East African Regional Meeting Follow-up on ICIUM 2004 & Antiretroviral (ARV) Adherence, Imperial Resort Beach Hotel, Entebbe, Uganda; April 27th-29th 2006: Trip Report

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About RPM Plus

RPM Plus works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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ACRONYMS

ART	Antiretroviral Therapy
ARV	Antiretroviral
ICIUM	International Conference on Improving Use of Medicines [WHO]
INRUD	International Network for Rational Use of Drugs
MSH	Management Sciences for Health
RPM Plus	Rational Pharmaceutical Management Plus (Program) [MSH]
STGs	standard treatment guidelines
USAID	U.S. Agency for International Development

BACKGROUND

In January 2006, Management Sciences for Health (MSH) hosted a meeting of the partners and donors who had collaborated to organize the 2004 International Conference on Improving Use of Medicines (ICIUM 2004) in order to prioritize recommendations from that meeting and strategize how to best collaborate in moving forward on implementing those recommendations. Adherence to ARV therapy was high on the prioritization list. With the large number of antiretroviral therapy programs starting in Africa, the issue of adherence is critical to both the control of the disease and the effective use of the resources being devoted to AIDS treatment. Yet surprisingly, adherence is not being addressed as a central component in many treatment programs and uniform indicators have not been developed. If adherence is low, treatment failure will occur and the likelihood of development of resistant virus is high.

Management Sciences for Health's Rational Pharmaceutical Management Plus (RPM Plus) program is providing technical assistance to Makerere University in Uganda to develop and coordinate a regional network of institutions to build capacity in supply management of medicines and other commodities used for HIV/AIDS, tuberculosis, and malaria treatment programs. The initiative, the Regional Technical Resource Collaboration for Pharmaceutical Management (RTRC), comprises groups from Uganda, Tanzania, Kenya and Rwanda.

In recent weeks each one of these groups and a group in Ethiopia has coordinated and conducted an Antiretroviral Treatment (ART) Adherence Survey. The objective of this survey was to identify the approaches for adherence monitoring being used by major HIV programs that provide or support the provision of ART services in Rwanda, Uganda, Ethiopia, Kenya and Tanzania.

This report is about the planned East African regional meeting on antiretroviral (ARV) adherence and follow-up on ICIUM 2004. The meeting was hosted by the MSH RPM Plus program with additional funds from the World Health Organization and was held from April 27th to 29th at the Imperial Resort Beach Hotel, Entebbe.

This meeting was intended to build on the results of the January meeting by facilitating the formation of national priorities and strategies for the participating East Africa countries. Specific objectives of the meeting were to:

1. Move a post ICIUM national agenda.
2. Discuss findings of the ARV adherence survey and plan how to develop and validate reliable and feasible indicators of adherence.
3. Plan formative in-depth qualitative and quantitative research as to reasons for good and poor adherence.

Purpose of Trip

The purpose of this trip was to help prepare, facilitate and participate in the above mentioned meeting and develop protocols and plans for ongoing work.

Scope of Work

Scope of work for Dr. Chalker:

- Prepare for and chair the meeting and facilitate the development of indicators and plans for validating them and plan formative in-depth qualitative and quantitative research as to reasons for good and poor adherence.

Scope of work for Dr. Lee:

- Facilitate the development of indicators and plans for validating them and plan formative in-depth qualitative and quantitative research as to reasons for good and poor adherence.

Scope of work for Dr. Matowe:

- Give technical assistance to the five RTRC groups and plan for ongoing work.

Scope of work for Dr. Mekonnen and Mr. Nwokike:

- Share experiences from Ethiopia and Namibia and plan for future developments.

Scope of work for Dr. Steel:

- to share the results of adherence work in South Africa and assist in the development of indicators of adherence

ACTIVITIES

Dr John Chalker during this visit:

- Helped prepare for the meeting and for the Local Organizing Committee to finalize all arrangements.
- Chaired the meeting and made presentations on introducing and summarizing the adherence monitoring survey, and introduced the work on determinants.

Dr David Lee during this visit:

- Facilitated sessions on indicator development and qualitative research on determinants.

Dr Lloyd Matowe during this visit:

- Helped prepare the meeting and work with all the regional groups and facilitated many workshop arrangements
- Also facilitated a session on candidate indicators

Mr Jude Nwokike during this visit:

- Shared experiences from Namibia and plans for future developments.

Dr Gavin Steel during this visit:

- Shared the results of adherence work in South Africa and assisted in the development of indicators of adherence.
- Gave a presentation on international findings on determinants of adherence.

Dr Negussu Mekonnen during this visit:

- Shared experiences from Ethiopia and plans for future developments.

Dr Michael Thuo during this visit:

- Shared experiences from Kenya and plans for future developments.
- Also facilitated a session on candidate indicators

The Entebbe Meeting

Thirty-eight participants took part in the workshop which took place at the Imperial Resort Beach Hotel, Entebbe, Uganda from April 27th-29th 2006. The agenda is in Annex 1, the list of participants in Annex 2, and the Minutes are in Annex 3 and an example of a Post ICIUM planning form is in Annex 4.

The objectives of the meeting were three fold: to promote a post ICIUM 2004 national and regional agenda: To discuss findings of an ARV adherence survey and plan work to develop and validate reliable and feasible indicators of adherence and to plan formative in-depth qualitative and quantitative research on determinants of good and poor ARV adherence. Each was taken in turn with most attention being given to the second.

All country teams met and discussed their countries priority areas of the post ICIUM research agenda and planned how to proceed with country advocacy and prioritization. These results are presented.

A survey was conducted to find out the current practices in measuring and calculating adherence and defaulting in East Africa as well as to find what data is routinely recorded and where in five East African countries: Ethiopia, Kenya, Rwanda, Tanzania and Uganda. Overall interviews were conducted with 24 programs or facility grouping managers providing ARVs in the 5 countries and facility managers or clinicians in 48 facilities with 86,807 patients on ART. These facilities included a wide range of types. Definitions of both adherence and defaulters or drop outs are very variable if done at all. There were 14 different definitions of defaulting. Measurement at individual or facility level is haphazard with various data sources and various methods of calculation. There is much data recorded at both the clinic and pharmacy, so that a standardized measurement should be possible. The INRUD Regional Adherence initiative (IRAI) has begun now in East Africa to get to a point whereby numbers are meaningful across time, programs and countries.

Candidate indicators have been suggested for: Self report from interviews or clinical records; Non Adherence, based on missed days from pharmacy records; and Defaulting: from attendance registers. Other system indicators have been suggested for: Availability and stock outs: from pharmacy records; Dispensing Rate: from exit interviews; Patient Knowledge Rate, from exit interviews; Drug Labeling Rate, from exit interviews; Adverse drug event, from exit interviews or clinical records or pharmacy records; Clinical or functional status on an accessory form; Pediatric Indicators; Depression screening questions; Additional Patient Indicators; Additional Facility Indicators and a Treatment Indicator. A sampling strategy was suggested. The next step is to test the feasibility and reliability of these candidate indicators in 5 sophisticated and 5 basic facilities in two countries.

The third objective was to plan a survey of determinants for both good and poor adherence. The strategy agreed was, using the newly developed indicators, to find examples of facilities with good and poor adherence, and in these facilities find patients with good and poor adherence, then use qualitative methods to find the reasons for good positive and negative deviance.

Key Collaborators

The INRUD group based in the Pharmacology Department of Makerere University Medical School, and in particular Dr Paul Waako were the local organizers of the workshop.

Teams including the national AIDS control programs from Rwanda, Tanzania, Kenya, Ethiopia and Uganda took part in a pre workshop adherence survey in each country which acted as a key resource for this workshop.

Dr Dennis Ross-Degnan and Dr Anita Wagner from Harvard Medical School led the facilitation of the follow-up on the 2004 International Conference on Improving Use of Medicines (ICIUM 2004) to plan for national dissemination of the ICIUM recommendations and begin a prioritization exercise: and were key facilitators for the adherence indicator development.

The USAID Mission in Uganda gave close and useful collaboration. Anne Cunningham gave useful advice and Jessica Oyugi dropped in and out of the workshop over the first two days.

Dr John Wasonga from the USAID Mission in Kenya attended and actively participated in the meeting.

Dr Edelisa D Carandang from the WHO/Technical Cooperation for Essential Drugs and Traditional Medicine from Geneva attended and actively participated in the meeting.

The WHO/Medicines Policy and Standards Department gave a grant to support the workshop.

The Vice Chancellor of Makerere University Professor Livingstone Luboobi and the Dean of the Faculty of Medicine- Professor Nelson Sewankambo attended and addressed the closing ceremony

NEXT STEPS

Immediate Follow-up Activities and Recommendations

Test the candidate standardized indicators with standardized collection methods and calculations in five sophisticated and five basic facilities in two countries for feasibility of collection. Modify the indicators and test again using trained data collectors to assess reliability. Then we need to test in the other three countries and also test for validity. We also need to disseminate that the INRUD Regional Adherence initiative (IRAI) has begun now in East Africa to promote collaboration and inclusiveness.

Once adherence and defaulting can be measured then a process of quantitative and qualitative research is planned to take place to look at why some facilities do well at adherence and some do badly, and why some individuals in both do well and do badly. Interventions can then be designed for testing to improve or maintain adherence levels. For those found to be effective they can then be scaled up to national level in the relevant countries.

Agreement or Understandings with Counterparts

None

Lessons Learned

Adherence and Defaulting are in urgent need of standardized measures and calculations.

ANNEX 1: AGENDA

East African Regional Meeting as a follow-up on ICIUM 2004 and on Antiretroviral (ARV) Adherence: Imperial Resort Beach Hotel, Entebbe, Uganda; April 27th-29th 2006

Objectives of the meeting are to:

1. Promote a post ICIUM 2004 national and regional agenda.
2. Discuss findings of an ARV adherence survey and plan work to develop and validate reliable and feasible indicators of adherence.
3. Plan formative in-depth qualitative and quantitative research on determinants of good and poor ARV adherence.

Thursday: April 27th: Morning

8.30-9.30 Introductions and Meeting Overview John Chalker

9.30-12.00 ICIUM Implementation Framework

9.30-10.30 Overview of ICIUM recommendations Dennis Ross-Degnan
and Steps in planning country prioritization strategies Anita Wagner

10.45 – 11.45 Country group priority decisions and reporting back

11.45-12.00 Summarize Regional opportunities (INRUD) John Chalker

12.00-1.00 Measuring Adherence Research

INRUD country reports on adherence monitoring (10 min each and discussion)

Overview of purposes of adherence survey John Chalker
a) Ethiopia Tenaw Andualem
b) Kenya Atieno Ojoo
c) Rwanda Joseph Ntaganira

Thursday: April 27th: Afternoon\

2.00-3.00 Measuring Adherence Research (cont'd)

Continuation INRUD country reports on adherence monitoring
d) Tanzania O Minzi
e) Uganda Paul Waako
Synthesis of research and project objectives John Chalker

PRDUC Tz adherence indicators (10 min) H Irunde
S Africa adherence indicator research (10 min) Gavin Steel
CDC adherence research plans (30 min) TBD

3.15-5.00: Developing Standard Adherence Monitoring Indicators

Defining and testing useful indicators (10 min) David Lee

Overview of Adherence Indicators in the international literature identifying potential candidate indicators followed by plenary discussion and identification of additional candidate indicators (30 min) Dennis Ross-Degnan

4 small group discussions (cross country) on feasibility of collecting candidate indicators ascribed to groups.

Thursday: April 27th: Evening

7.0 Continuing small group discussion over dinner on indicators

After dinner – Reports of small group findings to whole group, with discussion Michael Thuo & Lloyd Matowe

Friday: April 28th: Morning

8.30-1.00: Field Test of Adherence Monitoring Indicators

8.30-9.30 Formalize definitions of candidate indicators Dennis Ross-Degnan

9.30-10.0 Methods for testing feasibility and then validity of indicators MichaelThuo
Then in five country groups &
Details of strategy, study design, sample size, timeline, etc Lloyd Matowe
Coordination with other related projects
12.00-1.00 Plenary group discussion Stefan Peterson

Friday: April 28th: Afternoon:

2.00-5.00 Formative Research on Determinants of ARV Adherence

2.00-2.30:
Introduction: Rationale for study of determinants of ARV adherence John Chalker

Overview of international findings on determinants of good and bad adherence (15min) Gavin Steel

2.30-3.45
Discussion on designing studies of determinants David Lee

- Quantitative and Qualitative studies:

- Which programs, facilities, groups of patients are most and least adherent and why?
- Are there identifiable characteristics of patients and facilities with high and low levels of adherence?
- What are facilities doing to improve adherence, and what could they do better

This will include a panel with relevant experience on research methods used in PRDUC projects: Alice Nakiyemba and H Irunde

3.45-5.00 Break into five country groups, each with facilitator to plan possible research design

Saturday: April 29th: Morning

8.30-1:00 Planning INRUD Study on Determinants of ARV Adherence

8.30-10.00 David Lee
Brief review of previous day's discussions and continuation of country group work on developing draft work plans including a research framework (sampling, methods, timing, teams, budget, locations)

10.15-11.00 Report back on country work plans

11.00-1.00**:** Looking to the future: Intervention development Stefan Peterson
5 mins presentation of country practices and wish lists
Discussion of possible interventions

Saturday: April 29th: Afternoon

2.00-5.00 Planning Post-ICIUM Country Dissemination Activities

2.00-3.15 Ideas for country prioritization plans (15 minutes each) Country reps

3.15-3.30 Summary Anita Wagner

3.30-4.00 Discussion of possible regional activities; Next steps John Chalker

4.00-4.30 Closing and meeting wrap-up John Chalker

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ANNEX 3: MINUTES

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Sampling Issues

Number of Health Facilities

A study to examine adherence in a large system of care, such as the National AIDS Program, should include a minimum of 20 health facilities. If a system of care includes fewer facilities, then all of them should be included in a survey to measure system performance.

The data to calculate each indicator should be collected at each facility. The sample sizes suggested are sufficient for a moderately reliable set of adherence measures at each facility (such as when monitoring performance over time) and a very reliable cross-sectional or longitudinal estimates of these measures in the system as a whole.

Facility Level Indicators

Several indicators gather data about the infrastructure at each health facility. These include the presence of absence of a private space for counseling and a laboratory for CD4 or viral load testing. In addition, since consistent availability of medicines is a key determinant of adherence, several indicators measure the current and recent availability of ARVs and other key medicines to treat or prevent HIV-associated illnesses.

Current Patient Exit Interviews

At each facility it will be necessary to interview patients as they leave the facility in order to ask for self report on adherence, as well as check how long they spent at the clinic, how long they took to travel to the clinic, how many of their prescribed ARVs and other drugs were actually dispensed, whether the medicines are correctly labeled, whether the patient has experienced any adverse drug events in the last month, and whether they know how to take their medicine correctly. This sample should include interviews with 30 patients (or with all who came that day if fewer than 30 attended clinic).

The proposed patient indicators can also be used to assess adherence among pediatric patients. If the patient is a child who has been brought to the clinic by a carer, then there are two screening questions to ask the carer to see whether the child would be eligible for the survey. If the carer is not the one who usually gives the child medicine, then that child should not be included.

Retrospective Patient Visits

Retrospective data from attendance records, clinical records, and pharmacy records are useful because they allow computation of indicators related to success of short-term and long-term adherence, defaulting, and clinical outcomes. The attendance register is the primary source of data for identifying patients in treatment at a given period of time.

Two samples of patients are needed, one to measure indicators of recent short-term adherence and defaulting, and the other to measure longer-term indicators. (*Note: The initial field trial of the methods for measuring the draft indicators will inform us about the feasibility of taking each of these proposed samples.*)

Sample 1: Systematic sample of patients treated 2-3 months previously

This sample is drawn from the attendance register for patients who were scheduled for a visit (referred to as the index visit) during the month that began 90 days prior to the date of data collection. To minimize potential biases that might occur due to temporary changes in staffing or monthly supply of medicines, The sample of visits should be spread evenly across the month. These patients will be used for looking at missed appointments and whether patients came back or not within the subsequent 60 days. In addition it will be used for checking if an STG is followed, and for assessing clinical outcomes such as CD4 and Viral loads. Additional demographic data may also be collected as well for more detailed analysis of subgroups. Finally, if appropriate data are recorded in the clinical record, this sample can also be used for assessing adherence through self-report, and adverse drug reactions.

If possible, because of differences in the adherence issues facing newly treated and experienced patients, the sample should include patients of both types. Newly treated patients are defined as those who initiated ARV therapy with the 60 days prior to their index visit, while experienced patients are those who began receiving ARVs >60 days before the index visit. Depending on the information included in the attendance record and how easy it is to link to clinical records, the sample can be drawn in two ways:

Sampling strategy 1 (if date of initiation of ARV therapy is not easily accessible in attendance records):

a) Select 100 patients ARVs scheduled for a visit between 2 and 3 months ago;

b) If fewer than 30 of these patients were new patients (as defined above), then select additional new patients to ensure a sample of at least 30 new patients for computing the relevant indicators

Sampling strategy 2: (if date of initiation of ARV therapy is easily accessible in attendance records):

a) Select 50 newly treated patients scheduled for a visit between 2 and 3 months ago;

b) Select 50 experienced patients scheduled for visits during the same period.

Sample 2: Systematic sample of patients treated 6-7 (or 12-13) months previously

For measuring longer-term patient continuation and ARV adherence, another systematic sample is needed that includes 100 patients who were on ARV therapy in a period longer ago than 3 months, who will be followed forward to the present. Two logical possibilities for such longer-term continuation are six months and 12 months, so this sample should selected using the same procedures as Sample 1, from the month that began either 13 months (for the one-year measures) or 7 months (for the 6-month measures) before the date of data collection. If <100 patients were on ARVs during the period chosen, then all patients on treatment at that time should be selected.

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Using this sample of patients, pharmacy dispensing records can be used to measure the days not covered by dispensed pills (or “missed days”) during the follow-up period. If earlier clinical and pharmacy records are insufficient to follow patients in this way, then it may make sense to select this sample from 6-7 months ago, rather than 12-13 months ago.

Indicators and Methods

Patient Adherence to ARV Treatment

1. Full adherence (self-report): % of patients with perfect recent adherence to ARV treatment

Rationale	Perfect (or >95%) adherence is the primary treatment goal
Source of data	Patient self-report: "In the last 4 days have you missed any of the ARV doses you were supposed to take?" [Response: Yes/No]
Data collection	Patient interview: Based on sample of 30 patients attending on day of data collection (or all patients if <30 attend that day)
	Clinical records (if similar question is routinely asked and recorded): Based on record review of systematic sample of 100 patients used for indicator 1
Computation	(# of patients responding "No" / # of patients asked) * 100
Comments	Question can be asked for last 1, 2, 3, or 7 days. For any of these periods, this indicator is the equivalent of the 95% adherence rate (missing 1 dose in 7 days is 7.7% of doses on a twice daily regimen). Calculation can be the same if the question is asked for 30 days or for the period since last clinic visit, but interpretation would differ.

2. Average adherence (self-report): Average % of recent ARV doses taken as scheduled

Rationale	Completion of all scheduled ARV doses at the proper time is an important treatment goal
Source of data	Patient self-report: "In the last 4 days, how many of your ARV doses did you miss completely or not take at the time you were supposed to take them?" [Response: # of doses missed or not taken on time]
Data collection	Patient interview: sample of 30 patients attending on day of data collection (or all patients if <30 attend that day).
	Clinical records (if similar question is routinely asked and recorded): Based on record review of systematic sample of 100 patients used for indicator 1.
Computation	(Sum across all patients of [1 – (# of doses not taken on time / # of doses that should have been taken)] / # of patients asked) * 100
Comments	The value over 4 days for each patient will vary according to the dosing regimen, from 4 doses (for once a day triple combination therapy) to 24 doses (for twice a day triple therapy as single tablets). Different recall periods can be used (e.g., 3, 7, 30 days) but interpretation would differ for longer periods.

3. Long-term persistence in ARV use (dispensing data): Average % of days covered by supply of ARVs dispensed in a defined period

4. Achievement of persistence target (dispensing data): % of patients achieving a defined target (e.g., 95%) for persistence with ARV therapy in a defined period

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5. Discontinuation of ARV treatment (dispensing data): % of patients experiencing a gap in ARV availability of > 30 days during a defined period

Rationale	Adherence measures from pharmacy refill rates have been shown to correspond to clinical outcomes. If there are too few days of medicine dispensed, then we infer that the patient has missed doses.
Source of data	Pharmacy records
Data collection	Based on the sample of 100 patients on long-term ARV therapy selected for indicator #4: Using historical dispensing data in pharmacy or clinical records, identify the date and days' supply of all ARVs dispensed during the index visit and during all subsequent visits for this patient during the follow-up period chosen (either 6 or 12 months). If the # of days' supply in the last dispensing during the follow-up period is greater than the # of days left in the period, count only the days' supply equal to the # of days left in the period.
Computation	For individual patient: <u>Long-term persistence</u>: (Total # days' supply dispensed / # of days in period)] * 100 *** Note: If any long-term persistence rate is >100%, then change it to 100% *** <u>Achieving persistence target</u>: If long-term persistence ≥ defined persistence target <u>Discontinuation</u>: If patient ever experiences a gap of >30 days between end of days' supply in one dispensing (or end of total days' supply available if ARVs remain from previous dispensings) and date of the next dispensing For facility: <u>Average % persistence</u>: Sum of patient long-term persistence rates / # patients <u>% achieving persistence target</u>: (# of patients achieving defined persistence target / # of patients) * 100 <u>% discontinuation</u>: (# of patients experiencing a gap in ARV treatment > 30 days / # of patients) * 100
Comments	Pharmacy dispensing records are useful for measuring long-term persistence, but this method makes assumptions about completeness of the dispensing data and about how the medicines were consumed. Identifying reliable patient-specific longitudinal records may be a problem in some systems; if records are not easily retrievable (e.g., dispensings recorded on a single page or in a consistent place in the clinical record), this indicator may be too difficult to calculate. If the patient has more than one ARV in the treatment regimen, this indicator should be calculated separately for each medication.
Notes	*After testing these will probably be Complementary Indicators*

Patient Defaulting

1. Missed appointments: % of patients who do not appear for appointment on the day scheduled

Rationale	Rate of missed appointments is one measure of program success in actively engaging patients.
Source of data	Clinic or pharmacy records (if available) or review of current patient visits
Data collection	Based on systematic sample of 100 patient appointments that were scheduled during the month which began 3 months prior to the date of data collection. If possible, the sample should be evenly divided between patients who were in the first 60 days of ARV therapy (new patients) and patients who had been receiving ARVs for >60 days (experienced patients). Note: This indicator uses a sample of patients from 3 months in the past to allow calculation of the next two indicators. If both clinic and pharmacy records are available, sample should be divided evenly between the two visit types. If retrospective records are incomplete, this indicator can be based on all scheduled clinic and pharmacy appointments on day of data collection.
Computation	(# patients not appearing for appointment on day scheduled / # of patients in sample) * 100
Comments	Many programs use different definitions of defaulting. The intention of this indicator is to identify a trigger point for program action to reach out to patients at risk of defaulting.
Notes	*It may be possible to sample patients from 2 rather than 3 months ago.*

2. Recapture following missed appointment: % of patients missing appointment who reappear for a visit within 60 days

Rationale	Immediate follow-up with patients who fail to appear for clinic or pharmacy visits is a key strategy for promoting adherence.
Source of data	Clinical or pharmacy records
Data collection	Based on same sample of 100 patients used in indicator #1. Clinical records of all patients in the sample who fail to appear on the day scheduled should be followed to see how many reappear within the next 60 days. This indicator cannot be measured if individual patients cannot be traced in clinic or pharmacy records.
Computation	(# of patients reappearing for visit within 60 days / # of patients who missed appointment) * 100
Comments	Recapturing patients who miss appointment as quickly as possible is one measure of program success. If patients who miss appointments do not reappear for the next 60 days, they can be considered lost to follow-up.

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3. Treatment drop-out: % of patients who miss their appointment and do not attend an appointment in the next 60 days

Rationale	If patients fail to reappear for an appointment for 60 days, then they will have to be reassessed and probably started on a different ARV regimen.
Source of data	Clinic or pharmacy records
Data collection	Based on same sample of 100 patients used in indicator #1. Clinical records of all patients in the sample should be followed to see how many in total do not reappear within the next 60 days. This indicator cannot be measured if individual patients cannot be traced in clinic or pharmacy records.
Computation	(# of patients not reappearing for follow-up visit within 60 days of a missed appointment / # of patients in sample) * 100
Comments	If patients who miss appointments do not appear for a period of 60 days or more, they can be considered to have dropped out of treatment.

4. Long-term patient continuation: % of ARV patients who remain in active treatment after one year

Rationale	Success in maintaining patients on long-term ARV treatment is a key program goal.
Source of data	Clinic or pharmacy records
Data collection	Attendance records and patient medical records: Based on a systematic sample of 100 patients on ARV therapy (or all patients if <100 were on ARVs) either 6-7 or 12-13 months before the date of data collection. If possible, the sample should be evenly divided between patients who were in the first 60 days of ARV therapy (newly treated patients) and patients who had been receiving ARVs for >60 days (experienced patients). These patients' clinical or pharmacy records should be searched to see which patients attended the clinic to receive ARVs within the last 30 days. This indicator cannot be measured if individual patients cannot be traced in retrospective records.
Computation	(# of patients appearing for a visit in which they received ARVs in the last 30 days / # of patients on ARV treatment at the beginning of the follow-up period) * 100
Comments	This is a measure of long-term success in maintaining patients on ARV treatment. If data are available on patients who are no longer in treatment, it would be useful to record and analyze reasons for loss to follow-up (e.g., death, severe side effects, treatment defaulter, etc.). Patients whose care has been transferred to another facility should be excluded before calculating the indicator.
Notes	*It may be possible to sample for a month from 7 rather than 13 months ago.*

Quality of Treatment

5. Adherence to STGs: % of patients whose current treatment is consistent with national Standard Treatment Guidelines

Rationale	Patients treated according to established guidelines for ARVs are more likely to be adherent to care.
Source of data	Clinical records for the sample of 100 patients in indicator #1.
Data collection	Patient clinical records are examined to determine if current treatment is consistent with national STG for selection and dosing of ARVs.
Computation	(# of patients whose last treatment was consistent with STGs / # of patients records examined) * 100
Comments	Need to prepare a list of recommended STG regimens in the system of care. This may be difficult for data collectors to record reliably. In practice, it may be better to record each patient's regimen for later evaluation.

Availability of ARVs and Other Key Medicines

6. ARV availability: % of ARVs currently in stock

Rationale	Lack of availability of ARVs can be a key system-related barrier to adherence
Source of data	Observation in health facility pharmacies on day of data collection
Data collection	Check which medicines on a list of ARVs intended to be stock are actually in stock (amount sufficient for at least 10 patients)
Computation	(# of ARVs in stock / # of ARVs intended to be in stock) x 100
Comments	Need to prepare list of which ARVs are intended to be in stock

7. Key medicine availability: % of key medicines for HIV-associated illness currently in stock

Rationale	Lack of availability of key medicines needed to treat or prevent ARV side effects, opportunistic infections, or other HIV-associated illnesses can be a barrier to ARV adherence
Source of data	Observation in health facility pharmacies on day of data collection
Data collection	Check which medicines on a tracer list of key medicines needed to treat or prevent HIV-associated opportunistic infections and other illness are actually in stock (amount sufficient for at least 10 patients)
Computation	(# of medicines on tracer list in stock / # of medicines on tracer list) x 100
Comments	Need to prepare tracer list of up to 10 key medicines

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8. Individual medicine stock consistency: % of days in stock in last 90 days for each medicine on list of ARVs or key medicines for HIV-associated illness

Rationale	Failure to maintain continuous availability of ARVs and other key medicines needed to treat HIV-associated illnesses can be a barrier to patient confidence and long-term adherence.
Source of data	Pharmacy stock records
Data collection	Check stock records for each medicine on ARV or tracer list of key medicines to determine the number of days in stock in the previous 90 days (amount sufficient for at least 10 patients)
Computation	(# of days that medicine was in stock in last 90 days / 90) x 100 *Calculated separately for each listed medicine*
Comments	Need to prepare tracer list of up to 10 key medicines

9. ARV dispensing rate: % of patients who had all prescribed ARVs dispensed at the health facility

Rationale	Failure to dispense during the patient visit all ARVs that were prescribed is a primary barrier to adherence
Source of data	Patient exit interviews
Data collection	For sample of 30 patients attending on day of data collection (or all patients if <30 attend that day), check to see if all ARVs prescribed were dispensed
Computation	(# of patients dispensed all ARVs prescribed / # of patients surveyed) x 100
Comments	Need to ask if patients were told to fill prescription outside of health facility or to return earlier than usual to pick up additional ARVs

10. Non-ARV medicines dispensing rate: % of patients who had all prescribed medicines dispensed at the health facility

Rationale	Failure to dispense during the patient visit all non-ARV medicines prescribed can contribute to overall low adherence
Source of data	Patient exit interviews
Data collection	For sample of 30 patients attending on day of data collection (or all patients if <30 attend that day), check to see if all non-ARV medicines prescribed were dispensed
Computation	(# of patients dispensed all non-ARV medicines prescribed / # of patients surveyed) x 100
Comments	Need to ask if patients were told to fill prescription outside of health facility or to return earlier than usual to pick up additional non-ARV medicines

Health Facility Accessibility and Infrastructure

11. Extent of clinic hours: Number of hours clinic is open per week for routine AIDS care

12. Convenience of clinic hours: Whether clinic is open at least one evening or weekend day for routine AIDS care

Rationale	If the facility opening hours correspond to the patient's life or work schedule, then adherence to appointments is easier.
Source of data	Facility manager and patient interview
Data collection	On the day of data collection, ask the facility manager which days and times the clinic is open for routine AIDS care (including clinical treatment of AIDS patients and dispensing of ARVs). Verify with patients during patient interviews.
Computation	Extent of hours: Total number of hours clinic is routinely open for AIDS care Convenience: If clinic is open at least one evening or weekend day
Comments	The manager may claim longer opening hours than are actually so in routine practice. Patient interviews can help to verify the information provided.

13. Clinician patient load: Average number of AIDS patients seen per clinician hour

Rationale	Heavy patient volume can be a barrier to communication and adherence.
Source of data	Attendance records and interview with health facility administrator
Data collection	Determine how many patients were seen for consultative clinical visits during the previous month. In addition, determine the number of hours spent in clinic during the month by all the clinicians who provided these consultative services.
Computation	# of patients seen for AIDS consultative services in last month/ Total number of hours worked by clinicians who provided these consultative services
Comments	It may be hard to distinguish which visits are for AIDS consultative care and to determine which clinicians actually worked which hours. If necessary, compute the indicator based on the last week although this may be less representative.

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14. Presence of support staff: Average number AIDS patients per week per support staff

Rationale	The more staff that are present to provide social and emotional support, the more likely the patient is to receive personal care and adherence support.
Source of data	Facility manager and observation
Data collection	At the time of the visit ask about the number and type of staff routinely present for support services (adherence counseling, social and emotional counseling). Count the number of staff present during data collection to verify. The number of AIDS patients seen for consultative care per week is determined in indicator #13.
Computation	# of patients seen for AIDS consultative services in last week / # of support staff
Comments	It may be more accurate to ask to see a roster of all staff and their hours for a week if this is available.

15. Presence of laboratory: Whether facility has a laboratory that is actively measuring CD4 counts or viral loads on-site or within 5 minutes walk from the facility

Rationale	A laboratory that can measure CD4 counts or viral loads in or near the facility makes it more likely that these clinical markers will be monitored on a regular basis, which can promote discussion about adherence.
Source of data	Facility interview and observation
Data collection	At the time of data collection, ask whether the facility has a laboratory on-site or within 5 minutes walk. Visit the lab to find how many CD4 counts or viral loads the laboratory has done in the last month.
Computation	Presence of on-site or nearby laboratory that has done more than a defined minimum number of CD4 or viral load counts in the last month
Comments	Need to define in advance what a minimum number of lab tests would be.

16. Presence of private space for counseling: Whether facility has a private space available for adherence counseling

Rationale	A private space for counseling makes it more likely that patients can communicate openly and honestly with the counselor.
Source of data	Facility interview and observation
Data collection	At the time of data collection, ask whether the facility has any private space for counseling and observe whether or not it is actually in use.
Computation	Presence of actively used private space for counseling (Yes/No)
Comments	Need to agree on a definition of what constitutes adequate privacy in a given setting.

17. Patient waiting time: Average amount of time patients spend in the clinic during a visit

Rationale	If a patient has to spend a long time at the facility each time they have an appointment, they are less likely to be motivated or able to continue to attend appointments.
Source of data	Patient exit interview
Data collection	Based on a sample of 30 patients attending on day of data collection (or all patients if <30 attend that day): Ask when they arrived at the facility today and calculate the number of minutes between then and the time of leaving. In addition, record which services the patient received (clinical examination, laboratory test, adherence counseling, social service counseling, pharmacy dispensing
Computation	Sum across patients of number of minutes from entering the facility to leaving / # patients asked
Comments	The arrival time may be approximate as people may not know. An alternate would be following a number of patients through from arriving to leaving.

18. Patient travel time to care: Average amount of time spent traveling to health facility to receive care

Rationale	Length of time spent traveling to receive care can be a barrier to adherence.
Source of data	Patient exit interviews
Data collection	Based on a sample of 30 patients attending on day of data collection (or all patients if <30 attend that day): Ask how many minutes it took for the patient to travel to the health facility for this visit.
Computation	Sum across patients of # of minutes traveled to care for this visit / # of patients assessed
Comments	***Do we want to make this categorical, e.g. more than one hour travel?***

Information and Communication

19. Patient knowledge of ARV regimen: % of patients who know correct ARV regimen

Rationale	Detailed knowledge of the correct ARV regimen is essential to adherence.
Source of data	Patient exit interviews
Data collection	Based on a sample of 30 patients attending on day of data collection (or all patients if <30 attend that day): For each ARV in treatment regimen, ask "Could you please tell me when you take this medicine, how much you take each time, and whether you take it before or after eating?"
Computation	(# of patients knowing all 3 aspects of all ARVs / # of patients asked) * 100
Comments	Need to determine correct treatment regimen for all ARVs used.

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20. Proper medicines labeling: % of patients for whom all medicines dispensed are adequately labeled

Rationale	Proper labeling of all medicines promotes better knowledge about their use and is essential for patient safety.
Source of data	Patient exit interviews
Data collection	Based on a sample of 30 patients attending on day of data collection (or all patients if <30 attend that day): For each medicine, the labeling on the container in which they were dispensed must contain patient name, name of medicine, how many times a day to take medicine, and how much to take each time.
Computation	(# of patients with all dispensed medicines labeled correctly / # of patients assessed) * 100
Comments	Medicines must each be dispensed in a separate container (pill bottle or envelope), and each container must contain at a minimum the four items of labeling assessed.

Clinical Outcomes

21. Adverse drug event: % of patients reporting a key symptom indicative of an adverse drug event

Rationale	Adverse drug events (ADEs) are a barrier to adherence, especially if they are not managed promptly and effectively.
Source of data	Exit interviews, clinical records, or pharmacy records
Data collection	Based on a sample of 30 patients attending on day of data collection (or all patients if <30 attend that day): Ask patients if they have experienced any of a list of key ADE symptoms in the previous month. Record each symptom experienced. Alternatively, based on clinical and pharmacy records for the same sample of 100 patients used in indicator #1: Review patient records from most recent visit to see if any of the key ADE symptoms were mentioned and recorded during the visit.
Computation	(# patients reporting an ADE in previous month / # of patients asked) * 100
Comments	Prior to the survey, need to agree on the list of key symptoms to monitor for ADEs.

22. CD4 testing rate: % of patients with documented CD4 test results in last 6 months

23. Achievement of CD4 target: % of patients achieving CD4 count > xxx cells per µl on most recent lab test in the last 6 months

Rationale	Increase in CD4 count over time is an indirect measure of success in controlling HIV. Routine testing for CD4 can assist in adherence monitoring.
Source of data	Clinical records
Data collection	Based on same sample of 100 patients used for indicator #1: Search clinical record for most recent CD4 count.
Computation	CD4 testing rate: (# of patients with documented CD4 count in last 6 months / # of patients searched) * 100 CD4 count: (# of patients with most recent CD4 count >
Comments	Not all facilities do routine CD4 counts for all patients.
Notes	*Should this indicator be designed to capture the change in CD4 count for the one-year cohort? What is the appropriate CD4 target? Is there a standard?*

24. Viral load testing rate: % of patients with documented viral load test in last 6 months

25. Achievement of viral load target: % of patients achieving viral load counts <400 copies per ml on most recent lab test in last 6 months

Rationale	Reduction in viral load is the primary outcome intended for ARV therapy. If resources permit, routine monitoring of viral load is the best way to measure the clinical impact of ARV therapy and, indirectly, adherence.
Source of data	Clinical records
Data collection	Based on same sample of 100 patients used for indicator #1: Search clinical record for most recent viral load count within the last 6 months.
Computation	Viral load testing rate: (# of patients with documented CD4 count in last 6 months / # of patients searched) * 100 (# of patients with viral load count <400 copies per ml on most recent lab test / # of patients with viral load test results documented in last 6 months) * 100
Comments	Not all facilities do routine viral load counts for all patients.

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Alternate Adherence Measures from Pill Counts

26. Full adherence (pill count): % of patients with perfect recent adherence to ARV treatment

27. Average adherence (pill count): Average % of recent ARV doses taken

Rationale	Some programs use pill counts to monitor adherence. Pill counts during a single visit can be used to estimate adherence since the last visit.
Source of data	Pill counts from clinical or pharmacy records
Data collection	Based on record review of the systematic sample of 100 patients used for indicator 1. These indicators can also be calculated for the sample of 30 patients attending on the day of data collection used for indicator #1. Data are needed on both the total # of pills taken home during the previous visit (including pills remaining in the bottle at that time plus newly dispensed pills that were added) and the # of pills remaining in the bottle brought to this visit.
Computation	Consumption rate for each patient = [(# of pills taken home in previous visit - # of pills remaining in bottle this visit) / (# of days that have elapsed since previous visit * # of pills per day in the ARV regimen)] * 100 *** Note: If any consumption rate is >100%, then change it to 100% *** <u>Full adherence</u>: (# of patients for whom consumption rate equals 100% / # of patients with pill count data) <u>Average adherence</u>: (Sum of consumption rates across all patients / # of patients with pill count data)
Comments	Some patients dispose of medicines if they know that pill counts will be conducted at the clinic. Pill counts require considerable effort. If clinics already count pills, this method can provide alternate adherence measures. If a patient is taking >1 ARV, these indicators should be calculated separately for each medication.

28. Long-term persistence in ARV use (pill count): Average % of days covered by supply of ARVs used in a defined period

29. Achievement of persistence target (pill count): % of patients achieving a defined target (e.g., 95%) for persistence with ARV therapy in a defined period

30. Discontinuation of ARV treatment (pill count): % of patients experiencing a gap in ARV availability of > 30 days during a defined period

Rationale	If pill count data are routinely collected in a given setting at every visit for all patients, then these data can be used to calculate long-term adherence measures.
Source of data	Pill counts from clinical or pharmacy records
Data collection	Based on the sample of 100 patients on long-term ARV therapy selected for indicator #4: Using historical pill counts recorded in pharmacy or clinical records, identify the number of pills consumed between all visits for each patient during the follow-up period chosen (either 6 or 12 months). If the # of days' of medication in the last dispensing during the follow-up period is greater than the # of days left in the period, count only the days' supply equal to the # of days left in the period.
Computation	Days' supply used for each patient = Sum across all visits of [(# of pills taken home in previous visit - # of pills remaining in bottle this visit) / (# of days that have elapsed since previous visit * # of pills per day in the ARV regimen)] For individual patient: <u>Long-term persistence</u>: (Total # days' supply used / # of days in period)] * 100 *** Note: If any long-term persistence rate is >100%, then change it to 100% *** <u>Achieving persistence target</u>: If long-term persistence ≥ defined persistence target <u>Discontinuation</u>: If patient ever experiences a gap of >30 days between end of days' supply in one dispensing (or end of total days' supply available if ARVs remain from previous dispensings) and date of the next dispensing For facility: <u>Average % persistence</u>: Sum of patient long-term persistence rates / # patients with complete pill count data <u>% achieving persistence target</u>: (# of patients achieving defined persistence target / # of patients with complete pill count data) * 100 <u>% discontinuation</u>: (# of patients experiencing a gap in ARV treatment > 30 days / # of patients with complete pill count data) * 100
Comments	If complete over a series of visits, pill counts can be useful for measuring long-term persistence. If the patient has more than one ARV in the treatment regimen, this indicator should be calculated separately for each medication.
Notes	*After testing these will probably be Complementary Indicators*

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Additional Useful Data for Analysis

During the monitoring survey, it is helpful to collect some additional demographic and clinical data that are useful for analysis of subgroups or interpretation of the indicators. This will be particularly important when looking at risk factors for nonadherence in order to design adherence support interventions. If desired, these additional data extracted from the clinical record can be recorded on a supplementary data collection form. The key items of data on the following lists can be recorded for both of the retrospective samples, and many data elements can also be recorded for patients taking part in the exit interviews. The depression screening questions may only be useful for the exit interviews.

Demographic data

Age, gender, occupation, location of residence

Functional status

Bed ridden, ambulatory, working (or other functional status measure)

Additional clinical data

Weight change, key co-morbidities (OIs), WHO staging, length of ARV treatment, ARVs in treatment regimen.

Depression screening

Depression may be an important risk factor for nonadherence. Screening for and treating depression may be an effective way to promote ARV adherence. The following 4-question depression screener is in development in Uganda and may be a useful adjunct to an adherence survey, asked on patients during the exit interview. Each item is scored on a 1-5 scale with depressed

a. During the last week how upset or distressed have you felt?

b. During the last week how energetic and health have you felt?

c. During the last week how well have you been getting on emotionally?

d. During the last week how satisfied are you with your life?

Specific Issues with Pediatric Surveys

Children of different ages have differing abilities to provide data on self-reported adherence or knowledge about their regimen. The three relevant age groups are:

a) Young children who need a carer to give medicine and for whom self-report cannot be trusted;

b) Teenagers who usually look after themselves, take their own medicine, and for whom self-reports are likely to be as accurate as for adults;

c) Children in between these two ages, who may or may not be responsible for their own medicine, but for whom self-report may be more questionable.

For ARV adherence surveys that include pediatric patients, children or teenagers who come to the clinic by themselves should provide their own responses only if they report that they usually take their own medicine by themselves. If not, they should be excluded.

For a child brought to the clinic by a carer, responses should be obtained from the carer, but only if that person is the one usually responsible for administering the child's medicines. If the carer is not the one who normally gives the child medicine, then information about recent adherence or knowledge about the ARV regimen may be incorrect. Before beginning the exit interview for a child brought to the clinic by a carer, the following questions should be asked of the carer by the data collector:

a. Are you the one who usually gives this child his/her medicine?

b. Are you the one who brought the child to the clinic originally and was told how to take medicine?

If the answer to either question is negative, then do not continue the interview and exclude the child from the survey.

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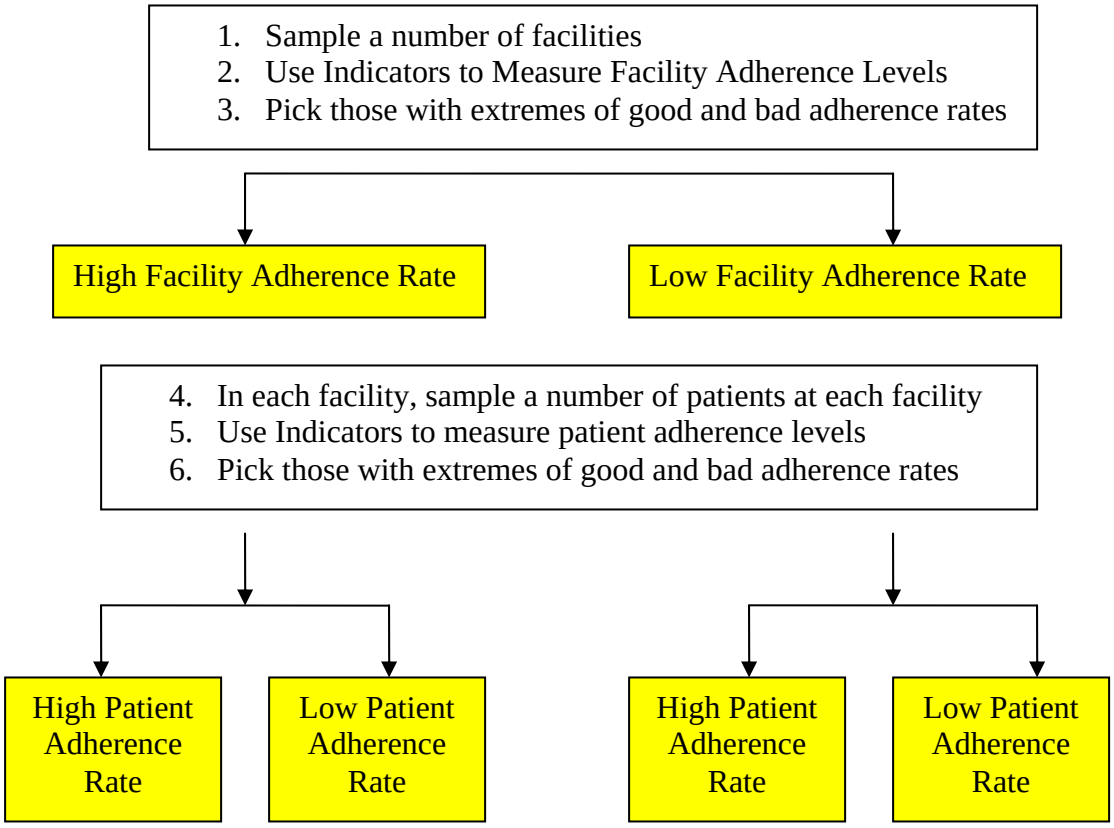
Objective 3: Measuring Determinants of Adherence

After much discussion it was decided that the strategic way forward was to focus on extremes of good and bad adherence at facility level and then at patient level as in the following diagram:

Diagram 1: Strategy for investigating determinants of adherence



Once we had found a sample of these four groups of patients a series of focus group discussions, in depth interviews and other qualitative techniques would be used to find out reasons for good and poor adherence rates.