Malawi Antiretroviral Treatment Programme
QUARTERLY REPORT
Results up to 31st December 2009

Executive Summary

By the end of December 2009, **198,846** patients were alive and on ART at **377** ART clinics in Malawi (**279** static clinics and **98** outreach / mobile clinics).

Out of the **271,105** patients ever initiated on ART, **198,846** (73%) were retained alive on ART, **32,008** (10%) had died, **39,115** (13%) were lost to follow-up (defaulted) and **1,136** (<1%) were known to have stopped ART. **79%** of adults and **79%** of children were retained alive on ART 12 months after ART initiation. An estimated **181,482** adults and **17,364** children (<15 years) were alive on ART by the end of December 2009.

In the fourth quarter of 2009 (October to December) a total of **17,702** new patients initiated ART. The opening of 55 new ART clinics in the last 6 months resulted in an unprecedented number of ART clinic transfers: **6,623** ART patients transferred between clinics (27% of the total **24,325** new ART clinic registrations). Among new registrations 39% were male, 61% female; 91% were adults and 9% children.

The number of infants starting ART in the fourth quarter of 2009 in WHO stage 1 or 2 with confirmed HIV infection (DNA-PCR) increased from **142 to 163**, while children under 18 months starting due to presumed severe HIV disease increased from **97 to 127**.

Improved integration of the supervision system for the public and private sector has led to a revision of data shown in previous monitoring reports: Patient retention in the private sector now appears slightly lower than in public sector clinics.

The programme has been affected by a critical ARV drug supply shortage during Q3/Q4 due to the delayed release of funding and the ensuing logistical complications resulting in widespread drug re-distributions between sites. However a targeted survey revealed that patients were affected only in isolated cases, requiring regimen changes or short term treatment interruptions in patients on alternative first line ARVs.

In November 2009, WHO issued a *Rapid Advice* on revised guidelines for provision of ART for adolescents and adults and for PMTCT in resource-constrained countries. In January 2010, the Department for HIV and AIDS, in collaboration with national stakeholders, launched the technical review and planning process to incorporate these new guidelines into the national programme. Revised national guidelines and new ARV drug regimens are expected to be implemented in the first half of 2011.

Table 1: ART programme resume 2003-2009 (public and private sector combined)

	2003	2004	2005	2006	2007	2008	2009
ART delivery sites	9	24	83	141	163	221	377
Patients alive on ART	No data	10,761	29,087	59,980	100,649	147,497	198,846
ART registrations per year	No data	10,183	25,634	46,351	61,688	76,581	88,126
Cumulative registrations	~3,000	13,183	38,817	85,168	146,856	223,437	312,476

Methods

This report includes quarterly data from all patients who registered at ART clinics in Malawi between October and December 2009 and cumulative data from all patients who ever registered up to 31st December 2009.

All health facilities with static ART clinics in the public and private sectors were visited in January 2010. Data collected cover all 279 static and 98 outreach / mobile ART sites. The majority of facilities were using the standard national monitoring & evaluation tools (paper-based or electronic data system); some NGO supported sites were using custom tools compatible with the national standard reporting requirements.

40 ART supervisors (MOH Department of HIV and AIDS staff, experienced ART clinic staff from the districts, MBCA and NGO partners) in 10 teams spent a total of **750 working hours** at the sites, each visit lasting an average of 2 ½ hours, but up to 2 full days at the busiest sites. Structured supervision included:

- Quality assessment of service provision
- M&E data verification
- Drug stock-level assessment
- Patient chart review, clinical mentoring for irregular cases

M&E data were collected from the patient master cards and the ART Registers. Much effort was made in ensuring that registration data and treatment 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 deserving clinic staff.

All data were entered into an MS Access data base at the Department for HIV & AIDS.

Results

National data for quarterly and cumulative ART registrations and treatment outcomes are summarized in 2 tables in **Annex 1**.

Access to ART

By the end of December 2009 there were **377 ART delivery sites** in Malawi, owned by government, mission, NGOs and the private sector. **55** of these were ART facilities in the private sector, charging a nominal MK500 per monthly prescription of drugs per patient.

New patients registered between October and December 2009

In Q4 2009, there were a total of 24,325 ART clinic registrations**,** representing **17,702** (73%) patients who newly initiated ART and 6,623 (27%) ART patients who transferred between clinics. Out of all clinic registrations, 39% were males and 61% were females, 91% were adults and 9% were children (<15 years). The majority of patients **(53%)** started ART in WHO Stage 3. The proportion of patients starting in Stage 1 or 2 with a low CD4 count **(34%)** has slightly decreased from the previous quarter while those starting in WHO stage 4 were **11%.** 1% were infants with confirmed HIV infection (DNA-PCR) and 2% started due to other reasons.

1,005 (4%) of patients registered during Q4 2009 were pregnant women (at the time of ART initiation).

Cumulative patients ever registered up to December 2009

By the end of December 2009, there were a cumulative total of 312,476 clinic registrations, representing **271,105** (87%) patients who newly initiated ART and 41,371 (13%) ART patients who transferred between clinics.

The cumulative number patients ever initiated on ART (271,105) exceeds the target stated in the 2006-2010 ART Scale-Up Plan (200,000) by 36%.

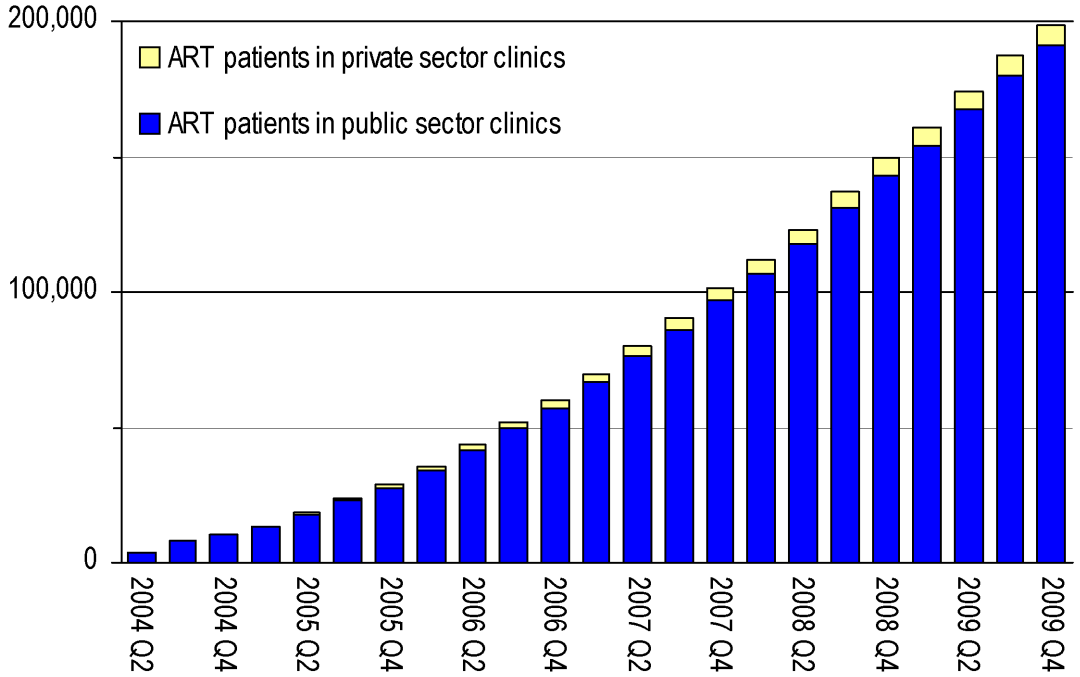
Out of all clinic registrations, 39% were males and 61% were females, 91% were adults and 9 % were children (<15 years). Private sector clinics accounted for **11,866** (3.8%) of total patient registrations.

Treatment Outcomes

By the end of December 2009, a total of **198,846 (73%) patients were alive and on ART**. This number includes 3,841 patients who were assumed to be 'in transit' as of the 31st December 2009, based on the difference between 45,212 patients *transferred out* and 41,371 patients *transferred in* at the facilities around the country. This difference is explained by patients registered as a *transfer out* in the last 2 months of the quarter who have not yet arrived at their new site by the end of the quarter.

Figure 1 shows the increase of patients alive on ART by the end of each quarter since the programme started in 2004. The number of patients alive on ART grew by 35% in 2009. This growth has had immense implications for human and program resources required to sustain this continued massive scale-up.

Figure 1: Patients alive on ART in public and private sector clinics in Malawi

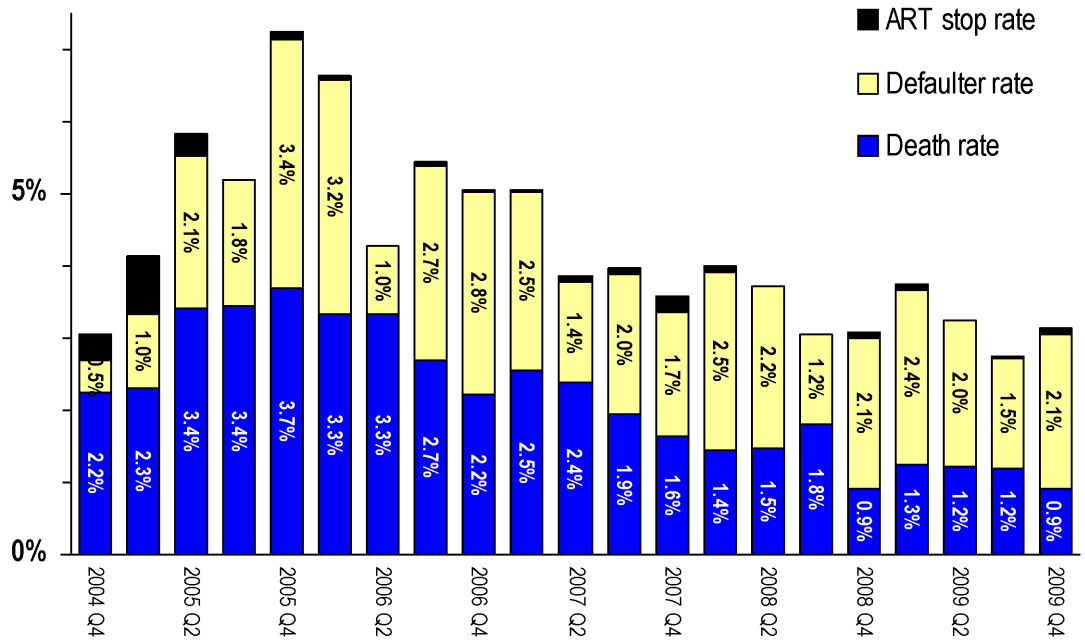


By end of December 2009, a cumulative **32,008** (10%) patients were known to have **died**, **39,115** (13%) were **lost to follow-up**/defaulted, and **1,136** (<1%) were known to have **stopped ART**. Based on previous operational studies, about half of the patients classified as lost to follow-up are thought to have died. During Q4 2009, there were **1,858** new deaths, **4,274** new defaulters and **185** new ART stops. This translates into a quarterly death rate of **0.9%** and a defaulter rate of **2.1%** among the patients alive and on treatment during this

quarter. **Figure 2** shows the general steady decrease of death and defaulter rates since the start of the national programme.

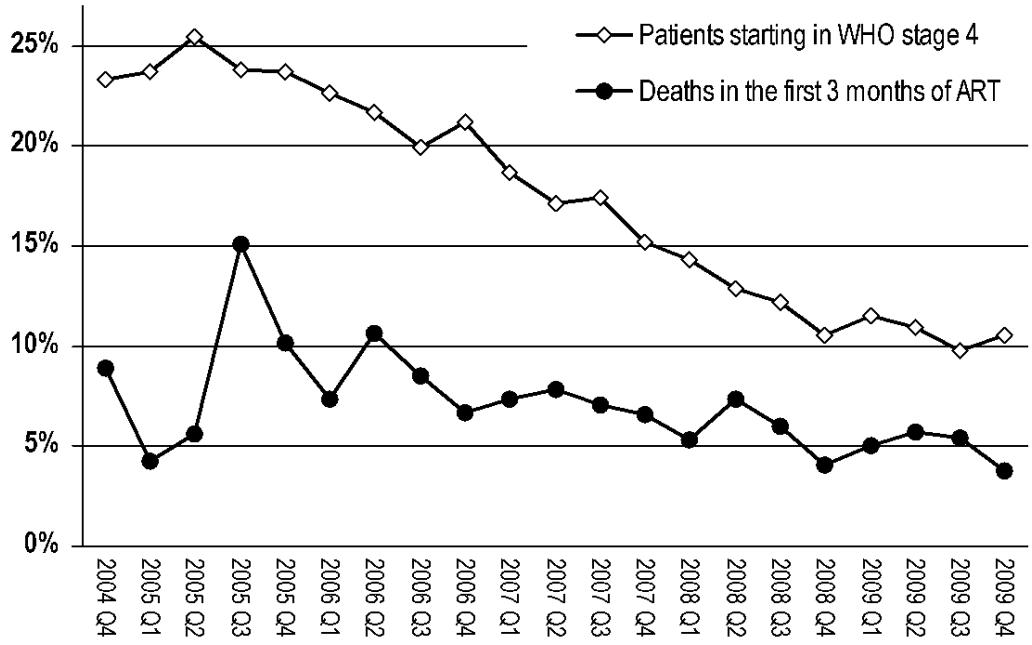
Figure 2: Quarterly rates of ART drop out (ART stop, defaulters and deaths)

Numerator: new ART stops, new defaulters and new deaths in the respective quarter
Denominator: total patients retained alive at the end of the previous quarter plus new patients registered in the respective quarter)



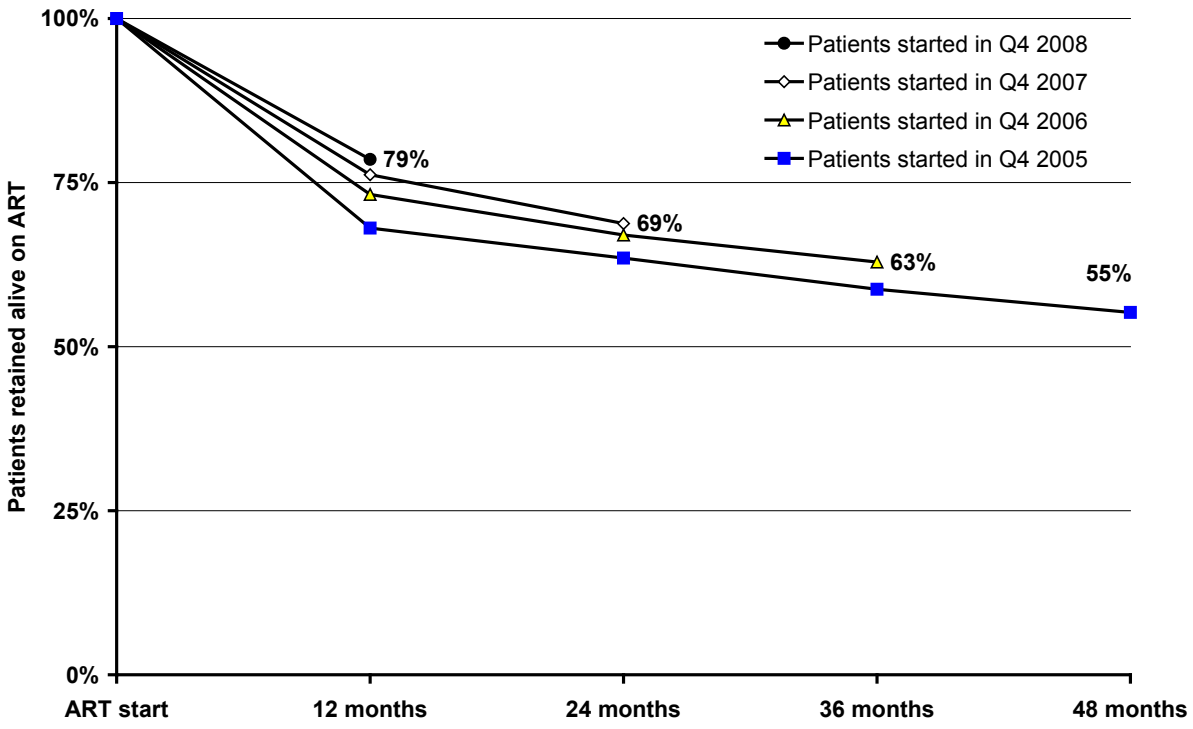
Early mortality has declined considerably (**Figure 3**). In 2005, 15% of new patients died within the first 3 months after ART initiation. Early mortality has declined to less than 5% in Q4 2009. This correlates well with the decline in the proportion of patients starting ART in WHO clinical stage 4 from 25% in 2005 Q2 to about 10% in Q4 2009. The decrease in early mortality is probably mainly a reflection of earlier ART initiation (patients in WHO stage 2 with a CD4 count below the threshold or in stage 3).

Figure 3: Patients starting ART in WHO stage 4 and deaths in the first 3 months after ART initiation. (Shown as proportions among new patients registered each quarter)



79% of adults and **79% of children** were retained alive on ART after 12 months on treatment: A 12, 24, 36, and 48-month **'cohort outcome analysis'** was conducted for patients registered in Q4 2008, Q4 2007, Q4 2006, and Q4 2005, respectively. A separate 12-month cohort outcome analysis was conducted for children who were under 15 years at the time of ART initiation and who registered for ART in Q4 2008. **Figure 4** shows the continuous improvement of long-term treatment outcomes over time. However, the current '12-month survival rate' is still below the WHO target of 85%.

Figure 4: 'Cohort survival analysis' 12, 24, 36 and 48 months after ART initiation



Secondary outcomes of patients retained on ART

Of the **195,005** patients alive on ART and registered (secondary outcomes are not available for 3,841 patients *in transit*): **93%** were on the first line regimen**, 6%** were on an alternative first line regimen, fewer than **1%** were on second line regimen and **1%** were on a non-standard ART regimen. Non-standard regimens are not necessarily substandard regimens; they include patients continuing an ART regimen that was started outside Malawi, patients in research programmes and patients in specialist care in whom specific circumstances lead to the choice of a non-standard regimen.

92% of 96,724 patients with pill count data were classified as >95% adherent. Manual estimation of adherence from pill counts is practically difficult and classification can be misleading. To improve on accuracy of data on adherence, the ART program will switch to a direct evaluation of doses missed in 2010 and it is expected that this will result in lower proportions of patients classified as 'good adherence'.

5,986 (4%) of patients on ART had documented drug side effects at their last clinic visit in 2009. It is likely that this is an under-ascertainment of the true rate of drug side effects.

HIV-related indicator diseases

Table 2 shows the number of ART patients diagnosed and treated for 4 key HIV-related indicator diseases. TB numbers were obtained from the TB registers; Kaposi' Sarcoma (KS) cases from the ART registers; new cryptococcal meningitis and oesophageal candidiasis

cases from the Diflucan registers kept in the pharmacy or from master cards in those sites not participating in the Diflucan programme. The number of patients diagnosed with oesophageal candidiasis and cryptococcal meningitis has declined, which is probably due to the non availability of fluconazole in most sites under the Diflucan programme. Tuberculosis has decreased slightly with KS cases increasing significantly this quarter compared to previous quarter. The Diflucan programme needs strengthening in order to make the drug more widely available. The programme should also consider the option of supplementing Fluconazole supplies.

Table 2: HIV-related indicator diseases

	TB cases	TB HIV tested		TB HIV pos		TB already on ART		Oes. cand.	Cryptoc. mening.	KS cases
2009 Q1	6,404	5,143	80%	3,413	66%	936	27%	1,225	538	520
2009 Q2	5,772	4,833	84%	3,209	66%	1,015	32%	810	571	476
2009 Q3	6,394	5,558	87%	3,416	61%	1,189	35%	1,459	561	450
2009 Q4	5,617	4,671	83%	3,103	66%	1,337	43%	916	386	610

TB / HIV

ART coverage among HIV infected TB patients was estimated at **68%** in Q4 2009. This estimate is based on the following triangulation of TB and ART program data:

TB Program Data: A total of **5,617** TB patients were registered in the TB treatment programme in Q4 2009 and **4,671 (83%)** had their HIV status ascertained (either through a new HIV test or through review of previous documented HIV test results). **3,103 (66%)** of these were HIV positive. **1,337 (24%)** of HIV positives were ART patients who started TB treatment while on ART.

ART Program Data: An estimated **1,611** new patients started ART in Q4 2009 with a current or recent episode of TB (27% of 2,207 total patients registered with TB were transfers ins and were subtracted from the total registrations to avoid double counting).

Assuming that on average 66% of all TB patients are HIV positive and hence eligible for ART, there were an estimated 3,707 HIV infected TB patients in need for ART (66% of 5,617 = 3,707). Considering that 1,337 of these patients were already on ART at the time of starting TB treatment, **2,360** were estimated to require ART initiation (3,707 – 1,337 already on ART). Therefore estimated ART coverage for HIV infected TB patients is =1,611/2,360 = **68%**

Certificates of excellence

Sites with excellent performance in patient and clinic management, including completion of ART registers and master cards and correct cohort analysis are awarded a certificate of excellence: 89 (40%) the sites in the public sector received a certificate of excellence. This is the same as last quarter.

ART workload and staffing

By the end of December 2009 there were **190** sites with fewer than 1,000 patients, **40** sites with 1,001–2,000 patients, **35** sites with 2,001–5,000 and **11** sites with over 5,000 patients registered. The number of sites with over 2,000 patients has increased from 43 to 46, reflecting the ever increasing workload.

For 201 of all clinics visited, the supervision team recorded the number of scheduled clinic days per week and the average number of clinicians, nurses and clerks working during clinic days. The total number of days in a week given for ART at these facilities in Q4 2009 was

540, translating into an average of 2.7 working days per facility in a week. **Table 3** shows the total number of staff days per week by cadre and region. The full-time equivalents (FTEs) indicate the equivalent of full-time ART clinicians, nurses and clerks. Thus, for the country as a whole, the equivalent of 151 clinicians was working full-time in ART delivery each week. The workload per staff in ART clinics is obviously increasing quarter by quarter (compare previous reports).

Table 3: Total average staffing of ART services by region (public sector)

Region	Sites	ART Clinic days	Clinician days/ wk.	Nurse days/ week	Clerk days/ week
North	37	79	86	93	85
Central	73	199	266	309	268
South	91	262	405	457	473
Total	201	540	757	859	826
FTE		2.7	219	248	239

Stocks of ARV drugs and drug for HIV-diseases as of December 2009

Physical stock counts for ARVs and drugs for HIV-related diseases were performed at all sites at the time of the supervision visit (January 2010). **Table 4** shows the total national drug stocks found at facilities with ART clinics. There were enough first line ARV starter packs (54,861 tins) to start about 50,000 new patients on ART, estimated to last for about 6 months at current rates of recruitment. First line ARV "continuation packs" (548,508 tins) were sufficient to keep the current 183,147 patients plus the new patients starting on treatment for about 2 months (up to February 2010). At the time of the supervision visit 15 ART clinics (5%) had no stocks of first line ARVs and while 10 of these were new sites that had not yet started enrolling patients, 5 were established clinics with patients on ART that required urgent re-allocation of drugs to avert treatment interruptions. Stocks of alternative first line ARVs (AZT 44,026 tins) were sufficient to last for about 5 months (up to May 2010) and stocks of EFV (57,577 tins) for 10 month (up to October 2010). New shipments of "continuation packs" are expected to arrive in country in February 2010 and critical stock shortages will occur if this is delayed.

Only 135 (49%) of facilities visited had any stocks of ARVs for maternal PMTCT prophylaxis and 113 (41%) had ARVs for infant PMTCT prophylaxis (single dose nevirapine or AZT combination regimen).

Table 4: Drug stocks at all facilities with ART clinics as of January 2010

Drug	Unit	North	Central	South	Total national stock	Sites with any stock
Lamivir Baby	14	508	427	2,574	3,509	26%
d4T 30mg / 3TC	15	22,564	10,142	22,155	54,861	93%
d4T 30mg / 3TC / NVP	15	22,722	10,746	58,449	91,917	94%
Triomune Baby	30	18,599	5,067	29,018	52,684	37%
d4T 30mg / 3TC / NVP	60	170,775	80,661	297,072	548,508	95%
AZT 3TC NVP	60	19,396	2,978	21,652	44,026	60%
AZT / 3TC	60	9,570	5,821	23,379	38,770	81%
NVP	60	1,489	1,230	6,332	9,051	26%
d4T 30mg / 3TC	60	12,086	2,642	24,723	39,451	52%
EFV	30	17,026	4,611	35,940	57,577	54%
TDF	30	2,967	73	3,375	6,415	11%
ABC	60	319	22	904	1,245	5%
ddI	30	1,392	0	1,033	2,425	4%
LPV/r	120	2,897	1,550	4,220	8,667	12%
CPT	60	153,164	12,392	124,417	289,973	48%
Cotrimoxazole	1	3,382,635	1,709,718	7,374,686	12,467,039	73%
Fluconazole	1	81,521	15,337	74,746	171,604	35%
Ceftriaxone	1	44,778	26,018	90,118	160,914	28%
Acyclovir	1	291,774	418,590	552,514	1,262,878	47%
Ciprofloxacin	1	287,622	42,420	349,461	679,503	53%
Vincristine	1	1,976	1,116	1,243	4,335	15%
Morphine	1	223,253	69,371	146,109	438,733	17%
Amitrityline	1	920,227	1,083,800	1,362,271	3,366,298	56%
NVP (PMTCT)	1	2,455	16,244	3,150	21,849	35%
NVP syrup (PMTCT)	1	3,617	167	8,763	12,547	36%
AZT (PMTCT)	1	204,968	352,416	233,616	791,000	27%
AZT syrup (PMTCT)	1	2,719	800	3,578	7,097	26%

Availability of CD4 counts

The total number of facilities with CD4 count machines in the country remained at 52, but only 44 of these produced any results during Q4 2009. However, the number of CD4 count tests performed increased by 21% to 53,017 compared to last quarter (43,882).

Table 5: CD4 counts performed by quarter

	Total CD4 machines	Functional CD4 machines	CD4 samples processed
2009 Q1	48	42	34,795
2009 Q2	52	47	41,171
2009 Q3	52	47	43,882
2009 Q4	52	44	53,017

Training

An increased number of ART trainings took place in Q4 2009, including 4 basic ART trainings for a total of **112 new ART providers** (5-day course). A total of **391** health workers attended 6 ART refresher trainings (2-day course). These trainings focussed on early Infant

diagnosis, paediatric ART and the new M&E tools. The cumulative number of HCW trained since the start of the national program remained above the target. Funding for training is given directly to the districts and hence there is a need for NAC to inform the HIV & AIDS Department when money is released to the districts so that the Department can follow up with the DHO's office on the training plans implementation. There was no training in the private sector due to problems with MBCA securing funding

Table 6: ART training by end December 2009

Sector	Target	Achievement
Public sector providers trained in Q4 2009	100	112
Private sector providers trained in Q4 2009	25	0
Public sector providers trained (cumulative)	2,600	2,853
Private sector providers trained (cumulative)	500	581

COMMENTS

2 day ART refresher training

2-day refresher trainings will continue in the next quarter to cover over 1,000 HCW throughout the country with support from CDC and MSH.

Revision of the ART scale up plan

In view of the new WHO recommendations released on world AIDS day (Dec 1 2009) the department is reviewing the scale-up plan 2010-2013 to align it with the recommendations that the MOH intends to adapt. This will be re-circulated to stakeholders for input.

Decentralisation of ART supervision

The ART supervision teams now consist of only 1 person from National level with the rest being from the districts, this is in line with the decentralisation process the department has embarked on with increased involvement of the Zonal and District Health offices.

Electronic data system (EDS)

The electronic data system has now been rolled out to 6 sites and a further 5 sites are planned for 2010. There are now 11 sites with more than 5,000 registered patients and manual supervision is becoming a challenge with teams taking 2 days to supervise one site.

TB/HIV integration

The TB team did not join the ART this quarter due to logistical problems, it is hoped that they will be able to join next supervision. It was agreed that the joint visits are useful and should continue though logistics & funding for the TB team need to be worked out. A TB//HIV guideline final draft has been produced by the TB/HIV Technical Working group in line with the TB/HIV framework.

HIV supervisors

The final post (Central zone) for the 5th Zonal HIV supervisor has been filled and the supervisor is expected to start in early 2010. The HIV supervisors meeting was held in January quarter where issues from the previous supervision were discussed and way forward mapped.

WHO Feasibility study

Malawi conducted a rapid appraisal study to assess the feasibility, impact and risk –benefits of introducing the WHO recommendations in Malawi at the request of the WHO. The results of the study were presented to the WHO technical advisory group in Geneva and were influential in the groups deliberations and recommendations.

Main Challenges

- **New WHO recommendations** for early initiation (CD4-350), phasing out of stavudine and introduction of more efficacious and less toxic drugs such as AZT & TDF, detection of ART failure using CD4 count / viral load monitoring will require extensive in-country consultations bearing in mind the financial, material and human resource implications that were noted after Malawi conducted a rapid WHO supported feasibility study.
- **Training and refresher trainings in the private sector** are not taking place in most districts.
- **Delayed release of funds** for ARVs and other commodities has led to stock outs of alternative first line regimens. There is need to engage our development partners to lobby the Global Fund on flexibility.
- **Transportation of CD4 & DBS samples** and results from the ART sites to the labs and back is still a big challenge.

Way forward and emerging issues under discussion

- **Family HIV care service (Pre-ART)**: A draft guideline has been produced and is currently undergoing final revision. It includes M&E tools such as family HIV care & exposed infants Master cards & registers
- **Strengthening Early Infant Diagnosis** (EID) using DNA-PCR and Early Infant Treatment (EIT) including presumed severe HIV disease detection and treatment in children below 18 months of age
- Discussions on Malawi's road map in terms of the **new WHO recommendations** are underway and the scale up plan 2010-2013 will be revised accordingly.

Participants in Q4 2009 ART Supervision

Loyd Chakwawa
Lincy Chalunda
Thom Chaweza
Janet Chikonda
Frank Chimbwandira
Zengani Chirwa
Stephen Chu
Stuart Chuka
Peter Donda
Rodney Gonani
R Gondwe
Bethany Hedt
Andreas Jahn
R Kaipa
Agnes Kalitsiro
Alfred Kapyepye
Joseph Kasola
Absalom Kaunda
Simon Makombe
Kondwani Makwenda
Cosmas Matewere
Gabriel Mateyu
Eustice Mhango
Shira Mitchell
Ekwala Mubiala
HB Mwenelupembe
Mapay Ngalala
S Ngoma
Msenga Ngwira
Joseph Njala
A Ntoseni
Sabina Phiri
M Piringu
Esther Ratsma
Erik Schouten
Monica Simfukwe
Mr M Suzumire
Everista Tchuwa
Cecelia Tenesi
Lyson Tenthani

Report compiled by

Frank Chimbwandira
Eustice Mhango
Simon Makombe
Joseph Njala
Lyson Tenthani
Mwai Makoka
Andreas Jahn
Erik Schouten
Zengani Chirwa
Kondwani Nampanda

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

15th March 2010