the survey

## Introducing indicators for monitoring and assessing the pharmaceutical situation (Slides 1–5)

*Slides 1–3* introduce the activity, why monitoring is important and who can use the results. Go through the slides and emphasize how the results can be used to improve the pharmaceutical sector.

*Slides 4 and 5* discuss indicators as basic tools in monitoring, pointing out that it is important to use a standardized procedure to enable comparisons. WHO has developed a hierarchical approach to monitoring and assessing country pharmaceutical situations. This approach is built around three groups of core indicators: Level I, II and III. Following the standard methodologies developed to assess these indicators, comparisons can be made in the pharmaceutical situation over time and among different facilities, districts and countries (*slide 4*).

The core indicators can be collected easily. Details are described in the manual included in this package, *Manual for core indicators on country pharmaceutical situations*.

Monitoring and assessment using indicators must be done at least every three years to assess trends and progress towards achieving the objectives of the pharmaceutical sector. Explain the pyramid (*slide 5,* see *Box 6*), noting that to get information on the pharmaceutical situation at the national level, a questionnaire on Level I indicators will be used. This training focuses on how to get information for Level II indicators.

***Box 6 Overview of the core indicator pyramid (Slide 5)***

**Level I** is a questionnaire on the existing infrastructures and key processes of each component of the pharmaceutical sector. The completion of the questionnaire can be accomplished in a relatively short time after identifying sources of accurate information.

For **Level II** indicators, a systematic survey has been developed to assess the degree of access and rational use of quality drugs. The operational procedure to carry out the survey is the focus of this package.

**Level III** indicators provide detailed evaluation and analysis of the pharmaceutical system and different key components.

## The survey sites and the survey team (Slides 6–7)

Using slide 6, explain the logistics of the survey.

Slide 7 can be filled out before or during the training so that the assignments may be discussed.

## The survey forms (Slides 8–17)

How the survey teams carry out the survey affects the accuracy and validity of the data. Consistency in data gathering and completing the survey forms is very important. The next discussion will review Survey Forms 1–15. A complete set of survey forms for discussion must be provided to each of the participants. Go through all the survey forms and discuss the notes at the bottom of each form. It is important

that all members of the survey team have the same understanding of each column and how and where to get the information. They should also know how to calculate the values on each of the forms. The survey forms have been designed to facilitate manual computation in the field.

Slide 8 gives the key topics to be discussed.

Slide 9 provides basic criteria for selecting key essential medicines to use in this survey. The selected essential medicines should be for common health conditions and should be ones that are expected to be always available at public facilities providing primary health care. List the selected key medicines on Slide 10 and review them with the participants. Caution data collectors to be careful when completing the survey forms as the same chemical entity can have several different product names.

*Slide 11* reviews how to check key essential medicines (Survey Forms 1, 2, 3, 11, 12, 13, and 14). The key essential medicines that have been selected for evaluation in this survey should be pre-printed on the survey forms.

*Slide 12* corresponds to Survey Forms 4 and 15. The survey team should have a common understanding of how to check conservation conditions. Go through the checklist and discuss the local situation. Ensure that everyone has the same understanding of when to indicate "true" or "false", for instance decide what are appropriate methods to control temperature for the climate.

*Slide 13* and the notes on the bottom of Survey Forms 5 and 10 explain how to measure affordability to treat pneumonia and another condition. The formula is on the survey form.

*Slide 14* explains how to select patients for the exit interview required for Survey Form 6. The exit interview of patients will obtain information on patient care and cost of treatment. It should be done after patients have been treated and received medicines, either near the dispensing area or as they are leaving the facility. It is important to construct a system that will allow the patients to be interviewed without disrupting the normal activity in the facility. Note that patient interviews should be timed to match peak hours at facilities in order to have enough patients to complete the survey forms.

Thirty (30) consecutive patients or any 30 patients after they are treated and have received their medicines must be interviewed for the following information:

- The number of medicines prescribed and dispensed.
- Whether each of the dispensed medicines is appropriately labelled with at least the name, dosage and duration written on the package given to the patient
- Whether the patient knows both the appropriate dosage and duration of each medicine.
- The amount paid out-of-pocket for medicines and non-diagnostic fees, i.e. visit or injection fees, but not lab or x-ray fees.

Data collectors should be trained how to identify patients, how to conduct interviews to determine whether patients know how to take the medicines and the amount they paid out of pocket for medicines and fees and how to determine whether medicines are adequately labelled. The logistics of intercepting patients for exit interviews should be practiced.

*Slide 15* is an example of a sampling procedure that can be used to select patient records for completing Survey Form 7 (see also *Sampling patients* below). Data collectors should be able to do the following:

- Confirm the availability and accessibility of medical records.
- Identify possible sources of retrospective prescribing data, including clinic registers, treatment logbooks, patient/family files, and retained prescription forms. The data collector must know where to locate these records in the facilities and how to use them.
- Identify the study period to be covered.

In order to complete Survey Form 7 consistently, data collectors also need to use common criteria for identifying which of the prescribed medicines to classify as injections and antibiotics. Immunizations and injectable contraceptives should not be counted as injections. Definitions of drugs considered as antibiotics must be discussed. Antimicrobial agents are not always classified in an identical way. Indicators for antibiotic use can be sensitive to certain drugs, especially in places with high incidence of parasitic infections, such as malaria or tuberculosis. Drugs such as antiprotozoals and antihelminthics are also usually placed in a different category of antibiotics. How to classify topical antibiotics widely used in areas where trachoma, bacterial conjunctivitis and bacterial skin infection are common will also need to be considered.

## Sampling patients

Techniques for conducting retrospective and prospective sampling should be practiced. An exercise using patient lists to select sample encounters is necessary. Data collectors should know how to get information from patient records both for general outpatients (Survey Form 7) and for cases of diarrhoea, pneumonia and ARI (Survey Form 9).

*Retrospective sampling*
Because of seasonal differences, variations in staffing, inconsistencies in the supply cycle etc., the survey should, as much as possible, cover the 12-month period prior to the date of data collection. If records during this period cannot be found or do not meet the sampling requirements, the study period can be shortened, making sure that there are no missing records during the period covered. This can be done by checking that all the months and days are represented in the record.

To complete Survey Form 7, data collectors should select 30 patients with any diagnosis seen during the last 12 months from general outpatient treatment records. Either the chronological or alternative sampling method described in *Box 7* may be used. Both sampling methods should be practiced during training. If records are not available, 30 patients may be selected from current treatment records provided there are sufficient records to randomly select the patients. If medical records are not available or too difficult to extract, it may be preferable to use prospective sampling methods (see description under *slide 14* above).

Retrospective and prospective sampling are described in further detail in the *Manual for core indicators on country pharmaceutical situations*.

***Box 7 Retrospective sampling: Selecting 30 patients from general outpatient records covering 12 months (365 days)***

**A. Chronological sampling method**

- Calculate the sampling interval by dividing the number of days covered by the outpatient list by the number of patients to be selected: 365 ÷ 30 = 12.2 days
- Number each day covered by the outpatient list.
- Select one patient encounter from the day numbered 1 on the list.
- Each subsequent encounter is selected by adding the sampling interval (12.2) to the previous total and rounding up. In other words, select one patient encounter from day 1, skip the sampling interval, and select one patient from day 14 (1 + 12.2 = 13.2 = 14 always round up).
  Third encounter = 13.2 + 12.2 = 25.4 = 26th day
  Fourth encounter = 25.4 + 12.2 = 37.6 = 38th day
  Fifth encounter = 37.6 + 12.2 = 49.8 = 50th day
- To choose a patient encounter from the patient list for each selected day, pick a random number between 0.0 and 1.0, multiply this number times the number of patient encounters on the list, and round upwards. For example, if you choose 0.4 and there are 18 patients on the list for the selected day: 0.4 x 18 = 7.2 = 8 (always round up). Review the 8th patient encounter when completing the survey forms provided the patient meets the inclusion criteria. If the patient does not meet the inclusion criteria, select the next patient on the list who does. Repeat this process, selecting one patient encounter from each selected day until 30 patient encounters have been reviewed.

**B. Alternative sampling method**

- Calculate the sampling interval by dividing the total number of patient encounters on the general outpatient list for the year by the number of patients to be selected. For example, if there are 5000 patient encounters on the general outpatient list covering the previous 12 months and 30 patient encounters are to be selected: 5000 ÷ 30 = 166.6. Select every 167th patient encounter from the list or the next one thereafter who meets the inclusion criteria.

*Slide 16*, discuss with participants which Standard Treatment Guidelines (STG) to use for the survey. The most current national STGs and Essential Medicines Lists (EML) should be distributed to data collectors to use for comparison purposes at the facilities. Survey Form 8 notes that the facilities must be able to show the documents to the survey team. Not knowing where the documents are located is an indication that they are not being used.

Use *Slide 17* to discuss how to select patients with specific conditions from an outpatient list. Each record will be reviewed to assess compliance to recommended treatment protocols in Survey Form 9. Thirty (30) patients seen during the previous 12 months should be sampled: 10 cases of non-bacterial diarrhoea in children under age 5, 10 cases of moderate pneumonia in children under age 5, and 10 cases of non-pneumonia acute respiratory tract infection in patients of any age. See *Box 7* and *Retrospective sampling* above for sampling instructions.

### The summary forms

Briefly review Summary Forms 1–4. There is a separate form for public health facility pharmacies/dispensaries, public health facilities, private pharmacies/drug outlets, and central/regional/district warehouses. Data from one facility is entered into each column. Data for one indicator is entered into each row. The first column lists the indicators and the second column specifies the value and the survey form on which the data can be found.

## Part II The field test

As part of the training, three public health facilities with dispensaries must be identified for the field test. The data collectors should be divided into three teams and each team assigned to one of the public health facilities. Private drug outlets should be identified in advance or selected by the teams on the day of the field test according to whichever procedure will be used during the actual survey.

Each team should have a complete set of Survey Forms 1–15 and Summary Forms 1–4. They should familiarise themselves with the sampling procedures, data gathering processes, and appropriate completion of each form. Each data collector should practice filling in a part of each survey form and calculating the values during the field test. After completing the survey forms, they should enter the data into Summary Forms 1–4. Any problems encountered in collecting data or completing the forms should be discussed during the debriefing. The coordinator should oversee the field test and review the completed forms to identify areas needing for further explanation.

## Part III Review the field test and calculations

Discuss the field test. Review all the survey forms and summary forms and discuss any difficulties in collecting data or completing the forms:

- Check that all computations are done properly. Each survey form must be checked for inconsistencies in data entry.
- Review sampling.
- Check the number of days covered by the review of stock records (Survey Forms 3 and 14)
- Discuss questions arising from the field test exercise
- Ensure data collectors have uniform approach to gathering data and completing forms

At this point the data collectors should know how to use the survey forms and summary forms.

# The actual survey

## Notifying facilities to be visited

- Obtain permission from officials responsible for public health facilities. In some cases verbal permission may be sufficient, in others it may be necessary to send a formal letter. *Box 8* provides a sample letter.
- Data collectors must be properly introduced to the facility (both for the field test and actual survey) by an endorsement letter from the health ministry/department or the WHO country office.

***Box 8 Sample letter to facilities***

Dear_____

Pharmaceuticals are important in maintaining and providing health services to the population. It is also important to know if the population has access to essential medicines of good quality and whether or not these medicines are being used properly.

The *name and location of facility* has been selected as one of the facilities to be included in a national survey to assess the pharmaceutical situation in *name of country* .

On *date of the visit*, our staff will be visiting your facility to gather some information on the availability of some key essential medicines and how these are being used. While at your facility, our staff will need to access *list all areas where access is needed, i.e. the last 12 months of outpatient records, the last 12 months of stock records*.

Thank you for your cooperation.

Sincerely,

## Travel schedule and logistics

The national coordinator should:

- Arrange the schedule and survey dates, including the necessary travel time to get to the selected geographic areas:
  - There should be five teams. A team of two field workers should be assigned to each geographic area.
  - All indicators from each public health facility and its dispensary can be collected in one day, including the visit to a nearby private drug outlet and central warehouse.
  - Each team can complete its portion of data gathering in about six days.
- Provide the necessary logistics: survey forms, calculator, and per diem or transport costs as applicable.
- Make copies of all the survey forms. The cover sheet of the survey forms packet lists the necessary number of copies.
- Indicate on the bottom of the *Summary Form 1: Public health facility pharmacies/dispensaries* the names of the geographic areas included in the survey and the numbers assigned to facilities in each area. Assign the same number to the public health facility and its dispensary and to the nearby private drug outlet. Note that each survey form has a box in the upper right hand corner. The facility number should also be recorded in this box.

## Data collectors

On arrival at the facilities, data collectors will need to speak to the person in charge of the facility and take a brief tour in order to be able to understand patient flow, where to locate the desired patients, and the existence and location of the necessary records. It is essential that this is done before any data is collected otherwise incomplete or incorrect data might be gathered wasting time or invalidating the results. A checklist for data collectors is provided in *Box 9*.

| ***Box 9 Checklist for data collectors*** | **Completed** |
|---|---|
| **At the geographic area level (region, province, district)** | |
| 1. Confirm that the necessary authorisation from the relevant authorities has been received and check on local logistical and security issues. Obtain any necessary additional authorisation letter | |
| 2. Identify the location of the facilities and the most efficient order in which to visit them | |
| **At the facility level (public health facility and private drug outlet)** | |
| 1. Take an initial tour of the facility and talk with key staff to understand the patient flow and existence and location of records | |
| 2. Determine the best order to complete the survey forms and which data collector will complete which forms | |
| 3. Confirm the availability and accessibility of records<br>▪ Location of general outpatient encounter records<br>▪ Patient records<br>▪ Stock records | |
| 4. Decide on retrospective or perspective sampling for survey forms based on the availability and accessibility of records | |
| 5. For retrospective sampling identify the study period to be covered | |

After completing the actual survey, data collectors should submit a brief report of the data collection process and, in particular, anything that will be important for the report writer in interpreting the results. Data collectors should also note if they had to visit more facilities then the ones actually included in the survey and record the reason facilities were skipped whether due to a lack of available records or other problems.

## Supervision of data collection

The supervision of the data collectors should aim to ensure that the agreed procedures and methods are being followed and the data collected are complete and of good quality. It should solve problems such as incomplete answers and omissions. Handling and storing data collection forms before they are processed and analysed is also important.

# What to do with the results

The coordinator should oversee the analysis of the data and the writing of the report. Complete guidance and a detailed suggested report outline are provided in *The Manual*.

## Computation, analysis and graphic display

The data must be checked in the field, however the data should be checked again for completeness and consistency before making the final calculations and analysis.

All the calculations can be done manually, but the computerized Summary Forms 1-4 included in this package can also be used to enter the data, do the computations and analysis and prepare reports. Data coding and entry must be double-checked.

For analysis of outcomes and impact, Level I indicators can be compared with the results and outcome measures of the Level II indicators. Results of Level I and Level II data can be compared with similar studies done in the past and with results from studies done in other countries.

## Written report

A report to communicate the information obtained should be prepared. This report is an important source of information and a basis for decisions on medicine policy and strategies. It should be persuasive and well prepared. The results must be discussed in a comprehensive and systematic manner, taking into account the objectives and strategies of the medicine policy. Clear recommendations based on the findings of the study should be included.

## Presentation and discussion of results and issues

The core indicators represent general measures of the current pharmaceutical situation. The study findings should be presented at the national level, to district/regional managers and at the health facility level. The result can also be discussed with other stakeholders involved in implementing national medicine policies: medicines inspectors, central medical stores, private drug outlets, and local industry. NGOs, professional organizations and academia should also know the results. Presentations should be comprehensive enough so that the audience will see how a problem in one component can affect another, but specific enough that the study's findings can be used as a launching point for discussing the audience's experiences and knowledge of problem areas and for identifying focused strategies to address problems.

# Annex 1 Coordinator checklist

| *Coordinator Checklist* | | |
|---|---|---|
| | **Task** | **Completed** |
| **Organise the Survey Process** | | |
| **Approval** | 1. Seek approval for the survey from government officials and necessary local agencies | |
| **Meeting** | 2. Many of the pre-training tasks may need to be done in consultation with government officials, expert groups, and other interested parties. Consider arranging a meeting of these persons to complete them. | |
| **Budget** | 3. Draw up a budget and, if necessary, request financial and technical assistance | |
| **Schedule** | 4. Schedule completion of Level I Questionnaire, Level II training and survey period, data analysis, report preparation, and workshops to discuss results | |
| **Level I** | 5. Coordinate and identify sources of information for Level I Questionnaire | |
| **Level II Site and Personnel Selection** | 6. Select geographic areas for Level II surveys | |
| | 7. Select facilities for Level II survey sites. At a minimum, the 30 public health facilities and 5 warehouses should be selected centrally. The 30 private drug outlets may be selected centrally or by data collectors once they are in the field. | |
| | 8. Select 3 public health facilities with dispensaries near training site for field tests. If the private drug outlets will be selected centrally for the actual survey, then they should be selected centrally for the field test as well. Otherwise the drug outlets can be selected by the data collectors once they are in the field. Facilities and outlets visited during the field test must be different from those selected for the actual survey. | |
| | 9. Prepare and send letters seeking permission from officials responsible for selected facilities to conduct field test and actual survey. Letters must include all areas where access is needed. Depending on the facility, this is the last 12 months of outpatient records, the last 12 months of under 5 paediatric ledgers and/or the last 12 months of stock records. Depending on the quality of records, it may be necessary to access current treatment records. | |
| | 10. Select 10 data collectors | |
| | 11. Assign data collectors into teams and assign teams to geographic areas. Fill in assignments on Slide 7 | |
| | 12. Identify who will encode/tabulate the data and do the computation. | |
| **Tailor Level II Survey Forms** | 13. Identify 15 key medicines (use morbidity data to aid selection) and pre-print on Survey Forms 1, 2, 3, 11, 12, 13 and 14 | |
| | 14. Identify preparation and unit an pre-print on Survey Forms 2 and 12 | |
| | 15. Review language on Survey Forms 4 and 15 to ensure it fits with normal terminology. During training ensure data collectors are using uniform criteria for evaluating items on the checklists. | |
| | 16. Identify additional condition and treatment of choice to treat pneumonia and the additional condition in children and adults and pre-print medicine, preparation, and number of units needed to complete treatment on Survey Forms 5 and 10. | |
| | 17. Identify lowest daily government salary and optional second unit of measure and preprint on Survey Forms 5 and 10. | |
| | 18. Determine the requirements for adequate labelling and patient knowledge if | |

| | | |
|---|---|---|
| | different from those listed. Modify criteria printed on forms if changes are made. | |
| | 19. Identify current approved STG and EML to be checked when completing Survey Form 8 and obtain copies of each for each survey team. | |
| | 20. Define 1st line antibiotics for mild/moderate pneumonia and identify any optional conditions and medicines that will be used to measure recommended or non-recommended practices for Survey Form 9 and pre-print on the form. | |
| | 21. Determine if any additional information is to be gathered by data collectors. | |
| | 22. Define what data collectors should categorize as antibiotics, make a reference list of antibiotics, and develop guidelines for data collectors to categorize generic versus branded medicines. | |
| **Prepare for Level II Training** | | |
| **Official Letters** | 1. Prepare official letter of introduction for data collectors. | |
| **Copies** | 2. Print and photo copy all materials for training session and field test:<br>▪ One copy per data collection team of the official letter of introduction<br>▪ Two copies per person of a complete set of survey forms, if possible, copy survey forms to be completed at public health facilities, private drug outlets, and warehouses on different coloured paper<br>▪ Two copies per data collector of a complete set of summary forms<br>▪ One copy per data collector of *The Manual*<br>▪ One copy per data collector of *The Guide*<br>▪ One copy per data collection team of the national EDL and STGs required for Survey Form 8<br>▪ One copy per data collector of antibiotic definition and reference list<br>▪ One copy per data collector of guidelines on categorizing generic versus branded medicines | |
| **Packets** | 3. Staple survey forms to be completed at the same facility together in order to ensure none are missed | |
| | 4. Assemble field test packets for all three data collection teams (advise data collectors to retain these documents for reference during the actual survey). Each team should receive:<br>▪ Official letter of introduction to the facilities and households to be surveyed<br>▪ One copy per person of Survey Forms 1–15<br>▪ One copy per person of Summary Forms 1–4<br>▪ One copy per person of *The Manual*<br>▪ One copy per person of *The Guide*<br>▪ One copies per team of the National EDL and STGs required for Survey Form 8<br>▪ One copy per person of the antibiotic definition and reference list<br>▪ One copy per person of the guidelines on categorizing generic versus branded medicines<br>▪ One calculator per person<br>▪ Two pencils with erasures per person<br>▪ Necessary transport costs | |
| | 5. Assemble discussion packets for data collectors:<br>▪ Field test packets<br>▪ One copy per person of a complete set of survey forms and summary forms | |
| | 6. Prepare information on transport, distance, and security for each data collector | |
| **Training Slides** | 7. Obtain sample outpatient lists, patient records, and sample stock cards and copy onto a transparency or photocopy for distribution to data collection teams (these will be used during the discussion) | |
| | 8. Fill in Slide 7 (team assignments) | |
| | 9. Fill in Slide 10 (list of key medicines) | |
| **Other materials** | 10. Compile one copy of a training reference packet including: completed Level I questionnaire, current national medicine policy document, relevant laws and regulations on medicines, information on enforcement and implementation of medicines laws, and information on pharmaceutical inspections | |

| | | |
|---|---|---|
| **During Level II Training** | | |
| **Note Taker** | 1. Arrange for someone to take notes during training of all decisions on how to interpret forms, changes in instructions, solutions to problems experienced in field test, etc. and prepare a list for distribution to the data collectors before they go into the field | |
| **Review** | 2. Review materials from field test to ensure proper completion of forms | |
| **After Level II Training** | | |
| **Official Letter** | 1. Prepare an official letter of introduction to the local health authorities, facilities to be surveyed | |
| **Survey Forms** | 2. Ensure key medicines are pre-printed on Survey Forms 1, 2, 3, 11, 12, 13 and 14; preparation and unit are pre-printed on Survey Forms 2 and 12; second condition, medicines of choice, their preparation, number of units needed to complete treatment, lowest daily government salary, and optional second unit of measure are pre-printed on Survey Forms 5 and 10; second condition in pre-printed on Survey Form 8, and, if additional tracer conditions are selected, the appropriate drugs are pre-printed on Survey Form 9 | |
| | 3. Pre-print geographic name and investigators | |
| **Copies** | 4. Print and photo copy all materials for actual survey:<br>▪ One copy per data collection team of the official letter of introduction to the local health authorities and facilities to be surveyed<br>▪ Six copies per team of Survey Forms 1–15. If possible, copy survey forms to be completed at public health facilities, private drug outlets, and warehouses on different coloured paper. Spare copies of forms should also be provided to data collectors.<br>▪ One copy per team of Summary Forms 1–4<br>▪ One copy per data collector of the notes on decisions made during the training session (see point 1 of *During Level II Training*, above)<br><br>And, depending on whether changes were made and whether or not data collectors retained the documents from the training session:<br>▪ One copy per data collector of *The Manual*<br>▪ One copy per data collector of *The Guide*<br>▪ One copy per data collection team of the national EDL and STGs required for Survey Form 8<br>▪ One copy per data collection of the antibiotic definition and reference list<br>▪ One copy per data collection of the guidelines on categorizing generic versus branded medicines | |
| **Packets** | 5. Staple survey forms to be completed at the same facility together in order to ensure none are missed | |
| | 6. Assemble Actual Survey Packets for each data collection team:<br>▪ One copy of the official letter of introduction to the local health authorities, facilities to be surveyed, and village/hamlet leaders<br>▪ Transport costs<br>▪ Per diem<br>▪ Six copies of Survey Forms 1–15<br>▪ Two copies of the notes on decisions made during the training session (see point 1 of *During Level II Training*, above)<br><br>And, depending on whether changes were made and whether or not data collectors retained the documents from the training session:<br>▪ Two copies of *The Manual*<br>▪ Two copies of *The Guide*<br>▪ Two copies of the National EDL and STGs required for Survey Form 8<br>▪ Two copies of the antibiotic definition and reference list<br>▪ Two copies of the guidelines on categorizing generic versus branded medicines<br>▪ Two calculators<br>▪ Four pencils with erasures | |
| **Supervise** | 7. Supervise the actual Level II survey, ensure that all data points are collected, that | |

| | | |
|---|---|---|
| **Level II Survey** | sampling is random, and survey forms are completed correctly. | |
| | 8. After the survey, check again that all data points have been collected, random sampling was used, and that the forms were completed correctly. Also check the computations. | |
| | 9. Collect written reports from data collectors on the data collection process and in particular anything that will be important in interpreting the results. | |
| **Analyse Data** | 10. Provide copy of Survey Forms to data analyser to complete Summary Forms 1–4. | |
| **Report Writing** | 11. Provide copy of Summary Forms, graphs, and data analysis and notes from data collectors to report writer. | |
| | 12. Oversee writing of report | |
| **Present Results** | 13. Coordinate presentation/feedback of results | |

# Annex 2 Training slides

## WHO Operational Package for Monitoring and Assessing Country Pharmaceutical Situations: A field work guide

**Why monitor and assess?**

- *To assess country capacity (infrastructures and resources)*
- *To review implementation strategies so adjustments can be made*
- *To measure outcome of pharmaceutical objectives (access and rational use of quality medicines)*

1 WHO - EDM

## Who can use the results from assessment and monitoring?

- Countries
  - to focus action, prioritize, measure achievement
- National policy-makers
  - to synchronise health and economic policies
  - to get a clear picture of national problems and identify and prioritize strategies
  - to present the performance of the pharmaceutical sector to donors and other government agencies

2 WHO - EDM

## Who can use the results from assessment and monitoring? (con't)

- Health facilities
  - to be aware of the institutional problems and identify strategies to improve the situation
- International agencies
  - to assess the structure and capacity of countries when developing new projects
  - to assess the progress and accomplishment of current projects
  - to assess the impact of aid
- Professional groups, NGOs and academia
  - to focus their advocacy activities and information campaigns

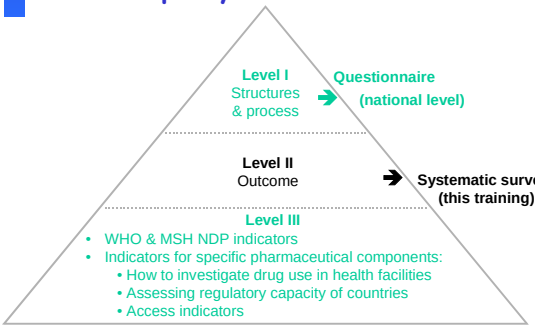
3 WHO - EDM

## Why is it important to use indicators?

- Monitoring and evaluation of standard indicators facilitates:
  - **comparing** the performance of facilities, districts, provinces and the overall situation in the country
  - seeing **trends** over time

4 WHO - EDM

## Core indicators to monitor national medicine policy




5 WHO - EDM

## The survey areas and the survey team

- 5 geographic areas:
  - 30 public health facilities and their dispensaries
  - 30 private drug outlets
  - 5 central warehouses
- In each area, one team of 2 persons can complete in one day:
  - Surveys of one public health facility and its dispensary, the private drug outlet nearest to the public health facility, and one warehouse
- With 5 teams of 2 persons each, the entire survey package can be completed in 6 days

6 WHO - EDM

## Team assignments

| TEAM/NAME | GEOGRAPHIC AREA | FACILITIES |
|---|---|---|
| ***Team 1*** <br> ***1.*** <br> ***2.*** | | 6 Public health facilities <br> 6 Private drug outlets <br> 1 Warehouse |
| ***Team 2*** <br> ***1.*** <br> ***2.*** | | 6 Public health facilities <br> 6 Private drug outlets <br> 1 Warehouse |
| ***Team 3*** <br> ***1.*** <br> ***2.*** | | 6 Public health facilities <br> 6 Private drug outlets <br> 1 Warehouse |
| ***Team 4*** <br> ***1.*** <br> ***2.*** | | 6 Public health facilities <br> 6 Private drug outlets <br> 1 Warehouse |
| ***Team 5*** <br> ***1.*** <br> ***2.*** | | 6 Public health facilities <br> 6 Private drug outlets <br> 1 Warehouse |

7 WHO - EDM

## Focus of the training

- Selecting key essential medicines for the country
- Completing the survey (use notes on survey forms as guide)
  - checking key medicines (1, 11, 13)
  - checking prices of key medicines (2, 12)
  - using stock records to measure stock out duration (3, 14)
  - using a checklist for inspection (4, 15)
  - getting treatment costs (5, 10)
  - selecting patients for exit interview (6)
  - sampling patients from outpatient list at health facility (7, 9)
  - checking availability of guidelines (8)
- Calculating and filling in indicator values for the 15 survey forms and 4 summary forms

8 WHO - EDM

## Selecting key Essential Medicines

- Identify 15-20 conditions most seen at outpatient PHC facilities
- Select key medicines to treat these conditions
  - These must be medicines that should always be available at all facilities providing primary health care
  - These must be on the national Essential Medicines List
  - These must be the most important therapeutically, based on national treatment guidelines or at least on the consensus of experts
  - The most widely used of the medicines meeting the above criteria

**Model list of key medicines**

| | |
|---|---|
| Diarrhoea | Oral rehydration salts, cotrimoxazole tablets |
| Acute respiratory tract infection | Amoxycillin, cotrimoxazole tablets, procaine penicillin injection, paediatric paracetamol tablet |
| Malaria | Choloquine tablets |
| Anaemia | Ferrous salt + folic acid tablets |
| Worm infestations | Mebendazole tablets |
| Conjunctivitis | Tetracycline eye ointment |
| Skin infection | Iodine, gentian violet or local alternative |
| Fungal skin infection | Benzoic acid + salicylic acid ointment |
| Pain | Acetylsalicylic acid or paracetamol tablets |
| Prophylactic drugs | Retinol (Vit.A) ferrous salt + folic acid tablets |

9 WHO - EDM

## List of key medicines _____

(name of country)

| Conditions | Key medicines |
|---|---|
| 1. | |
| 2. | |
| 3. | |
| 4. | |
| 5. | |
| 6. | |
| 7. | |
| 8. | |
| 9. | |
| 10. | |
| 11. | |
| 12. | |
| 13. | |
| 14. | |
| 15. | |

10 WHO - EDM

## Availability of key essential medicines, expired medicines, medicine prices, stock out duration, and record keeping

***Survey Forms 1, 11, 13***

- Check which of the key essential medicines listed are available at the facility
- Check if there are expired key medicines on the shelves

***Survey Forms 2, 12***

- Determine the lowest price paid by the facility and patient (out-of-pocket) for each key medicine

***Survey Forms 3, 14***

- Get the stock cards of all key essential medicines
- Calculate the percentage of medicines with records covering at least 6 of the last 12 months
- Calculate the equivalent number of days per year that each medicine is not in stock and the average number of stockout days for the medicines reviewed

11 WHO - EDM

## Conservation conditions and handling of medicines in dispensing and storage areas

***Survey Forms 4, 15***

- Establish a common definition and understanding of each item on the checklist
- Conditions must be defined within the context of actual situations at storage and dispensing areas

12 WHO - EDM

## Affordability of treatment

***Survey Forms 5 and 10 - Calculating the cost of treating uncomplicated pneumonia and another condition***

- Identified in advance and preprinted on the forms will be:
  - A second condition
  - The treatment of choice for adults and children
  - The lowest daily salary of a government worker
  - A second standard of measure, if desired
- In the field, data collectors will:
  - Record the unit price, including syringe if applicable
  - Calculate the total cost of treatment and the affordability of the treatment using the formulas indicated




## Patient care - how to select patients for exit interview

***Survey Form 6***

- Interview 30 consecutive patients or any patient who has been treated after medicines have been dispensed
  - Check each medicine's label for the medicine's name, dosage and duration. An adequate label must have all three written on it.
  - Ask the patient how to take each medicine. The patient must know the dosage and duration of all dispensed medicines.
  - Ask the patient how much was paid out-of-pocket for medicines and in non-diagnostic fees (include visit and injection fees but not lab or x-ray fees)




## Prescribing practice - how to do systematic sampling of outpatients

***Survey Form 7***

- Simple method for selecting 30 patients from the general outpatient list
  - If there are 5000 patients treated during the entire period and the sample size is 30
  - 5000 ÷ 30 = 166.6

    every 167th patient in the list should be selected
- See retrospective and prospective sampling in *The Manual* for alternate methods

***Notes:*** *Cover one year period or current treatment records sufficient to randomly select 30 patients. Prescribing indicators have limitations when applied to well-child visits, pre and post-natal visits, specialist consultations, or even separate clinics for adults and paediatric cases because treatment practices are different and results may be difficult to interpret.*




## Availability of standard treatment guidelines (STG) and essential medicines lists (EML) at the facility

***Survey Form 8***

- Check for presence of guidelines. The facility must be able to show the documents to count them as present.
- Selected treatment guidelines may be included in a combined STG publication or disease specific STG document.
- Identify current national EML. Check for presence of each EML. Only count EMLs that have been updated within the last 5 years.




## Treatment of tracer diseases - how to select patients and how to do the assessment

***Survey Form 9***

- Select 30 outpatients seen at different dates during a one year period (see *The Manual* for a description of retrospective and prospective sampling)
  - 10 outpatient children under 5 years of age with non-bacterial diarrhoea;
  - 10 outpatient children under 5 years of age with pneumonia; and
  - 10 outpatients of any age with non-pneumonia, non-bacterial acute respiratory tract infection.
- For each case, check whether the treatment corresponds to the description in the column [A]