

# Monitoring of medicines in the health system

July 2010

This rapid response was prepared by the Uganda country node of the Regional East African Community Health (REACH) Policy Initiative.

## Key messages

As recommended by several partners including the Global Fund, World Health Organisation, and the World Bank, among others, the following are essential indicators that should be a part of any monitoring program for medicines and medical products in the health system (*Global Fund Monitoring and Evaluation tool kit, February 2009*):

- Percentage of facilities with all tracer medicines in stock on the day the facility is visited
- Percentage of facilities that keep adequate logistics data for inventory management
- Number and percentage of facilities with staff trained in stock management
- Number and percentage of facilities that maintain acceptable storage conditions and handling procedures
- Percentage and number of Product losses by value due to expired drugs, damage and theft per value received
- Existence of standard procedures for the quality control of health products at initial receipt at the central level
- Percentage of product batches of pharmaceuticals that have undergone a quality control process at the initial receipt according to standard procedures
- Percentage of health facilities that have a procedure in place to report product quality issues
- Percentage of medicines prescribed based on national treatment guidelines or an essential medicines list or formulary
- Percentage of dispensed medicines adequately labelled with dosage instructions
- Percentage of health facilities with an adherence register or other similar record-keeping system available to report adherence rates



## Who requested this rapid response?

This document was prepared in response to a specific question from a policy maker in Uganda.

## ! This rapid response includes:

- Key findings from research
- Considerations about the relevance of this research for health system decisions in Uganda

## X Not included:

- Recommendations
- Detailed descriptions
- Information on monitoring complementary medicines

## What is SURE Rapid Response Service?

SURE Rapid Responses address the needs of policymakers and managers for research evidence that has been appraised and contextualised in a matter of hours or days, if it is going to be of value to them. The Responses address questions about arrangements for organising, financing and governing health systems, and strategies for implementing changes.

## What is SURE?

SURE – Supporting the Use of Research Evidence (SURE) for policy in African health systems - is a collaborative project that builds on and supports the Evidence-Informed Policy Network (EVIPNet) in Africa and the Regional East African Community Health (REACH) Policy Initiative (see back page). SURE is funded by the European Commission's 7th Framework Programme. [www.evipnet.org/sure](http://www.evipnet.org/sure)

## Glossary

of terms used in this report:

[www.evipnet.org/sure/rr/glossary](http://www.evipnet.org/sure/rr/glossary)

# Background

An efficient health system ensures equitable access to essential medicines and medical products, the quality, safety, efficacy and cost-effectiveness of which should be assured too. Achieving this state of affairs may require creating or strengthening national policies, standards, guidelines, and putting in place regulations that support these. This process requires among other things, evidence-based selection of medicines and other products, and procurement, supply, storage and distribution systems that minimize leakage and other waste. In addition support for the rational use of essential medicines is necessary and may be in terms of strategies to assure adherence, reduce resistance and maximize patient safety, and well being.

In addition to the role of pharmaco-vigilance, monitoring use and distribution within the health system is critical if the system is going to be equitable, efficient and accountable. There are several mechanisms and frameworks that can be used to monitor medicines and their use in a health system; for example the WHO has developed a core indicator package used in the regular and repeated assessment of country pharmaceutical situations. With it WHO is able to support Ministries of Health (MoH) in assessing the current pharmaceutical situation, facilitating access to information which MoH can use as a guide in determining priority areas for intervention, tracking progress, planning programs, assessing program effectiveness, co-ordinating donors and raising funds. With any mechanism of monitoring what is crucial is identifying relevant indicators for the given context.

The Ministry of Health, in collaboration with the World Health Organization (WHO) and Health Action International Africa (HAI-Africa) represented by the Coalition for Health Promotion and Social Development (HEPS-Uganda), has since 2006 conducted medicines prices and availability monitoring in 3 sectors (public, mission, private). In addition the Medicines and Health Service Delivery Monitoring Unit was set up by the President in September 2009, to monitor and curb malpractices in medicines use and availability in the health system, among other things. It is not clear what framework the latter unit of these two uses but the former is based on the standardized WHO/HAI monitoring guidelines. This paper will present indicators that should be included in any of the mechanisms one chooses to use in a low and middle income country like Uganda. They have been based on and adapted by the author from the monitoring and evaluation kit developed by the Global Fund, World Health Organization, World Bank and Partners for monitoring programs for health systems strengthening.

## How this Response was prepared

After clarifying the question being asked, we searched for systematic reviews, local or national evidence from Uganda, and other relevant research. The methods used by the SURE Rapid Response Service to find, select and assess research evidence are described here:

[www.evipnet.org/sure/rr/methods](http://www.evipnet.org/sure/rr/methods)

# Summary of findings

## Indicators for monitoring medicines in the health system.

Indicator 1: Percentage of facilities with all tracer medicines in stock on the day the facility is visited
<p><b>Rationale</b></p> <ul style="list-style-type: none"> <li>Measures the current availability of key essential* medicines to treat common health problems in facilities on the day the facility is visited; physical availability is a basic measure of access to essential medicines for the population.</li> <li>This indicator can also be used for monitoring the effectiveness of the distribution system.</li> </ul>
<p><b>Definition</b></p> <p><i>Numerator:</i> Number of health facilities with all the selected tracer medicines in stock (present and not expired) on the day of the visit</p> <p><i>Denominator:</i> Total number of health facilities surveyed</p>
<p><b>Measurement</b></p> <ul style="list-style-type: none"> <li>Data collection methods: facility visits are required using a standardized list of tracer medicines to assess the availability of non-expired medicines and commodities on the day of the visit. The assessor goes through the shelves and identifies which of the medicines on the list are available at the facility at the time of the survey.</li> </ul>
<p>Data source: The quality of data generated by facility visits is likely to be better than those based on reporting systems.</p> <p>Frequency: Every 2-3 years</p>
<p>* the WHO does provide a list of tracer medicines (see <a href="http://www.who.int/medicinedocs/index/assoc/s14877e/s14877e.pdf">www.who.int/medicinedocs/index/assoc/s14877e/s14877e.pdf</a>), however individual countries may have a list of medicines considered essential varying, or at least some elements and it usually would depend on the epidemiology (such as the presence of malaria or the type of HIV epidemic).</p>
Indicator 2: Percentage of facilities that keep adequate logistics data for inventory management
<p><b>Rationale</b></p> <ul style="list-style-type: none"> <li>This indicator determines the extent to which stock records are maintained.</li> <li>The presence of adequately maintained and accurate stock records contributes to proper medicine management and estimation of need and facilitates the reordering of medicines.</li> </ul>
<p><b>Definition</b></p> <p><i>Numerator:</i> Number of health facilities that keep accurate logistics data for inventory management</p> <p><i>Denominator:</i> Total number of health facilities surveyed</p>
<p><b>Measurement</b></p>

- A list of 15 key essential medicines to treat the most common health problems is a prerequisite.
- The information is collected from a representative sampled survey of health facility dispensaries.
- For each of the key medicines, examine the data on the stock card and count the physical stock and then compare physical and recorded stock. The error rate can then be identified.
- The percentage of facilities with adequate stock records is equal to the number of facilities that have adequate records for key medicines reviewed divided by the total number of facilities.

*Data sources:* health facility survey

*Frequency:* every 2–3 years

### **Indicator 3: Number and percentage of facilities with staff trained in stock management**

#### **Rationale**

- This indicator measures the existence of skilled staff at health facilities and civil society organizations responsible for managing medicines (and health products, vaccines and other health equipment).
- The presence of skilled and qualified staff members at a minimum ensures the efficient management of health products, vaccines and technologies.

#### **Definition of the indicator**

##### *Numerators*

1) Health facilities: number of health facilities where at least one staff member responsible for stock management has been trained in stock management

2) Civil society organizations: number of civil society organizations where at least one staff member responsible for stock management has been trained in stock management

##### *Denominators*

1) Total number of health facilities

2) Total number of civil society organizations

#### **Measurement**

- The numerator is calculated by adding the number of health facilities or civil society organizations with staff responsible for stock management trained during the reporting period.
- This can be measured at the national and sub-national levels from administrative records.

*Source:* administrative records

*Frequency:* quarterly

### **Indicator 4: Number and percentage of facilities that maintain acceptable storage conditions and handling procedures**

#### **Rationale**

The quality of medicines (and health products, vaccines and technologies) highly depends on storage and handling capability. Tracking the standards and procedures for storage and handling is therefore critical in ensuring the existence of acceptable standards to assure safe storage and handling of products and commodities.

#### **Definition**

*Numerator:* Number of facilities that maintain acceptable storage conditions and handling procedures

*Denominator:* Total number of facilities

<p><b>Measurement</b></p> <ul style="list-style-type: none"> <li>• A prerequisite is a checklist of minimum criteria for adequate conservation conditions and handling of medicines at facilities based on WHO good storage practices and national guidelines, if available.</li> <li>• A representative sample of health facility dispensaries or private drug outlets is surveyed, and the conservation conditions and handling of medicines is rated using the checklist.</li> <li>• Only indicate “true” if all conditions included in the statement are true. If any condition of the statement is false, indicate “false”.</li> <li>• The conservation conditions and handling of medicines is equal to the total number of “true” responses to items on the checklist on the conservation conditions and handling of medicines divided by 10 and multiplied by 100.</li> </ul>
<p><i>Data sources:</i> administrative records</p> <p><i>Frequency:</i> annually</p>
<p><b>Indicator 5: Percentage and number of Product losses by value due to expired drugs, damage and theft per value received</b></p>
<p><b>Rationale</b></p> <p>A well-managed distribution system should achieve the following objectives:</p> <ul style="list-style-type: none"> <li>• maintain a constant supply of medicines</li> <li>• keep products in good condition throughout the distribution process</li> <li>• maintain accurate inventory records</li> <li>• rationalize drug storage points</li> <li>• minimize medicine losses due to spoilage and expiry</li> <li>• reduce theft and fraud</li> <li>• provide information for forecasting medicines and other health product needs</li> </ul> <p>By determining the extent of losses due to expired medicines, damage or theft, this indicator measures the performance of distribution systems for health products.</p>
<p><b>Definition</b></p> <p><i>Numerator:</i> Value of products expired, damaged or theft during the last calendar year taken out of the stock</p> <p><i>Denominator:</i> Total value of products received during the last calendar year</p>
<p><b>Measurement</b></p> <ul style="list-style-type: none"> <li>• This indicator can be used for measuring losses at the health facility level but also at the central level (national, regional and district medical stores).</li> <li>• The numerator is generated by summing the total value of products expired, damaged or stolen at a health facility during the last calendar year taken out of the stock. The denominator is the sum total of value of products received during the last calendar year.</li> <li>• The national average is derived by summing the percentage values for all the facilities surveyed and dividing by the total number of health facilities surveyed.</li> </ul>
<p><i>Data sources:</i> inventory control records from facility records or national, regional and district warehouse records</p>

*Frequency: annually*

**Indicator 6: Existence of standard procedures for the quality control of health products at initial receipt at the central level**

**Rationale**

- Quality control is concerned with sampling, specifications and testing and with the organization, documentation and release procedures that ensure that the necessary and relevant tests are carried out.
- It also ensures that materials or products are not released for use until their quality has been judged satisfactory for their intended purpose.
- Quality control of medicines should cover all activities to ensure that people who need medicines receive safe, efficacious and high-quality medicines.
- Each procurement agency should have access to a quality control department, which should meet the general requirements for facilities, policies and procedures, staff expertise, experience and training.
- The quality control department must be capable of undertaking the full range of tests required or of managing any subcontracting of such work to third parties correctly while retaining responsibility for the quality of the work done.
- As part of quality assurance, a supply system should have a defined protocol at the central level for managing quality control testing activities for purchased medicines and other health products.

**Definition of the indicator**

This indicator measures the existence of standard procedures for the quality control of health products at the central level to assess the quality of health products at initial receipt.

**Measurement**

- The indicator is generated by conducting a desk review at the central level to ascertain the existence of the standard procedures for the quality control of health products.
- The indicator does not measure the actual process of quality control. To assess whether the procedures are implemented, an additional indicator is required; indicator 7 is recommended to complement this one.

*Data sources: administrative records*

*Frequency: annually*

**Indicator 7: Percentage of product batches of pharmaceuticals that have undergone a quality control process at the initial receipt according to standard procedures**

**Rationale**

*As for indicator 6.*

**Definition of the indicator**

*Numerator:* Total number of product batches of pharmaceuticals that have undergone a quality control process at the initial receipt according to standard procedures

*Denominator:* Total number of product batches received in the last calendar year

**Measurement**

- The numerator is generated by a count of all pharmaceutical product batches with evidence that a

<p>sample of medicine for each batch was randomly selected and tested for quality control at the initial receipt of each respective batch. For each batch received, a sample of medicines is supposed to be randomly selected and tested for quality control.</p> <ul style="list-style-type: none"> <li>• The denominator is the total count of all pharmaceutical product batches received during a calendar year.</li> </ul>
<p><i>Frequency:</i> annually</p> <p><i>Data sources:</i> administrative records</p>
<p><b>Indicator 8: Percentage of health facilities that have a procedure in place to report product quality issues</b></p>
<p><b>Rationale</b></p> <p>As part of quality assurance system, dispensing health facilities should be equipped with a defined protocol to report quality issues for received medicines to the central level.</p>
<p><b>Definition of the indicator</b></p> <p><i>Numerator:</i> Total number of health facilities that have a procedure in place to report product quality issues</p> <p><i>Denominator:</i> Total number of health facilities surveyed</p>
<p><b>Measurement</b></p> <ul style="list-style-type: none"> <li>• The numerator is derived from a check and count of all sampled health facilities that have a procedure in place to report product quality issues.</li> <li>• The denominator is the total number of sampled health facilities.</li> </ul>
<p><i>Data sources:</i> health facility survey</p> <p><i>Frequency:</i> every 2–3 years</p>
<p><b>Indicator 9: Percentage of medicines prescribed based on national treatment guidelines or an essential medicines list or formulary</b></p>
<p><b>Rationale</b></p> <p>This indicator measures the degree to which prescribing practice conforms to the national treatment guidelines. More and more countries are formulating national treatment guidelines and essential medicine lists and formularies. For most, this should be the basis for all public procurement and prescribing of medicines.</p>
<p><b>Definition of the indicator</b></p> <p><i>Numerator:</i> Number of prescribed medicines included on the national treatment guidelines or essential medicine list or formulary at a health facility</p> <p><i>Denominator:</i> Total number of medicines prescribed at a health facility</p>
<p><b>Measurement</b></p> <ul style="list-style-type: none"> <li>• The indicator is generated from a random representative sample of outpatient encounters (retrospective or prospective) at health facilities.</li> <li>• If there is a current officially endorsed set of national treatment guidelines and/or essential medicine list and/or formulary, copies should be provided to each survey team.</li> <li>• Request all available records for the past 12 months before beginning sampling.</li> <li>• Then determine how many of the prescribed medicines at each of the randomly selected health</li> </ul>

<p>facilities are included on the national treatment guidelines and/ or essential medicine list and/or formulary, even if they are not prescribed under an internationally recognized name.</p> <ul style="list-style-type: none"> <li>• The national average is derived by adding the percentage values for each of the selected health facilities and then dividing the value by the number of facilities sampled.</li> </ul>
<p><i>Data source:</i> health facility survey</p> <p><i>Frequency:</i> every 2–3 years</p>
<p><b>Indicator 10: Percentage of dispensed medicines adequately labelled with dosage instructions</b></p>
<p><b>Rationale</b></p> <p>This indicator assesses the quality of dispensing practice. If medicines are to be used properly, the person dispensing them should label them appropriately.</p>
<p><b>Definition of the indicator</b></p> <p><i>Numerator:</i> Total number of medicines adequately labelled at each health facility sampled</p> <p><i>Denominator:</i> Total number of medicines dispensed at each health facility sampled</p>
<p><b>Measurement</b></p> <ul style="list-style-type: none"> <li>• An adequate label at a minimum requires the name of the medicine, how much is to be taken and the frequency of administration.</li> <li>• Interview people leaving the dispensing area or leaving the facility after they have been treated and received medicines. People can be interviewed consecutively or as convenient.</li> <li>• Check whether each medicine label conforms to at least all the requirements noted above for adequate labelling.</li> <li>• Count a medicine as adequately labelled only if all requirements are met.</li> <li>• The national average is equal to the sum of percentage of medicines adequately labelled at all public health facility dispensaries sampled divided by the number of facilities sampled.</li> </ul>
<p><i>Frequency:</i> every 2–3 years</p> <p><i>Data sources:</i> health facility survey</p>
<p><b>Indicator 11: Percentage of health facilities with an adherence register or other similar record-keeping system available to report adherence rates</b></p>
<p><b>Rationale</b></p> <ul style="list-style-type: none"> <li>• Adherence to life-long treatment such as antiretroviral therapy is critical to ensure positive treatment outcomes and prevent the development of drug resistance.</li> <li>• The availability of adherence tools supports prescribers and dispensers in monitoring adherence and in helping to identify reasons for suboptimal adherence from the perspective of both users and front-line health workers.</li> </ul>
<p><b>Definition of the indicator</b></p> <p><i>Numerator:</i> Total number of health facilities with an adherence register or other similar record system available to report adherence rates</p> <p><i>Denominator:</i> Total number of health facilities surveyed</p>
<p><b>Measurement</b></p> <ul style="list-style-type: none"> <li>• The numerator is derived from a check and count of all sampled health facilities that an adherence register or other similar record system is available to report adherence rates.</li> </ul>



- The denominator is the total number of health facilities sampled

*Frequency:* every 2–3 years

*Data sources:* health facility survey

*Adapted from: Monitoring and Evaluation tool kit: HIV, TB, and Health Systems strengthening: The Global Fund*

## Conclusion

This paper has presented the core indicators that should form the foundation of any medicines monitoring system in a low and middle income country like Uganda. It is essential that monitoring of medicines and other supplies in the health system is done; this will increase efficiency, transparency and accountability. Monitoring, furthermore, will ensure a good flow of medicine related information and give supporting evidence when formulating guidelines or policy, it ensuring good access and rational use for prescribers, distributors and users, and ensuring quality and safety of the available medicines and medicinal products.

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### **This summary was prepared by**

Rhona Mijumbi, Supporting Use of Research Evidence for Policy (SURE Project), Office of the Principal, College of Health Sciences, Makerere University, New Mulago Hospital Complex, Administration Building, 2nd Floor, P.O Box 7072, Kampala, Uganda

### **Conflicts of interest**

None known.

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### **For more information contact**

Rhona Mijumbi, [mijumbi@yahoo.com](mailto:mijumbi@yahoo.com)



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