



**Report on the Desk Study Conducted in Preparation for
Discussion on Harmonisation of National Reporting
Requirements for ART Medicines Supply Management**

by

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Desk Study for AIDS Medicines and Diagnostic Services
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ABBREVIATIONS

ADR	adverse drug reaction(s)
AIDS	acquired immunodeficiency syndrome
AMDS	AIDS Medicines and Diagnostics Services
ART	antiretroviral therapy
ARV	antiretroviral (drug)
CIDA	Canadian International Development Agency
Danida	Danish International Development Agency
DFID	Directorate for International Development (United Kingdom)
EU	European Union
FHI	Family Health International
GFATM	Global Fund for AIDS, Tuberculosis, and Malaria
HAART	highly active antiretroviral therapy
HIV	human immunodeficiency virus
IDA	International Dispensary Association
JSI	John Snow, Inc.
JICA	Japan International Cooperation Agency
M&E	monitoring and evaluation
MSF	Médecins Sans Frontières
MSH	Management Sciences for Health
NGO	non-governmental organisation
PEPFAR	President's Emergency Program for AIDS Relief
OI	opportunistic infection
OGAC	Office of the United States Global AIDS Co-ordinator
SIDA	Swedish International Development Agency
TAP	Treatment Acceleration Programme
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNGASS	United Nations General Assembly Special Session (on HIV/AIDS)
UNICEF	United Nations Children's Fund
UNFPA	United Nations Fund for Population Activities
USAID	United States Agency for International Development
WB	World Bank
WHO	World Health Organisation

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MSH and JSI representatives were concurrently requested by WHO to provide detailed information from countries where they have established anti-retroviral treatment (ART) programmes. Maria Morales, and Douglas Keene from MSH were invited to contribute information from several countries including Ethiopia, Kenya, Rwanda, Tanzania, Uganda, and Vietnam.¹ Naomi Printz and Jaya Chimnani of JSI provided information on the reporting requirements of the GFATM and PEPFAR and focused on Kenya and Nigeria as case examples.

Valuable advice was forthcoming from World Bank represented by Yolanda Tayler in Washington and Bert Voetberg in the Kenya Office. IDA Solutions sincerely appreciates the positive responses from USAID and other major donor and financing organisations.

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¹ this information was not yet received by the time of publication of this report

EXECUTIVE SUMMARY

The global expansion in the HIV/AIDS responses, which now includes treatment programmes, has been made possible by increased funding from a wide variety of donors and financing organisations. While necessary for accountability and progress monitoring, feedback reports to donors are now creating a burden on recipients due to lack of harmonisation. UNAIDS with the support of WHO and other major stakeholders are now implementing processes aimed at achieving unified monitoring and evaluation (M&E) at country level as part of the “Three Ones” concept. Consequently calls have been made to harmonise the reporting requirements including the development of M&E tools that target antiretroviral therapy (ART) and medicines supply management.

In preparation for discussion on the harmonisation process, WHO requested IDA Solutions to perform this desk study as a situation analysis regarding reporting requirements including M&E tools used by various countries, donors and financing organisations.

Information was gathered by direct communication with stakeholders as well as an extensive literature review on issues regarding the reporting requirements by countries, international donors and financing organisations. Existing M&E tools for HIV/AIDS responses, harmonisation of the reporting requirements, and the current initiatives in ART medicines supply management at country level were analysed. Collaboration with two other technical agencies, MSH and JSI/Deliver, enabled swift gathering of data within a limited time period.

The desk study revealed that all donors do require feedback that responds specifically to their own programme goals. Differences between donor requirements are mostly dependent on whether their goals are technical or financial in nature. The technical support oriented donors often centre their requirements on processes indicators, as well as output, outcome, and impact indicators while those that are finance oriented tend to be more concerned about accountability and impact. For this reason, it was necessary to differentiate between “reporting requirements” and “monitoring and evaluation tools”.

The major donors and their partners have already embarked on the harmonisation process under the guidance of the WHO’s extensive experience in the development and implementation of M&E tools. Appropriate M&E tools covering other aspects of the comprehensive HIV/AIDS response already exist, but a set of tools specific to medicines supply chain management is still missing. To be comprehensive, these tools need to be cognisant of the entire logistics procurement and supply cycle whereas to be effective and practical they need to be harmonised with other tools of comprehensive HIV/AIDS care and support at country and regional levels.

1. INTRODUCTION AND TERMS OF REFERENCE OF THE DESK STUDY

Recently there has been considerable interest in the development and use of indicators as tools in health care for monitoring the quality and performance of health services. These tools potentially contribute significantly towards planning, management and evaluation of drug supply in order to promote efficient and sustainable access to medicines.

At a workshop conducted by partners within the AIDS Medicines and Diagnostic Services (AMDS) network in Nairobi, Kenya in December 2004, country participants expressed an urgent need for different donors to harmonise their reporting requirements at country level in order to increase transparency and productivity in various antiretroviral (ART) programme areas. A meeting is now due to discuss an internationally agreed framework that harmonises and simplifies national reporting using common indicators for monitoring and evaluation (M&E). Countries and partners, including donor agencies would use these to determine their own priorities for ART medicines procurement and supply management, as well as progress tracking.

1.1. AIM OF THE DESK RESEARCH

In line with the agreed terms of reference, this desk study was therefore conducted with the aim of providing an international situation analysis regarding the reporting requirements, including the M&E indicators for ART medicines supply management. Information obtained from the study would generate this report for use at the planned harmonisation meeting due in Geneva on October 10 -11, 2005.

1.2. SPECIFIC RESEARCH QUESTIONS FOR THE DESK STUDY

The study was to address the following specific questions:

- 1.2.1 What reporting requirements do various major donor organisations expect from recipients of resources for ART medicines and related commodities?
- 1.2.2 What M&E tools currently exist for ART medicines and related commodities?
- 1.2.3 Have any of the M&E tools been implemented in a manner that has generated, “lessons learnt and best practices” for sharing among different organisations?
- 1.2.4 Based on this desk study, what recommendations can be made in contribution towards the goal of harmonisation of reporting requirements for ART medicines supply management?

2. RESULTS AND FINDINGS

2.1 Definitions

For the purposes of clarification the following are some important terms used and how they were defined in this desk study:

- **“Harmonisation”** refers to effective co-ordination of a variety of efforts or contributions from different sources in order to maximise the overall impact of a targeted cause.²
- **“Reporting requirements”** refers to what donors and lenders expect as feedback from recipients in order to ensure accountability, measurable progress, and continuous quality improvement in their funded activities.³
- **“Indicators”** are defined as quantitative measures often expressed as rates, ratios, or percentages and include or imply a numerator and denominator. Indicators are used as tools for monitoring the quality and performance of health services.²
- **“Medicines Supply Cycle”** is defined as the chain that includes drug selection, procurement, distribution, and patient drug use.⁴
- **“Medicines supply management”** refers to issues involved in the effective administration of pharmaceutical supplies covering the whole medicines supply cycle.⁴
- **“Monitoring and Evaluation”** refers to the use of sets of tools (Indicators) that enable supervision of progress in programme implementation, problem identification, strategy refinement, and the assessment of programme effectiveness, impact, and sustainability.²
- **“ART Patient Monitoring Guidelines”** refers to the Interim Patient Monitoring Guidelines for HIV Care and ART that were based on the WHO Patient ART Monitoring Meeting held in Geneva on 29-31 March 2004.

2.2 Distinction between “reporting requirements” and “monitoring & evaluation tools”

In the reviewed literature the term “reporting requirements” broadly referred to what donors and lenders expected as feedback from recipients in order to ensure accountability, measurable progress, and continuous quality improvement in their

² The Global Fund to Fight AIDS, Tuberculosis and Malaria: *Monitoring and Evaluation Toolkit: HIV/AIDS, Tuberculosis and Malaria. Annexes: Selected indicators for HIV/AIDS, Tuberculosis and Malaria.* June 2004

³ Reference (#) Ebrahim A. Seeking NGO-donor partnership for greater effectiveness and accountability. Report of the Multilateral Investment Fund (MIF) & Sustainable Development Department (SDS) Inter-American Development Bank (IDB). Workshop held on May 12-13, 2004.

⁴ Jonathan D. Quick et al., editors. *Managing drug supply: the selection, procurement, distribution, and use of pharmaceuticals.* 2nd ed. Kumarian Press 1997. Management Sciences for Health in collaboration with World Health Organization.

funded activities. Every donor or financing agency therefore expected to receive these regardless of the exact nature by which that feedback was to be achieved.

In the context of the terms of reference of this desk study it was important to examine and differentiate between general “reporting requirements” by donors and the “monitoring and evaluation tools” for medicines supply management. Communicating with a number of donors that were involved in the study it was evident that most of them could relate to some form of reporting requirements within their own organisation but they might not prescribe any specific M&E tools to be used. The following is an example of a reflective response obtained from Dr Voetberg of the World Bank in his response to the request to fill in the questionnaire regarding reporting requirements and M&E indicators:

“..The questionnaire will be impossible for me to complete for two reasons: 1) the World Bank finances more than 30 HIV/AIDS related projects in Africa only (see the attached) and to collect the information requested for all those projects would require a major and time-consuming process; 2) the projects financed by the World Bank are implemented through or by the client governments. The detailed information requested is not usually collected by the World Bank and not readily available from World Bank sources. The Bank reviews progress in project implementation from time to time but does not necessarily collect or maintain the data that you request. Finally, in the usual Bank financed projects the Bank would support or follow the national systems for drug supply management.”⁵

From this description it is evident that being a financing organisation, the World Bank’s main thrust is not on process indicators. They are more concerned about accountability by their recipient countries based upon the specific objectives set by the recipient. The same can be expected from other donors such as the Global Fund (GFATM).

The review of literature also revealed that M&E constitutes only one of several mechanisms of reporting and it refers to the use of sets of tools (indicators) that enable supervision of progress in programme implementation, problem identification, strategy refinement, and the assessment of programme effectiveness, impact, and sustainability. A significant amount of work has already been undertaken to develop M&E tools for various activities of the comprehensive HIV/AIDS responses that are being promoted by various donors as discussed later.

In this desk study a literature review was done to determine some generic reporting requirements found in the literature. Apart from M&E, other mechanisms of reporting that were found include the following:

- **Stakeholder based planning;** - in which community members are engaged in the design stage of the programme in order to capture their sense of responsibility and promote transparency and accountability

⁵ Obtained via e-mail dated: Wednesday, September 14, 2005 from Dr. Bert Voetberg Lead Health Specialist AIDS Campaign Team for Africa World Bank, Kenya Country Office.

- **Standards and codes of conduct;** - ensuring that projects adhere to these when they exist in given settings
- **Performance Audits (Internal and External);** - with reporting to donors, governments, and communities
- **Financial Audits (Internal and External);** - requiring reports from reputable auditing firms
- **Stakeholder meetings;** - requiring meeting for purposes of internal learning among staff, particularly in large organisations with separate units or divisions.
- **Peer evaluations;** - which include sharing of mistakes or failures with peers in order to correct those errors.
- **Periodic reports and disclosures;** - also involving reporting to donors, governments, and communities
- **Site visits;**- by the donors or their representatives or different stakeholders
- **Information dissemination;** - donors encouraging media publicity or written publications to disseminate information regarding the major achievements by the funded projects.⁶

Once these reporting mechanisms were identified, the study then searched for evidence of the existence and/or use of any of those mechanisms among the major donors and lenders who fund in ART medicines supply management to determine if they had the same requirements. The results of this search are shown in Table 1 where (√) indicates only where there was positive evidence for the existence of the particularly requirement.

The conclusion from this part of the study exercise was that reporting requirements do exist in all donor agencies but they may come in different forms. The question for further work is therefore to find out if any of these could be harmonised among the different donors.

Table 1. Matrix of existing reporting requirements by major donors consulted

	World Bank	GFTAM	WHO	UNAIDS	UNICEF	USAID/PEPFAR	EU	DFID
Stakeholder based planning	√	√	√	√	√	√		
Monitoring and Evaluation indicators			√			√		
Standards and codes of conduct	√	√	√	√	√	√	√	√
Performance Audits (Internal and External)	√	√	√	√	√	√	√	√
Financial Audits (Internal and External)	√	√				√	√	√
Stakeholder meetings	√	√	√	√	√	√		
Peer evaluations			√			√		
Periodic reports and disclosures	√	√					√	√
Site Visits	√	√	√	√	√	√	√	√
Information dissemination (media publicity or written publications)	√	√	√	√	√	√	√	√

⁶ Reference (#) Ebrahim A. Seeking NGO-donor partnership for greater effectiveness and accountability. Report of the Multilateral Investment Fund (MIF) & Sustainable Development Department (SDS) Inter-American Development Bank (IDB). Workshop held on May 12-13, 2004.

2.3 Need for harmonisation of reporting requirements

There is good evidence for donors and recipients striving to make their partnerships more effective through harmonised reporting. For example on May 12-13, 2004, the Multilateral Investment Fund & Sustainable Development Department, Inter-American Development Bank sponsored a workshop seeking NGO-Donor Partnership for greater effectiveness and accountability.⁶ This report defined principles of accountability, and discussed steps in building NGO-Donor Partnerships through common accountability procedures, and sharing experiences

There is also a fair amount of published materials on harmonisation of reporting requirements for HIV/AIDS activities in general, most of which has been developed through inter-donor collaboration (discussed later in 5.4). However little has so far been achieved in the way of addressing the issue of harmonisation of reporting requirements for ARV medicines supply management.

Reports from many donor-partner workshops indicate that recipients often find themselves having to report back not only to donors but also to multiple stakeholders such as the beneficiary communities, governments, public opinion, private sector organisations, and their own organisations. This reporting potentially becomes too much time consuming and leads to wastage of scarce the resources. To ensure efficiency, reporting requirements need to be harmonised in such a way that a set or requirements serves multiple constituents simultaneously. In other words: reporting needs to be streamlined so that so that it satisfies donors, governments, and communities all at once.

Use of standard harmonised reporting provides national programmes with valuable measures of the same themes found in different populations, permitting triangulation of findings. This enables regional or local discrepancies and peculiarities to be noted and addressed. This prevents duplication or resources ultimately improving the overall effectiveness of the national response. The use of harmonised reporting also ensures comparability of information across countries and over time and promotes sharing of lessons learnt and best practices.

2.4 Monitoring and Evaluation of HIV/AIDS activities

As defined earlier, M&E refers to the use of sets of tools (indicators) that enable supervision of progress in programme implementation, problem identification, strategy refinement, and the assessment of programme effectiveness, impact, and sustainability. Significant amount of work has already been undertaken to develop M&E tools for various activities of the comprehensive HIV/AIDS responses that are being promoted by various donors. Much of that work has emerged in the past few years in support of national strategies toward the rapid scale-up of ART. Gladly this work has been developed with close collaboration between the WHO, UNAIDS and their partners.

The “Three Ones” concept initiated by UNAIDS and agreed to by other partners, has become the rallying point for most country level harmonisation programmes. The various M&E tools generated elements at the national, regional, district and facility levels. They describe the methods, tools and intervals for collecting key indicators of progress towards the goal of universal access to treatment.

Some examples of M&E documents include the following:

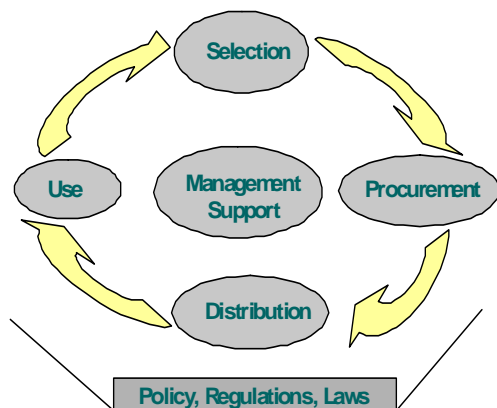
- *A guide to monitoring and evaluating HIV/AIDS care and support* (available at: <http://www.who.int/hiv/strategic/me/en/>).
- *National guide to monitoring and evaluating programmes for the prevention of HIV in infants and young children* (available at: <http://www.who.int/hiv/strategic/me/en/>).
- *HIV drug resistance surveillance guidelines* (available at: <http://www.who.int/3by5/publications/en/>).
- *Interim patient monitoring guidelines for HIV care and ART* (available at: <http://www.who.int/3by5/publications/en/>).
- *The **monitoring** and **evaluation** toolkit for HIV/AIDS, tuberculosis and malaria* (available at: www.theglobalfund.org).

In line with all these M&E indicators that support comprehensive HIV/AIDS responses, a set of tools with a special focus on the ART medicines supply management is needed as an essential element in any national comprehensive treatment, care, support and prevention programme. In fact the “3 x 5” initiative is centred on the goal of availing medicines to patients who need them in all regions of the world. Therefore the supply chain may attract funding all by itself hence the need to have detailed and specific tools that ensure its success. The medicines supply system, therefore, must build a security component into the storage and distribution systems. While focusing specifically on medicines supply management these M&E should be developed with a view to the harmonisation of efforts and also in relation to the other indicators that have been developed for the comprehensive HIV/AIDS response. Direct communication with the major donors during this study confirmed that the major global agencies, including WHO, UNAIDS, the Global Fund to fight AIDS, Tuberculosis and Malaria, USAID and the World Bank are interested in developing a complete package of such tools.

2.5 The medicines supply management cycle

To enable systematic identification of the potential key indicators, it is important to review the full medicines management cycle shown in Figure 1., in order to reflect on all the key elements involved. This sketch illustration has existed for the past two decades when it was used in the discussion to do with general medicines supply management in the context of the WHO/EDM's essential drugs programme. Pharmacy Managers should be familiar with it.

Figure 1: The Medicines Management cycle



Ref: Jonathan D. Quick et al., editors. Managing drug supply: the selection, procurement, distribution, and use of pharmaceuticals. 2nd ed. Kumarian Press 1997. Management Sciences for Health in collaboration with World Health Organization.

The medicines management cycle ensures that the correct quantities of good quality products reach the desired destinations at the right time. The products for the ART program are first selected and registered for use. The required amounts are then determined for the short-term and longer term. The products are then procured from either local sources or they are imported and cleared through customs and quality control checks.

The procured products usually need to be sent to a central repository from where inventory management and distribution takes places. The logistics requirements of transport and storage at perhaps several levels need to be co-ordinated smoothly to ensure that the products reach the service delivery points where they can be accessible to the targeted patients.

While the products are being used by patients, feedback on consumption patterns is provided in order to determine the specific product requirements for that population. Product use also involves rational prescribing and proper dispensing. While the patient is consuming the medicines, monitoring for toxicities, efficacy and patient adherence to the prescribed regimen may be important. In the case of ART these monitoring parameters nowadays come with such terms as pharmacovigilance, therapeutic quality assurance, and early resistance warning respectively.

Patient medicines consumption data is used for making fresh selection hence completing the management cycle that is comprised of selection, procurement, distribution and use. The four major steps in the supply management chain must be supported by an effective policy and legal framework, consisting of operational procedures, regulatory of quality, and an efficient registration process that allows for expeditious registration of new products.

Using this management cycle it is possible to visualise an ideal ART management system as that which must be both responsive and supportive of the policies,

regulations, protocols and guidelines that determine availability of the required resources, skilled personnel as well as the delivery of a comprehensive package of services. The M&E tools for ART medicines and supply management should therefore ideally be focused around the following:

- Product selection
- Forecasting and quantification
- Procurement
- Human resource and organisational capacity
- Medicines management information systems
- Quality assurance (product and service)
- Warehousing, inventory control and storage
- Distribution and transport systems
- Funding sources and budgeting

Having established this as a reasonable platform for assessing the current situation, this desk study focused on determining whether there were any existing funded ART programs that employed M&E tools that reflected on the medicines management cycle. The results of this are discussed below for the respective major donors that were studied.

2.6 Current situation regarding reporting requirements and M&E Indicators for ART medicines supply management among the major donors

The extent to which reporting requirements and M&E indicators are utilised by the various donors varies significantly regarding ART medicines supplies management: see Table 2.

Table 2: Matrix of the situation regarding some common ART M&E Indicators and levels of supply chain monitored among the major donors

		World Bank	GFTAM	WHO	UNAIDS	UNICEF	USAID/ PEPFAR	EU	DFID
Reporting requirements exist		√	√	√	√	√	√	√	√
M&E indicators exist		√	√	√	√		√		
M&E indicators implemented		√					√		
M&E indicators evaluated									
Level of supply chain monitored	Product Selection	√	√	√	√	√	√	√	√
	Forecasting and quantification		√				√	√	√
	Procurement	√	√	√	√	√	√	√	√
	Human resource and capacity			√			√		
	Medicines Management information system			√			√		
	Product and service quality assurance			√			√		
	Inventory control and storage			√			√		
	Distribution and transport systems			√				√	√
	Funding sources and budgeting	√	√	√	√	√	√	√	√

2.6.1 World Bank

The World Bank being a financial lending organisation was found to have reporting requirements that are mainly intended to ensure accountability requiring audits. From the context of a centralised system, the organisation admitted that it would not be possible to have one set of M&E tools since they depend on countries to develop their own systems. It is worth re-capping the response from Dr Voetberg of the World Bank regarding reporting requirements and M&E indicators:

“..The questionnaire will be impossible for me to complete for two reasons: 1) the World Bank finances more than 30 HIV/AIDS related projects in Africa only (see the attached) and to collect the information requested for all those projects would require a major and time-consuming process; 2) the projects financed by the World Bank are implemented through or by the client governments. The detailed information requested is not usually collected by the World Bank and not readily available from World Bank sources. The Bank reviews progress in project implementation from time to time but does not necessarily collect or maintain the data that you request. Finally, in the usual Bank financed projects the Bank would support or follow the national systems for drug supply management.”⁷

The World Bank has also shown evidence of concern over procurement procedures inline with the need to ensure efficient use of funds. The World Bank sponsored the production of by Yolanda Tayler in 2004.⁸ The document is a decision-maker's guide to the procurement of medicines and related supplies. It discusses the challenges in scaling up treatment and issues regarding intellectual property rights. It then gives a review of the supply cycle in an effort to provide technical support in the management of ART supplies.

Apart from this, the World Bank generally depends on the countries' systems for monitoring and evaluation. Due to the wide range of projects covering entire regions, the WB has supported the harmonisation of reporting requirements in regional countries that receive funding from them. A good example is the ongoing development of a harmonised M&E system within the Treatment Accelerated Project (TAP) countries.⁹ That system has very good indicators that could represent medicines supplies management even though they are designed as general performance indicators for TAP program and not specifically for drug management.

2.6.2 Global Fund for AIDS, TB and Malaria

The GFATM's approach to M&E is currently focused on outcomes and results as opposed to the process measures of HIV medicines and related commodities. They

⁷ *Obtained via e-mail dated: Wednesday, September 14, 2005 from Dr. Bert Voetberg Lead Health Specialist AIDS Campaign Team for Africa World Bank, Kenya Country Office.*

⁸ Tayler Yolanda (editor). The World Bank. Battling HIV/AIDS: A decision maker's guide to the procurement of medicines and related supplies. 2004.

⁹ Personal communication with TAP country representatives.

do have an M&E toolkit², which presents their reporting requirements. That tool mainly focuses on people reached by treatment, rather than process measures.

2.6.3 World Health Organization

The WHO has extensive experience in developing M&E indicators in general but historically through the WHO/Essential Drugs Programme, they have accumulated perhaps the greatest amount of effort in the Medicines Supply Management indicators. In 1999 WHO published a manual of indicators for monitoring national drug policies. The manual provides an explanation of the procedures used to develop the indicators in seven priority areas for improving access to pharmaceutical in both the private and public sectors in developing countries. These areas include the establishment of appropriate legislation and regulation, selection of essential drugs, and the registration process, budget allocation policies, improvement of procurement procedure, strengthening drug distribution logistics, establishment of drug pricing policy, and the role of information and continuing education to improve drug use.

The manual also has model lists of structural, process, and outcome indicators. These indicators could be considered as generic and a good starting point for developing ART medicines supply management specific indicators. The advantage of these is that they were successfully field-tested. A good number of those indicators have been found to work although the manual itself was criticised as being too complicated and overly difficult. Experts suggest that the best approach would be for WHO to issue a list of preferred indicators, after which countries can deviate to select relevant indicators.

The WHO has also used the same wealth of experience to lead a collaborative initiative in which the Interim Patient Monitoring Guidelines for HIV Care and ART have been produced. These guidelines are based on a the WHO Patient ART Monitoring meeting held in Geneva, 29-31 March, 2004. While these M&E indicators are patient oriented, there is significant convergence with the data sets that could be used in monitoring drug supply.

The WHO also collaborated with Partner organisations such as the WB, UNICEF, UNAIDS, USAID, CDC, and GFTAM to produce the Monitoring and Evaluation Toolkit for HIV/AIDS, TB and Malaria. The toolkit aims to provide country level M&E workers with rapid access to key resources and standard guidelines for HIV/AIDS, TB and malaria. It presents a framework in which to present a selection of standard indicators for the three diseases and refers to a range of M&E guidelines and tools including additional indicators on specific programme areas. This could also serve as a useful reference document in the process of developing the ART Medicines supply indicators.

2.6.4 United Nations AIDS Program

The most significant stride made by the UNAIDS in the area of harmonisation of monitoring and evaluation is its initiation of the “Three Ones” concept. In April 2004, national AIDS programmes, civil society, major donors and UNAIDS endorsed the Three Ones principles to achieve the most effective and efficient use of resources, and to ensure rapid action and results-based management.

The **three ones** are:

- One agreed HIV/AIDS action framework that provides the basis for co-ordinating the work of all partners
- One national AIDS co-ordinating authority, with a broad based multi-sector mandate
- One agreed AIDS country-level **monitoring and evaluation system**.

As a result many country level HIV/AIDS programme co-ordinating bodies have embarked on strong campaigns to develop the most relevant M&E indicators for their specific comprehensive responses. Communication country level programmes shows that many of them have established and filled new post of logisticians or supply managers. Most of them are however still within their planning stages and do not have any concrete indicators for ART medicines supply management.

2.6.5. UNICEF

As a UN agency, UNICEF's contribution has been observed in partnership with WHO, UNAIDS in almost all the inter-donor collaborative effects. Its reporting requirements are therefore tied to other organisations. They were partners in the development of the UNAIDS M&E toolkit.²

2.6.6 PEPFAR/OGAC/USAID

The U.S. President's Emergency Plan for AIDS Relief (PEPFAR), now in its second year of full funding, has an ambitious goal of treating 2 million and preventing 7 million new HIV infections over a five-year period. The Office of the U.S. Global AIDS Coordinator (OGAC), within the Department of State, has identified a set of HIV prevention indicators intended to gauge progress in reaching this goal in PEPFAR focus countries.¹⁰ Care and treatment indicators have also been identified. Country teams in the 15 PEPFAR focus countries -- Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Vietnam, and Zambia -- are required to report data for these indicators in their annual reports. Preliminary FY 2004 indicator data for the 15 focus countries were presented in PEPFAR's first annual report to USA Congress.

PEPFAR's reporting requirements and M&E indicators are were discussed extensively by JSI who collaborated in this desk study. They covered PEPFER and GFATM and specifically focused on Kenya and Nigeria. In one of JSI's concluding remarks the following was quoted:

Although both PEPFAR and GFATM have supplied a small number of indicators to measure supply chain management performance, the number and type of indicators selected do not necessarily cover the comprehensive range of procurement and supply chain management functions. As an example, the GFATM recommended indicators include some outcome indicators (relating to product availability) as well as some process indicators (e.g., relating to availability of guidelines and training of providers) but not the full range of either process or outcome indicators related to procurement and supply chain management functions. Based on a review of the

¹⁰Accessed at: <http://www.state.gov/s/gac/rl/c14961.htm>.

indicators recommended and used in the two countries, it is clear that there are inconsistencies in defining and measuring certain indicators, for example product availability.¹¹

USAID has in the past provided limited assistance for the purchase of medicines but with the recently increased emphasis on ART world wide, this donor has provided both material and technical support for logistics management supply. This has been done through technical agencies like JSI and MSH. Douglas Keene and Helena Walkowiak reviewed the USAID-Funded procurement of HIV/AIDS-Related Pharmaceutical products. That document discussed the constraints and options for improvement of procurement procedures as a way of contributing toward better supply management. MSH is expected to present a separate report regarding USAID reporting requirements and M&E indicators focusing in several countries including, Ethiopia, Kenya, Rwanda, Uganda, and Vietnam.

2.6.7 European Union

Having failed to get a direct response from EU, the review focused on published data. The Commission of the European Communities recently produced a communication from the Commission to the Council and the European Parliament. This document provides a Coherent European Policy Framework for external action to confront HIV/AIDS, Malaria, and Tuberculosis.¹² The document contains reporting requirements and the need for harmonisation and effective collaboration with the most affected countries particularly in the developing world.

2.6.8 DFID

Although attempts to obtain information through direct communication did not yield fruit, literature provided evidence for DFID's extensive involvement in ARV medicines supply management. DFID has designated technical agencies such as Crown Agents who acting as implementation support agents. The technical agents among other roles conduct site visits. They often use a system of tracing products to from the Central repository to the provinces and districts to check for equitable distribution of products.

2.6.9 Other donors

Due to time limitations direct communication with other organisations that are known to participate in ART medicines supply management support (e.g., CIDA, SIDA, DANIDA, JICA and MSF) has not been possible.

2.7 Suggested indicators for medicines supply management

Suggestions of the most commonly used reporting requirements and M&E indicators by donors were obtained by two ways; 1) direct communication with Medicines Supply Managers, 2) review of literature.

¹¹ JSI: A review of PEPFAR, GFATM and Country Specific requirements and indicators. Prepared for AIDS Medicines and Diagnostics Services, September 28,2005. The report was presented separately to WHO/AMDS

¹² Commission of the European Communities, Brussels, 26.10.2004. COM (2004)726final.

2.7.1 Information from Drug Supply Managers

As most donors did not seem to have concrete suggestions for universal reporting requirements and M&E indicators, effort was made to find out whether medicines supply managers at country level could contribute something. Contact was made with managers from Botswana, Ghana, Malawi, Uganda, Zambia, and Zimbabwe. These managers included directors of Pharmaceutical Services, and directors of national drug stores. In these countries combined, a variety of donors were represented. Table 3 shows the most common reporting requirements and M&E indicators used in their countries. It was interesting to note that the Drug Supply Managers were reporting only a few ART-related M&E indicators. This might suggest that these indicators were not being implemented although they had been proposed.

Table 3. Commonly used Reporting Requirements and M&E indicators according to Drug Supply Managers from six countries.

Most Common Reporting requirements	<ul style="list-style-type: none"> - Stakeholder planning - Procurement procedure - Quarterly report - Site visits - Product tracking - Financial audits
Most Common M&E requirements	<ul style="list-style-type: none"> - Treatment regimens - Number of patients changing regimen - Morbidity and Mortality records

2.7.2 Suggestions from the literature

In an attempt to come out with suggestions on some appropriate common indicators for ART medicines supply in this study, the literature was also screened.

Table 4: Literature sources found to contain potential ART medicines supply management M&E indicators

Reference of Source	Description of indicators
Pharmacy Indicators generated at the HIV Patient ART Monitoring Meeting, International Conference Centre, Geneva, 29-31 March 2004 (see Appendix 3).	Indicator definition and calculation, Data Source, Frequency Probable Use Cover: Standard and Procedures, skill development, stock management, quality, drug availability, stock management, legislation & regulation, financial, public sector procurement procedures, inventory management, and distribution.
Interim Program indicators as discussed in March Meeting Work group and Plenary and reviewed at the Extended-MERG Workshop 28th October 2004 (See Appendix 4).	Cover: Drug therapy starting, additional starting, access and coverage, outcomes for cohorts, success for cohorts, success indicators for clinical assessment and success for assessment of function.
Pascale Brudon, Jean-Daniel Rainhorn, Michael R. Reich. Indicators for monitoring national drug policies: A practical manual 2 nd . WHO, Geneva 1999.	This manual presents tools to evaluate the performance of the pharmaceutical sector and to monitor the implementation of a national drugs policy.

Souly Phanouvong and Nancy Blum. Mekong Malaria Initiative Antimalaria Drug Quality Monitoring and Evaluation Indicators. Global Assistance Initiatives, United States Pharmacopoeia, March 2004.	Contains indicators for monitoring quality of antimalaria drugs but the same indicators could be used for monitoring the quality of ARVs
The Global Fund to Fight AIDS, Tuberculosis and Malaria: <i>Monitoring and Evaluation Toolkit: HIV/AIDS, Tuberculosis and Malaria. Annexes: Selected indicators for HIV/AIDS, Tuberculosis and Malaria.</i> June 2004	Aims to provide country level M&E workers with rapid access to key resources and standard guidelines for HIV/AIDS, TB and malaria.

2.8 Patient tracking, pharmacovigilance and drug resistance monitoring

Patient tracking enables recording of patient clinical data, which can reveal clinical responses as well as adverse events. This can be linked to drug usage by individual patients at facility level. When these data are combined at facility level and posted to higher levels, information for pharmacovigilance becomes available.

Patient tracking enables the recording of adherence patterns through number of prescription fillings, and pill counts to determine consumption. Since adherence can be directly linked to therapeutic failures, this can also indicate early drug resistance (See Appendix 2, suggested categories of indicators 5,6, 8,9 and 10).

3. CONCLUSIONS OF THE DESK STUDY

- **Indicators for medicines supply management:** There is already a fair amount of experience with the use of Medicines Supply Management indicators that have been field tested in many countries under WHO/EDP guidance. These could serve as a good starting point in the development of ART Medicines supply management with extra indicators added, particularly at patient drug use level, such as indicators for monitoring adherence, side effects, and clinical response.
- **The UNAIDS “Three Ones” concept** that has already been embraced by major donors, will motivate others to use a single M&E system at a country level. Successes and failures of those M&E indicators that have been developed for other areas of comprehensive HIV/AIDS response, e.g., those for prevention of mother to child transmission, care & support, drug resistance, and the interim patient monitoring indicators should be shared.
- **The Pharmacy Indicators** contained in the Patient Monitoring Guidelines for HIV Care and ART that were generated at the HIV Patient ART Monitoring Meeting, International Conference Centre, Geneva, 29-31 March 2004 are useful in providing a linkage between the Patient Monitoring Indicators and Drug Supply Management Indicators.
- **Convergence**
 - **Reporting requirements** are needed and available in all donor organisations, although the methods of reporting may differ. The most common methods of reporting include: stakeholder based planning, monitoring and evaluation tools, standards and codes of conduct, audits, stakeholder meetings, peer evaluations, periodic reports, disclosures, site visits, and Information dissemination.
 - **Reporting requirements** are needed to ensure accountability, lessons learnt, and continuous improvement by all donors. Therefore a reporting method that can achieve this, should be standardised or harmonised.
 - **Impact associated M&E indicators** such as numbers of patients placed on ART, morbidity and mortality relative to ART, and reduction in transmission rates are common to all donors and financing organisations.
- **Differences**
 - **Finance orientated donors** (WB, GFATM, EU) are more concerned with accountability and impact indicators which depend on country level systems. These donors depend on consultants for process monitoring and evaluation.
 - **Technically orientated donors** (USAID, DFID, WHO, UNAIDS, UNICEF) are more concerned with process, output, outcome, as well as impact. These donors provide technical support for monitoring and evaluation. Examples of such indicators are those at the levels of selection, procurement, distribution, and patient monitoring.

4. SUMMARY OF RECOMMENDATIONS

- All major donors should buy into the process of developing and implementing the ART Medicines Supply Management indicators as has happened with the other M&E indicators for comprehensive HIV/AIDS responses
- M&E Indicators for ART Medicines Supply Management need to build on what exists in country and not duplicate or complicate.
- Drug Supply Managers are key stakeholders in the development of the Medicines Supply Management M&E indicators as many of them are familiar with the M&E Indicators for Essential Drug Supply, which were developed and field tested by WHO in 1999.

5. LIST OF REFERENCES

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Global Fund to Fight AIDS, Tuberculosis and Malaria. *Guide to the Global Fund's Policies on Procurement and Supply Management*. May 2005. www.theglobalfund.org

The Global Fund to Fight AIDS, Tuberculosis and Malaria: *Monitoring and Evaluation Toolkit: HIV/AIDS, Tuberculosis and Malaria. Annexes: Selected indicators for HIV/AIDS, Tuberculosis and Malaria*. June 2004 http://www.theglobalfund.org/en/links_resources/library/evaluation_framework/

The President's Emergency Plan for AIDS Relief: *Indicators, Reporting Requirements, and Guidelines for Focus Countries*. Revised for FY2006 Reporting. July 29, 2005.

The WHO M&E Webpage, a good concentration of already done M&E work:

<http://www.who.int/hiv/pub/me/en/>

The main M&E reports so far are at http://www.who.int/hiv/pub/me/me_toolkit2004/en/index.html and <http://www.who.int/hiv/pub/me/naparv/en/index.html>

EU AIDS policies:

http://europa.eu.int/comm/development/body/theme/human_social/lib_health1_en.htm
http://europa.eu.int/comm/development/body/theme/human_social/pol_health1_en.htm

Appendix 1: Terms of Reference of the Desk Study

In preparation for discussion on the harmonisation process the WHO requested IDA Solutions for this desk study under the following terms of reference:

- Conduct a desk review of the reporting requirements, including the M&E indicators for drug supply management, required by the donor organisations (including but not limited to Global Fund, World Bank, DFID, OGAC, USAID) that are contributing financial resources to support treatment scale up with purchases of HIV medicines and diagnostics
 - List by donor, the main reporting requirements (policy, principles and standard reporting formats) and indicators measured
 - Identify measuring methods for the indicators described
 - Analyse the convergence and differences between requirements of the donors for drug supply management
 - Identify indicators common to all donors and which are used by a subset of donors only
 - Determine which reporting requirements differ as a matter of organisational policy and which may be more due to different interpretations of converging requirements.
- Describe used or proposed data sets and monitoring indicators for each of patient tracking, pharmacovigilance and drug resistance monitoring, and review where, and how, these can be linked to monitoring of supply management (and vice-versa). Show common data fields

Appendix 2: Approach Used In Carrying Out The Desk Study

Review of literature

An extensive literature review was conducted to obtain up-to-date information regarding the issues of reporting requirements by international donors and lenders, M&E of HIV/AIDS responses, harmonisation of reporting requirements, and the current initiatives in ART medicines supply management focusing on pharmaceutical selection, procurement, distribution, dispensing, and patient drug use.

Using telephone and e-mail communication to contact individuals and organisations, information was obtained from various donors, implementing agencies, WHO country representatives as well as governmental and non-governmental representatives. Organisations that were contacted or whose documents were reviewed during the desk study are shown in table below

Use of questionnaires

In addition a semi-structured questionnaire (see annex 6) was sent to representatives of several organisations backed up by follow-up telephone calls wherever this was feasible. Due to time restrictions the response to the long questionnaire was low. As a result a simplified version of the questionnaire was made to target Pharmacy Supply Managers. It was felt that the views of these stakeholders would be vital since preliminary results were showing that the major donors felt that their requirements were often country specific. Also experience with ART medicines supply management was anticipated to be relatively limited since in most resource-poor countries, expanded antiretroviral rollout has only been in place over the past three years. However most Pharmacy Supply managers were likely to have broad experience with medicines procurement, supply and use indicators in general due to their long historical involvement in WHO's Essential Drugs Programme.

Organisations that were contacted or whose documents were reviewed during the desk study

Donors and financing agencies	Collaborating Agencies	National Government Representatives
FHI	AA4A	Vietnam
OGAC/ PEPFAR	JSI	Kenya
DFID	MSH	Tanzania
EU	TAP	Uganda
UNIAIDS		Rwanda
UNICEF		Zimbabwe
USAID		Nigeria
WHO		Ethiopia

Collaborators' input

Two technical support agencies MSH and JSI/Deliver were concurrently contracted by the WHO to study some programmes in those countries where they were currently involved. MSH gathered and contributed information from several countries including Ethiopia, Kenya, Rwanda, Tanzania, Uganda, and Vietnam. JSI/Deliver provided information on the reporting requirements of the GFTAM and PEPFAR and focused Kenya and Nigeria as case examples. These enabled sharing of responsibilities in data gathering resulting in faster progress being made in that exercise. Co-ordination of the IDA Solutions consultants with the WHO's Medicines and Diagnostic Services and the collaborating agencies was made possible through weekly teleconference calls.

Limitations of the approach

Due to time restrictions the response rate to the questionnaire was low. Communication with key organisations depended on conducting interviews with certain individuals, many of whom were not easily available.

Much of the information for this desk study was to be obtained from literature and therefore it is possible that some documents were missed out in the review process.

Most organisations that were likely to have useful information are however thought to have been covered. Responses were received from WHO, WB, GFTAM, USAID as well as the collaborative involvement of JSI and MSH.

Appendix 3: Suggested Categories of Indicators

The 15 Categories are intended to cover all stages of the Medicines Supply Chain. In each category indicators could be added or removed depending on relevance to the country situation.

1. Standards and procedures

- 1.1 Number of ART sites with an approved and implemented work plan for the implementation of an ART program developed in collaboration with an implementation committee
- 1.2 Number of ART sites with the most current edition of national ART guidelines available in the medicines dispensary
- 1.3 Number of ART sites that have approved Standard Operational Procedures (SOPs) available and easily accessible to all relevant staff
- 1.4 Number of ART sites that have adequate lockable space that has refrigerator to store ARVs in bulk
- 1.5 Number of ART sites that have adequate lockable space that has refrigerator to store ARVs in small quantities

2. Skill development

- 2.1 Percentage of pharmacy staff trained by type of training modules (ADR, Counseling, Inventory Management, Diseases specific OI management)
- 2.2 Percentage of pharmacy staff trained that are currently working with the ART program

3. Pharmaceutical services at the facilities and stock management

- 3.1 Primary data are collected by the health center on a routine basis or through supervisory visits
- 3.2 Quantity of essential drugs received, consumed, expired, lost and remaining balance
- 3.3 Number of months the current stock of unexpired essential drug by type will be sufficient to provide services based in the consumption during the last quarter
- 3.4 Percentage of health centers where one or more essential drugs was out of stock for 3 or more days
- 3.5 Number of essential drugs whose physical count did exactly match the record in the bin cards.
- 3.6 Percentage of facilities where average variation in physical count and record count is less than 5%
- 3.7 List of drugs that did not move during the last three months

4. Distribution

- 4.1 Number of customer orders dispatched
- 4.2 Value of orders dispatched to regional medical store
- 4.3 Value of orders dispatched to all health facilities
- 4.4 Stock returns as a percentage of the value of all issues.
- 4.5 Percentage of customer orders dispatched on schedule out of the total orders dispatched
- 4.6 Number of non-scheduled (emergency) orders received from each of the customer
- 4.7 Number of orders received up to last month by regions
- 4.8 Percentage of quantity of drugs supplied to each of the facilities out of their demand

5. Quality of Pharmaceutical Services and Pharmacovigilance

- 5.1 Number of ART prescriptions dispensed per day per pharmacist
- 5.2 Average number of prescriptions dispensed per day per pharmacist
- 5.3 Percentage of days that the temperature of drug refrigerator was within acceptable range
- 5.4 Percentage of facilities that had temperature of drug refrigerator within acceptable range for more than 90% of days
- 5.5 Average number of drugs per prescription
- 5.6 Percentage prescriptions that contained antibiotics
- 5.7 Percentage of drugs actually dispensed
- 5.8 Percentage prescriptions that contained injections
- 5.9 Percentage of drugs prescribed as per standard treatment guidelines
- 5.10 Percentage of drugs prescribed as per national essential drug list
- 5.11 Percentage of drugs prescribed with generic name

- 5.12 Percentage of drugs adequately labeled
- 5.13 Percentage of Adverse Drug Reports (ADR) prepared and reported out of the total ADR cases reported/observed
- 5.14 Percentage of prescriptions that are dispensed ART as per guidelines/SOP
- 5.15 Percentage of pharmacy staff member who counseled the client receiving ART as per SOP
- 5.16 Percentage of clients interviewed who could correctly recall the dosages of all the drugs they were dispensed

6. ART Starting indicators

- 6.1 Number assessed and eligible for ARV treatment
- 6.2 Percentage starting ARV treatment
- 6.3 Percentage transferred in on first regimen
- 6.4 Percentage transferred in on second regimen

7. ART Access and coverage indicators

- 7.1 Percentage diagnosed HIV positive (nationally defined) / estimated number living with HIV
- 7.2 Percentage assessed for ARV treatment eligibility / number diagnosed with HIV
- 7.3 Percentage currently on ARV treatment / estimated number in area eligible for HIV treatment

8. ART Outcomes for cohorts starting in a particular quarter

- 8.1 Percentage still on first-line regimen
- 8.2 Percentage changed to second-line regimen
- 8.3 Percentage lost
- 8.4 Percentage transferred out
- 8.5 Percentage died
- 8.6 Percentage stopped ART but remained in care

9. ART Success indicators for cohorts

- 9.1 Percentage on long-term survival
- 9.2 Percentage still on first regimen
- 9.3 Percentage still on second regimen
- 9.4 Percentage still on ARV
- 9.5 Percentage of those who died

10. ART Success indicators for clinical assessment

- 10.1 Median CD4 count when starting ART

11. ART Success indicators for assessment of function

- 11.1 Percentage at work or attending school
- 11.2 Percentage ambulatory but not in work/school
- 11.3 Percentage bed ridden

12. Medicines and Supplies management legislation

- 12.1 Percentage of drug outlets (both private and public) inspected by regulatory authority
- 12.2 Percentage of drug outlets (both private and public) in violation
- 12.3 Percentage of number of drugs/batches tested out number of drugs/batches procured
- 12.4 Percentage of number of drugs/batches that failed quality control testing, out of number of drugs/batches tested

13. Financial issues

- 13.1 Total Salary & staff benefits
- 13.2 Total Vehicle maintenance & repair costs
- 13.3 Total vehicle fuel costs
- 13.4 All other Operating Costs
- 13.5 Total Operating Costs as a percentage of the value of issues
- 13.6 Total Operating Costs as a percentage of inventory value

14. Value of Accounts payable to suppliers

- 14.1 Value of public drug budget spent per capita in the last year

14.2 Percentage value of public drug budget spent by major hospitals out of value of public drug budget spent

14.3 Percentage value of drugs purchased with international aid out of the total drug purchased

15. Public Sector Procurement Procedures

15.1 Number and Value of Purchase Orders Issued

15.2 Value of Emergency Orders as a Percentage of all Purchase Orders Issued

15.3 Average lead time (in months) for all complete orders delivered during the period by suppliers

15.4 Percentage value of drugs purchased through competitive tender, out of value of drugs purchased

15.5 Average time period of payment for orders, out of average time period of payment stated in contract

Appendix 4: Pharmacy Indicators generated at the HIV Patient ART Monitoring Meeting, International Conference Centre, Geneva, 29-31 March 2004

No	Indicator definition and calculation	Data Source	Frequency Probable Use
<i>(Calculated from the status reported from all the centers)</i>			
Standard and Procedures			
1.	<i>Def:</i> # of ART sites with an approved work plan for the implementation of ART program developed in collaboration with implementation committee and <u>that the plan is followed.</u>	Supervisory Check list (Evidence of the existence of implementation plan)	This indicator will be assessed on a <u>quarterly</u> basis This indicator will show us if the work is progressing as per approved work plan to ensure that activities are not ad-hoc
2.	<i>Def:</i> # of ART sites with most current edition of national ART guidelines available in the dispensary.	Supervisory Check list (Evidence of the existence of most current national ART guidelines)	This indicator will be assessed on a <u>quarterly</u> basis This indicator will help us ensure that all the ART sites have the most current national ART guidelines
3.	<i>Def:</i> Number of ART sites that have approved SOPs available and that all relevant staff have easy access to it.	Supervisory check lists	This indicator will be calculated on a <u>quarterly</u> basis This indicator will help us ensure that all the staff at all the ART sites have access to standard SOPs.
4.	<i>Def:</i> Number of ART sites that have adequate lockable space that has refrigerator to store ARVs in bulk	Supervisory check lists	This indicator will be calculated on a <u>quarterly</u> basis This indicator will help us ensure that the ARVs are stored as per requirements
5.	<i>Def:</i> Number of ART sites that have adequate lockable space that has refrigerator to store ARVs in small quantities to dispense	Supervisory check lists	This indicator will be calculated on a <u>quarterly</u> basis This indicator will help us ensure that the ARVs are stored as per requirements
<i>(Calculated from the status report for each of the center)</i>			
Skill development			
6.	<i>Def:</i> % of pharmacy staff trained by type of training modules (ADR, Counselling, Inventory Management, Diseases specific OI management) <i>Calculation:</i> <u>Numerator:</u> Cumulative number of staff category and type of interventions <u>Denominator:</u> Total number of staff planned to be trained by category and type of intervention	Training report	Training report is prepared as and when the training takes place. This indicator will be included in the <u>quarterly</u> report. This indicator will show us how we are progressing towards archiving our training goal.
7.	<i>Def:</i> % of pharmacy staff trained that are currently working with the ART program <i>Calculation:</i> <u>Numerator:</u> Total number of staff trained that are currently working with the ART program <u>Denominator:</u> Total number of staff trained by type of interventions till the end of the quarter.	Training report, Human resource reports	This indicator will be calculated on a <u>quarterly</u> basis This indicator will give us an indication how successful we are in motivating the staff that we trained to work for the project.

Stock Management			
8.	<p><i>Def:</i> Number of months the current stock of unexpired ARV by type will be sufficient to provide services based in the consumption during the last quarter.</p> <p><i>Calculation:</i> <u>Numerator:</u> Quantity of unexpired ARV by type that is available at the end of the month (both bulk and pharmacy)</p> <p><u>Denominator:</u> Average Quantity of ARV by type that was consumed per month during the last quarter</p>	Quarterly reports from the centers	<p>This indicator will be calculated by each of the facilities <u>Quarterly</u></p> <p>This indicator will help the clinic to assess the current stock position of the ARVs and if it falls below the desired level, they should start the process of ordering it.</p>
9.	<p><i>Def:</i> Number of days that ARV drug by type was out of stock during the last quarter</p> <p><i>Calculation:</i> Count the number of days the stock of a given drug was out of stock (0 level) from the bin cards. Consider the stock in both the bulk and pharmacy store.</p>	Quarterly reports from the centers. (Bin cards as the primary source of data.)	<p>This indicator will be calculated on a <u>quarterly</u> basis</p> <p>This indicator will help us to have an idea about the supply system of ARV drugs.</p>
10.	<p><i>Def:</i> % drugs whose physical count did exactly match the record in the bin cards.</p> <p><i>Calculation:</i> <u>Numerator:</u> Number of drugs whose physical count exactly corresponded to the value in the bin card</p> <p><u>Denominator:</u> Total number of ARV drugs that were counted (all should be counted)</p>	Quarterly reports from the centers	<p>This indicator will be calculated on a <u>quarterly</u> basis</p> <p>This indicator will help us to have an idea about the accuracy of account of ARV drugs.</p>
Quality			
11.	<p><i>Def:</i> % of ADR reports prepared and reported out of the total ADR cases reported/observed</p> <p><i>Calculation:</i> <u>Numerator:</u> Number of ADR prepared</p> <p><u>Denominator:</u> Total number of ADR cases reported/observed</p>	Quarterly Reports	<p>This indicator will be calculated on a <u>quarterly</u> basis</p> <p>This indicator will help us ensure that all the ADR cases will be documented acted on at all the ART sites.</p>
12.	<p>% of prescriptions that are dispensed ART as per guidelines/SOP</p> <p><i>Calculation:</i> <u>Numerator:</u> Number of ART prescriptions that were correctly dispensed as per guidelines/SOP</p> <p><u>Denominator:</u> Total number of ART prescriptions sampled to check</p>	Prescriptions and dispensing records.	<p>This indicator will be calculated on a <u>quarterly</u> basis</p> <p>This indicator will help us to have an idea about the adherence to the prescribing guidelines of ART</p>
13.	<p>% of pharmacy staff member who counseled the client receiving ART as per SOP</p> <p><i>Calculation:</i> <u>Numerator:</u> Number of pharmacy staff member observed that counseled the clients as per SOP during dispensing ART</p>	Observation by the supervisor with a check list	<p>This indicator will be calculated on a <u>quarterly</u> basis or on an ad-hoc basis</p> <p>This indicator will help us to have an idea about the adherence of the pharmacist with the dispensing procedures outlined in the SOP</p>

	<p><u>Denominator:</u> Total number of pharmacy staff member that were observed while they were dispensing ARV to the clients.</p>		
14.	<p>% of clients interviewed who could correctly recall the dosages of all the drugs they were dispensed</p> <p><i>Calculation:</i> <u>Numerator:</u> Number of clients who could correctly recall the dosages of all the drugs they were dispensed</p> <p><u>Denominator:</u> Total number of sampled clients who were asked to recall the dosages of all the drugs that they received</p>	Client interview by the supervisor	<p>This indicator will be calculated on a <u>quarterly</u> basis on an ad-hoc basis</p> <p>This indicator will help us to have an idea about quality of counseling that the pharmacist provides to the ART clients.</p>
15.	<p><i>Def:</i> Number of ART prescriptions dispensed per day per pharmacist</p> <p><i>Calculation:</i> <u>Numerator:</u> Total number of prescriptions dispensed in a month</p> <p><u>Denominator:</u> Total number of pharmacist day (Pharmacist 1 * number of days worked + Pharmacist 2 * number of days worked etc.)</p>	Quarterly Reports Human Resource Reports	<p>This indicator will be calculated on a <u>quarterly</u> basis</p> <p>This indicator will help us ensure that the pharmacists are not overloaded with work that may reduce the quality of their service</p>

Indicator Table: Indicators Related to Drug Supply Management

Sr. No	Indicators	Calculation Level / Frequency ¹³						
		Freq	Fac	Dis	Reg	Nat	RMS	CMS
Drug Availability and Stock Management								
16.	Quantity of essential drugs received, consumed, expired, lost and remaining balance (Data source: Bin cards, Drug dispensing register)	Mon	√					
		Qtr					√	
		HY						√
		AN						
17.	Number of months the current stock of unexpired essential drug by type will be sufficient to provide services based in the consumption during the last quarter. (Data source: Bin cards)	Mon	√					
		Qtr						
		HY						
		AN						
18.	Number of days that essential drugs by type was out of stock (Data source: Bin cards)	Mon	√					
		Qtr						
		HY						
		AN						
19.	% of health centers where one or more essential drugs was out of stock for 3 or more days (Data source: Facility Monthly Reports) Note: Indicator to be included in the HIS	Mon						
		Qtr		√				
		HY			√			
		AN				√		
20.	Number of essential drugs whose physical count did exactly match the record in the bin cards. (Data source: Supervisory Checklist)	Mon						
		Qtr	√					
		HY						
		AN						
21.	% of facilities where the average variation in physical count and record count is less than 5% (Data source: Supervisory Checklist)	Mon						
		Qtr		√				
		HY			√			
		AN						
Quality								
22.	Average number of prescriptions dispensed per day per pharmacist (Data source: Supervisory Checklist)	Mon						
		Qtr	√	√				
		HY			√			
		AN				√		
23.	% of days that the temperature of drug refrigerator was within acceptable range (Data source: Supervisory Checklist)	Mon						
		Qtr	√					
		HY						
		AN						
24.	% of facilities that had temperature of drug refrigerator within acceptable range for more than 90% of days (Data source: Supervisory Checklist)	Mon						
		Qtr		√	√			
		HY						
		AN						
25.	Average number of drugs per prescription (Data source: Supervisory Checklist)	Mon						
		Qtr	√					
		HY			√			

¹³ Mon=Monthly, Qtr=Quarterly, HY=Half-yearly, AN=Annually, RMS=Regional Medical Stores; CMS=Central Medical Stores

		AN				√		
26.	% prescriptions that contained antibiotics (Data source: Supervisory Checklist)	Mon						
		Qtr	√					
		HY			√			
		AN				√		
27.	% of drugs actually dispensed (Data source: Supervisory Checklist)	Mon	√					
		Qtr						
		HY			√			
		AN				√		
28.	% prescriptions that contained injections (Data source: Supervisory Checklist)	Mon						
		Qtr	√					
		HY			√			
		AN				√		
29.	% of drugs prescribed as per standard treatment guidelines (Data source: Supervisory Checklist)	Mon						
		Qtr	√					
		HY			√			
		AN				√		
30.	% of drugs prescribed as per Nedlist (Data source: Supervisory Checklist)	Mon						
		Qtr	√					
		HY			√			
		AN				√		
31.	% of drugs prescribed with generic name (Data source: Supervisory Checklist)	Mon						
		Qtr	√					
		HY			√			
		AN				√		
32.	% of drugs adequately labelled (Data source: Supervisory Checklist)	Mon						
		Qtr	√					
		HY			√			
		AN				√		
Legislation and Regulation								
33.	% of drug outlets (both private and public) inspected (Data Source: Inspection Visits)	Mon						
		Qtr			√			
		HY				√		
		AN						
34.	% of drug outlets (both private and public) in violation (Data Source: Inspection Visits)	Mon						
		Qtr			√			
		HY				√		
		AN						

Indicator Table: Indicators Related to Drug Supply Management

Nr	Indicator	Periodicity
Financial		
1.	Total Salary & staff benefits	Quarterly
2.	Total Vehicle maintenance & repair costs	Quarterly
3.	Total vehicle fuel costs	Quarterly
4.	All other Operating Costs	Quarterly
5.	Total CMS Operating Costs	Quarterly
6.	Total Operating Costs as a % of the value of issues	Quarterly
7.	Total Operating Costs as a % of inventory value	Quarterly
8.	Value of Accounts payable to suppliers	Quarterly
9.	Value of public drug budget spent per capita in the last year	Yearly
10.	% value of public drug budget spent by major hospitals out of value of public drug budget spent	Yearly
11.	% value of drugs purchased with international aid out of the total drug purchased	Yearly
Public Sector Procurement Procedures		
12.	Number and Value of Purchase Orders Issued	Quarterly
13.	Vale of Emergency Orders as a % of all Purchase Orders Issued	Quarterly
14.	Value of stock returns to suppliers	Quarterly
15.	Average lead time (in months) for all complete orders delivered during the period by suppliers	Quarterly
16.	Number and value of GRNs issued during the period	Quarterly
17.	Value of inventory at end of the period	Quarterly
18.	Current inventory level expressed in months of consumption	Monthly
19.	% value of drugs purchased through competitive tender, out of value of drugs purchased	Yearly
20.	% Average time period of payment for orders, out of average time period of payment stated in contract	Yearly
21.	% of number of drugs/batches tested out number of drugs/batches procured	Half-yearly
22.	% of number of drugs/batches that failed quality control testing, out of number of drugs/batches tested	Yearly
Inventory management		
23.	Number of days each drug was out of stock (0 quantity)	Monthly
24.	List of drugs that did not move during the last three months	Monthly
25.	Value of all stock losses (by reasons expiry, damaged and others) as a % of value of inventory at end of period	Quarterly
26.	% of all Class V Drugs out of stock	Monthly
Distribution		
27.	Number of customer orders dispatched	Monthly
28.	Value of orders dispatched to RMS	Half-yearly
29.	Value of orders dispatched to all health facilities	Half-yearly
30.	Stock returns as a % of the value of all issues.	Half-yearly
31.	% Number of customer orders dispatched on schedule out of the total orders dispatched	Half-yearly
32.	Number of non-scheduled (emergency) orders received from each of the customer	Quarterly
33.	Number of orders received up to last month by regions	Quarterly
34.	% of quantity of drugs supplied to each of the facilities out of their demand	Quarterly

Appendix 5: Interim Program Indicators as discussed in March Meeting Work Group and Plenary and reviewed at the Extended-MERG workshop 28th October 2004

<p>Starting indicators</p> <ul style="list-style-type: none"> - number assessed and eligible for ARV treatment; - number (%) starting ARV treatment;
<p><i>Additional starting indicators</i></p> <ul style="list-style-type: none"> - % transferred in on first regimen - % transferred in on second regimen
<p>Access and coverage indicators</p> <ul style="list-style-type: none"> - % diagnosed HIV positive (nationally defined) / estimated number living with HIV - % assessed for ARV treatment eligibility / number diagnosed with HIV - % currently on ARV treatment / estimated number in area eligible for HIV treatment
<p>Outcomes for cohorts starting in a particular quarter</p> <ul style="list-style-type: none"> - still on first-line regimen - changed to second-line regimen - lost - transferred out - died - stopped ART but remained in care
<p>Success indicators for cohorts</p> <ul style="list-style-type: none"> - long-term survival - % still on first regimen - % still on second regimen - % still on ARV - % died
<p>Success indicators for clinical assessment</p> <ul style="list-style-type: none"> - median CD4 count when starting ART
<p>Success indicators for assessment of function</p> <ul style="list-style-type: none"> - % at work or attending school - % ambulatory but not in work/school - % bed ridden

Appendix 6 - questionnaire

Questionnaire to investigate the reporting requirements for drug supply management

Desk Study by IDA Solutions
September 9, 2005

Introduction

Recently there has been considerable interest in the development and use of indicators as tools in health care for monitoring the quality and performance of health services. These tools can significantly contribute towards planning, management and evaluation of drug supply in order to promote efficient and sustainable access to medicines.

At a workshop conducted by partners within the World Health Organisation's AIDS Medicines and Diagnostic Services (AMDS) network in Nairobi, Kenya, country participants expressed urgent need for different donors to harmonize their reporting requirements at a country level in order to increase transparency and productivity in various antiretroviral (ART) programme areas. A meeting is now being planned to discuss an internationally agreed framework that harmonizes and simplifies national reporting using common indicators for monitoring and evaluation (M&E). Countries and partners, including donor agencies would use these to determine their own priorities for ART medicines procurement and supply management, as well as track progress.

The questionnaire below is part of a desk study being conducted on behalf of the WHO and it is designed to provide a baseline situation analysis regarding the reporting requirements including the M&E indicators for medicines supply management. Information obtained from the study will be used to prepare a guiding report for use at the planned meeting. Your organization is being kindly requested to assist by taking time to answer the following questions based upon your experience. Inclusion of any specific reporting forms which are presently used in your programs would greatly enhance the content of the information that you will provide to us.

Your cooperation in providing a prompt response to the questionnaire is sincerely valued since the harmonization meeting is planned to take place on October 10, 2005. We would therefore very much appreciate receiving your response before September 20, 2005.

Background of your organization's activities

1. Which of the following best describes your organization?
 - 1.1 a donor organization Y.... / N.....
 - 1.2 an implementing agency Y.... / N.....
 - 1.3 a government department Y.... / N.....
 - 1.4 other; state what you are;

2. In which country or countries are your organization's operations located?
List countries.....

3. For how many years has your organization been involved in the operations that you listed in 2. above? Years.....
4. Has your organization been involved in supporting HIV/AIDS medicines and diagnostics procurement and distribution activities? Y.../ N.....

Section A

1. As an organization do you have central guidelines for monitoring and evaluation for use by your projects? Y.../ N.....
2. If you do not have central guidelines for monitoring and evaluation, what do you have in terms of reporting requirements?
.....
.....
3. Please give one or two examples of what your organization considers to be the most relevant country specific reporting requirements for ART medicines supply management system? Examples of country specific reporting requirements:
.....
.....
4. What do you consider to be the key indicators in the medicines supply management system that would need to be part of an overall national reporting system for ARVs and related drugs? Key indicators:
.....
.....
5. In countries where there are many donors, how are the ART medicines and supplies activities by various organizations coordinated?
 - 5.1 By an ART Task Force Y.../ N.....
 - 5.2 By a government department Y.../ N.....
 - 5.3 By another assigned agency; state what it is.....
6. Who specifically does your organization expect to produce the report on medicines and supplies management?
 - 6.1 an ART Task Force Y.../ N.....
 - 6.2 a government department Y.../ N.....
 - 6.3 Another assigned agency; state what it is.....
.....
7. Does your organization expect reporting to be project specific? Y.../ N.....
8. In your experience so far in terms of reporting requirements for HIV-AIDS medicines and supplies, do you have examples of effectively coordinated reporting systems that could be used as “best practice” cases for the purposes of sharing with others?
.....

.....
.....

9. In your opinion how can pharmacies or laboratories at health facilities play an important role in data collection and dissemination? Y..../ N.....

10. If yes in 7., please briefly explain how?
.....
.....

Section B

Please indicate (Yes [Y] or No [N]) whether your organization uses the following indicators and state whether there are others that have been omitted in each category.

1. Standards and procedures

1.6 Number of ART sites with an approved and implemented work plan for the implementation of an ART program developed in collaboration with an implementation committee Y..../N.....

1.7 Number of ART sites with the most current edition of national ART guidelines available in the medicines dispensary Y..../N.....

1.8 Number of ART sites that have approved Standard Operational Procedures (SOPs) available and easily accessible to all relevant staff Y..../N.....

1.9 Number of ART sites that have adequate lockable space that has refrigerator to store ARVs in bulk Y..../N.....

1.10 Number of ART sites that have adequate lockable space that has refrigerator to store ARVs in small quantities Y..../N.....

1.11 Other indicators that fit into this category:

2. Skill development

2.1 Percentage of pharmacy staff trained by type of training modules (ADR, Counseling, Inventory Management, Diseases specific OI management) Y..../N.....

2.2 Percentage of pharmacy staff trained that are currently working with the ART program Y..../N.....

2.3 Other indicators that fit into this category:

3. Pharmaceutical services at the facilities and stock management

3.1 Primary data are collected by the health center on a routine basis or through supervisory visits Y..../N.....

3.2 Quantity of essential drugs received, consumed, expired, lost and remaining balance Y..../N.....

3.3 Number of months the current stock of unexpired essential drug by type will be sufficient to provide services based in the consumption during the last quarter Y..../N.....

3.4 Percentage of health centers where one or more essential drugs was out of stock for 3 or more days Y..../N.....

3.5 Number of essential drugs whose physical count did exactly match the record in the bin cards. Y..../N.....

3.6 Percentage of facilities where average variation in physical count and record count is less than 5% Y..../N.....

3.7 List of drugs that did not move during the last three months Y..../N.....

3.8 Other indicators that fit into this category:

4. Distribution

- 4.1 Number of customer orders dispatched Y..../N.....
- 4.2 Value of orders dispatched to regional medical store Y..../N.....
- 4.3 Value of orders dispatched to all health facilities Y..../N.....
- 4.4 Stock returns as a percentage of the value of all issues. Y..../N.....
- 4.5 Percentage of customer orders dispatched on schedule out of the total orders dispatched Y..../N.....
- 4.6 Number of non-scheduled (emergency) orders received from each of the customer Y..../N.....
- 4.7 Number of orders received up to last month by regions Y..../N.....
- 4.8 Percentage of quantity of drugs supplied to each of the facilities out of their demand Y..../N.....
- 4.9 Other indicators that fit into this category:

5. Quality of Pharmaceutical Services and Pharmacovigilance

- 5.1 Number of ART prescriptions dispensed per day per pharmacist Y..../N.....
- 5.2 Average number of prescriptions dispensed per day per pharmacist Y..../N.....
- 5.3 Percentage of days that the temperature of drug refrigerator was within acceptable range Y..../N.....
- 5.4 Percentage of facilities that had temperature of drug refrigerator within acceptable range for more than 90% of days Y..../N.....
- 5.5 Average number of drugs per prescription Y..../N.....
- 5.6 Percentage prescriptions that contained antibiotics Y..../N.....
- 5.7 Percentage of drugs actually dispensed Y..../N.....
- 5.8 Percentage prescriptions that contained injections Y..../N.....
- 5.9 Percentage of drugs prescribed as per standard treatment guidelines Y..../N.....
- 5.10 Percentage of drugs prescribed as per national essential drug list Y..../N.....
- 5.11 Percentage of drugs prescribed with generic name Y..../N.....
- 5.12 Percentage of drugs adequately labeled Y..../N.....
- 5.13 Percentage of Adverse Drug Reports (ADR) prepared and reported out of the total ADR cases reported/observed Y..../N.....
- 5.14 Percentage of prescriptions that are dispensed ART as per guidelines/SOP Y..../N.....
- 5.15 Percentage of pharmacy staff member who counseled the client receiving ART as per SOP Y..../N.....
- 5.16 Percentage of clients interviewed who could correctly recall the dosages of all the drugs they were dispensed Y..../N.....
- 5.17 Other indicators that fit into this category:

6. ART Starting indicators

- 6.1 Number assessed and eligible for ARV treatment Y..../N.....
- 6.2 Percentage starting ARV treatment Y..../N.....
- 6.3 Percentage transferred in on first regimen Y..../N.....
- 6.4 Percentage transferred in on second regimen Y..../N.....
- 6.5 Other indicators that fit into this category:

7. ART Access and coverage indicators

- 7.1 Percentage diagnosed HIV positive (nationally defined) / estimated number living with HIV Y..../N.....
- 7.2 Percentage assessed for ARV treatment eligibility / number diagnosed with HIV Y..../N.....
- 7.3 Percentage currently on ARV treatment / estimated number in area eligible for HIV treatment Y..../N.....
- 7.4 Other indicators that fit into this category:

8. ART Outcomes for cohorts starting in a particular quarter

- 8.1 Percentage still on first-line regimen Y..../N.....
- 8.2 Percentage changed to second-line regimen Y..../N.....
- 8.3 Percentage lost Y..../N.....
- 8.4 Percentage transferred out Y..../N.....
- 8.5 Percentage died Y..../N.....
- 8.6 Percentage stopped ART but remained in care Y..../N.....
- 8.7 Other indicators that fit into this category:

9. ART Success indicators for cohorts

- 9.1 Percentage on long-term survival Y..../N.....
- 9.2 Percentage still on first regimen Y..../N.....
- 9.3 Percentage still on second regimen Y..../N.....
- 9.4 Percentage still on ARV Y..../N.....
- 9.5 Percentage of those who died Y..../N.....
- 9.6 Other indicators that fit into this category:

10. ART Success indicators for clinical assessment

- 10.1 Median CD4 count when starting ART Y..../N.....
- 10.2 Other indicators that fit into this category:

11. ART Success indicators for assessment of function

- 11.1 Percentage at work or attending school Y..../N.....
- 11.2 Percentage ambulatory but not in work/school Y..../N.....
- 11.3 Percentage bed ridden Y..../N.....
- 11.4 Other indicators that fit into this category:

12. Medicines and Supplies management legislation

- 12.1 Percentage of drug outlets (both private and public) inspected by regulatory authority Y..../N.....
- 12.2 Percentage of drug outlets (both private and public) in violation Y..../N.....
- 12.3 Percentage of number of drugs/batches tested out number of drugs/batches procured Y..../N.....
- 12.4 Percentage of number of drugs/batches that failed quality control testing, out of number of drugs/batches tested Y..../N.....
- 12.5 Other indicators that fit into this category:

13. Financial issues

- 13.1 Total Salary & staff benefits Y..../N.....
- 13.2 Total Vehicle maintenance & repair costs Y..../N.....
- 13.3 Total vehicle fuel costs Y..../N.....
- 13.4 All other Operating Costs Y..../N.....
- 13.5 Total Operating Costs as a percentage of the value of issues Y..../N.....
- 13.6 Total Operating Costs as a percentage of inventory value Y..../N.....
- 13.7 Other indicators that fit into this category:

14. Value of Accounts payable to suppliers

- 14.1 Value of public drug budget spent per capita in the last year Y..../N.....
- 14.2 Percentage value of public drug budget spent by major hospitals out of value of public drug budget spent Y..../N.....
- 14.3 Percentage value of drugs purchased with international aid out of the total drug purchased Y..../N.....
- Other indicators that fit into this category:

15. Public Sector Procurement Procedures

- 15.1 Number and Value of Purchase Orders Issued Y..../N.....
- 15.2 Value of Emergency Orders as a Percentage of all Purchase Orders Issued Y..../N.....
- 15.3 Average lead time (in months) for all complete orders delivered during the period by suppliers Y..../N.....
- 15.4 Percentage value of drugs purchased through competitive tender, out of value of drugs purchased Y..../N.....
- 15.5 Percentage Average time period of payment for orders, out of average time period of payment stated in contract Y..../N.....
- 15.6 Other indicators that fit into this category:

End of questionnaire

Note: In case you need clarification regarding this questionnaire please indicate the most convenient way to contact you in a timely manner and whether you feel you were the right person to be contacted for this information