

ANTIRETROVIRAL TREATMENT IN MALAWI RESULTS UP TO 30th SEPTEMBER, 2008

Executive Summary:

By the end of September 2008, there were **214** health facilities in Malawi in the public and private health sector delivering ART to HIV-positive eligible patients. In the third quarter of 2008 (July to September), there were **20,393** new patients registered on ART (38% male, 62% female; 92% adults and 8% children). Of those starting, 57% started due to Stage 3, 12% due to Stage 4 and 30% based on a low CD4 count in Stage 1 or Stage 2.

By the end of September 2008, there were **204,440** patients ever registered on ART (39% male, 61% female; 92% adult, 8% children) of which 25,588 had started on ART due to TB. The 204,440 patients who had ever registered on ART include the patients who transfer-in from other sites, and it is understood that these patients are counted twice. If we assume that all patients who transfer-out then transfer-in, then the number of new patients ever started on ART is 179,505.

Cumulative treatment outcomes by end of September were: 66% alive and on ART at the site of registration, 11% dead, 10% lost to follow-up, 12% transferred out to another facility (and were presumably alive) and <1% stopped treatment.

Of the **135,264** patients alive and on ART:- 95% were on the first line regimen, 5% were on an alternative first line regimen and less than 1% were on second line regimen.

By the end of September 2008 there were 30 sites with over 1,000 patients alive and on treatment; 8 sites with over 2,000 and 4 with over 5,000 patients alive and on treatment.

Resume from January 2003 to September 2008:

	By Dec 2003	By Dec 2004	By Dec 2005	By Dec 2006	By Dec 2007	By Sep 2008
Total number of ART sites	9	24	83	141	163	214
New patients started ART in the year (Jan – Dec)	No data	10,183	25,634	46,351	61,688	57,584
Cumulative patients registered on ART	3,000 (approx)	13,183	38,817	85,168	146,856	204,440
Patients alive on ART	No data	10,761	29,087	59,980	100,649	135,264

Introduction and Methodology:

This is a report on the status of antiretroviral therapy (ART) in Malawi up to September 30th, 2008.

ART site visits: between October and November 2008, all health facilities in the public and private sectors earmarked for ART were visited and data from 214 health facilities were collected. The visits were conducted by the Ministry of Health HIV Unit, MBCA, partners from DHOs, ART supervisors and MSF.

Each visit lasted up to half a day during which a structured supervision and a drug stock-level assessment were carried out, and this was followed by a monitoring and evaluation exercise. Data on ART parameters were collected from the patient master cards and the ARV Register. Much effort was made in ensuring that outcomes (particularly death and defaulter) were correct, and we believe that outcomes are accurately represented in this report. During the visits, certificates for excellent performance awarded at the last visit were presented to the clinic staff.

Data collection in public / private sector, outcome status censored on 30th September, 2008:

The first data set is the status of new patients who were started on free ART in Malawi between July 1st and September 30th, 2008, **the “quarterly analysis”**. In the public sector only, data on ART clinics and staff complements, HIV-related diseases, and HIV counselling and testing were also collected for this 3-month period.

The second data set is the status of all patients who ever started on free ART in Malawi up to September 30th, 2008, **the “cumulative analysis”**.

The third data set collected only in the public sector is the **12-month, 24- month and 36-month cohort outcome analysis**, with data collected on patients starting ART in Malawi in Q3 2007, Q3 2006, and Q3 2005 respectively

PUBLIC SECTOR RESULTS:

General:

By the end of September 2008, there were **170** free-standing health facilities, owned by government, mission and NGOs in Malawi in the public health sector delivering ART free of charge to HIV-positive eligible patients. All the facilities were using the national monitoring tools.

In the third quarter of 2008 (July to September), there were **19,747** new patients started on ART (38% male, 62% female; 91% adults and 9% children. By the end of September 2008, there were **197,084** patients who had ever started on ART (39% male, 61% female; 92% adults and 8% children). Cumulative treatment outcomes by end of September were:- 66% alive and on ART at the site of registration, 11% dead, 10% lost to follow-up, 12% transferred out to another facility (and were presumably alive) and <1% stopped treatment. Of the 130,239 patients alive and on ART:- 95% were on the first line regimen, 5% were on an alternative first line regimen and less than 1% were on a second line regimen.

	By Dec 2003	By Dec 2004	By Dec 2005	By Dec 2006	By Dec 2007	By Sep 2008
Public sector ART sites	9	24	60	103	118	170
New patients started ART in year	No data	10,183	24,657	43,981	59,628	55,635
Cumulative patients started ART	3,000	13,183	37,840	81,821	141,449	197,084
Patients alive on ART	No data	10,761	28,110	57,356	96,712	130,239

Qualitative assessment of sites: A qualitative assessment of the patient master cards and registers was carried out. The table, with pertinent results, compares the 160 facilities in Q3 2008 with the previous qualitative assessment facilities in Q2 and Q1 2008. The standards were generally good, and Q3 2008 was similar in many respects to Q2 2008. Two third of the facilities had done a correct cohort outcome analysis and 80% of sites had done a correct quarterly and cumulative cohort analysis.

Parameter	ART sites (%) Q1 2008 N=157	ART sites (%) in Q2 2008 N=162	ART sites (%) in Q3 2008 N=160
ARV Register:			
ARV Register numbers correct & match master cards	149 (95%)	156 (96%)	155 (97%)
All columns in the ARV register always completed	149 (95%)	155 (96%)	156 (98%)
Dates of all adverse outcomes recorded	129 (82%)	138 (85%)	137 (86%)
All ARV outcomes updated every three months	130 (83%)	134 (83%)	129 (81%)
Patient Master Card:			
Case finding data properly completed on each card	142 (90%)	148 (91%)	148 (93%)
Regular record of weight done at each patient visit	155 (99%)	160 (99%)	157 (98%)
In each monthly visit all outcome columns completed	154 (98%)	155 (96%)	152 (95%)
Pill counts for adherence done according to directives	156 (99%)	158 (98%)	143 (89%)
HIV-diseases always indicated on back of master card	135 (86%)	146 (90%)	147 (92%)
Cohort Analysis:			
Quarterly cohort analysis done by the site before visit	138 (88%)	140 (86%)	130 (81%)
Cumulative analysis done by the site before visit	113 (72%)	136 (84%)	128 (80%)
Cohort outcomes correctly done	90 (57%)	106 (65%)	107 (67%)

Certificates of excellence: Sites which show an excellent performance in completing ART registers and master cards and correctly doing cohort analyses are awarded a certificate of excellence. Results for the last three quarters, including the current quarter are shown below:

January to March 2008: 75 (48%) of sites received a certificate

April to June 2008: 100 (62%) sites received a certificate

July to September 2008: 104 (65%) the sites received a certificate

ART Clinics and Staff: a record is made in all facilities of the number of days in a week that the ART clinic is open to see either new or follow-up patients plus the number of staff who operate the clinic when it is functioning. The total number of days in a week given for ART at all facilities in Q3 2008 was 461, translating into an average of 2.9 working days in a week when facilities operate an ART clinic. The table shows the number of staff days per week for clinicians (mainly clinical officers), nurses and clerks for each of the regions and for the country as a whole. The FTE parameters indicate the number of clinicians, nurses and clerks working full-time per week on ART. Thus, for the country as a whole, the equivalent of 140 clinicians was working full-time in ART delivery each week. The workload to man ART clinics is obviously increasing quarter by quarter (compare previous reports).

Region	Sites	ARV Clinic days/ week	Clinician days/ week	Nurse days/ week	Clerk days/ week
North	31	77	77	86	81
Central	60	176	281	339	264
South	69	208	341	368	278
Total	160	461	699	793	623
FTE			140	159	125

Quarterly Analysis for the period July 1st to September 30th, 2008:

1. New patients started on ART in public sector between July and September 2008:

The national data for new patients started on ART in these three months are shown in **Table 1** on quarterly analysis.

There were 19,747 new patients started on ART, with males representing 38% and females representing 62% of the total. Adults comprised 91% of patients and children (aged 14 years or less) comprised 9%. The majority of patients (57%) were started on ART because of being in WHO Stage 3 and the percentage of people starting because of low CD4 count (29%) is increasing and due to WHO stage 4 (12%) is decreasing.

The number of patients started on ART because of TB was 1,934. This constitutes 10% of new patients started on ART and 51% of eligible (estimated at 70% of all new TB registrations) patients registered for TB (N=5,370) during the quarter.

The number of women referred from PMTCT to start on ART was 686.

The table below shows the recruitment of new patients to ART in Q3 2008, Q2 2008, Q1 2008 and Q4 2007, compared with what is expected in terms of ceilings and targets given to facilities. In quarter 3, 2008, there were 170 facilities these sites should have placed a maximum of 19,275 new patients on ART and in the event placed over 100%.

In each quarter:	Q4 2007	Q1 2008	Q2 2008	Q3 2008
Number of facilities	118	157	162	170
Expected number of patients to start ART	16,350	19,275	19,725	19,725
Observed number (%) of patients started on ART	14,908 (91%)	17,642 (91%)	19,206 (97%)	19,747 (100%)

2. HIV testing, CD4 testing capability and HIV-related diseases: July - September 2008

HIV test data:

The data on HIV test results for patients tested in the 170 facilities between July 1st and September 30th, 2008 are shown below.

Region	Tested	Positive		Referred for ART	
North	32,362	3,358	10%	3,172	94%
Central	65,454	9,147	14%	8,651	95%
South	98,894	18,981	19%	14,239	75%
Total	196,710	31,486	16%	26,062	83%

Altogether, there were 196,710 clients and patients tested in the 3-month period. Of those HIV-positive, 83% were referred for clinical assessment for ART – for

unknown reasons this percentage was less in the South compared with the other 2 regions.

CD4 machines:

There were 41 facilities with CD4 count capability. In a significant number of sites (8) machines were not working or no test was performed in the period July – September 2008.

Region	North	Central	South	Total
CD4 machines	8	18	15	41
CD4 machines functioning	6	15	13	34
Total CD4 tests	3,511	11,531	22,373	37,415

HIV-related indicator diseases:

The number of patients with 4 key HIV-related indicator diseases, diagnosed and treated in the 170 facilities during the quarter, was recorded. TB numbers were obtained from the TB registers; Kaposi’ Sarcoma (KS) numbers from the ART registers; numbers of those with cryptococcal meningitis and oesophageal candidiasis from the DIFLUCAN registers kept in the pharmacy or from master cards in those sites not participating in the DIFLUCAN programme. The data are shown in the table below: the number of patients diagnosed with Oesophageal Candidiasis and Cryptococcal Meningitis are lower this quarter compared to previous quarters.

Region	North	Central	South	Total
Tuberculosis	418	1,189	3,763	5,370
Kaposi's Sarcoma (KS)	34	141	343	518
Oesoph. Candidiasis (OC)	319	346	947	1,612
Cryptococcal meningitis (CM)	190	257	942	1,389

Cumulative analysis for patients ever started on ART up to September 30th, 2008

The national data for all patients who ever started on ART up to the end of September 2008 are shown in **Table 2** on cumulative analysis.

The number of patients started on ART because of TB was 25,588. This constitutes 13% of all patients started on ART.

The cumulative primary treatment outcomes were as follows. There were 66% of patients being alive and on ART in the facility where they were first registered, and 12% transferred out to another facility and thought to be alive. Date of death was recorded for all patients who died: 6,721 (31%) died in month 1; 4,644 (21%) died in month 2; 2,495 (12%) died in month 3 and 7,892 (36%) died at a later date. Default rates (i.e., patients lost to follow-up) were at 10%. The number of patients stopping treatment was small at less than 1%.

Treatment outcomes of cohorts at 12-, 24- and 36- months

Treatment outcomes of cohorts were performed at 12-months, 24-months and 36-months. The 12-months survival was from patients registered for free ART between July and September 2007 and censored on 30th September. The 24-months survival was from patients registered for free ART between July and September 2006 and censored on 30th September 2008. The 36-months survival was from patients registered for free ART between July and September 2005 and censored on 30th September 2008. Results are shown in the table.

	12 month	24 month	36 month
Total registered	15,647	11,876	7,655
Transfers	1,965 13%	1,877 16%	1,467 19%
Total patients	13,682	9,999	6,188
Alive on ART	10,377 76%	6,776 68%	3,719 60%
Died	1,365 10%	1,663 17%	1,397 23%
Lost to follow-up	1,877 14%	1,521 15%	1,031 17%
Stopped ART	63 0%	39 0%	41 1%

The 12-month survival analysis indicated that 76% of patients were alive. The 24-month survival indicated that 68% were alive while the 36-month survival analyses indicated that 60% of patients were alive.

Stocks of ARV drugs and drug for HIV-diseases as of September 2008

In each public sector facility a stock count was performed of ARV drugs and certain specific drugs for HIV-related diseases.

ARV Drugs and drugs for HIV-related diseases:

Stocks of ARV drugs (first line and alternative first line and second line) are shown underneath in tabular form. According to the stocks at the time of the assessment, there were enough First line ARV drugs to start about 85,000 new patients on therapy (this lasts for 12 months at current rates of recruitment) and enough “Continuation packs” to keep the current 135,264 patients plus the new patients starting on treatment for about 6 months.

Drug	Pack	North	Central	South	Total
d4T 30mg / 3TC	15	12,283	25,644	47,089	85,016
d4T 40mg / 3TC	15	951	1,627	2,188	4,766
d4T 30mg / 3TC / NVP	15	12,520	25,895	48,433	86,848
d4T 40mg / 3TC / NVP	15	977	1,608	2,407	4,992
d4T 30mg / 3TC / NVP	60	123,630	316,061	394,688	834,379
d4T 40mg / 3TC / NVP	60	4,224	8,530	8,815	21,569
AZT / 3TC	60	1,719	6,143	14,175	22,037
NVP	60	8,180	8,337	28,329	44,846
d4T 30mg / 3TC	60	2,786	2,806	41,190	46,782
d4T 40mg / 3TC	60	199	60	405	664
EFV	30	692	4,813	9,814	15,319
TDF	30	159	2,192	3,205	5,556
Kaletra	180	3	2,034	4,999	7,036
CPT	120	72,301	118,993	135,972	327,266
Fluconazole		9,935	12,713	39,704	62,352
Acyclovir		6,396	41,781	167,275	215,452
Ceftriaxone		180	1,942	14,371	16,493
Ciprofloxacin		81,150	176,428	139,730	397,308
Vincristine		6,496	2,844	3,095	12,435
Morphine		101,834	27,939	47,048	176,821
Amitriptyline		397,209	582,150	669,735	1,649,094

PRIVATE SECTOR RESULTS:

By the end of September 2008, there were **44** facilities in Malawi in the private health sector delivering ART at a subsidised rate to HIV-positive eligible patients. This is one facility less than in the last quarter due to the merge of 2 clinics in Lilongwe. In the third quarter of 2008 (July to September), there were **637** new patients started on ART (47% male, 53% female, 95% adult, 5% children). By the end of September 2008, there were **7,335** patients who had ever started on ART (51% male, 49% female, 95% adults, 5% children).

	By Dec 2003	By Dec 2004	By Dec 2005	By Dec 2006	By Dec 2007	By Sep 2008
Private sector ART sites	0	0	23	38	45	44
New patients started ART in year	0	0	977	2,370	2,060	1,949
Cumulative patients started ART	0	0	977	3,347	5,407	7,353
Patients alive on ART	0	0	977	2,624	3,937	5,025

The results of the private sector are shown in Tabular Form in **Table 1** and **Table 2**.

For the cumulative analysis (**Table 2**), there were 7,335 patients ever registered on ART, 51% of whom were male, 49% were females and 5% were children. Of those starting, 47% started due to Stage 3, 18% due to Stage 4 and 35% based on a low CD4 count in Stage 1 or Stage 2. There were 469 patients started on ART due to TB. Of the 7,335 patients started on ART, 68% were alive and on ART, 7% were dead, 9% were lost to follow-up, 15% were transferred out and less than 1% had stopped treatment. Of the 5,006 patients alive and on ART:- 90% were on first line regimen, 9% were on an alternative first line regimen and 1% were on a second line regimen.

COMMENTS

- ART scale up in Malawi continues to progress well. Sites are doing well, despite the increasing burden of work. The majority of sites are taking the initiative of doing quarterly and cumulative cohort analysis, although nearly one third of sites are still not coming up with correct outcomes. Continuous support and supervision is key to maintain the quality of the programme.
- ARV drug stocks were again assessed, and nationally drugs stocks are adequate. However, some sites are over-performing to a large extent and causing problems with drug stocks (both for starter packs and continuation packs). The quarterly drug stock taking assists in the activity of re-distributing drugs from under- to over-performing sites.
- Some drugs for HIV-related diseases, particularly morphine and vincristine, are out of stock in most facilities.
- The ART team of the MOH is planning to have consultative meetings with all DHOs and ZHOs in the coming months to discuss the programme and exchange ideas on the further roll out.
- The number of people alive and on treatment increased in the last quarter by a considerable higher number compared to previous quarters. One of the reasons is that records in one of the larger sites were cleaned and updated. This resulted in an increase of the number of people alive and on treatment.
- Clinical supervision. Two of the three remaining HIV Supervisors have left and there is an urgent need to ensure that the number of Supervisors is increased to five; one per Zonal Health Office.

- Rewarding good performance in ARV clinics. The quarterly issuing of certificates for excellent performance continues to be a popular and cheap way to motivate staff.

We finally thank all the facilities for their sincere welcome and co-operation with the HIV Unit and its partners during these supportive visits, and we congratulate the staff in these facilities for their excellent work.

Participants in ART Supervision:

Chandarith Cheang	MOH, UNV
Janet Chikonda	MOH
Moses Chilombe	MSF
Felix Chinguwo	MOH, Ntcheu
Stuart Chuka	MBCA
Peter Donda	MOH, Dedza
Dementria Elpideo	MSF Thyolo
Andreas Jahn	MOH, HIV Unit
Agnes Kalitsiro	CHAM, Mlambe MH
Joseph Kasola	MOH, Chitipa
Absalom Kaunda	MOH, Mzimba
Omba Lwanda	MOH, KCH
Simon Makombe	MOH, HIV Unit
Owen Makonyola	MSF Thyolo
Kennedy Malisita	MOH, QECH
Benjamin Mazalo	SUCOMA Clinic
Eustice Mhango	MOH, HIV Unit
Clement Mtika	MOH, Mzuzu
Ekwala Mubiala	MOH, UNV
Halex Mulinde	Lighthouse
Issa Mwalwanda	CHAM, Ekwendeni MH
Olesi Pasulani	MSF Thyolo
Monica Simfukwe	MOH, Chintheche
Everista Tchuwa	MOH, Chilumba
Evelyn Zambaza	MOH, Nsanje

Report compiled by:

Kelita Kamoto	MOH, HIV Unit
James Mpunga	MOH, HIV Unit
Simon Makombe	MOH, HIV Unit
Andreas Jahn	MOH, HIV Unit
Erik Schouten	MOH, HIV Unit

14th November 2008

New patients registered for ART between 01/07/2008 and 30/09/2008

		Public Sector		Private Sector		National Total	
Total registrations		19,747		646		20,393	
Sex	Males	7,503	38%	306	47%	7,809	38%
	Females	12,244	62%	340	53%	12,584	62%
Age	Adults	18,057	91%	615	95%	18,672	92%
	Children	1,690	9%	30	5%	1,720	8%
Occupations	Housewives	4,079	21%	118	18%	4,197	21%
	Farmers	6,938	35%	23	4%	6,961	34%
	Army / Police	203	1%	3	0%	206	1%
	Teachers	463	2%	29	4%	492	2%
	Business people	2,410	12%	121	19%	2,531	12%
	Health workers	195	1%	13	2%	208	1%
	Student	1,117	6%	33	5%	1,150	6%
	Other occupations	4,143	21%	291	45%	4,434	22%
	Occupation unknown	200	1%	15	2%	215	1%
	Reason for ART	WHO clinical stage 3	11,299	57%	292	45%	11,591
WHO clinical stage 4		2,413	12%	81	13%	2,494	12%
CD4 count <250		5,778	29%	273	42%	6,051	30%
Reason unspecified		266	1%	0	0%	266	1%
Total cases with TB		1,934	10%	29	4%	1,963	10%
Referrals from PMTCT		686	3%	17	3%	703	3%
Primary outcomes	Total patients registered	19,747		646		20,393	
	Alive on ART	18,859	96%	604	93%	19,463	95%
	Defaults	3	0%	0	0%	3	0%
	ART stops	37	0%	0	0%	37	0%
	Transfers out	345	2%	22	3%	367	2%
	Deaths total	504	3%	20	3%	524	3%
	Month 1	325	64%	18	90%	343	65%
	Month 2	141	28%	1	5%	142	27%
	Month 3	27	5%	0	0%	27	5%
	After month 3	10	2%	1	5%	11	2%
ARV regimens	Start	18,441	98%	564	93%	19,005	98%
	Alternative 1st line total	395	2%	35	6%	430	2%
	AZT	146	37%	0	0%	146	34%
	EFV	222	56%	9	26%	231	54%
	AZT+EFV	14	4%	0	0%	14	3%
	Unspecified / other	13	3%	26	74%	39	9%
	Second line regimen	22	0%	5	1%	27	0%
Ambulatory status	Ambulatory status known	18,836		604		19,440	
	Ambulatory	18,411	98%	604	100%	19,015	98%
Work status	Work status known	18,836		604		19,440	
	Working	18,134	96%	603	100%	18,737	96%
Side effects	Side effects counted	18,766		553		19,319	
	With side effects	448	2%	14	3%	462	2%
Adherence	Pillcounts done	13,875		177		14,052	
	Pillc shows >95% adherence	12,693	91%	176	99%	12,869	92%

Cumulative patients registered for ART up to end 30/09/2008

		Public Sector		Private Sector		National Total	
Total registrations		197,084		7,356		204,440	
Sex	Males	75,971	39%	3,753	51%	79,724	39%
	Females	121,113	61%	3,603	49%	124,716	61%
Age	Adults	180,484	92%	7,012	95%	187,496	92%
	Children	16,600	8%	344	5%	16,944	8%
Occupations	Housewives	39,284	20%	1,164	16%	40,448	20%
	Farmers	59,444	30%	167	2%	59,611	29%
	Army / Police	2,632	1%	73	1%	2,705	1%
	Teachers	6,214	3%	327	4%	6,541	3%
	Business people	23,123	12%	1,129	15%	24,252	12%
	Health workers	2,349	1%	167	2%	2,516	1%
	Student	13,768	7%	419	6%	14,187	7%
	Other occupations	44,868	23%	3,654	50%	48,522	24%
	Occupation unknown	4,918	2%	255	3%	5,173	3%
Reason for ART	WHO clinical stage 3	122,050	62%	3,457	47%	125,507	61%
	WHO clinical stage 4	34,920	18%	1,302	18%	36,222	18%
	CD4 count <250	37,367	19%	2,597	35%	39,964	20%
	Reason unspecified	2,744	1%	0	0%	2,744	1%
	Total cases with TB	25,588	13%	471	6%	26,059	13%
	Referrals from PMTCT	4,499	2%	54	1%	4,553	2%
Primary outcomes	Total patients registered	197,084		7,356		204,440	
	Alive on ART	130,239	66%	5,025	68%	135,264	66%
	Defaults	20,591	10%	672	9%	21,263	10%
	ART stops	658	0%	12	0%	670	0%
	Transfers out	23,839	12%	1,096	15%	24,935	12%
	Deaths total	21,754	11%	551	7%	22,305	11%
	Month 1	6,721	31%	206	37%	6,927	31%
	Month 2	4,644	21%	80	15%	4,724	21%
	Month 3	2,495	11%	53	10%	2,548	11%
After month 3	7,892	36%	212	38%	8,104	36%	
ARV regimens	Start	123,948	95%	4,526	90%	128,474	95%
	Alternative 1st line total	5,831	4%	427	8%	6,258	5%
	AZT	2,846	49%	0	0%	2,846	45%
	EFV	2,179	37%	0	0%	2,179	35%
	AZT+EFV	262	4%	0	0%	262	4%
	Unspecified / other	544	9%	427	100%	971	16%
	Second line regimen	458	0%	72	1%	530	0%
Ambulatory status	Ambulatory status known	121,837		5,025		126,862	
	Ambulatory	119,741	98%	5,001	100%	124,742	98%
Work status	Work status known	121,837		5,025		126,862	
	Working	118,969	98%	4,992	99%	123,961	98%
Side effects	Side effects counted	121,652		5,025		126,677	
	With side effects	3,896	3%	18	0%	3,914	3%
Adherence	Pillcounts done	90,460		681		91,141	
	Pillc shows >95% adherence	85,292	94%	681	100%	85,973	94%