

First Feasibility and Reliability Test of Indicators for Adherence to Antiretroviral Medicine: National Survey in Kenya, October 2–7, 2006

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ACRONYMS

ADR	adverse drug reaction
AIDS	acquired immunodeficiency syndrome
AMPATH	Academic Model for the Prevention and Treatment of HIV
ART	antiretroviral therapy
ARV	antiretroviral
CBO	community-based organization
CCC	Comprehensive Care Center
DAR	Daily Activity Register
DH	district hospital
FBO	faith-based organization
GOK	Government of Kenya
ICIUM	International Conference on Improving Use of Medicines [WHO]
INRUD	International Network for Rational Use of Drugs
MoH	Ministry of Health
MSH	Management Sciences for Health
MSF	Médecins Sans Frontières
NASCOP	National AIDS Control Program
OI	opportunistic infection
PEPFAR	U.S. President's Plan for Emergency AIDS Relief
PGH	provincial general hospital
RPM Plus	Rational Pharmaceutical Management Plus (Program) [MSH]
Sida	Swedish International Development Agency
STGs	standard treatment guidelines
TH	teaching hospital
USAID	U.S. Agency for International Development

BACKGROUND

In collaboration with national AIDS control programs, International Network for Rational Use of Drugs (INRUD) groups conducted a survey to ascertain the current practices in measuring and calculating adherence and defaulting behaviors by patients receiving antiretroviral (ARV) medicines in antiretroviral therapy (ART) programs as well as to find what data are 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 that provide ARVs in the five countries and with 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 dropouts vary considerably, if they exist at all. Fourteen different definitions of defaulting were used. Measurement at individual or facility level is haphazard, using various data sources and various methods of calculation. Nevertheless, as much information is recorded at both the clinic and pharmacy, a standardized measurement should be possible.

A regional meeting was held at the Imperial Resort Beach Hotel, Entebbe, Uganda, April 27–29, 2006, in which 38 participants took part. They came from Management Sciences for Health (MSH), the national AIDS control programs, and local INRUD groups who had coordinated the survey. The meeting was held to discuss findings of the ARV adherence survey and plan work to develop and validate reliable and feasible indicators of adherence.

Candidate indicators were suggested for the following: self-report from interviews or clinical records; nonadherence, based on missed days from pharmacy records; and defaulting, based on information from attendance registers. Other system indicators have been suggested for availability and stock-outs—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 was to test the feasibility and reliability of these candidate indicators in five sophisticated and five basic facilities in two countries. This report is on the first feasibility and reliability test, which was conducted in Kenya from October 2 to 7, 2006.

PROCEDURES

Facility Sampling

A list was obtained from the National AIDS/Sexually Transmitted Infections (STIs) Control Program of all country facilities that treated patients with ARVs. Only those treating at least 100 patients with ART in September 2005 were chosen. A further limitation was that for logistics reasons, the North East and Coastal Provinces were excluded. Those facilities remaining were chosen to obtain a mixture of levels of care, different programs, and logistics for data collection teams. Sites selected had been providing ART services for more than 12 months and served more than 100 ART patients. The sites selected are listed in Table 1.

Table 1. Site Selection

Site Names and Level of Care					
Geographic Location	Provincial Level	District Level	Health Center FBO/CBO/Private	Teaching and Referral	Pediatric-Only Sites
1. Central Province	Nyeri PGH	Thika DH	Nazareth Mission Hospital		
2. Western Province	Kakamega PGH	Busia DH	St. Mary's Mumias, Hospital		
3. Rift Valley Province	Rift Valley PGH	Kericho DH	Tenwek Mission Hospital	Moi Teaching and Referral Hospital	
4. Nyanza Province	New Nyanza PGH	Siaya DH	St. Monica Mission Hospital		
5. Eastern Province	Embu PGH	Meru DH	Mwea Mission Hospital		
6. Nairobi Province		Mbagathi DH	EDARP Kayole**	Kenyatta National Hospital	Lea Toto Kangemi Clinic (CBO)*
Total number of sites	5	6	6	2	1

*Alternate site: Gertrude's Garden Children Hospital (private)

**Reserve/alternative site: Riruta Health Centre

Pilot data collection sites during training: Kiambu DH (GOK only); Tigoni SDH (PEPFAR only)

FBO = faith-based organization; CBO = community-based organization; PGH = provincial general hospital;

DH = district hospital

Training

Three days were reserved to work with the team leaders to introduce them to the forms and then to visit different facilities to adapt the forms for the settings. Because this trial was the first, many adaptations were made to the forms. Standard lists of necessary ARVs and key

medicines for opportunistic infections (OIs) were drawn up based on national standard treatment guidelines (STGs) and previous survey data on frequency of OIs. This procedure gave the team leaders an understanding of the process of finding standardized solutions to different conditions. Probably the biggest problems were to find a way of sampling patients in the different systems. This issue is addressed in the sampling sections.

Three days were then reserved for training the data collectors. For the first day, after a general introduction, each team leader was assigned to introduce one instrument. Each column was discussed, in turn, with all the variations that one may find. The data collectors made a facility visit the next morning to witness a trial run of the whole data collection procedure. The forms were again gone over that afternoon in the light of that experience. Role-plays were used for the exit interviews. The morning of the third day also included a facility visit. Two facilities were visited (two teams to each) and the whole process was tried. These trials were discussed in detail that afternoon.

Data Collectors

The data collectors were all pharmacists or pharmacy interns.

Language

The language of discussion was mainly English. Translations of parts of the exit interviews were made into Swahili.

Logistics

Facilities

The National AIDS Control Program (NASCO) wrote to each facility chosen, informing it of our visit and requesting collaboration.

Each facility was phoned by an MSH staff member to ensure it was open on the planned day of visit and to find a phone number of a contact person working in the HIV clinic. Two days before the planned visit the team leader phoned the contact number to arrange times and introduce what we were doing.

Teams

The 12 data collectors were grouped into four teams on the second day of the training. The teams were used in the trial run on the third training day.

Contracts

Each data collector signed a contract spelling out duties and payments.

Transport

Four vehicles with drivers were hired for the week.

Hotels

MSH booked hotels with agreed rates. The team leaders were given the money to pay for the hotel bills for themselves and their team. It thus became the team leaders' duty to carry these funds.

Communication

Team leaders was given air time for their cell phones. Any problem with process or interpretation was communicated to the research coordinator (John Chalker) for a discussion, so any lesson could be passed on to the other groups. Each evening all team leaders communicated with the research coordinator.

Stationery

Each group had the following materials—

- A collection of forms (enough for each group member to do each task and a set of forms to give to the facility director if requested)
 - 15 facility forms; 10 exit interview procedures; 36 exit interview data forms; 10 recent and 10 long retrospective procedures; 36 recent and 36 long retrospectives data forms; 10 recent and 10 long-term patient identifier forms
 - Ten copies of the introductory letter from NASCOP

The total for all four groups was 40 letters from NASCOP; 60 facility forms; 40 exit interview procedures; 144 exit interview data forms; 40 recent and 40 long retrospectives procedures; 144 recent and 144 long retrospectives data forms; 40 recent and 40 long-term patient identifier forms.

- A clipboard for each member to write on
- Notebooks, pens, and pencils
- A large folder (one for each facility) to keep all forms for each facility
- A laptop computer with data entry forms for each facility

Data Entry

Each team carried a laptop computer. Each evening the day's data were entered on the computer.

On one day of the weekend after data collection (October 7 or 8), each group met to finalize its data collection. On the following Monday (October 9), we all met for a collective debriefing and final checking (sheet by sheet) of the data entry.

Each team leader wrote a short paragraph on his or her experience and problems faced at each facility.

FEASIBILITY AND RELIABILITY SURVEY

Four data collection instruments were developed for the following situations: facility interviews, patient exit interviews, recent attendance retrospective, and longer ago attendance retrospective. These were developed by the project coordinator and then during the week's preparation they were adapted and altered in light of experience.

Facility Interviews

A sample Facility Interview Form is in Appendix 2. The facility interview included questions on the days and hours the clinic is open and whether it is open at convenient times, such as evenings or weekends. The workload per clinician and per support staff was also calculated. The availability of private space for counseling and laboratory services for CD4 and viral load was noted. Then a list of key ARVs (Table 2) and non-ARV medicines (Table 3) that should be present in a well-functioning clinic was developed based on national treatment guidelines and the most common opportunistic infections. Whether these medicines were in stock at the time of the visit and the number of days over the last 90 days they had been in stock were noted.

Main Problems

The following problems came up—

- Finding the number of patients a week was not always as easy as we thought it would be. Sometimes we needed to count each patient (up to 1,500). This process took a long time. The suggested solution is to estimate the number of patients per page and multiply by the number of pages to get an approximation.
- Community workers were often attached to the clinic but not in the clinic. The solution was to note them but only to count the support staff in the clinic.
- Not all facilities had meaningful stock records (6/20 missing for ARVs and 9/20 for other medicines, see Table 5). In all cases, data collectors could determine if stock was available at that moment, but stock records were sometimes very complex, because stocks may be in one store and not another. Survey of the stock records should probably therefore be dropped because the data are not always available, are difficult to interpret, and can take a long time to gather.
- Another complication of the medicine availability situation was that in at least one facility, ARV medicines were free, but medicines for OIs were not free and were part of the cost-recovery scheme. We judged those medicines requiring patient payment to be “not available.”

Table 2. List of Key ARVs for Kenya

1	Lamivudine 150 mg tablet
2	Lamivudine syrup 10 mg/ml
3	Stavudine 40 mg capsule
4	Stavudine 30 mg capsule
5	Nevirapine 200 mg tablet
6	Nevirapine syrup 10 mg/ml
7	Efavirenz 200 mg tablet
8	Efavirenz 600 mg tablet
9	Efavirenz syrup 30 mg/ml
10	Zidovudine 300 mg tablet
11	Zidovudine 100 mg tablet
12	Zidovudine syrup 10 mg/ml

Note: If any of the ARVs were within combination tablets, they were counted as present.

Table 3. List of Key Non-ARV Medicines for Kenya

1	Acyclovir tablets 200 mg
2	Co-trimoxazole tablets 480 or 960 mg
3	Co-trimoxazole suspension 240 mg/5ml
4	Fluconazole tablets 150 or 200 mg
5	Ketoconazole tablets 200 mg
6	Erythromycin tablets 250 or 500 mg
7	Nystatin oral drops 10,000 IU/ml
8	Multivitamin tablets

Table 4 gives the consolidated data and Table 5 shows the indicators per facility. From tables 4 and 5 we can see that most clinics were open five days a week, but two were open only two days a week and only one in the evening or on weekends. The weekly patient loads were immensely variable (from 1,525 to 48). The patient load when looked at in terms of patients per hour per clinician or patients per support staff per week gives a much better idea of how busy the clinic is. An intervention that involves staff time is more likely to be acceptable where staff have more time available. Therefore, when the patients per hour per clinician are 0.6 more time is available than if it is 19.6. The average of 3.2 is one patient every 19 minutes or so per clinician. A similar variability exists with patients per support staff per week, averaging 32.6 but varying from almost 90 to 8.

Access to laboratory services and private counseling rooms was fine in all but two facilities. Needed antiretroviral medicines were almost universally present, the only exception being pediatric formulations when no children were being treated. In some facilities very few non-ARV medicines were available in the clinic. The patient could get the medicine but needed to go to another pharmacy window, thereby queuing twice.

Table 4. Key Results of Facility Questionnaire

Indicator	Average	Maximum	Minimum
Patient load/week	313	1,525	48
Hours/week	38.6	49	18
Patients/hour/clinician	3.2	19.6	0.6
Patients per week per support staff	32.6	89.5	8
Access to laboratory services	90%	NA	NA
Private adherence counseling rooms	90%	NA	NA
% ARVS in stock	93.3	100	83.3
% days ARVS in stock	85.5	100	58.3
% key non-ARV medicines in stock	86.2	100	37.5
% days key non-ARV medicines in stock	75.9	100	16.7
Convenient operation time (operate on weekends or evening)		One facility	

Note: NA = not applicable

Table 5. Consolidated Results of Facility Questionnaire

Indicator			11	12	13	14	16	17	18	19	20	21	
	Type of Facility	Programs	% ARVs Now in Stock	% Key Medicines Now in Stock	Average % Days ARVs in Stock	Average % Days Key Medicines in Stock	Weekly Number Patients	# Hours per Week	Convenient Times Y/N	Patients/ Hour/ Clinician	Patients/ Week/ Support Staff	Lab Present Y/N	Private Space Y/N
Facility 1	DH	Other	83	87.5	91.7	87.5	229.5	40	N	0.6	25.5	Y	Y
Facility 2	DH	GOK only	83	87.5	83.3	87.5	358	27	N	6.6	89.5	N	Y
Facility 3	PH	GOK only	92	88	91.7	91.7	196	40	N	19.6	39.2	Y	Y
Facility 4	PH	GOK + PEPFAR	92	100		97.8	229.5	32	N	3.4	34.2	Y	Y
Facility 5	FBO Hospital	GOK + PEPFAR	91	100	83.3	29.4	108	42.5	N	1.3	21.6	Y	Y
Facility 6	TH	PEPFAR Only	100	75			1525	36	N	2.1	34.7	Y	Y
Facility 7	FBO Hospital	GOK + PEPFAR	92	75	92	76	292	45	N	3.2	24.3	Y	Y
Facility 8	FBO Hospital	GOK + PEPFAR	83	100	—	—	102	45	N	0.8	10.2	Y	Y
Facility 9	DH	GOK + PEPFAR	92	100	—	—	405	45	N	2.3	45.0	Y	N
Facility 10	PH	GOK + PEPFAR	92	100	—	—	396	45	N	2.9	44.0	Y	Y
Facility 11	DH	GOK only	83	62.5	58.3	—	130	40	N	1.0	14.0	Y	Y
Facility 12	PH	GOK only	83	88	83	70	79	18	N	2.2	20.0	N	Y
Facility 13	FBO Hospital	GOK + PEPFAR	100	100	100	100	121.25	47.5	N	0.9	17.4	Y	Y
Facility 14	PH	GOK + PEPFAR	100	87.5	100	78.47	195	45	N	4.3	24.0	Y	Y
Facility 15	DH	GOK + PEPFAR	100	75	100	100	182	37.5	N	1.6	22.8	N	N
Facility 16	TH	GOK + PEPFAR	100	38	100	17	329	45	N	1.8	17.3	Y	Y
Facility 17	DH	GOK + MSF	100	100	100	—	650	37.5	N	2.8	46.0	Y	Y
Facility 18	NGO	PEPFAR only	100	85.7	98.8	—	400	42.5	N	2.3	57.0	Y	Y
Facility 19	Pediatric Clinic (NGO)	PEPFAR only	100	87.5	—	—	48	18	N	1.8	8.0	Y	Y
Facility 20	FBO Hospital	GOK + PEPFAR	100	87.5	100	—	292	49	Y	3.0	58.0	Y	Y
Average or %			93.3%	86.2%	91.6%	75.9%	313.4	38.88	5.0%	3.2	32.6	85.0%	90.0%
Maximum			100.0%	100.0%	100.0%	100.0%	1,525	49	—	19.6	89.5	—	—
Minimum			83.3%	37.5%	58.3%	16.7%	48	18	—	0.6	8	—	—
Median			91.7%	87.5%	95.2%	87.5%	229.5	41.25	—	2.2	24.9	—	—

Notes: FBO = faith-based organization; PGH = provincial general hospital; DH = district hospital; TH = teaching hospital; GOK = Government of Kenya; PEPFAR = U.S. President's Emergency Plan for AIDS Relief; NGO = nongovernmental organization; MSF = Medecins Sans Frontieres. Blank cells indicate no data were collected.

Exit Interviews

The survey was designed for 30 exit interviews per facility, with the main indicator being a self-report on adherence in recent days, and to collect other factors affecting adherence, such as the time to clinic, time spent in clinic, adverse drug reactions (ADRs), whether medicines are labeled correctly, and whether the patient has correct knowledge on taking medicine. (See Appendix 3 for exit interview instructions.)

A standard introduction in the relevant language was worked out and practiced. To find out about adverse drug reactions, the five main ADRs were chosen from MSH Kenyan data (Table 6). Strategies for asking about these symptoms over the last week were discussed and agreed on. The definition of properly labeled included each medicine's being in a separate container or envelope with the medicine's name, dose per time, and number of times per day written on it.

Table 6. Adverse Drug Reactions

ADR	Symptom to Ask About
Peripheral neuropathy	Pain, numbness, tingling in legs or feet
Rash	Rash
Lipodystrophy	Change of fat distribution, such as enlarged breasts; buffalo hump; loss of fat tissue in face, buttocks, legs
Hepatotoxicity	Jaundice, yellow eyes
Gastrointestinal tract toxicity	Nausea, vomiting, diarrhea

Logistical Problems

Logistically, four issues arose—

- The first issue was to know which patients to interview. Only those patients on ARVs who were not just starting on ARVs were needed. The solution turned out to be to ask the pharmacist to ask the patient to report for an interview. This procedure was quite easy and did not appear to cause problems. In all cases the interviews were voluntary; only one or two patients refused.
- The second issue was to get the requisite number of interviews. If each interview took 10 minutes, then 30 interviews represent five hours of work. In many facilities the patients are only there in the morning. Thus, two or three team members should be engaged in patient interviews early in the day (while the selected records are being collected). This procedure means that more than one place for interviews needs to be arranged.
- The third issue is the logistics of the interview itself. It is easiest to carry out at a table or on a bench, so that the interviewer can hold the data entry sheet and the patient's medicines, as appropriate. If three interviewers are working at the same time, three places of relative privacy must be found. This requirement can stretch the ability of small facilities.

- In some facilities, very few patients came. Ensuring the data collection is scheduled for a day when patients are expected is important.

Language Problems

It was decided that most patients would speak Swahili, so that was the agreed language practiced. In fact, many of the data collectors did not speak very good Swahili.

Reliability Interviews

Three patients were interviewed by two different people in each facility to check for reliability of each question. This procedure meant that the first record created would have to be compared with the second record in each case. The second interviewer had to write a patient identifier, such as “E6” if it was Edwin’s sixth patient, and so on.

The reliability surveys showed that many questions were not reliable. In particular, the ADRs could be 100 percent different. Clearly, questioning about ADRs needs much more practice in training to become standardized. The other big difference was in terms of time to clinic and time in clinic. Actual practice of the arithmetic is needed.

Results

Table 7 gives the consolidated indicators overall, and Table 8 gives the data per facility. At an average of 20 per facility, 373 interviews were managed. In two facilities, very few patients appeared on the day of the visit; in another facility, no patients came. Clearly, ensuring the survey is conducted on a scheduled day for treating patients on ARVs is important.

The interviewees were an average age of 35.4 years (maximum 43 and minimum 7), and 61 percent were female. On average, they had been on treatment for 14 months (maximum 34; minimum 4.7). The main adherence indicators of self-report showed that an average 95 percent of patients claimed full adherence over the previous three days, (with facilities ranging from 100 percent to 80 percent), with an average of 97 percent of doses taken (ranging in facilities from 100 percent to 83 percent).

Table 7. Selected Results of the Exit Interviews

Indicator	Average	Maximum	Minimum
Self report: full adherence (%)	95.2	100	80
Average adherence (%)	97	100	83.8
Able to do normal activity (%)	80.7	100	33.3
Average travel time to clinic (minutes)	167	496	42
Average time in clinic (minutes)	80	186.7	40.7
Know ARV dosage (%)	98.1	100	86.7
Med. properly labeled (%)	79.1	100	24.1
All ARVs dispensed (%)	100	100	100
All non-ARVs dispensed (%)	75.3	100	13.3
ADR occurrences (%)	61.7	85	0

Travel time and time in clinic are averaging more than 2 and a half hours and 1 hour 20 minutes, respectively. This time commitment on the part of the patient is quite large. One patient traveled from Mombassa to the Rift Valley so that no one would recognize her. Most patients knew their regimen and all had their ARVs dispensed. Many medicines were not properly labeled, however. Labeling was defined as the medicine being in a separate container that has the name of the medicine and when to take it. Not all non-ARV medicine was dispensed because in some instances the patient had to go to a different pharmacy to acquire the medicine, on some occasions through insurance and on others by self-purchase.

Table 8. Composite Results of the Exit Interviews

Indicator		22	23	24	25	15	15	26	1	2				
Facility	Number of Interviews	Average Age	Average % Female	% of Normal Activity	Average Months on Treatment	Average Time in Travel	Average Time in Clinic	% Know ARV Dosage	% Medicines with Good Labels	% ARVs Dispensed	% Non-ARVs to Be Dispensed	% of ADR	% Self-Reported Full Adherence	Average Adherence
1	29	37.3	55.2	89.7	22	267	97	100.0	24.1	100.0	93.1	72.4	100.0	100.0
2	30	36.9	63.3	70.0	8	307	96	100.0	100.0	100.0	50.0	76.7	100.0	100.0
3	27	40.6	59.3	74.1	10	187	68	100.0	100.0	100.0	88.9	74.1	100.0	100.0
4	0	—	—	—	—	—	—	—	—	—	—	—	—	—
5	20	37.4	80.0	90.0	9	202	65	100.0	100.0	100.0	90.0	85.0	95.0	97.5
6	30	34.0	73.3	80.0	34	43	60	100.0	100.0	100.0	96.7	66.7	90.0	97.8
7	17	37.1	64.7	76.5	15	161	83	94.1	94.1	100.0	100.0	58.8	94.1	94.1
8	3	34.0	0.0	100.0	6	240	80	100.0	66.7	100.0	100.0	33.3	100.0	100.0
9	13	34.8	69.2	84.6	14	116	42	100.0	92.3	100.0	76.9	76.9	100.0	100.0
10	30	39.2	53.3	90.0	14	245	71	96.7	100.0	100.0	76.7	60.0	93.3	98.3
11	21	13.3	47.6	95.2	6	152	82	95.2	100.0	100.0	71.4	47.6	100.0	100.0
12	30	40.6	50.0	46.7	11	224	94	100.0	56.7	100.0	86.7	60.0	93.3	98.3
13	3	42.3	33.3	33.3	5	165	150	100.0	66.7	100.0	100.0	0.0	100.0	100.0
14	20	38.4	50.0	70.0	13	496	98	100.0	80.0	100.0	30.0	40.0	90.0	95.0
15	15	37.7	46.7	93.3	5	59	74	86.7	60.0	100.0	13.3	66.7	80.0	67.8
16	20	33.4	65.0	90.0	15	134	68	95.0	65.0	100.0	30.0	40.0	95.0	95.0
17	21	33.5	90.5	95.2	13	237	85	95.2	61.9	100.0	85.7	61.9	90.5	95.2
18	29	32.4	79.3	86.2	11	216	41	100.0	75.9	100.0	100.0	58.6	96.6	93.1
19	3	7.3	66.7	100.0	5	175	47	100.0	100.0	100.0	100.0	66.7	100.0	100.0
20	12	43.1	33.3	75.0	19	276	187	100.0	41.7	100.0	58.3	33.3	100.0	100.0
Total	373	—	—	—	—	—	—	—	—	—	—	—	—	—
Average or %	19.6	35.4	38.6%	80.7%	14.0	167	80	98.1%	79.1%	100.0%	75.3%	61.7%	95.2%	96.8%
Maximum	30	43.1	90.5%	100.0%	34.0	496.3	186.7	100.0%	100.0%	100.0%	100.0%	85.0%	100.0%	100.0%
Minimum	3	7.3	0.0%	33.3%	4.7	42.5	40.7	86.7%	24.1%	100.0%	13.3%	0.0%	80.0%	67.8%
Median	20	37.1	59.3%	86.2%	11.4	202.2	80.0	100.0%	80.0%	100.0%	86.7%	60.0%	96.6%	99.2%

Recent Retrospective

For the recent retrospective, the survey is most interested in the clinical notes. The main purpose of the recent retrospective sample is to look at missed appointments and recapture rate (that is, whether the patient who missed came back within 60 days of the missed appointment). In addition, adherence through self-report, pill count, or both can be followed, if it is recorded in the notes. Other aspects of clinical care are noted, including any ADRs (as defined Table 6); the CD4 testing rate (percentage of patients with documented CD4 test results in last three months); the percentage of patients achieving CD4 count > 300 cells per μ l on most recent lab test; the percentage of patients with a documented viral load test in the last three months; and the percentage of patients achieving viral load counts < 400 copies per ml on the most recent lab test in last three months.

The data collectors selected a sample of 120 patients from the patient register for the month that ended 60 days prior to the date of data collection (that is, for collection in October, we looked at patients who attended in July). (After the first visit, where a number of clinic records were still with the data-entry people, we changed this sample to the month that ended 90 days prior to the date of data collection.)

The patient identifier sheets were used to record the patient identifier number and date of visit. We used three sheets of 40 patients each so that the data-entry clerk could be collecting the first 40 while the others were being selected. The instructions for sample selection were to determine the number of pages of patients attending that month (for example, July in the first visit) and divide that number into 120 to determine the number of patients to choose randomly per page. We needed 120 in case the patients were untraceable. Ultimately, a 100-patient sample was needed. If pediatric and adult patients were recorded in different attendance registers, numbers proportional to the relative number on ART in that program were chosen.

Problems found were—

- There was no attendance register. In this case, the pharmacy records or the appointment book was used.
- Data collectors could not tell which patients were on ARVs. Again, the pharmacy records or the ARV appointment book was used.
- In some cases data on next appointment attended were not possible to follow. When patients had 90-day intervals between appointments, the next appointment was after the day of data collection. In one facility that had 60-day intervals between appointments, the information was not always available in the clinical notes because they had been removed for data entry into a computer. As a result, suggested changes were to go back a month earlier, using the month ending 90 days prior to data collection, note number of days till next appointment, and follow recapture rate for 30 days after missed appointment (not 60 days from index visit).

Reliability Interviews

Five patient records were processed by two different people in each facility to check for reliability of the extraction process.

The reliability surveys showed that some areas of extraction were not reliable. In particular—

- The judgment about whether an OI or ADR had occurred in the last three months was varied. This result seems to occur because such data can be written anywhere. As a result, some collectors found relevant data and others did not. Also, data collectors need to interpret the data to determine whether symptoms indicate an ADR.
- The number of months on treatment also varied. This result seems to occur because in different note systems this information is recorded in different places. As a result, some collectors found relevant data and others did not. A difference exists between when the patient first came to the clinic and when he or she was put on ARVs. Data collectors interpreted the notes differently.

Results of Recent Retrospective

In the 20 facilities, 1,265 records were examined, which is an average of 63 per facility. Of these, 978 were classified as experienced patients (≥ 3 months) and 287 as new patients (< 3 months). The average age was 35 years (range of 8–43 years) and 64 percent were female (range of 38–78 percent). Nine percent had an OI at the index visit (range 0–21 percent) and 20 percent had an ADR since the index visit (range 1–37 percent). Twenty-one percent had had a CD4 count since the index visit (range 0–100 percent), with 56 percent showing 300 cells per μl (range 0–100 percent) or more. Only 4 percent had had a viral load test.

For the self-report, 608 of 1,265 records showed the data. Full adherence was recorded in 96.2 percent of these cases (range 100–87.5 percent), and average adherence was 98.9 percent (range 100–87.5 percent). Pill count was recorded in only 150 cases (of 1,265 total). Full adherence was recorded in 71 percent of these cases (range 100–57.1 percent), and average adherence was 63 percent (range 99–0 percent).

The results of attending or not attending the next appointment are as follows: 77.6 percent (range 96–46 percent) attended their next appointment on the exact date or before. Of those who missed, 88.2 percent (100–0 percent) appeared within 60 days of the index visit, and 11.8 percent (100–0 percent) did not. However, because of recording errors in the notes, interview intervals being longer than available time, and absence of notes that were awaiting data entry; these results reflect more on program patterns than patient behavior. In the future, the survey team should go back a month earlier to that ending 90 days prior to data collection, note the number of days till the next scheduled appointment, and follow the recapture rate for 30 days after a missed appointment (not 60 days from index visit). In addition, data collectors will record whether the patient came back within three days of a missed appointment.

Table 9. Data Consolidation for Recent Retrospective

Indicator	All							26	27	28	29	30
Facility	Number of Patients Recorded	Number of Experienced Patients	Number of New Patients	Average Months on Treatment	Average Age	% Female	% OIs	Since Index Visit				
								% Symptom of ADR (# Ys)	% CD4 Test	% CD4 > 300 Cells per µl	% Viral Load Test	% Viral Load < 400 Copies per ml
1	38	35	3	14.1	31.4	76.3	5.3	10.8	39.5	60.0	0.0	—
2	50	46	4	9.8	41.3	46.0	6.0	5.0	0.0		0.0	—
3	31	21	10	4.7	42.5	64.5	0.0	25.8	3.2	100.0	0.0	—
4	58	45	13	9.7	31.9	53.4	5.4	23.1	28.3	50.0	6.7	50.0
5	74	38	36	6.2	40.4	73.0	5.9	23.9	4.1	66.7	0.0	—
6	99	76	23	13.2	37.2	63.6	12.2	16.5	22.7	48.3	1.0	0.0
7	60	44	16	7.8	35.7	68.3	6.7	35.0	23.3	57.1	0.0	—
8	96	79	17	11.3	35.5	46.9	15.6	1.1	100.0	—	—	—
9	98	87	11	12.1	31.9	57.1	6.2	24.7	29.6	72.4	20.4	75.0
10	100	76	24	8.0	36.5	70.0	7.8	22.0	7.0	71.4	0.0	—
11	51	42	9	9.7	39.3	62.7	11.1	9.8	13.7	42.9	0.0	—
12	86	75	11	11.8	36.5	70.6	10.5	18.6	1.2	0.0	0.0	—
13	91	50	41	3.4	37.5	70.3	4.4	2.2	7.7	28.6	0.0	—
14	77	62	15	12.4	38.0	76.6	20.8	29.9	42.4	40.0	6.5	0.0
15	53	31	22	7.6	31.6	67.9	11.3	18.9	17.0	88.9	0.0	—
16	—	—	—	—	—	—	—	—	—	—	—	—
17	24	20	4	5.8	37.3	50.0	4.2	29.2	58.3	28.6	0.0	—
18	76	64	12	11.4	32.7	72.4	14.5	36.8	40.8	61.3	0.0	—
19	58	45	13	8.9	8.2	37.9	8.6	24.1	27.6	68.8	22.4	0.0
20	43	40	3	14.2	31.9	72.1	9.3	28.6	54.8	50.0	0.0	—
Average	63.2	48.8	14.4	9.8	34.7	—	—	—	—	—	—	—
Percent	—	77.2%	22.8%	—	—	63.7	9.2	19.7	21.1	56.3	3.7	38.1
Maximum	100	87	41	14.2	42.5	76.6	20.8	36.8	100.0	100.0	22.4	75.0
Minimum	24	20	3	3.4	8.2	37.9	0.0	1.1	0.0	0.0	0.0	0.0
Median	60	45	13	9.7	36.5	67.9	7.8	23.1	23.3	57.1	0.0	0.0

Long Retrospective

For the long retrospective, the survey is most interested in the pharmacy records. The main purposes for this sample are to look at the dispensing record over the last 12 months (or 10 months or 6 months). In other words, we are looking at the number of days of ARVs dispensed in a set number of days. Coupled with this information, the survey is looking at whether patients are still on treatment at the end of the year and whether they have had a gap of 30 days or more in their medicine over the year.

If recorded, the following data were also noted: pill count between the patient's latest two visits, whether the patient has had any ADRs or OIs in the last 6 months, whether the patient has had CD4 or viral load tests in the last 6 months, and if so whether clinical milestones were achieved. These latter were recorded only if in the pharmacy records.

Opportunistic infections were defined as one of the six in Table 11, which are the most commonly recorded OIs in Kenya.

Table 11. Opportunistic Infections

	Condition	Acronym
1	Tuberculosis	TB
2	Oral or esophageal candidiasis	OC
3	Cryptococcus meningitis (Indian ink positive)	CM
4	Pneumocystis carinii pneumonia	PCP
5	Fungal skin infections	FSI
6	Bacterial skin infections	BSI

Methods and problems in selection were the same as for the recent retrospective. The difference was that patients attending 13 months ago were looked at (so for October 2006, the survey looked at patients who attended in September 2005). In some cases, facilities had changed their record-keeping system some months before. To accommodate this issue, if the system had changed 10 months before the date of the visit, then the last 10 months (310 days) were looked at rather than 365 days. In other cases, no clinical attendance register was found; in those cases, the MSH dispensing software was used to extract and sample patients who attended in September 2005 and then examine their records.

Results for Long Retrospective

An average of 50 records per facility were examined, or a total of 986 records. Of these, 583 were experienced patients (≥ 3 months) and 348 were new patients (< 3 months) (55 unknown). They averaged 33.4 years of age (range 9–41 years), and 62 percent were female (range 33–79 percent). In the last six months, 13 percent had an OI (range 0–26 percent) and 30 percent an ADR (range 5–48 percent). Forty-six percent had had a CD4 count (range 7–88 percent), 61 percent of which had more than 300 cells per μl (range 20–79 percent). Only 6 percent had had a viral load test since the date of the index visit, of which 53 percent had viral loads less than 400 copies per ml. Only 11 percent had a pill count recorded.

Overall for the 986 patients, only 82 percent of days over the year were covered by dispensed medication. However, if we look at only those 86 percent (range 100–69 percent) still in treatment at the end of the year, this figure rises to 92 percent. Similarly, 26 percent had a gap in treatment of more than 30 days. However, looking at only those still on treatment, this figure is reduced to 12 percent.

Only 79 percent (range 100–25 percent) attended their next appointment on or before the exact day. Of those who missed, 76 percent reattended within 60 days.

Problems with Method

- Sample selection was not always easy because records of who attended were not always clear.
- This method is strong but relies on accuracy of data entry. Problems with coverage may be real or may be an artifact of record-keeping. Certainly with the dispensing tool, omissions in data entry were found when it was not being used in real time for dispensing. The other error found was when the computer was set on an American date system. Then dispensing was being wrongly entered as 9 July (7/9/2006) rather than 7 September, for example.
- Where pharmacy records were included in clinical records, extracting data from one patient's notes could take as long as 15 minutes. At that rate, examining 100 records would be impossible. Simplification may be needed. It sometimes took a particularly long time to check for months on treatment, OIs, and ADRs. In future tests (after Rwanda), we should simplify the form. We could exclude OIs and ADRs and only decide if the patient is new or experienced.

The Reliability Survey

The reliability surveys showed that some areas of extraction were not reliable. In particular—

- The judgment of whether patients had an OI or ADR in the last three months varied. This seems to be because such data can be written anywhere and needs interpretation as to whether it is an ADR or not. As a result, some collectors found relevant data and others did not.
- Number of months on treatment varied a lot. This seems to be because in different note systems this information is recorded in different places. There is a difference between when the patient first came to the clinic and when he or she was put on ARVs. Data collectors interpreted the notes differently.

Table 12. Long Retrospective Data Consolidation

Indicator				3			4	5	5	6	7		
Facility	Number of Patients	Number of Experienced Patients	Number of New Patients	Average Months on Treatment	Average Age	% Female	% Days Covered by Medicine in a Year	% Days Covered by Medicine if Still in Treatment	% > 95% Days Covered	% with Gap in Medicines > 30 Days	% with Gap in Medicines > 30 days if Still in Treatment	% Attended Next Appointment	If Missed, % Attended in Next 60 Days
1	48	31	17	6.9	37.1	68.8	97.1	98.3	83.3	2.1	0.0	95.8	100.0
2	33	25	8	6.0	36.4	51.5	75.4	81.2	82.1	17.9	14.8	87.5	0.0
3	39	26	13	6.5	38.3	56.4	54.8	73.2	78.3	8.7	0.0	94.4	0.0
4	50	34	16	8.2	29.7	50.0	77.9	96.2	61.7	38.3	24.3	84.2	100.0
5	32	23	9	8.3	39.3	56.3	74.9	85.0	100.0	0.0	0.0	78.6	100.0
6	33	17	16	5.6	34.1	72.7	25.2	53.3	12.1	78.8	42.9	44.4	14.3
7	65	30	35	3.5	35.0	75.4	84.5	100.0	61.5	26.2	2.8	87.5	75.0
8	62	—	—	0.0	32.7	49.1	78.7	83.0	14.5	60.0	56.0	25.0	79.1
9	99	66	33	6.1	32.6	63.6	79.8	92.8	45.5	40.4	24.0	76.8	87.5
10	100	58	42	6.7	35.8	61.0	84.3	92.5	57.0	26.0	14.1	68.0	66.7
11	54	27	27	5.2	40.6	63.0	98.8	99.2	81.5	5.6	3.8	93.2	75.0
12	34	25	9	10.9	39.4	79.4	96.7	98.1	73.5	14.7	15.6	91.2	100.0
13	6	6	0	12.8	36.2	33.3	92.5	92.5	16.7	0.0	0.0	100.0	—
14	22	10	12	6.5	22.4	72.7	97.1	97.2	59.1	36.4	33.3	63.6	100.0
15	34	27	7	9.3	41.4	61.8	92.8	96.3	76.5	8.8	3.3	91.2	100.0
16	100	52	48	3.0	32.5	60.0	79.1	98.7	58.6	30.6	8.5	83.7	75.0
17	32	21	11	9.4	34.4	59.4	54.1	56.4	100.0	5.9	0.0	80.6	87.5
18	64	42	22	5.5	31.6	65.6	89.6	95.4	58.7	28.6	18.5	76.6	93.3
19	45	32	13	4.5	8.7	57.8	97.2	98.0	68.9	8.9	9.1	100.0	—
20	41	31	10	9.8	31.6	63.4	91.8	94.9	63.4	14.6	12.8	77.5	88.9
Total	986	—	—	—	—	—	—	—	—	—	—	—	—
Average	49.3	29.2	17.4	6.0	33.6	—	—	—	—	—	—	—	—
Percent	—	59.1%	35.3%	—	—	62.1	81.6	91.9	60.4	26.3	12.3	79.0	75.5
Maximum	100	66	48	12.8	41.4	79.4	98.8	100.0	100.0	78.8	56.0	100.0	100.0
Minimum	6	6	0	0.0	8.7	33.3	25.2	53.3	12.1	0.0	0.0	25.0	0.0
Median	43	27	13	6.5	35.4	61.4	84.4	95.1	62.6	16.3	11.0	83.9	87.5

Table 13. Long Retrospective Data Consolidation Form 4 (2) All

Indicator	26	26	27	28	29	30	31	32	34		
	Reported in the Last Six Months							In Last Two Reported Appointments			
Facility	% Any Dispensing in Last 60 Days?	% Symptom of OI	% Symptom of ADR	% CD4 Test	% CD4 > 300 Cells per µl	% Viral Load Test	% Viral Load < 400 Copies per ml	% Records with Pill Count	% of Pill Count Full Adherence	Pill Count Adherence Average % Recorded	% Achieve > 95% Coverage
1	95.8	16.7	47.9	87.5	61.9	0.0	—	97.9	85.1	98.0	89.4
2	93.8	7.4	17.9	6.9	50.0	0.0	—	0.0	—	—	—
3	93.3	3.6	40.7	48.1	41.7	0.0	—	0.0	—	—	—
4	74.0	26.3	37.9	34.1	71.4	2.1	0.0	0.0	—	—	—
5	90.0	7.4	34.6	7.4	50.0	0.0	—	31.3	80.0	0.0	0.0
6	—	7.1	7.7	31.6	66.7	0.0	—	42.4	71.4	7.1	7.1
7	69.2	11.8	30.3	48.3	66.7	0.0	0.0	35.4	60.9	94.9	78.3
8	90.9	—	—	—	—	—	—	0.0	—	—	—
9	75.8	—	—	—	—	—	—	0.0	—	—	—
10	85.0	—	—	—	—	—	—	0.0	—	—	—
11	96.3	18.0	24.1	51.9	57.1	0.0	—	0.0	—	—	—
12	94.1	3.0	30.3	15.2	20.0	0.0	—	0.0	—	—	—
13	100.0	0.0	33.3	33.3	50.0	0.0	—	16.7	100.0	100.0	100.0
14	95.5	9.1	9.1	18.2	50.0	4.5	0.0	0.0	—	—	—
15	88.2	11.8	32.4	29.4	20.6	0.0	—	0.0	—	—	—
16	73.5	—	—	—	—	—	—	0.0	—	—	—
17	93.5	0.0	37.5	50.0	40.0	0.0	—	18.8	50.0	93.6	66.7
18	85.9	20.3	44.1	67.8	58.5	0.0	—	9.4	83.3	58.9	50.0
19	97.8	20.5	27.3	70.5	71.0	68.2	60.7	0.0	—	—	—
20	95.1	12.5	5.0	47.5	78.9	0.0	—	22.0	77.8	95.8	77.8
Percent	85.8	12.6	30.3	45.7	60.7	5.7	53.1	11.8	75.9	82.7	65.5
Maximum	100.0	26.3	47.9	87.5	78.9	68.2	60.7	97.9	100.0	100.0	100.0
Minimum	69.2	0.0	5.0	6.9	20.0	0.0	0.0	0.0	50.0	0.0	0.0
Median	93.3	10.4	31.3	40.8	53.6	0.0	0.0	0.0	78.9	94.3	72.2

CONCLUSION

As a first trial of feasibility and reliability, the survey uncovered a great deal of information. The four instruments were all basically sound, allowing data to be collected, although self-report was recorded only in just under half the cases and pill count in about 12 percent of patients. The reliability data have given areas to concentrate on harder during data collection training.

Self-report is always possible from exit interviews. Patient attendance at next appointment and recapture rate are possible to obtain from both the clinical notes of the recent retrospective and the pharmacy records for the long retrospective, as long as the right periodicity is used. The number of days covered by dispensed medication over a set number of days proved possible to measure, as did whether a gap existed in treatment of 30 days or more and whether patients were still in treatment at the end of the year. These data are the main candidates for proxy indicators of adherence. They will need to be tested for validity in the next phase of the project.

We now have formulated instruments, data entry forms, and analysis spreadsheets. The next step is to test these products again in another environment. Rwanda is planned for November 20, 2006. With that data, we can plan a major simplification and testing with less supervision in other of the East African countries.

APPENDIX 1. TEAM LEADER DESCRIPTIONS OF THE PROCESS AT EACH FACILITY

Group 1

Team leader: Patrick Boruett

Data collectors: Joyce Mbithi, Evans Mwangangi, James Owour-Siaya

Facility 1: District Hospital

This hospital is a government institution with three programs for providing ART: Government of Kenya (GOK), the Academic Model for the Prevention and Treatment of HIV (AMPATH), and Médecins Sans Frontières (MSF) Spain. MSF Spain has 2,600 patients enrolled in its program, which started in 2001, but is not taking any others. From October 2005, a new cohort of 554 patients represents those enrolled in the GOK program. All new patients from June 2006 are being registered in the AMPATH program.

Sampling of patients on ARTs in September 2005 and July 2005 was done using computer printouts provided by MSF and the Ministry of Health (MoH). A sampling ratio of 5:1 was used for the MSF and GOK programs. All services are provided at the Comprehensive Care Center (CCC).

The District Hospital is situated a few meters from the Kenya-Uganda border and serves patients not only local people but also those from the neighboring districts. The hospital's CCC is open to all patients from Monday to Friday, 8 a.m. to 5 p.m. The clinic serves approximately 110 patients every week on average. The clinic has one doctor/consultant, five clinical officers, one pharmacy technologist, three nurses, one nutritionist, one social worker, three counselors, and four home-based care workers.

Challenges: Printouts of the patient list included those on treatment as at September and not necessarily those who collected medicine in the specified period. Most of the files in the GOK program were not available.

Comments: The programs have comprehensive information in the clinical records. Pill count is done and recorded on prescriptions that are filed in clinical records. Self-reported adherence is also documented. Patients with missed pills of over 5 percent are referred to adherence counselors.

Facility 2: District Hospital

Most of the files were missing clinical records, and some files did not have records for the index visit (even whether the patient had been to the clinic). On counter-checking these records and comparing them with the pharmacy records, the same patients had regularly collected their medication! The explanation given for this mix-up was that the clinic usually gets overwhelmed and in the rush to serve its patients not all clinical records are filled. The biggest dilemma was deciding how to interpret records for a patient who attended every month and collected medicines every four weeks but whose records are missing. Most of the indicators were filled in as missing.

Facility 3: Provincial Hospital

Sampling was done from the clinic visit register. Pharmacy records could also have been used. Manual records on dispensing are maintained at the facility. The clinic records are complete. Specific appointment dates are not on clinic record.

The medical records were easy to retrieve; they are updated regularly with complete clinical notes. The prescriptions are filled in pharmacy. The pharmacy is used for both the main hospital and the CCC, but ARV patients are asked to come into the pharmacy. Records of September 2005 through March 2006 had been sent to NASCOP; hence copies were not readily available.

Facility 4: Provincial Hospital

Program: PEPFAR and GOK

ARVs and OIs medicines are dispensed separately for each program. The MSH dispensing tool is used to dispense medicines in both programs. The sampling was done using patient transactions for September 2005 and June 2006. A sampling ratio of 2:1 (GOK:PEPFAR) was used. The clinic register for PEPFAR did not distinguish between patients on ARVs and those with OIs.

Challenges: Exit interviews were not done because Thursday is reserved for multidisciplinary meetings. Clinical records for July 2006 to September 2006 were not in clinical files; they had been taken for scanning and data entry at the CDC facility. Record-keeping staff had to leave for a meeting so we had to pick the files ourselves.

Facility 5: Mission Hospital

The total number of cumulative patients on ARVs is about 280. The facility serves 15–20 patients per day on ARVs. The records are well kept, and all the data asked for in the clinical records data sheets were filled in. Neither clinical nor pharmacy records are computerized.

We sampled using the clinic attendance register, which indicated whether a patient is on ARVs. The hospital uses both a CCC and ART number (for patients on ARVs). We removed the files ourselves because of shortage of staff. Because the dispensing records used sometimes the CCC and sometimes the ART number for the same patient, tracking patients was difficult. Dispensing was done for 30 days.

Summary of Records Completed

Facility	Exit Interview	Reliability Exit	Recent	Recent Reliability	Long	Long Reliability
Facility 1	29	4	40	5	48	3
Facility 2	30	4	50	4	33	0
Facility 3	32	3	31	5	39	5
Facility 4	0	0	63	5	54	4
Facility 5	20	4	75	5	34	5

Group 2

Team leader: Dr. Susan Gichuki

Data collectors: Peter Nguhi, Michael Kochola, Edwin Barasa

Facility 6: Teaching and Referral Hospital

The program serves the hospital and 15 satellite centers. A meeting was in progress when we arrived; it therefore took us one hour to get started (9 a.m.) because all the relevant personnel were in attendance. The database contains data from all the 16 facilities; therefore retrieving data only on the hospital took longer. The pharmacy record keeping was poor, so we had to use clinical records.

Clinical data were missing from the files for the last three weeks or more because records were with the computer department. As a result, many patients were classified as missing their next appointment when in fact they may well have attended.

Facility 7: Mission Hospital

The facility uses both a software application (Careware) to manage clinical records and the MSH dispensing tool to keep pharmacy records.

Because of the unreliability and unavailability of the data in the MSH dispensing tool, which had been used since January 2006, we used the manual clinical records to get data for both the recent and long retrospective data. The Careware clinical tool was made available later in the day for use in the long retrospective.

Retrieving records through the staff was slow, and most of the files that we had selected were missing or did not contain the index date.

Facility 8: Mission Hospital

The initial plan was to visit Facility 9 on Wednesday and this one on Thursday, but because of the travel logistics we changed this schedule around. The change interfered with exit interviews because this facility was to have more ART patients attend clinic on Thursday and Facility 9 was to have more patients on Wednesday.

We were an hour late because we used the shorter but extremely terrible road. Nevertheless, the staff were supportive, and the data were accessible from the dispensing tool and the manual clinical records. The dispensing tool was, however, very unreliable because of poor data entry. We did only three exit interviews, one with an interviewee who could not communicate in English or Swahili.

Facility 9: District Hospital

The records were easily accessible from the dispensing tool (long retrospective) and the manual clinical records, and we did the random selection using the tool for clinical records. The exit interviews were, however, not very successful because of the unavailability of a room in an accessible and convenient place for the patients. As a result, we missed some

patients. We later got a room next to the pharmacy, but only one person could do the interviews.

Facility 10: Provincial Hospital

We did the random selection for both long and short retrospective using the attendance register. For long retrospective, however, we had to do another selection for November 2005, using the dispensing tool, because after September 2005, a change of recording system made records hard to find.

Data for the long retrospective was accessed from the dispensing tool, while data for the short retrospective was accessed from the manual clinical records. The operation was smooth.

Summary of Records Completed

Facility	Exit Interview	Reliability Exit	Recent	Recent Reliability	Long	Long Reliability
Facility 6	30	5	99	4	33	0
Facility 7	17	5	60	5	65	3
Facility 8	3	0	96	3	62	0
Facility 9	13	0	98	4	99	0
Facility 10	30	1	100	2	100	0

Group 3

Team leader: Lillian Gitau

Data collectors: Dr. Jacinta Mukonzo, Dr. Mburu Mwangi, Dr. Evans Mwangangi

Facility 11: District Hospital

Program: GOK

Sampling: We used the Daily Activity Register (DAR) for the long retrospective. The attendance register records both the ARV and non-ARV patients, but which patients were on ARVs was clearly marked. The sampling was only for those that were on the ARVs. There were a total of 13 pages, and nine patients per page were sampled. The clinic ran for four days a week a year ago and five days a week currently. For the recent retrospective, the pharmacy register was used because the clinic had no attendance record. A total of 10 patients were sampled per page.

Challenges: All data for the long retrospective survey were found in the clinical records because the pharmacy had no records. The ADR and OI information was found only in the clinical notes.

The Medical Superintendent raised a concern about patient's consent for the interview. He suggested that it should have been included on the tool. He also requested feedback from the study.

No pill counts or self-reports were recorded. At each appointment 30 days of medicines were given to a patient, but appointment dates were less than 30 days apart. Therefore, the total quantity dispensed for 12 months was often for more than 365 days. There were no stock cards/records for the non-ARV medicines.

General comments: The letter sent by NASCOP informing the facility about the adherence monitoring survey had not been received at the time we arrived.

Facility 12: Provincial General Hospital

Program: GOK

Sampling: The DAR contained both the ARV and non-ARV patients, but which patients were on ARVs was clearly marked.

Long retrospective: 12 pages; 10 patients per register page

Recent retrospective: 30 pages; 4 patients per register page

The members of the staff were very helpful in providing the records.

Challenges: Data were obtained mainly from the patient files. We also used the MSH dispensing tool in the pharmacy because dispensing data were not available in the patients' files for the long retrospective survey.

We had to correlate the information from the files with that in the dispensing tool for each patient. In most cases we also had to get the actual prescriptions for information not available in the dispensing tool. This process took a very long time—we left the facility at 7:30 p.m.

Facility 13: Mission Hospital

Program: GOK and Catholic Relief Services

Sampling: The staff members were very helpful in providing the records.

Long retrospective: The DAR available for the long retrospective had about 30 patients who attended the clinic in September 2005. It was not possible to tell whether these patients were on ARVs. After sampling all the patients on the register, it emerged that not all were on ARVs. We also realized that the patient identifiers had changed after computerization in November; therefore it was not possible to follow-up on these patients. This problem made it impossible then to proceed with the sampling even after spending a long time with the data clerk to try to figure out their system. The answer to sample for the last six months and not the full year came too late to sample more than 6 patients. Using the computer printouts and the patient notes, we were able to complete the data entry forms.

Recent retrospective: A computer printout was used to sample and collect the information. The clinical notes were not used.

Challenges: We could not perform enough exit interviews. The day of the visit was not a routine clinic day and therefore only two patients were interviewed. Most of the patients encountered had come for CD4 counts.

Facility 14: Provincial General Hospital

Program: GOK and PEPFAR

Sampling: The DAR records have both the ARV and non-ARV patients, but which patients were on ARVs was clearly marked. The staff members were very helpful in providing the records.

Challenges: For the long retrospective survey, the pharmacy records for the GOK program did not have all the information needed; hence patients' clinical records had to be used. The clinical notes were scanty and poorly kept.

Facility 15: District Hospital

Program: GOK and PEPFAR

Sampling: The DAR records have both the ARV and non-ARV patients, but which patients were on ARVs was clearly marked. The staff members were very helpful in providing the records.

Challenges: For the long retrospective survey, the pharmacy records did not have all the information needed; hence patients' clinical records had to be used as well. The clinical notes were scanty. In many cases the patients were given appointments far in the future; hence clinical information was missing.

Interestingly, the patients came for monthly refills without going through the clinic. This information was captured in the pharmacy records. Some of the index visit dates sampled did not appear in the clinical notes.

The dispensing tool had information starting November 2005.

The stock cards were not up-to-date.

Summary of Records Completed

Facility	Exit Interview	Reliability Exit	Recent	Recent Reliability	Long	Long Reliability
Facility 11	22	5	51	2	54	5
Facility 12	30	2	86	5	34	5
Facility 13	3	0	91	0	6	0
Facility 14	19	3	76	1	20	0
Facility 15	15	3	53	0	33	0

Group 4

Team leader: Dorine Kagai

Data collectors: Oscar Abuga, James Owour, Dr. Torome

Facility 16: Teaching Hospital

Program: GOK and PEPFAR

They have two systems of care; however, both cohorts of patients are seen by the same clinicians and medicines are dispensed from the same pharmacy.

We were unable to do the recent retrospective analysis because the chief records officer had not been authorized by the deputy director to release the patients' files to us. Later, we established that the authority had been written but was still in the director's office.

Long retrospective sample and data were collected from the MSH dispensing tool in the pharmacy. This procedure was challenging because the computer was being used while dispensing to the patients, making it difficult for us to access the data. We had to load the tool onto a laptop before being able to effectively collect the data. The process of loading the tool onto the laptop took a long while because the pharmacist was not sure how exactly to do so.

For the long retrospective, we could not identify some dates when patients had actually commenced ART because all patients were assumed to have started in January 2005, while changing over from the manual to computerized system.

Patient flow was slow, allowing only 20 exit interviews to be conducted.

Facility 17: District Hospital

Program: GOK and MSF-B

Though patients are seen by the same clinicians, the recording and filing systems are different, and dispensing is at two different pharmacies. We therefore established the proportions of patients between the two programs as follows—

- September 2005, GOK = 40 percent, sample of 50; MSF-B = 60 percent sample of 70
- June 2006, GOK = 50 percent, sample of 60; MSF-B = 50 percent, sample of 60

Long retrospective GOK sample was obtained from the MSH dispensing tool at the GOK pharmacy. However, because the tool was in use while dispensing to patients, the long retrospective data were mainly collected from patient-centered manual records at the pharmacy and patients' files.

Recent retrospective GOK sample was drawn from the clinical attendances register at the clinic and the data were collected from the patients' files.

Both recent and long retrospective MSF samples were drawn from the MSF "fuschia" database, and both sets of data derived from patients' files. This process was, however, very problematic because all the data are centrally administered by one person who had to be

called and only made the lists of patients for the two samples available at 2 p.m. and 3:30 p.m. Thus very little data was obtained for the MSF cohort. The September 2005 list consisted of all clinical attendances. It was not possible to know which patients were on ART.

Patient files were not released in large numbers. Data collectors had to search for the files by themselves and only retrieve a few at a time. These had to be returned in their respective positions before retrieving more. This procedure consumed a lot of time and slowed down the entire data collection process.

Exit interviews were mainly administered to GOK patients. The MSF patient flow was very low.

Facility 18: Clinic

Program: PEPFAR program run by Catholic Relief Services

The recent retrospective sample was drawn from the clinical attendances book specifically for patients on ART, and the data were collected from patients' files. However, only 80 of the sample of 120 were used. Some files could not be retrieved because the patients had transferred out. Because it was a heavy clinic day, quite a significant number of patients were in the clinic.

The pharmacy attendance registers for September 2005 were not available at the facility because they had been surrendered to the main EDARP office. Hence the long retrospective sample was drawn from EDARP central database, which is located at the facility. The data were obtained both from the database and patients' files.

Exit interviews were administered to 30 patients because the patient flow was heavy. Most patients were willing to be interviewed.

Facility 19: Children's Program

Program: PEPFAR

Generally, both clinical and pharmacy records are collected and maintained in one computer with little distinction between them.

Recent retrospective sample was drawn from the ARV drug daily issues record book, which is usually completed by nurses at the end of each day. The data were then collected from the patients' files, which were well organized, but had little information.

The long retrospective sample was drawn from the MSH dispensing tool. However, the facility suffered a power failure. Therefore, the long retrospective data were obtained from patients' files as well. The information in the files was scanty, and we would have obtained more data if we had been able to use the dispensing tool.

At this facility, only HIV-positive children (0 to 18 years of age) are enrolled. Patients on ART are only booked and seen on Mondays and Thursdays. The rest of the clinic days are for

general care and treatment of those not on ART or those on ART needing some other treatment.

Only three exit interviews were conducted because the patient flow was extremely low. Administration of the interview was challenging because mainly the guardians were interviewed, many of whom are very old, hence presenting a barrier of communication. Pill counts and self-reporting are done. However, no standard question is asked for the self-reporting and no record is kept of the pill counts.

The facility performs CD4 percentage for children under five years of age and CD4 counts for those over 5 years of age, contrary to the national guidelines, which give a cutoff age of 6 years.

Facility 20: Mission Hospital

Program: GOK and PEPFAR through Catholic Relief Services

Both cohorts of patients are seen by the same clinicians and dispensed to at the same pharmacy.

The clinic does not have any kind of records/registers. The only records available were at the pharmacy in the MSH dispensing tool. The records for the two sets of cohorts are distinct; hence, we established the proportions of patients and sampled accordingly.

- Long: September 2005, GOK = 10 percent, sample 12; PEPFAR = 90 percent, sample 108
- Recent: June 2006, GOK = 40 percent, sample 50; PEPFAR = 60 percent, sample 70

The facility has the Careware database, which is maintained by the monitoring and evaluation personnel. Data that are fed into this database are derived from the dispensing tool and patient files.

Both recent and long retrospective samples were drawn from patient attendance records in the dispensing tool.

Recent retrospective data were derived from patients' files. Despite being seen by the same clinicians, the PEPFAR patient files contained much more comprehensive information compared with GOK patient files, which contained scanty to no information at all. We therefore concentrated more on PEPFAR patient files.

Long retrospective data was derived both from the dispensing tool and patient files.

Exit interviews were administered to 12 patients. We however missed pediatric patients whose clinic is on Tuesdays only.

GOK patients pay for the ARVs and medicines for opportunistic infections and for CD4 and viral load tests, whereas PEPFAR patients receive all services free of charge.

Summary of Records Completed

Facility	Exit Interview	Reliability Exit	Recent	Recent Reliability	Long	Long Reliability
Facility 16	20	4	0	0	100	0
Facility 17	21	2	24	0	32	0
Facility 18	29	5	76	0	64	0
Facility 19	3	3	58	2	45	3
Facility 20	12	2	43	2	41	3

APPENDIX 2. FACILITY INTERVIEW FORM

Final DATA COLLECTION FORM 1A: FACILITY

Facility Questionnaire

Facility

Name Facility _____

Programme/System of Care _____

Name of data collector _____

Date _____

Greeting and request for interview

	# Hrs		# Hrs
Mon		Friday:	
Tues		Saturday	
Wed		Sunday	
Thurs			
Total hours =			

Q1. Which Days of the week and what time is the clinic open?
for seeing patients with HIV/AIDS on ARVs

Q2. Is it the same services every day?

If not which ones are different?

Q3. Was it the same hours three months ago? Y / N. If n

Q4. Was it the same hours 1 year ago? Y / N. If

(Indicator 16: Extent of clinic hours: Number of hours clinic is open per week for routine HIV/AIDS care including ARVs)

(Indicator 17: Convenience of clinic hours: Whether clinic is open at least one evening or weekend day for routine HIV/AIDS care)

(evening means at least a two hour session after five pm)

Y ? N

Q5. I am interested to know how many HIV/AIDS patients you see in a week. Can I see the attendance register please?

a) Check register for number in last 4 weeks (28 days)

per 2 weeks

b) Divide by 4 to get average number per week =

Note: If numbering a problem count for last complete week only

This is all HIV/AIDS patients (not just those on ART)

This is the clinician load, so we need clinic appointment book or record.

This is not the pharmacy record.

Q6. How many Doctors and/or Clinical Officers seeing HIV/AIDS patients do you have during a normal clinic ?

(Check while in the clinic) (include 'clinical' nurse if doing triage system)

Divide Q5 by (Q1* Q6) to get average number of HIV/AIDS patients seen per clinician hour =

(Indicator 18: Clinician patient load: Average number of HIV/AIDS patients seen per clinician hour =

Q7. How many of the following staff working directly with HIV/AIDS patients do you have during a normal clinic?

(count one staff only once)

social workers

nurses

counsellors

pharmacists

pharmaceutical technologist

Nutritionist

Other (specify)

Total

(Check while in the clinic)

If community workers or volunteers attached describe here _____

(Indicator 19: Presence of support staff: Average number HIV/AIDS patients

per week per support staff, = Q5/Q7 =

Q8. Do you have access to a laboratory for measuring CD4 counts on the premises or within your program?

If so is it functioning??

Q9. Do you have access to a laboratory for measuring viral loads on the premises or within your program?

If so is it functioning??

Q10. Do you have access to a laboratory for measuring CD4 counts within a five minute walk?

If so is it functioning??

Q11. Do you have access to a laboratory for measuring viral loads within a 5 minute walk?

If so is it functioning??

How much do patients have to pay for these tests? _____

(Indicator 20: Presence of laboratory: Whether facility or program has access to a laboratory that is actively measuring CD4 counts or viral loads within program or within 5 minutes walk from the facility, = if Yes to Q8, 9, 10 or 11. = Y)

= Y / N

Q12. Is there private space for Adherence Counseling

(Check while walking around the clinic)

(private space means a discreet area where a conversation with a patient cannot be overheard)

(Indicator 21: Presence of private space for counseling: Whether facility has a private space available for adherence counseling = Y / N from Q 12)

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First Feasibility and Reliability Test of Indicators for Adherence to ARV Medicine: National Survey in Kenya

Final DATA COLLECTION FORM 1B: FACILITY

Q13. Could I see your stock area and supply records for ARVs please?

Take the chosen list of essential ARVs and mark if each drug is in stock today and the number of days present in the last 90. Make sure you see all supplies of drugs

If treating children			Fixed dose combination	# days in stock in last 90
Drug		Y/N	Y/N	
1	Lamivudine 150mg tab			
2	Lamivudine syrup 10mg/ml			
3	Stavudine 40 mg			
4	Stavudine 30 mg			
5	Nevirapine 200mg			
6	Nevirapine syrup 10mg/ml			
7	Efavirenz 200mg			
8	Efavirenz 600mg			
9	Efavirenz syrup 30mg/ml			
10	Zidovudine 300mg tab			
11	Zidovudine 100mg tab			
12	Zidovudine syrup 10mg/ml			
Total				
Percentage or average				

Q14. Could I see your stock area and supply records for general medicine supply please?

Take the chosen list of key medicines and mark if each drug is in stock today and the number of days present in the last 90. Make sure you see all supplies of drugs

Drug	Y/N	# days in stock in last 90
1		
2		
3		
4		
5		
6		
7		
8		
Total		
Percentage or average		

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APPENDIX 3. EXIT INTERVIEW GUIDE

2. Patient Exit Interview QUESTION SHEET - 1

Standard Greeting, Introduction and request for an Interview

If the patient is a child with a carer: Ask Pre Questions:

1. Is the child responsible for giving themselves the medicine? Y / N

If No ask the carer:

A) Are you the one who usually gives this child his/her medicine? Y / N

B) Who brought the child to the clinic originally and was told how to take medicine?

Was it you or another person? Y / N

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

For DATA COLLECTION FORM 2 (1): EXIT INTERVIEWS

Clm. C ***Please could I ask you your age?***

Clm. D Note Gender: Male / Female

Clm. E ***What is your occupation?***

Clm. F ***Are you able to actively continue with your normal activities now with your illness?***

Clm. G Ask when they started ART and write how many ***months*** on ARV treatment?

Clm. I Ask how long it took to come to the clinic today from their house or place of work

Calculate total time to travel in minutes.

Clm. J Ask what time did they arrive here at the clinic this morning?

Calculate total time in clinic during this visit in minutes.

(If patient doesn't know the time try and relate it to something else such as the beginning of clinic, and calculate the time).

Clm. K-N

TAKE YOUR LIST OF COMMON ADVERSE DRUG REACTIONS and ask in turn whether the patient has suffered any of these symptoms in the last week

ASK TO SEE all the ARVS and non ARVS dispensed and the prescription for all drugs prescribed and fill in

Clm. P Were all ARVS dispensed: Y or N

Clm. Q Were all Non ARVS dispensed: Y or N

2. Patient Exit Interview QUESTION SHEET – 2

Clm. R: **Look to see if each medicine was dispensed in a separate container or envelope? Does each container or envelope contain: Drug Name, dose per time, number times per day?**

If yes fill Y, otherwise N

For DATA COLLECTION FORM 2 (2): EXIT INTERVIEWS

Say: *"Some patients find it difficult to take all the medicines every day in exactly the way they are supposed to."*

Clms S-AD Fill in turn: Take each ARV in turn and ask:
How many times a day do you take this medicine?
In the last three days have you missed any?
In the last three days how many times have you missed?

Say: *"Good luck and Thank you"*

Adverse Drug Events

ADR	Symptom to ask about
1. Peripheral neuropathy	Pain, numbness, tingling in legs or feet
2. Rash	Rash
3. Lipodystrophy	Change of fat distribution such as enlarged breasts, Buffalo hump, loss of fat tissue in face, buttocks, legs
4. Hepatotoxicity	Jaundice, yellow eyes
5. GIT toxicity	Nausea, vomiting, diarrhoea

Opportunistic Infections

Condition	Acronym
1. Tuberculosis	TB
2. Oral or esophageal candidiasis	OC
3. Cryptococcus meningitis (Indian ink positive)	CM
4. Pneumocystis carinii pneumonia	PCP
5. Fungal skin infections	FSI
6. Bacterial skin infections	BSI