



**HIV Patient ART Monitoring Meeting  
International Conference Centre,  
Geneva, 29-31 March 2004 and Beyond**

## Preface

This document summarizes the deliberations and activities related to a meeting held in Geneva in March 2004 and a number sub-group deliberations and the Extended-MERG workshop held 28<sup>th</sup> October 2004. As such the original Meeting summary conclusions have been discussed in these various fora and this report includes the conclusions from these additional deliberations. However, this is a rapidly changing field and all conclusions need to be considered as interim conclusions. We would welcome all comments and suggested amendments to the guidelines or draft indicators which came out of these deliberations and you can email us at [3by5help@who.int](mailto:3by5help@who.int) or [hivmoniteva@who.int](mailto:hivmoniteva@who.int) .

## Executive Summary

The March 2004 meeting, organized by WHO and co-sponsored by USAID and UNAIDS brought together a number of professionals in the field to discuss and identify those core variables to be collected for optimum patient management for ART monitoring (including ART delivered in various settings, including PMTCT and Care for Women and Children programs) and for allowing for the evaluation and feedback of programs at various levels of the country's health care system and harmonization of demands across relevant research or donor organizations operative in resource poor settings.

The need to develop a patient and clinic monitoring system for ART had been discussed at a WHO/UNAIDS Workshop on Strategic Information for Anti-Retroviral Therapy Programmes June 30-July 2, 2003 Geneva. (summary report <http://www.who.int/hiv/strategic/mt300703/en/>). The need for this was reinforced at the recent WHO/UNAIDS consultation on technical and operational recommendations for emergency scale up of ART in resource-limited settings, 21<sup>st</sup> November 2003, Lusaka.

The data which all of these systems require include *demographic, clinical, laboratory, treatment regimens, use of services* and *functional indicators* at the various levels. While one of the meeting's objective was to agree on the core data to be collected for managing and monitoring HIV care and treatment, many countries are already in the process of developing systems to collect such information.

The participants at the March meeting included representatives from different countries, NGOs, Universities, US Government and UN agencies (UNAIDS, UNICEF, WHO) and represented a variety of backgrounds: clinicians, program and health information systems managers, technicians of special data collection methods and logistics and supplies managers.

Using a variety of methods - formal presentations, small and large group discussions, working groups and booths at which the various participants could demonstrate specific paper- or electronically-based patient monitoring systems - the meeting achieved the following outcomes, some of which were consolidated in subsequent smaller workgroups:

- Standardization of patient management and monitoring variables and registries linked to these; this resulted in the production and publication of the Interim Patient Monitoring Guidelines for HIV Care and ART ([http://www.who.int/hiv/pub/prev\\_care/en/](http://www.who.int/hiv/pub/prev_care/en/))
- A draft outline of program monitoring at the various health system levels based on this patient-based information; these were further discussed at a meeting held on the 28<sup>th</sup> of October 2004, entitled the Extended MERG workshop and organized by UNAIDS. As a consequence of this and other deliberations the indicators were amended. Some dropped, some altered and some new ones included.
- It was furthermore recognized, that these patient-based indicators need to be linked to other indicators, like health facility ones, and other relevant information. Finally, these indicators will also be strongly influenced by the need of countries and tailored according to their requirements.
- A better understanding of data capturing systems (paper and electronic)
- The exploration of linkages/cross cutting issues related to ART resistance, TB and chronic care;
- In terms of drug supplies, most participants argued that while ART treatment may involve new drugs, pharmacies continue to purchase and receive other essential drugs so there must be some infrastructure in place even in the most remote areas.
- While pharmacies or laboratories were identified as playing an important role in data collection and dissemination, no specific recommendations were made as it was felt that this would need to be worked out on a country-to-country basis.
- The indicators, which a drug supply system would need to address, and some of relevant questions which were raised and listed.
- Identification of next questions and steps forward in order to implement the findings and test those as soon as possible.

A number of cross-cutting issues which were addressed during these discussions included:

- Differences in health care settings (infrastructure, volume, etc)
- Issues of confidentiality and security;
- Data needs;
- Data collection processes;
- Timeliness of collection and analyses;
- Quality improvement;
- Need for long term and sustained commitment by all partners;
- The use of the data collected and the provision of appropriate and timely feedback.

As a follow-up several key points were confirmed:

- Make final and standardize patient management and monitoring variables and patient registries;
- Linking treatment card with registries;
- Develop confidentiality guidelines/policies.
- Develop early warning systems to anticipate supply stock outs including a rapid response (drug supply component);

- How to “de-identify” data sets;
- Selection of data capturing systems (short and long term);
- Incorporate a two-way feedback system at country level;
- Disseminating recommendations;
- Develop a Package, including the Patient Monitoring Card and an outline of relevant Registries for country use, including a user-friendly guide and training module;
- Monitor and evaluate the use of the Package.

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## ***1.0 Aims of the March 2004 Meeting***

The aims of this meeting were twofold:

1.1) to discuss and identify the core variables to be collected for optimum patient management for anti-retroviral (ART) monitoring in various settings, including for mother-to-child-transmission (MCTC) and care for women and children programs;

1.2) to identify those variables used for monitoring patient management which would also allow for the evaluation and feedback of programs at various levels of the country's health care system and to encourage harmonization of demands across relevant research or donor organizations operating in resource poor settings.

## ***2.0 Background:***

The need to develop patient and clinic monitoring systems for ART, MTCT+ and related programs was discussed at a WHO/UNAIDS *Workshop on Strategic Information for Anti-Retroviral Therapy Programs* June 30-July 2, 2003 Geneva. Summary report of this meeting is available at <http://www.who.int/hiv/strategic/mt300703/en/>.

A recent WHO/UNAIDS consultation on technical and operational recommendations for emergency scale up of ART in resource-limited settings, 21<sup>st</sup> November 2003, Lusaka, also stressed the importance of regular monitoring of the uptake of HIV testing, care provision, and ART delivery.

The meeting brought together a diverse set of health care professionals - including clinicians, program and health information systems managers, technical experts on data collection methods and logistics and supplies managers - to build on existing experience of concerning HIV treatment and care monitoring, including ART. The underlying premise of this meeting was that patient and clinic monitoring systems comprise the foundation for program monitoring and evaluation.

A clear need exists to standardize ART monitoring systems, especially as a wide range of organizations and funders seek to scale up HIV treatment and care programs in middle- and lower income countries. The meeting focused primarily on patient management and monitoring of HIV treatment and care, provision of antiretroviral treatment, and linking this to other monitoring systems like ART resistance and drug supplies.

## ***3.0 Specific objectives of the March Meeting***

The specific objectives of the meeting included:

3.1 to discuss and agree on minimum variables to be collected at patient level for

- a) individual patient management;
- b) individual patient monitoring across sites;
- c) program monitoring and evaluation at health centre, sub-national and national levels based on patient level information and within the context of international reporting requirements.

3.2 to discuss and agree on patient based variables which will be useful in providing a link with the monitoring and evaluation of other programs, including ART resistance, drug supplies, TB and other chronic care.

3.3 to discuss and provide recommendations on mechanisms for collecting data at patient level.

3.4 to discuss and provide recommendations on mechanisms of reporting and providing feedback at the level of health centre, district, provincial, national and international levels.

3.5 to discuss and provide recommendations on systems to be developed or modified, including paper or electronic data collection and transfer systems.

#### ***4.0 Process of the March Meeting***

To address these specific objectives, the meeting was organized into four distinct sections, held over two-and-a-half days (Appendix 1). After the meeting was opened, a number of invited presentations 'set the scene' for the meeting. While some of these presentations summarized the conclusions of the meeting held in June 2003, others focused more on the meeting and its set tasks.

Subsequent to the opening presentations, participants were asked to join one of three work groups. One group had the task to identify those variables, which would be required for monitoring patient management. The second group was asked to identify which of the variables required for patient management, could be used for monitoring related programs. Members of the third group were asked to consider to what extent drug supply programs could draw on information captured by patient monitoring. After extensive discussions, the groups were brought together and in a large group meeting, feedback was received from each of the three groups, and the deliberations and conclusions from each of the working groups were discussed within the large group.

On the final morning, participants were again asked to break into small groups. One group continued to work on the detailed issues relating to the patient management and monitoring variables and the related registries. A second group discussed the type of different technological means through which these data were to be collected at health centre, district, regional and national levels. While most of the discussions during the meeting were focused on which variables to collect, some time was spent on discussing the different possibilities of how to collect and transfer these data. The third group continued to discuss issues related to drug procurement.

In addition to the sessions described above, representatives of the various groups were provided on the first day with the opportunity to display some of the paper – and electronically-based data collection and transfer systems at lunch-time booths. This included a number of systems which had already been developed and tested in the field.

### ***5.0 Participants of the March Meeting***

The participants at this meeting included representatives from ministries of health from different countries, non-government organizations, academic institutions, US government and UN agencies (UNAIDS, UNICEF, WHO), clinicians, program and health information systems managers, software specialists and logistics and supplies managers (Appendix 2).

### ***6.0 Presentations of the March Meeting***

The presentations during the meeting were state-of-the-art reviews and highlighted items necessary to be discussed during the meeting (Appendix 8).

### ***7.0 Main Conclusions from Working Groups and Plenary Group Discussions***

#### ***7.1 Patient Management and Monitoring***

This diverse group of professionals discussed at length over the three days which variables need to be included as part of the minimum dataset. While most of the variables were agreed on over the course of the meeting, discussions were held in subgroups between March and July 2004 to finalize and agree on the variables. During this period the variables were also field tested in Uganda.

The specific objectives of this group were to:

- identify and discuss variables: ideal, minimum and realistic
- identify low level indicators which can also be used for monitoring drug resistance
- discuss how these data could be collected within each clinical unit, including who and how these data will be collected
- agree on the next steps for implementation at local, country and global levels.

The group used an update of the original HIV Care/ART Card developed by IMAI<sup>1</sup> as a starting point and reviewed and graded each field, discussed the utility of each field and defined those data elements that require coding, and detailing instructions for training.

One issue which arose throughout this discussion was confusion between the content of the variables and the format of how these variables were going to be represented on a treatment card. The group concurred that a minimum set of variables should be collected at all sites and that are critical to ARV patient care monitoring. The ‘HIV Care/ART Card’ was one example of how these variables could be presented.

Another issue which was debated at the March and subsequent meetings was to what extent these variables and the means by which they were collected represented all the clinical data concerning

a particular patient to be collected on a single card, like the IMAI HIV Care/ART Card<sup>1</sup>, or to what extent these variables, and cards on which they are represented, are abstractions of data collected from a number of sources. It was ultimately agreed that in different settings, the minimum variable list will be employed in different ways: in some case as abstractions in another as the full medical record.

During the third day, a new break-out group was created to discuss potential variables to extract from the Minimum Data set as depicted in the HIV Care/ART Card to a monthly ART register. After the March Meeting, a number of sub-groups were convened which developed the work from the March Meeting and resulted in the publication of the *Interim Patient Monitoring Guidelines for HIV Care and ART* on the web. ([http://www.who.int/hiv/pub/prev\\_care/en/](http://www.who.int/hiv/pub/prev_care/en/))

## 7.2 Program monitoring and evaluation

The participants of the Program Monitoring and Evaluation Group were asked at the March Meeting to build on the patient-based Minimum Data Set and how they could be used to monitor different programs at facility, district, national and global levels.

Their specific objectives included to:

- identify the variables to monitor the programs, and their relationships with variables collected at health facility level
- how and how often these data will be transferred to higher level facilities including a critical review of the applicability of new technologies (e.g. software, smart cards, cell phones) in addition to paper based systems.
- how and how often these data will be analysed, by whom at which level and including a critical review of the applicability of various methods and means
- how and how often results of these analyses will be fed back to relevant levels
- to formulate recommendations on integration with the national HMIS with emphasis on records management including security and confidentiality, use and applications for M&E and surveillance.
- to agree on the next steps for implementation at local, country and global levels.

At the March 2004 Meeting, this group began by brainstorming for a day and agreed on various indicators, some of which were considered essential and some which were not considered essential. Having identified the essential ART indicators to determine impact, outcomes, and success measurements for program evaluation, the group also identified a number of 'optional' and 'additional' indicators, all of which were available from the Minimum Dataset or that could be aggregated directly from them. It was also discussed whether these indicators ought to be reported broken down by age or gender. The four areas of indicators for programs included starting indicators, access and coverage indicators, outcomes for cohorts, success indicators for cohorts, clinical assessment and assessment of function. Time intervals for assessment and reporting at facility, sub-national and national levels were also discussed as well as whether these indicators ought to be broken down by gender and age (Appendix 3). These indicators were reviewed at an UNAIDS organized Extended MERG Workshop held on the 28<sup>th</sup> of October 2004

(Table 1). The suggestions, which came out of the October workshop, included the proposal was to drop the differentiation between ‘essential’ and ‘optional’.

The March group suggested that whole numbers, not percentages should be used when possible. They agreed that the access and coverage indicators that compare services versus need worked better at the higher levels and were not necessarily that important at the clinic level. Transfer patients could distort the overall success indicators for a cohort since they transfer in with prior ARV experience and may already be very sick. Concerning the success indicators, weight gain was seen as only beneficial as a short-term indicator at the clinic level and its inclusion in both the nationally agreed upon indicators and the program indicators was hotly debated. At the October meeting it was agreed to drop weight gain altogether, recognizing it was useful for clinical assessment of individual clinical response but not for program monitoring. The group recommended to use only the drug resistance indicators that are already being collected and not to initiate new data collection for drug supply.

The March group identified some other indicators such as decreasing number of opportunistic infections and other symptomatic conditions, which could be included as a success indicator but recording of these may be problematic. Finally at the October workshop, change in CD4 count was questioned but median CD4 count when people started ART was considered to be a reasonable program indicator. What was missing from the original indicators was long-term survival, which the participants of the October workshop wanted incorporated as an indicator (Table 1 – Appendices 3 and 9)

### *8.3 Monitoring Drug Supplies*

This Group began by looking at a number of macro level issues because in many countries drugs are procured at the national-level, travel through the supply chain and are dispensed at the pharmacy level. The objectives for this group were to:

- identify those patient-based variables to monitor the drug supply programs, and their relationships with variables collected at health facility level
- how and how often these data on drug supplies will be transferred to higher level facilities including a critical review of the applicability of new technologies (e.g. software, smart cards, cell phones) in addition to paper based systems.
- how and how often these data on drug supplies will be analysed, by whom at which level and including a critical review of the applicability of various methods and means
- how and how often result of these analyses will be fed back to relevant levels
- formulate recommendations on integration with the national HMIS with emphasis on records management including security and confidentiality, use and applications for M&E and surveillance.
- agree on the next steps for implementation at local, country and global levels.

When discussing supply chain management, the seminal theme was whether the infrastructure already in place was sturdy enough to incorporate the volume and chronicity of ART drugs. Should we aim to improve and build on the supply system currently in place in most countries for other essential drugs or should we develop a parallel supply chain to replace that system—

one that will eventually be used for the procurement and distribution of all drugs and supplies? Many participants argued that while ART treatment may involve new drugs, pharmacies continue to purchase and receive other essential drugs so there must be some infrastructure in place even in the most remote areas. Others voiced concerns that large scale and well-funded ART monitoring systems may take over the distribution infrastructure at the cost of other essential drugs and supplies.

**Table 1 Interim Program Indicators as discussed in March Meeting Work Group and Plenary and reviewed at the Extended-MERG workshop 28<sup>th</sup> October 2004**

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

The participants also discussed the intersection of the drug supply chain and the Minimum Dataset at the point where the patient receives his treatment medicines. How does the data from the patient system transfer to the pharmacy/drug supply system? Furthermore, how does the drug supply information feed back into the system at the district or program level? The group agreed that tracking beyond the pharmacy can be extremely difficult. Many felt that pharmacies or laboratories can play an important role in data collection and dissemination. No specific recommendations were made and would need to be worked out on a country-to-country basis. The potential indicators, which a drug supply system would need to address and some of the relevant questions, which are raised and need to be addressed are listed in Table 2.

**Table 2 List of potential indicators to be considered for monitoring and evaluating drug supply systems**

Indicator / Data Elements	Use	Applicable Level	Data Elements / Source	Frequency of collection
Number of ART Patients by age, gender (TB , pregnancy status, weight) -Currently in Treatment -New Patients -Transferred in - Transferred out -Defaulters - Type of and number on Therapy: first line, second line etc - number switched	quantification	Facility (C) International ( R) National (R) Feedback to appropriate level	Client profile Dispensing register	Monthly / Quarterly as appropriate
Stock movement -consumption -Stocks on hand (quantity, stock months) -losses and adjustments - Quantity on order - number of orders / quantities (routine / emergency) - number of orders / quantities received -Stock outs / number of days -Quantity under threat of expiry (as appropriate, 1month, 2months etc.	Supply chain management	Collected at all levels Reported to next higher levels -> Feedback	Stock keeping records Requisition and order vouchers	Monthly / Quarterly as appropriate
<ul style="list-style-type: none"> <li>•Financial values of commodities</li> <li>•Adherence</li> <li>•Adverse Drug Reaction</li> <li>•Confidentiality</li> </ul>	Open for discussion Shall we collect the information? If yes who will collect it? Clinics or Pharmacists			

The Drug Supply Group also considered the potential value of ART drugs. The drugs not only have a value as a commodity, with an initially limited supply and a very high demand, but also have an intrinsic value with the ability to commute a ‘death sentence’ into a chronic illness. The drug supply system, therefore, must build a security component into the storage and distribution systems. The items to be monitored for commodity management, as dealt with in one country, was discussed. An outline of such indicators is described in Appendix 4.

#### *8.4 Data collection and transfer systems*

The primary focus of this meeting was on what data will be collected at the clinical level. However, time was also devoted to how to collect and store the relevant patient based-data and transfer it between levels (from facility to local, district, province, etc.). It was agreed during the various discussions that we need to build the relevant systems around a common minimum data set, assuming that the relevant data will be collected using systems that are already in existence. In most rural settings at the clinic-level, the system in use for patient management and monitoring is most likely to be a paper-based. However, to analyze and monitor HIV services efficiently, some care and treatment information collected on paper will need to be transferred to an electronic system. Furthermore, given the fact that HIV care will become a long –term, chronic condition, countries may want to move toward an integrated electronic data collection system that can integrate information for patient management, laboratory and drug supply use and program indicators for each of those areas.

Countries should assess the feasibility of different information collection systems including mobile phones, hand- held devices, smart cards, and local/wide area networks. While maintaining a paper-based information at the foundation, health care information systems can be integrated with different forms of electronic patient monitoring system, bar coded drug supply system, locally networked laboratory systems or some other combination of different technologies.

Several participants took the opportunity to display and present their data collection systems and technology during a special one hour “booths visit” scheduled outside the plenary room on the first day. The booth displays included: paper-based clinical monitoring systems; personal computer stand-alone or locally networked systems or computerized systems for single institutions. Wide-area communication-based systems or distributed communications-based systems, including Personal Digital Assistants (PDAs) such as cell phones and chip cards. The plenary sessions and group discussions also provided opportunities for participants to discuss what worked or did not work in the clinics they managed and countries they worked in.

Some salient points in the discussion of information systems were:

- proprietary systems from the first world are expensive and may not work; countries must have ownership of their software systems and be able to program, maintain and service them.
- paper based systems are not necessarily easier to maintain; they still require training, time to fill out or aggregate the documents, and ample storage space.

- a standard data set and communication standards are essential for a successful medical health information system (HIS).
- the adoption of standardized ART indicators to track drug prescriptions, inventories, laboratory results, adverse reactions, reasons for changing or stopping therapy, and others are only helpful to clinicians if the data are easily retrievable and the feedback systems are well established.
- feedback systems need to work across institutions of the same level but also between institutions of different levels, including health centre, sub-national and national levels.
- HIS managers need a long-term plan for eventual conversion from paper to software
- If software-based monitoring forms become overzealous in their detail, the quality plummets—no one takes the time to input all the data.

Finally, the various groups discussed the potential for software-based systems to provide ‘real time’ disease management guidelines, drug supply shortages, and incidents of drug resistance.

### *8.6 Confidentiality and Security*

This topic generated a dynamic discussion on confidentiality and security. Confidentiality was the assurance that medical information will be used only for appropriate care and treatment of individuals and populations; security was defined as the protections that assure that no breaches in confidentiality will occur. First and foremost, participants agreed that guidelines from developed countries like the United States would need to be adapted for relevance in resource poor settings. What guidelines and protocols need to be in place to ensure the confidentiality and security of information collected for ART monitoring? How do we de-identify data earmarked for analysis? Where should the information be stored and who should have access? Noticeably, the group had more questions than answers, however, in the rush to set up a data collection system, privacy must be protected. The group suggested that a protocol needs to be created for Confidentiality and Security of the ART data, as information is transferred from the clinic level to the national level. Training staff members who have access to sensitive information would need follow.

The security and confidentiality discussion also reached over to the issue of stigma. What guarantees can patients be given that the information is secure and will be held in strict confidence—particularly when the stigma of AIDS is so pervasive that people may refuse treatment if asked to fill out the information in the patient cards? Participants agreed that in areas of low prevalence, the stigma may be high and the need for confidentiality of medical data is imperative. This raised the issue of whether we are doing everything we can to de-stigmatize AIDS and to treat it simply as a chronic disease? The issue of stigma lead to a discussion of equity. Who gets access to ART; who decides. Are governments and donor doing everything it can to facilitate equity in access to ART? A recommendation from the floor urged clinicians to avoid having to make the decisions as to who receives treatment; this is an area where the community and other stakeholders can and should play a vital role.

## **8.0 Summary and Conclusions**

During the meeting basic patient level information to be collected for patient management and monitoring had been extensively discussed. These patient-based variables were integrated with some of the program and drug supply requirements for monitoring and evaluation as well as linkages to be made with other information systems, in particular national health information systems. Mechanisms for data collection were discussed within the context of two-way reporting and feedback required at the various levels of national monitoring and evaluation systems.

There were a large number of health care professional representing a broad range of different health related areas from users, provider and funders of services representing people with a broad spectrum of technical expertise. They debated a whole range of cross cutting issues, including different setting and associated problems relating to infrastructure, volume of patients, chronicity of treatment and care, data needs at the different levels, resources required for data collection and analysis, timeliness of the analyses and two-way feedback to relevant people and organizations, feedback resulting in quality improvement, both in the terms of the information collected and ultimately resulting in improved treatment and care services. The discussion also touched on the need to ensure confidentiality and security of the information at all levels, while at the same time working on reducing the amount of stigma associated with HIV infection where possible.

Some of the recommendations coming out of the meeting included

- Further refinement of the patient management and monitoring variables, which did take place (Appendix 7)
- Linking the variables for patient management with registries (Appendix 7)
- Further work for relevant organizations on international recommendations for confidentiality and security issues
- Developing early warning systems to anticipate drug supply stock-outs and rapidly respond
- Selecting data collection systems based on appropriate technology.
- Need to provide appropriate resource and training for people in terms of data collection and analysis.
- Setting country- and internationally-based two-way feedback systems.

## **9.0 Where we go from here**

Some of the issues, which still needed to be addressed over the coming months included:

- 1) Developing an agreed set of minimum dataset of inpatient variables, as the currently agreed set of variables for patient management and monitoring including demographic factors and outpatient variables. ( *The Interim Patient Monitoring Guidelines for HIV Care and ART* [http://www.who.int/hiv/pub/prev\\_care/en/](http://www.who.int/hiv/pub/prev_care/en/) )
- 2) Developing appropriate electronic data capturing systems which will capture the agreed minimum demographic, inpatient and outpatient data set as discussed at this and other relevant meetings.

3) Obtaining buy-in from other donor and research organizations on data standards and core variables for HIV care.

Meeting were planned and held later in 2004 to reach consensus on these important issues. As part of this process, the Extended MERG Workshop was held on the 28<sup>th</sup> October 2004 (Appendices 5,6 and 9).

## References

1) IMAI - Chronic HIV Care with ARV Therapy, Annex C. WHO/3 by 5 Geneva January 2004



<b>12.00 – 12:30</b>	<b>Discussion</b>
<b>12.30 – 13:00</b>	<b>Introduction to Booths - Cyril Pervilhac</b>
<b>13:00 – 14:00</b>	<b>Lunch</b>
<b>14:00 – 15:00</b>	<b>(1) Booth visits</b>
<b>15:00 – 15.30</b>	<p>Afternoon, Chair: Festus Ukwani</p> <p><b>a) Introduction to the 3 break out group work – Eddy Beck</b></p> <p><i>- Patient Group.</i></p> <p><i>- Program Group.</i></p> <p><i>- Drug Supply Group.</i></p> <p>to identify and discuss variables: ideal, minimum and realistic</p> <p>to discuss how these data could be collected within each clinical unit, including who and how these data will be collected</p> <p>how and how often these data will be transferred to higher level facilities including a critical review of the applicability of technologies (e.g. paper based, software, smartcards, cell phones)</p> <p>how and how often these data will be analysed, by whom at which level and including a critical review of the applicability of various methods and means</p> <p>how and how often result of these analyses will be fed back to relevant levels</p> <p>to formulate recommendations on integration with the national HMIS with emphasis on records management including security and confidentiality, use and applications for M&amp;E and surveillance.</p>
<b>15:30 – 16.00</b>	<b>Coffee/Tea</b>
<b>16:00 – 18:00</b>	<b>b) Group work</b>
<b>18:30 – 20.00</b>	<b>Cocktail reception</b>

## **Day 2 – 30 March 2004**

<b>9.00 – 9.15:</b>	<p>Morning, Chair: Mary Freyder</p> <p><b>Summary of previous day activities &amp; orientation of second day</b></p>
<b>9.15 – 12.30:</b>	<b>Work groups continued: developing summary findings and recommendations</b>

**12:30 – 13.30**      **Lunch**

**13.30 – 14:00**

**Afternoon, Chair: Mark Shields**

*Clinical Group: summary findings  
and recommendations*

**14.00 - 14:30**

*Program Group: summary findings  
and recommendations*

**14:30 - 15:00**

*Drug Supply Group: summary  
findings and recommendations*

**15.00 – 17.30**      **Discussion**

**17.30 – 18.00**      **Summary of the day**

**Day 3 – 31 March 2004**

**8.30 – 10:00**      Morning, Chair (1): John Amenyah  
**Recommendations from groups**

**10:00 – 10.30**      **Session 5: Confidentiality and ethical issues in comprehensive  
ART & MTCT Clinical Monitoring Systems**

Presenter: Xenophon M. Santas

**10.30 – 11.00**      **Session 6: Designing and Implementing Clinical Encounter Forms  
and Modules to Support HIV Care**

Presenter: John Milberg

**11.00 – 11.30** **Coffee/ tea**

**11.30 – 13.00**      Morning Chair (2): Paul De Lay

**Where do we go from here?**

**13.00**      **Close of Meeting**

**WHO 28/3/2004**

## APPENDIX 2 LIST OF WORKING GROUP PARTICIPANTS

WG 1: Patient Group  
WG 2: Program Group  
WG 3: Drug Supply Group

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**APPENDIX 3 INTERIM PROGRAM INDICATORS at HEALTH CENTRE, SUB-NATIONAL and NATIONAL LEVEL  
modified at Extended MERG Workshop 28<sup>th</sup> October 2004**

					Sub-national				National			
	Total	Gender breakdown	Age* breakdown	Reporting time interval	Total	Gender break-down	Age break-down	Reporting time interval	total	Gender breakdown	Age breakdown	Reporting time interval
Suggested age break-down: <1 year, 1-5; 6-14; 15-45; >45 years												
<b>"Starting indicators"</b>												
number assessed and eligible for ARV treatment	√	√	√	quarterly	√	√	√	quarterly	√	√	√	annually
number (%) starting ARV treatment	√	√	√	quarterly	√	√	√	quarterly	√	√	√	annually
additional data element: % transferred in on first regimen	√	√	√		√	√	√		√	√	√	
additional data element: % transferred in on second regimen	√	√	√		√	√	√		√	√	√	

	Health Centre Facility				Sub-national				National			
	Total	Gender breakdown	Age* breakdown	Reporting time interval	Total	Gender break-down	Age break-down	Reporting time interval	total	Gender breakdown	Age breakdown	Reporting time interval
<b>Access and coverage indicators</b>												
% diagnosed HIV + (national def) / estimated number living with HIV	√	√	√	annually	√	√	√	annually	√	√	√ <sub>I</sub>	annually
% assessed for ARV treatment eligibility / number diagnosed with HIV	√	√	√	annually	√	√	√	annually	√	√	√	annually
% currently on ARV treatment / estimated number in area eligible for HIV treatment	√	√	√	annually	√	√	√	annually	√	√	√	annually

	Health Centre Facility				Sub-national			National				
	Total	Gender breakdown	Age* breakdown	Reporting time interval	Total	Gender break-down	Age break-down	Reporting time interval	total	Gender breakdown	Age break-down	Reporting time interval
<b>Outcomes for cohort starting in particular quarter</b>	AT 6 / 12 MONTHS AFTER FIRST REGIMEN BEGINS AT 6 / 12 MONTHS (AT 6 AND 12 MONTHS)							AT 6 AND 12 MONTH				AT 12 MONTHS report annually
still on 1st regimen	√	√	√	√	√	√	√		√	√	√	
changed to second line	√	√	√	√	√	√	√		√	√	√	
still on 2nd regimen	√	√	√	√	√	√	√		√	√	√	
lost	√	√	√	√	√	√	√		√	√	√	
transferred out	√	√	√	√	√	√	√		√	√	√	
died	√	√	√	√	√	√	√		√	√	√	
stopped+ in care	√	√	√	√	√	√	√		√	√	√	

	Health Centre Facility				Sub-national				National			
	Total	Gender breakdown	Age* breakdown	Reporting time interval	Total	Gender breakdown	Age breakdown	Reporting time interval	total	Gender breakdown	Age breakdown	Reporting time interval
<b>"Success indicators" (for cohorts)</b>			AT 12 MONTHS				AT 12 MONTHS				AT 12 MONTHS	report annually
% still on first regimen	√	√	√	√	√	√	√	√	√	√	√	√
% still on second regimen	√	√	√	√	√	√	√	√	√	√	√	√
% still on ARV	√	√	√	√	√	√	√	√	√	√	√	√
% died	√	√	√	√	√	√	√	√	√	√	√	√
<b>"Success" from clinical assessment/ laboratory (for cohorts)</b>												
Median CD4 count when starting ART	√	√	√	12/24 months	√	√	√	12/24 months	√	√	√	√

	Health Centre Facility				Sub-national				National			
	Total	Gender breakdown	Age* breakdown	Reporting time interval	Total	Gender break-down	Age break-down	Reporting time interval	total	Gender breakdown	Age breakdown	Reporting time interval
<b>"Success" from assessment of function (for cohorts)</b>												
at work or attending school %	√	√	√	12 months	√	√	√	12 months	√	√	√	12 and 24: report annually
ambulatory but not in work/school %	√	√	√		√	√	√		√	√	√	12 and 24: report annually
bed ridden %	√	√	√		√	√	√		√	√	√	12 and 24: report annually

	Health Centre Facility				Sub-national				National			
	Total	Gender breakdown	Age* breakdown	Reporting time interval	Total	Gender break-down	Age break-down	Reporting Time interval	Total	Gender break-down	Age break-down	Reporting time interval
<b>Drug supply indicators</b>				annually				annually				report annually
% of persons interrupting ARV treatment because of inadequate drug supplies	√	√	√		√	√	√		√	√	√	report annually
% of eligibles not starting ARV treatment because of inadequate drug supplies	√	√	√		√	√	√		√	√	√	
<b>TB screening indicator</b>	√	√	√		√	√	√		√	√	√	
% screened for TB	√	√	√	annually	√	√	√	annually	√	√	√	annually

## APPENDIX 4 List of indicators related to drug supply, use and management

### Indicators

*Indicators related to pharmaceutical services at the facilities*

Primary data is collected by the health center on a routine basis or through supervisory visits. One indicator (Sr. No 4 in bold) is captured through HMIS formats. HMIS data facility data collection format needs to be modified to collect data to calculate this indicator. This indicator is calculated at district, regional and national level as thought appropriate by HMIS management.

**Indicator Table: 1**

Sr. No	Indicators	Calculation Level / Frequency <sup>1</sup>						
		Freq	Fac	Dis	Reg	Nat	RMS	CMS
<b>Drug Availability and Stock Management</b>								
1.	Quantity of essential drugs received, consumed, expired, lost and remaining balance (Data source: Bin cards, Drug dispensing register)	Mon	√					
		Qtr					√	
		HY						√
		AN						
2.	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						
3.	Number of days that essential drugs by type was out of stock (Data source: Bin cards)	Mon	√					
		Qtr						
		HY						
		AN						
<b>4.</b>	<b>% of health centers where one or more essential drugs was out of stock for 3 or more days</b> (Data source: Facility Monthly Reports) <b>Note: Indicator to be included in the HIS</b>	Mon						
		Qtr		√				
		HY			√			
		AN				√		
5.	Number of essential drugs whose physical count did exactly match the record in the bin cards. (Data source: Supervisory Checklist)	Mon						
		Qtr	√					
		HY						
		AN						
6.	% of facilities where the average variation in physical count and record count is less than 5%	Mon						
		Qtr		√				
		HY			√			

<sup>1</sup> Mon=Monthly, Qtr=Quarterly, HY=Half-yearly, AN=Annually, RMS=Regional Medical Stores; CMS=Central Medical Stores

	(Data source: Supervisory Checklist)	AN							
<b>Quality</b>									
7.	Average number of prescriptions dispensed per day per pharmacist (Data source: Supervisory Checklist)	Mon							
		Qtr	√	√					
		HY			√				
		AN					√		
8.	% of days that the temperature of drug refrigerator was within acceptable range (Data source: Supervisory Checklist)	Mon							
		Qtr	√						
		HY							
		AN							
9.	% 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							
10.	Average number of drugs per prescription (Data source: Supervisory Checklist)	Mon							
		Qtr	√						
		HY			√				
		AN					√		
11.	% prescriptions that contained antibiotics (Data source: Supervisory Checklist)	Mon							
		Qtr	√						
		HY			√				
		AN					√		
12.	% of drugs actually dispensed (Data source: Supervisory Checklist)	Mon	√						
		Qtr							
		HY			√				
		AN					√		
13.	% prescriptions that contained injections (Data source: Supervisory Checklist)	Mon							
		Qtr	√						
		HY			√				
		AN					√		
14.	% of drugs prescribed as per standard treatment guidelines (Data source: Supervisory Checklist)	Mon							
		Qtr	√						
		HY			√				
		AN					√		
15.	% of drugs prescribed as per Nedlist (Data source: Supervisory Checklist)	Mon							
		Qtr	√						
		HY			√				
		AN					√		
16.	% of drugs prescribed with generic name (Data source: Supervisory Checklist)	Mon							
		Qtr	√						
		HY			√				
		AN					√		
17.	% of drugs adequately labeled (Data source: Supervisory Checklist)	Mon							
		Qtr	√						
		HY			√				
		AN					√		

Legislation and Regulation								
18.	% of drug outlets (both private and public) inspected (Data Source: Inspection Visits)	Mon						
		Qtr			√			
		HY				√		
		AN						
19.	% of drug outlets (both private and public) in violation (Data Source: Inspection Visits)	Mon						
		Qtr			√			
		HY				√		
		AN						

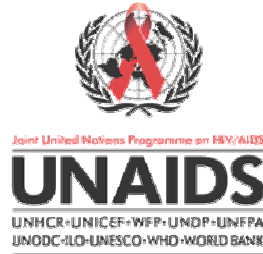
*Indicators Related to Drug Supply Management*

Following table lists the indicators related to the procurement, management and supplies of drugs through Central Medical Stores and Regional Medical Stores. Since the system is expected to be computerized it is recommended that these indicators be calculated both at the regional and national level.

**Indicator Table: 2**

Sr	Indicator	Periodicity
<b>Financial</b>		
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
<b>Public Sector Procurement Procedures</b>		
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
<b>Inventory management</b>		
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
<b>Distribution</b>		
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



## **Agenda Extended MERG**

### **Sub-National ART Monitoring and Concentrated Epidemics**

**Workshop, Geneva, 28<sup>th</sup> October 2004, Room M105**

#### **1. Background**

This UNAIDS workshop will use the opportunity of the presence of partners following the MERG meeting of 25-26 October 2004 to have discussions over a set of key issues related to program monitoring of ART Monitoring focusing on sub-national indicators and developing guidance for monitoring and evaluation for concentrated epidemic settings. The workshop aims at contributing to move this agenda in a very practical way in order to set the stage for a larger consensus meeting with all the key partners involved at a latter stage.

The WHO March meeting held in Geneva, 28<sup>th</sup>-30<sup>th</sup> March 2004 produced the Interim Patient Monitoring Guidelines in addition to a provisional list of health facility, sub-national and national ART indicators for programme monitoring and evaluation. These have been produced in the *Summary Report of the HIV Patient ART Monitoring Meeting International Conference Centre, Geneva 29-31 March 2004*. The summary report has been subsequently reviewed by rapporteurs of the March Meeting and amended accordingly.

USG partners visited Geneva on the 28<sup>th</sup> of June for discussions on predominantly national ART indicators. One day was also reserved for in-depth discussions on the patient-based variables, which were subsequently published as the Interim Patient Monitoring Guidelines. At the time, it was agreed that discussion concerning the Sub-national indicators were to be deferred till the autumn. The topic of the Sub-national indicators was raised again at an informal meeting between USG and WHO staff members in August at the CDC/UNAIDS M&E Training Workshop. It was agreed that the week of the MERG meeting in October 2004 could provide an opportune event to further discuss this topic.

Meanwhile USG partners have been developing some of their own program indicators. This workshop will allow for exchanges to be made between UN agencies and the USG partners on

these outputs and to facilitate the process of harmonization of ART indicators at health facility, sub-national and national levels for program monitoring and evaluation of ART scale-up. In addition the need for applications tools needed for countries in terms of. operations manual and training modules will be discussed.

Moving toward global harmonization of monitoring and evaluation data collection methods increasingly has becoming the goal of governments and international bodies. Much of the latest guidance in the era of expanding care and treatment has been focused on high prevalence settings. The need for clear guidance for concentrated epidemic settings affecting most at risk populations has been called for by donors and national program managers. Thus, a multi-agency technical working group is being assembled to plan and outline and content areas for a guidance document for this critical area.

## **2.0 Aims**

- 1) Update on status of patient/ programme monitoring tools and indicators for analysis at facility, district, and national level
- 2) Review how to adapt and apply those at country level - next steps, manuals, frameworks. Training materials, technical assistance
- 3) Discuss and identify most at risk groups and core indicators for concentrated HIV epidemics and plan key areas for monitoring and evaluation guidance.

## **3. Background Materials**

The following materials will be provided in advance of the meeting:

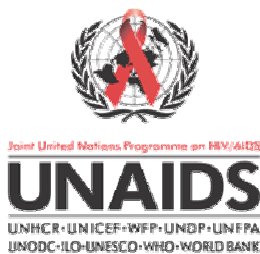
- Interim Patient Monitoring Guidelines
- Update on Patient Tracking and summary table
- Current registers, monthly and cohort reports, lists of indicators to calculate by level
- Summary Report of the HIV Patient ART Monitoring Meeting International Conference Centre, Geneva 29-31 March 2004.
- PEPFAR sub-national indicators
- Draft training module
- Draft operational framework

## **4. Expected outcomes:**

- a) Further agreement on indicators and patient monitoring tools and plans for manuals/ training materials for immediate country adaptation and use
- b) Review and agree on the critical elements of an operational framework
- c) Based on the findings of the preceding MERG meeting, to produce an outline and plan of action for monitoring and evaluation guidance for concentrated epidemics, especially a draft framework of ART indicators.

## 5. Plan of the Day

9.00 Welcome and Introduction	Paul De Lay
Sub-national ART Indicators:	
9.15 summary of the Geneva March Meeting	Eddy Beck
9.30 update on current patient monitoring system- registers, reports, indicators at facility and district level	Francesca Celletti
10.00 PEPFAR Sub-national Indicators	Mary Freyder
10.30-10.45 Coffee/Tea	
10.45 Discussion - Sub-national Indicators	Facilitators: Mary Freyder Cyril Pervilhac
Discussion - Application of Sub-national Indicators	
11.45- 12.15 Operational framework and discussion	Facilitators: Cyril Pervilhac, Deborah Rugg
12.15 Summary: Health Facility and Sub-national ART Indicators	Paul De Lay
12.30 - 13.30 Lunch	
13.30 - 14.00 M&E for Concentrated Epidemics	David Wilson/ Cameron Wolf
14.00 Discussion – Planning a Guidance Document & Review of Indicators	Chair: Daniel Low-Ber
15.30- 15.45 Coffee/Tea	
16.00 Discussion (continued)	
17.30 Summary: Concentrated Epidemics	Cameron Wolf
17.45 Summary of the Day and Way Forward	Paul De Lay
18.00 Close of Workshop	



**UNAIDS - Extended MERG Workshop  
Sub-National & Concentrated Epidemics ART Indicators  
Geneva, Switzerland (WHO-Room M105) on 28th October 2004**

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