



*Government of Malawi Ministry of Health*

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## **Integrated HIV Program Report October – December 2011**

- *HIV Testing and Counselling*
- *Post Exposure Prophylaxis*
- *HIV Exposed Child Follow-Up*
- *Pre-ART*
- *Prevention of Mother to Child Transmission /  
Antiretroviral Therapy*
- *TB / HIV*
- *Sexually Transmitted Infections*
- *Supply of HIV Program Commodities*

## 1 Executive Summary

This is the second quarterly HIV Program report after implementation of the 2011 Integrated Clinical HIV Guidelines<sup>1</sup> in July 2011. A summary of the key achievements between **October and December 2011** is provided below:

- Scale-up of integrated HIV services had reached the following number of sites:
  - **806** HTC sites (565 within and 241 outside of health facilities)
  - **554** (static) ART sites
  - **479** PMTCT sites (Option B+)
  - **402** Pre-ART sites
  - **401** sites with HIV-exposed child follow-up
- **299,017** persons tested and counselled for HIV and **29,745 (10%)** were HIV positive; **129,928 (43%)** people tested for the first time.
- **134,909 (81%)** of 166,697 women at ANC had their HIV status ascertained; **11,350 (8%)** of these were HIV positive and **8,695 (77%)** of these received ARVs.
- **108,660 (86%)** of 126,273 women at maternity had their HIV status ascertained; **9,397 (9%)** of these were HIV positive and **7,830 (83%)** of these received ARVs during labour.
- **8,455 (8%)** of infants discharged alive from maternity were known to be HIV exposed, **7,808 (92%)** of these received ARV prophylaxis.
- **14,017** women started ART under *Option B+*: **7,218 (51%)** were pregnant and **6,799 (49%)** were breastfeeding.
- **34,727** patients started ART during this quarter; this represents almost a **doubling of the quarterly number of ART initiations** compared with the period before implementation of the 2011 guidelines.
- **78%** of adults and **77%** of children were retained alive on ART 12 months after ART initiation.
- **323,638** patients were alive and on ART by end of December 2011; **25,161 (8%)** were on ART regimen 5A (tenofovir / lamivudine / efavirenz)
- **10,865** HIV exposed children and **14,609** pre-ART patients enrolled for follow-up in *HIV Care Clinics (HCC)*
- **839** health workers were trained in the new integrated PMTCT/ART curriculum during Q4, bringing the total number of health workers re-trained in the new guidelines to **4,205**. The HIV Clinical Mentoring Program was launched with the initial training of **306** mentors during Q4 2011. All training details were captured in the new national HIV training data base (*TrainSMART*) at MOH.
- **105** new HTC providers were trained during Q4 and **99** passed their exit exam and qualified as HTC providers.

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<sup>1</sup> Available from:

<http://www.hivunitmohmw.org/uploads/Main/Malawi%20Integrated%20Guidelines%20for%20Clinical%20Management%20of%20HIV%202011%20First%20Edition.pdf>

## 2 Integrated HIV Program Overview

In July 2011, Malawi started implementing a revised HIV Program in all health facilities following the **2011 Malawi Integrated Clinical HIV Guidelines**. These guidelines were developed in 2010/11 by the PMTCT/ART Technical Working Group led by the Department for HIV and AIDS of the Ministry of Health. Key program policies include:

- **PMTCT Option B+**: universal life-long ART for all HIV infected pregnant and breastfeeding women regardless of clinical or immunological stage.
- Standard **HIV exposed child follow-up** to age 24 months. This program aims to improve early infant diagnosis and ART initiation using DNA-PCR testing for all infants from age 6 weeks; rapid antibody testing is considered diagnostic from age 12 months and repeated at 24 months. HIV exposed child enrolment and follow-up is integrated with maternal ART follow-up (Option B+) to improve retention and adherence.
- **Early ART initiation**: universal ART for children under 2 years (confirmed HIV infection), children 2-4 years with an absolute CD4 count of  $\leq 750$  (CD4% no longer required), children over 5 years and adults with a CD4 count  $\leq 350$ , patients co-infected with HIV and hepatitis B.
- Transition to **more favourable first line ART regimens** for adults (Malawi regimen 5A: tenofovir / lamivudine / efavirenz) and children (Malawi regimen 2: zidovudine / lamivudine / nevirapine), including provision of paediatric ARV formulations for all children under 25kg. Transition to regimen 5A had to be restricted to certain patient groups due to funding limitations.
- Standard **pre-ART services** for all HIV-infected persons not yet eligible for ART. The pre-ART program aims to reduce the incidence of HIV-related diseases and to enable early ART initiation based on the new CD4 cell threshold (350) through scheduled CD4 count monitoring. Malawi had no standard pre-ART program until July 2011, although some sites had already started offering elements of the new standard pre-ART package.
- Provider-initiated provision of **contraceptives and condoms** for all adults in pre-ART and ART clinics to reduce the rate of unwanted pregnancies among HIV-infected adults and to reduce HIV-transmission between sexual partners.
- Isoniazid preventive therapy (**IPT**) for pre-ART patients to reduce the incidence of TB and intensified TB case finding (**ICF**) for all patients in pre-ART and ART follow-up to enable early diagnosis and treatment of TB.
- Roll-out of scheduled **viral load monitoring** to improve early detection of treatment failure and initiation of second line ART.

Implementation of PMTCT Option B+ requires provision of ART services at all health facilities with Maternal and Child Health services. This required a massive acceleration of the **decentralization of ART services** from 303 (static) sites by June 2011 to over 600 sites by end of 2011.

## 3 Supportive Site Supervision

### 3.1 Methods

The Department for HIV and AIDS has coordinated quarterly supportive supervision visits to all health facilities with ART services since the start of the national treatment program in 2004. Supervision teams are composed of: experienced HIV clinicians; nurses and M&E staff from health facilities in the public and private sector; district and zonal PMTCT and ART coordinators; program officers and technical staff from the Department for HIV and AIDS; technical staff from implementing partners. The TB and HIV programs are working towards a full integration of their respective site supervision exercises.

Each quarter, a one day pre-supervision meeting is organised for all supervisors participating in the upcoming round to share program updates, discuss observations from the previous round, distribute materials and organise logistics, transport and accommodation.

Standard supervision forms are used to guide the supervision protocol, to update site information and collect M&E reports. Custom forms with previous data for each site are printed from the HIV Department database. The supervision forms include:

- Contact details of HIV service providers at each site
- Quality of service checklist
- Follow up on action points noted during the previous visit
- Next visit date
- M&E reports from HTC, ANC, maternity, exposed child and pre-ART follow-up, ART and TB
- Physical Drug stock-level assessment
- Identification of sites as priority for Clinical Mentoring programme

One copy of the supervision form is returned to the Department for HIV and AIDS, where data are entered in a custom MS Access database to produce national reports and to manage program logistics and the commodity supply chain. A second copy of the supervision form is left at the sites.

The supervision protocol includes a systematic review and verification of primary records (patient cards and registers) at all sites. This effectively provides a quarterly quality audit for M&E records, which has resulted in exceptional accuracy and completeness of HIV Program data in Malawi. At the same time, the systematic chart review helps to identify complex cases or deviations from clinical protocol, allowing the supervision team to provide targeted mentoring and clinical advice. The quarterly supervision exercise also aims to boost staff morale and motivation through *Certificates of Excellence* that are awarded by MOH to sites with an excellent score on the quality of service checklist. The involvement of a growing number of health workers from sites all over the country who participate in the quarterly supervision exercise has helped to build a strong identity for the national HIV program and has greatly facilitated communication between program staff at the national, zonal, district and facility level.

The HTC Program conducts a separate supportive site supervision exercise each quarter, targeting a sample of HTC sites both within and outside of health facilities. Supervision teams consist of district, zonal and national level HTC coordinators, supported by implementing partners.

## 3.2 Supervision Outcomes

**647** public and private sector facilities were visited for **clinical HIV program supervision** during the last 3 weeks of January 2012. The large number of sites included in this supervision round was covered by **67** supervisors working in **20** teams. The teams spent a total of **1,651 working hours** at the sites. Each site visit lasted **2.6** hours on average, but up to 2 days was spent at the busiest sites. **170** clinic teams were awarded a *Certificate of Excellence* for **excellent performance** during the Q4 supervision visit. **201** sites had significant weaknesses and were rated to require **intensive mentoring**. The capacity to provide mentoring visits to these many sites will need to be established over the next months.

**Table 1:** Outcomes of integrated HIV services supervision for 2011 Q4

Zone	Total facil. visited*	Supervision hours spent at facilities		Performance (# and % of sites)	
		Total	Average per site	Excellent perform.	Mentoring needed
NZ	116	291	2.5	26 22%	44 38%
CEZ	93	218	2.3	24 26%	22 24%
CWZ	147	345	2.4	23 16%	37 25%
SEZ	145	413	2.9	41 28%	48 33%
SWZ	146	384	2.7	56 38%	50 34%
<b>Malawi</b>	<b>647</b>	<b>1,651</b>	<b>2.6</b>	<b>170 26%</b>	<b>201 31%</b>

\* includes facilities that were visited for assessment of readiness, but that may have not (yet) been designated to provide integrated HIV services.

**Table 1** provides a summary of the supervision outcomes by zone. Most facilities were using the standard national M&E tools, but 24 high burden sites were using the standard electronic data system for ART (EDS). Some NGO supported sites were using custom tools compatible with the national standard reporting requirements.

A total of **141** sites in the South West, Central West and Central East Zones were visited for supportive **HTC site supervision** for Q4 2011. Almost all sites visited had adequate numbers of HTC providers, but many had inadequate quantities of reagents. HTC Guidelines were available in the HTC rooms. Only about 2/3 of HTC providers had participated in proficiency testing (PT) during this quarter and some counsellors had not received feedback from the previous PT exercise. There were similar challenges in all visited sites, related to the need for more consistent supervision at the district level. Most district HTC supervisors had failed to visit any sites due to fuel shortages and district budget constraints. Many HTC providers needed refresher trainings and sites needed updated IEC materials and stop watches.

## 4 Inventory of Sites and Services

**Table 2:** Facilities with integrated HIV services in the 5 Zones. Availability of services defined by performance (at least 1 patient enrolled) during 2011 Q4

Zone	Total fac.(1)	Facilities providing HIV services				CD4 count machines (2)		
		Exp. child	Pre-ART	PMTCT B+	ART	Installed	Functional	Results
NZ	117	69 59%	70 60%	75 64%	89 76%	13 11%	11 85%	2,789
CEZ	93	49 53%	43 46%	61 66%	66 71%	10 11%	7 70%	2,772
CWZ	153	82 54%	84 55%	107 70%	130 85%	22 14%	13 59%	3,962
SWZ	146	104 71%	106 73%	112 77%	136 93%	18 12%	17 94%	20,686
SEZ	153	97 63%	99 65%	124 81%	133 87%	16 10%	10 63%	7,094
<b>Malawi</b>	<b>662</b>	<b>401 61%</b>	<b>402 61%</b>	<b>479 72%</b>	<b>554 84%</b>	<b>79 12%</b>	<b>58 73%</b>	<b>37,303</b>

(1) Total facilities in the public / private sector designated to provide integrated HIV services in this quarter. Individual site selection is reviewed and may change each quarter.

(2) CD4 machines that have produced at least 1 result during the reporting period are defined as functional.

A total of **806** sites were reported to be providing HTC services in Q4 2011 and **241** of these were outside of health facilities. In addition, HTC is provided as mobile, door-to-door and community-based testing.

**Table 2** shows the distribution of the **662** sites designated to provide clinical HIV services in Q4 2011, by zone. At the national level, there were **554** (static) sites with at least one patient on ART, **479** sites had enrolled women under PMTCT Option B+; **402** sites were providing pre-ART services and **401** had enrolled HIV exposed children for follow-up. The South West Zone had achieved the highest ART site coverage (93% of designated sites) while the South East Zone continued to lead with the highest proportion of sites that had started providing PMTCT Option B+ (81%).

CD4 count machines were installed at **79** sites, but only **58 (73%)** of these had produced at least 1 result during Q4. The total number of CD4 results produced during Q4 was **37,303** and more than half of this output was from the South West Zone, implying that many CD4 machines were running considerably below capacity.

## 5 HIV Testing and Counselling Program Outputs

**299,017** people were tested and counselled for HIV between October and December 2011. This represents a further decrease of 22% from the previous quarter which was caused by wide-spread stock outs of HIV test kits at the sites (see page 21 for further supply chain details). **29,745 (10%)** of all people tested were HIV positive.

Out of **299,017** people tested and counselled, **33%** were males and **67%** were females. Among females, **48%** were pregnant and **52%** were not pregnant.

**54%** of all people tested and counselled were 25 years and above, **38%** were between 15-24 years and **7%** were children below 15 years.

51,125 (17%) accessed HTC with their partners (as a couple).

129,928 (43%) of 299,017 people tested and counselling accessed HTC for the first time in their life. Based on the cumulative number of people who accessed HTC for the first time, a total of 3,597,326 people were tested since introduction of the 'first time HTC access' indicator in July 2007.

Detailed HTC service data are shown in the Annex.

## 6 Post Exposure Prophylaxis (PEP)

A total of 642 persons received PEP during Q4 2011. This is a further increase by 25% from the previous quarter (515). The increase was seen in all 5 zones and it was mainly driven by a significantly higher uptake of PEP at many sites, likely due to the re-training of health workers in the 2011 Integrated Clinical HIV Curriculum which includes a streamlined PEP protocol.

## 7 Provider-Initiated Family Planning (PIFP)

The 2011 Integrated Clinical HIV Guidelines encourage health workers to routinely provide condoms to all adults in pre-ART and ART clinics. Women should also be able to receive at least the standard injectable contraceptive (Depo-Provera) during any pre-ART or ART visit. This policy aims to address the significant unmet need for family planning that had been observed among HIV patients in Malawi and to reduce the number of unwanted pregnancies among HIV-infected women (*PMTCT Prong 2*). HIV program reporting on PIFP is limited women who received an injection of Depo-Provera in pre-ART and ART clinics during the last quarter. Reporting does not account for family planning need nor does it include women who accessed family planning from elsewhere.

**Table 3:** Number and % of women retained in HIV care \* who were on injectable contraceptives (Depo) by the end of 2011 Q4.

Zone	Pre-ART		ART		Both patient groups	
	Tot. women	On Depo	Tot. women	On Depo	Tot. women	On Depo
NZ	1,007	241 24%	18,481	3,215 17%	19,489	3,456 18%
CEZ	744	145 19%	15,340	2,700 18%	16,083	2,845 18%
CWZ	1,239	77 6%	37,933	3,421 9%	39,172	3,498 9%
SEZ	2,890	751 26%	48,437	14,019 29%	51,327	14,770 29%
SWZ	5,203	1,737 33%	63,905	13,389 21%	69,108	15,127 22%
<b>Malawi</b>	<b>11,083</b>	<b>2,951 27%</b>	<b>184,096</b>	<b>36,745 20%</b>	<b>195,179</b>	<b>39,696 20%</b>

\* estimated from the total number of patients retained in pre-ART and ART, multiplied by the proportions of females and adults registered

Table 3 shows that 39,696 (20%) women received Depo-Provera from HIV clinics in Q4 2011, which is a considerable increase from the 13,285 (8%) recorded in the previous quarter. The absolute number of women receiving Depo was highest among ART patients in the South East Zone (14,019; 29%). The overall number of

women in pre-ART follow-up had increased from 3,970 in Q3 to 11,083 and 2,951 (27%) of these had received Depo-Provera. A further increase in PIFP provision and uptake is expected over the next few quarters.

## 8 Cotrimoxazole Preventive Therapy (CPT)

All patients in HIV care are universally eligible for CPT in order to reduce the frequency and severity of several HIV-related diseases. Patients with confirmed HIV infection are provided lifelong CPT in pre-ART and ART clinics. CPT is also given to HIV exposed children until exposure to breast milk has stopped and HIV infection has been ruled out (usually around age 24 months). Fewer than 5% of patients are expected to require stopping of CPT due to toxicity.

**Table 4** shows that **325,669 (90%)** of all HIV patients in Q4 2011 were on CPT. Coverage had increased in all 3 eligible patient groups compared with the previous quarter. At the national level, CPT coverage was slightly higher among pre-ART (92%) than among ART patients (90%), and lower among HIV exposed children (79%). The Central West Zone reported the highest CPT coverage among ART patients (96%).

**Table 4:** Number and % of patients retained in HIV care who were on cotrimoxazole and isoniazid preventive therapy (CPT, IPT) by the end of 2011 Q4.

Zone	CPT								IPT	
	Exp. child		Pre-ART		ART		All patient groups		Pre-ART	
	Tot. pat.	On CPT	Tot. pat.	On CPT	Tot. pat.	On CPT	Tot. pat.	On CPT	Tot. pat.	On IPT
NZ	1,251	846 68%	2,469	2,278 92%	33,859	30,815 91%	37,579	33,940 90%	2,469	0 0%
CEZ	1,130	871 77%	1,946	1,876 96%	27,652	24,957 90%	30,728	27,703 90%	1,946	0 0%
CWZ	2,591	1,971 76%	3,355	3,152 94%	68,441	65,869 96%	74,387	70,992 95%	3,355	0 0%
SEZ	4,115	3,251 79%	6,374	5,747 90%	80,155	72,410 90%	90,644	81,408 90%	6,374	0 0%
SWZ	5,306	4,457 84%	11,550	10,517 91%	112,102	96,653 86%	128,958	111,626 87%	11,550	0 0%
<b>Malawi</b>	<b>14,393</b>	<b>11,395 79%</b>	<b>25,694</b>	<b>23,571 92%</b>	<b>322,209</b>	<b>290,703 90%</b>	<b>362,296</b>	<b>325,669 90%</b>	<b>25,694</b>	<b>0 0%</b>

## 9 TB / HIV Interventions

### 9.1 Intensified Case Finding (ICF)

TB is one of the most important HIV-related diseases in Malawi and a considerable proportion of (mainly early) deaths on ART are attributed to undiagnosed TB. ICF is carried out using a standard symptom checklist at every HIV patient visit. ICF outcomes are documented on HIV exposed child, pre-ART and ART patient cards, but routine M&E reporting is currently limited to ART patients in order to reduce the burden of reporting secondary cohort outcomes. It is assumed that implementation of ICF is similar in pre-ART and exposed child follow-up.

**297,489 (92%)** of all patients retained on ART were screened for TB at their last visit before end of December 2011. As of that visit, **475 (<1%)** patients had one or several symptoms from the TB screening checklist and had presumably been referred for examination by a clinician and for TB investigations. **2,336 (1%)** had confirmed TB (clinical or lab based). Out of these, **1,943 (83%)** were confirmed to be on TB treatment and **393 (17%)** had not yet started or had interrupted TB treatment. Data are shown in the **Annex (Cumulative ART outcomes)**.

## 9.2 Isoniazid Preventive Therapy (IPT)

All pre-ART patients with a negative screening outcome for TB symptoms are eligible for IPT. The first (large scale) procurement of isoniazid and pyridoxine for the HIV programs has been delayed and implementation of IPT is expected to start in Q2 2012.

## 10 HIV-Related Diseases

**Table 5** shows the number of patients treated for 4 key HIV-related indicator diseases (data from TB, ART and Diflucan registers or ART treatment cards). The number of new TB cases further increased from 5,207 in Q3 to **5,332** in Q4 2011 and the HIV ascertainment rate increased to **90%** (from **83%** in Q3 2011). This was probably due to a new distribution of HIV test kits that took place during Q4. **62%** of TB patients whose HIV status was ascertained were positive and **52%** of these were already on ART when starting TB treatment. The continuous increase in the number and proportion already on ART may be due to the scale-up of intensified active TB case finding (ICF) in ART clinics, resulting in increased the TB case detection rates among ART patients. New oesophageal candidiasis (OC) cases increased to **716** in Q4 while cryptococcal meningitis (CM) cases remained at **219**. Reporting on OC and CM is linked to the availability of fluconazole, and has been unreliable in 2011.

**Table 5:** Number new cases of key HIV-related diseases registered per quarter (KS = Kaposi Sarcoma, CM = cryptococcal meningitis, OC = oesophageal candidiasis).

	TB				KS *	CM *	OC *
	Tot. cases	HIV status asc.	HIV positive	Already on ART	Tot. cases	Tot. cases	Tot. cases
2011 Q1	5,008	4,372 87%	2,813 64%	1,221 43%	590	209	744
2011 Q2	5,000	4,243 85%	2,827 67%	1,273 45%	468	392	481
2011 Q3	5,207	4,344 83%	2,837 65%	1,381 49%	540	218	426
2011 Q4	5,332	4,788 90%	2,957 62%	1,526 52%	604	219	716

## 11 HIV-Exposed Child Follow-Up

### 11.1 Methods and Definition of Indicators

There are multiple entry points into HIV exposed child follow up: children of HIV infected mothers may be enrolled at birth at maternity; they may be found at Under 1 or Under 5 Clinics through active screening for HIV exposure; they may be identified when presenting sick to OPD; or they may be seen with their mothers in ART follow-up. Although the targeted enrolment age is below 2 months, children may theoretically be enrolled up to 23 months of age (when HIV infection can be ruled out by rapid antibody test and breast milk exposure is likely to have stopped).

Initial registration data and details for every visit are recorded on an *Exposed Child Patient Card* and a subset of the registration data is copied in the *HIV Care Clinic (HCC) register* (one record per patient). Registration data are reported from the HCC register on a quarterly basis. Follow-up outcomes are reported monthly, selecting children who were **2, 12 and 24 months** old in the respective reporting month. Outcomes are determined from the latest visit details recorded on each card. HIV infection status is evaluated as **known negative** if a negative DNA-PCR or rapid test result was available at the last visit; HIV infection status is evaluated as **known positive** if a positive DNA-PCR result was available at any age or a positive rapid antibody test was available from age 12

months; HIV infection status is counted as **unknown** if HIV infection has not been confirmed and/or a negative test result pre-dated the last visit (assuming on-going HIV exposure through breast milk). All children under 24 months with confirmed HIV infection and those under 12 months with confirmed HIV antibody and symptoms of *presumed severe HIV disease* are **eligible for ART**.

The main outcome indicator for the HIV exposed child follow-up program is **HIV-free survival at 24 months of age**. This is defined as the proportion of children who were discharged as confirmed uninfected by the age of 24 months.

## 11.2 HIV Exposed Child Registration Data

This is only the second quarterly report from the new standard follow-up program for HIV exposed children and the data should be regarded as preliminary: **10,865** HIV exposed children were registered during Q4 2011, which is an almost **3-fold increase** compared with the previous quarter. **3,478 (32%)** of these were enrolled under the age of 2 months.

## 11.3 Birth Cohort Outcomes

There were **3,131** infants in the **2 month age cohort**. **462 (15%)** had received a DNA-PCR result and **145 (31%)** of these were confirmed HIV infected. An additional **72** infants were diagnosed with *presumed severe HIV disease*, which means that a total of **217** infants were eligible for ART. **20 (9%)** of these had started ART. Out of the entire 2-month age cohort, **3,004 (96%)** were retained in exposed child follow-up, **20 (9%)** had started ART and **10 (<1%)** were discharged confirmed uninfected<sup>2</sup>. **6 (<1%)** were known to have died and **74 (2%)** had been lost to follow-up.

There were **1,684** children in the **12 month age cohort**. Current HIV infection status was known for **254 (15%)** children (DNA-PCR or rapid antibody test) and **35 (14%)** of these were confirmed HIV infected. **48 (3%)** additional children had been diagnosed with *presumed severe HIV disease*, which means that a total of **83** children were eligible for ART. **43 (52%)** of these had started ART. Out of the entire age cohort, **1,550 (92%)** were retained in exposed child follow-up, **43 (3%)** had started ART and **31 (2%)** were discharged confirmed uninfected<sup>2</sup>. **41 (2%)** were lost to follow-up and **13 (1%)** were known to have died.

There were **550** children in the **24 month age cohort**. Current HIV infection status was known for **416 (76%)** children (DNA-PCR or rapid antibody test) and **42 (10%)** of these were confirmed HIV infected. **8** additional children had been diagnosed with *presumed severe HIV disease*, which means that a total of **50** children were eligible for ART. **32 (64%)** of these had started ART. Out of the entire age cohort, **108 (21%)** were retained in exposed child follow-up, **32 (6%)** had started ART and **316 (62%)** were discharged confirmed uninfected<sup>2</sup>. **39 (8%)** were lost to follow-up and **15 (3%)** were known to have died.

**HIV-free survival** in this quarter was **62%**, which was more plausible than in the Q3 report (35%). There was still a difference between the 374 children who were confirmed not infected in the 24 month age cohort and the 316 classified as *discharged uninfected*. It is possible that some of these children were retained in follow-up beyond age 24 months due to continued breast feeding. The exposed child cohort reports are expected to further consolidate over the next quarters.

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<sup>2</sup> A small number of children may be rightfully discharged as 'confirmed uninfected' by 2 or 12 months of age, provided that HIV exposure through breast milk has definitely stopped (e.g. maternal death) and a negative HIV test was obtained at least 6 weeks thereafter.

## 12 Pre-ART

This is the second quarterly report from the new standard pre-ART follow-up program and the data should be regarded as preliminary.

### 12.1 Pre-ART Registration Data

A total of **14,609** patients were newly registered for pre-ART follow-up in Q4 2011, which is a 70% increase from the previous quarter. **1,573 (11%)** of these were children aged 2-14 years. Several sites had already established pre-ART services before July 2011 and the cumulative number of pre-ART patients ever registered was **64,921**.

### 12.2 Cumulative Pre-ART Follow-up Outcomes

**25,694 (40%)** of all patients ever registered were retained in pre-ART follow-up by the end of Q4 2011; **29,017 (45%)** had started ART; **8,717 (13%)** had been lost to follow-up; **1,153 (2%)** were known to have died. The proportion of patients who started ART will continue to increase in the cumulative pre-ART cohort analysis over time.

**23,571 (92%)** of patients retained in pre-ART were on CPT. **2,951 (27%)** of 11,083 women had received Depo-Provera from their pre-ART clinic. The implementation of IPT for pre-ART patients is expected to start by mid 2012. This is due to delayed procurement of isoniazid and pyridoxine for the IPT program. Further details on CPT, Depo-Provera and IPT are presented in **Tables 3 and 4** in the respective sections above.

## 13 PMTCT / ART

The implementation of **PMTCT Option B+** has effectively integrated PMTCT and ART services. The program aims to initiate lifelong ART for all HIV infected women as early as possible from the 2<sup>nd</sup> trimester of pregnancy. ART may be started and continued at ANC, labour and delivery, and at ART clinics. All infants born to HIV-infected women are supposed to start daily nevirapine prophylaxis for the first 6 weeks of life. Nevirapine syrup is given to women at the earliest opportunity to take home with instructions how to give it to the new-born.

### 13.1 Data Sources and Reporting Methods

All patients starting ART are recorded using standard program monitoring tools (ART patient treatment cards and ART clinic registers). **ART baseline data** for all patients registered are reported each quarter from ART clinic registers. **ART outcomes** of all patients ever registered are reported after reviewing the cards of all new patients and of those who were on ART at the end of the previous quarter, updating the status of patients who have subsequently died, stopped or been lost to follow-up. Secondary outcomes such as current regimen, CPT status, side effects, adherence and TB status are reported for all patients retained on ART.

ART scale-up has resulted in a growing proportion of HIV-infected women who are already on ART when becoming pregnant. Implementation of *Option B+* will further increase ART coverage in this group. The ART program only captures pregnancy (and breastfeeding) status at the time of *ART initiation*. The quarterly ART report thus provides information on the number of new women starting ART while pregnant (or while breastfeeding), but total **maternal PMTCT coverage** should be estimated from the number of pregnant women who were on ARVs at the end of pregnancy. This information is available from **ANC cohort reports** that are based on women's final status at their last ANC visit and include women already on ART when becoming pregnant and on those who

started ART during their current pregnancy. Over 95% of pregnant women in Malawi attend ANC and ANC reports therefore provide almost complete data for the whole pregnant population. **Infant PMTCT coverage** is estimated from maternity reports, based on the number of infants born to known HIV-infected women and discharged alive who started nevirapine prophylaxis. Only about 70% of women deliver at a health facility in Malawi and maternity reports are therefore likely to underestimate the total infants receiving ARV prophylaxis.

New standard M&E tools for ANC and maternity were implemented in Malawi in January 2010 and revised tools will be distributed in 2012 to reflect the new PMTCT policy. ANC and maternity clinic registers and reporting forms include patient management information as well as all relevant data elements for M&E of the maternal and child health and HIV programs. The ANC register was specifically designed to avoid data duplication that previously affected PMTCT reports from ANC due to the inability to account for individual women's outcomes in the course of multiple visits. The cohort reporting system is designed to aggregate women's outcome data after they have completed their ANC visits. Data from ANC and maternity are collated and presented separately because records do not allow identification of individual women and hence are subject to double counting if not separated.

Coverage was calculated by dividing the number of patients served by population denominators. The denominators were derived from expected pregnancies based on population projections and HIV prevalence from epidemiological surveillance.

## 13.2 HIV Services at ANC

The full national data from ANC are presented in the **Appendix**.

**146,765** women attended ANC for their first visit between October and December 2011. This is equivalent to 97% of the estimated 151,750 pregnant women in the Malawian population during one quarter, which would meet the expected ANC attendance rate in Malawi. However, the number of new ANC women in the quarterly reports usually exceeds the expected number of pregnancies in the population, which is likely explained by a considerable number of women from neighbouring countries who are accessing health services in Malawi. In Q4 2011, several sites did not compile this data element and the unusually low figure is due to incomplete data; however, the ANC cohort outcome reports (see below) were complete for almost all sites.

The following report covers the outcomes of the **166,697** women who started ANC between April and June 2011 and who had finished ANC by December 2011. **13,724 (8%)** of women started ANC in their first trimester. **77,122 (46%)** of women were tested for syphilis at ANC and **1,431 (2%)** were syphilis positive. The syphilis testing rate almost doubled from the previous quarter due to a much wider availability of syphilis test kits following a push-distribution.

The total number of visits for the cohort under review is **430,410**. Only **22%** of women in this cohort attended the minimum of 4 focussed ANC visits.

### 13.2.1 HIV Ascertainment at ANC

**134,909 (81%)** of ANC attendees had their HIV status ascertained. Out of these, **8,184 (6%)** presented with a valid documented previous HIV test result and **126,725 (94%)** received a new HIV test result at ANC. A total of **11,350 (8%)** women were found HIV positive. This is lower than the estimated 12% HIV prevalence among pregnant women and this is likely due to problems with sensitivity of HIV rapid testing in high volume service provision settings.

The **126,725** women whose HIV status was ascertained at ANC represent **84%** of the expected 151,750 pregnant women in the population. The rate of HIV status ascertainment at ANC has continued to increase slightly from the previous quarters.

### 13.3 ARV Coverage at ANC

**8,695 (77%)** of HIV infected women attending ANC received maternal ARVs. This represents **48%** coverage of the estimated 18,210 HIV positive pregnant women in the population in this quarter (12% of 151,750). This is an increase from the previous quarters is partly due to the higher degree of data completeness.

Of the **8,695** women who received any ARVs, **1,188 (14%)** were given a single tablet of nevirapine to take home and **3,877 (45%)** were started on AZT combination regimen.

**7,400 (65%)** of 11,350 HIV positive women were assessed for ART eligibility through a CD4 count and/or WHO clinical staging, or by the fact that they were already on ART. **3,708 (50%)** were found eligible and **3,630** were on ART during their ANC follow-up. With implementation of the new guidelines in July 2011, all HIV-infected pregnant women were universally eligible for ART. More than half of women in this cohort were still on one of the previous prophylactic PMTCT regimens. This is explained by the 6-month ANC cohort reporting period which started before the changeover to the new guidelines.

**10,295 (91%)** of HIV infected women at ANC were on Cotrimoxazole Preventive Therapy.

**573 (5%)** of HIV infected women attending ANC received the infant dose of ARVs (nevirapine syrup) to take home.

### 13.4 HIV Services at Maternity

The full national data from maternity are presented in the **Appendix**.

Between October and December 2011, **120,165** women were admitted for delivery to maternity; **6,108 (5%)** of these were referred to another facility before delivery, resulting in **126,273** total admissions to maternity during Q4 2011. The number of women attending maternity is equivalent to **79%** of the expected 151,750 deliveries in the population during the quarter. Out of all admissions, **116,447 (95%)** delivered at health facilities, while **6,143 (5%)** had already delivered before reaching a facility. The 116,447 (77%) of 151,750 facility deliveries exceeds the estimated rate of facility deliveries in the 2010 DHS (72%) and indicates a high level of data completeness. This was achieved through the inclusion of ANC and maternity reports in active data collection during the quarterly **site supervision exercise**, which now covers virtually all sites with MCH services.

A total of **112,725 (94%)** deliveries were conducted by skilled birth staff, **1,698 (1%)** by paramedical staff and **5,742 (5%)** were not attended by any of the above (probably mainly among women who delivered before reaching maternity). **12,172 (10%)** of women developed obstetric complications. The most common leading complications were obstructed / prolonged labour (**3,956 cases; 33%**) and haemorrhage (**1,910 cases, 16%**). A total of **122,590** babies were born, **117,968 (96%)** were singletons and **4,622 (4%)** were twins/multiples. There were **120,224 (98%)** live births and **2,366 (2%)** stillbirths. **119,242 (99%)** of babies born alive were discharged alive and **982 (1%)** died before discharge. **120,042 (>99%)** of women were discharged alive and **123 (<1%)** women died before discharge, which is equivalent to a maternal mortality ratio of 102 per 100,000 live births among women attending maternity.

### 13.4.1 HIV Ascertainment at Maternity

**108,660 (86%)** women had their HIV status ascertained at maternity. Out of these, **103,659 (95%)** presented with a valid previous HIV test result and **5,001 (5%)** received a new HIV test result. A total of **9,397 (9%)** women were HIV positive and **99,263 (91%)** were negative. The **108,660** women whose HIV status was ascertained at maternity represent **72%** of the expected 151,750 women delivering in the population.

HIV exposure status was ascertained for **104,268 (87%)** out of 119,242 babies born and discharged alive. **8,445 (8%)** of these were born to a known HIV positive mother.

### 13.4.2 ARV Coverage at Maternity

A total of **7,830 (83%)** of HIV infected women attending maternity received ARVs during labour. This is a slight decrease from the previous quarter. Out of these, **6,112 (78%)** were on ART, **1,285 (16%)** received the labour dose of AZT combination regimen, **433 (6%)** received single dose nevirapine. This is a complete reversal of the proportions seen in previous quarters and is consistent with the progressing roll out of Option B+. **7,549 (80%)** women were already taking ARVs during pregnancy: **6,031 (80%)** of these were on lifelong ART and **1,518 (20%)** had received AZT combination prophylaxis. ART should be taken for more than 4 weeks during pregnancy to ensure optimal effectiveness. **4,806 (80%)** of women on ART had received the respective regimen for over 4 weeks during pregnancy.

A total of **7,808 (92%)** of infants who were known HIV exposed and discharged alive received ARV prophylaxis at maternity. This represents **43%** coverage of the estimated 18,210 HIV exposed infants born in the population in this quarter (12% of 151,750). **6,605 (85%)** of HIV exposed infants received nevirapine (in line with Option B+) and **1,203 (15%)** started AZT combination regimen.

## 14 ART Access and Follow-Up Outcomes

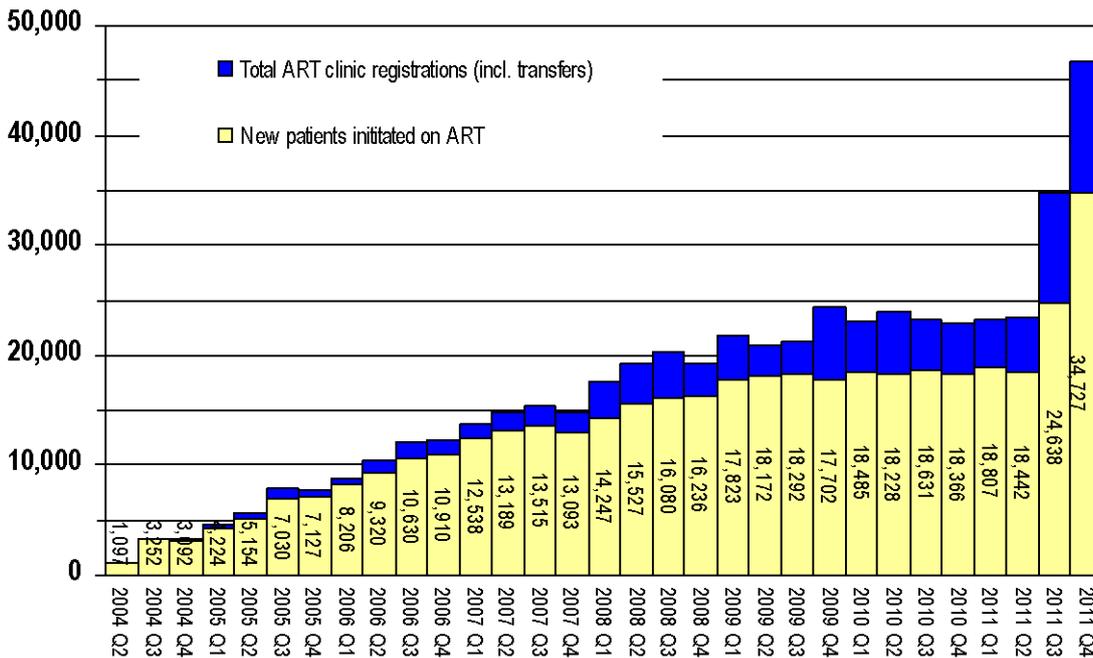
The full national data from the ART Program are shown in the **Annex**.

### 14.1 New ART Registrations during Q4 2011

By the end of December 2011, there were **554 static ART sites** in Malawi, managed by government, mission, NGOs and the private sector. Out of these, **67** were ART facilities in the private sector, charging a nominal MK500 per monthly prescription of drugs per patient.

**Figure 1: Patients newly initiated on ART and total ART clinic registrations per quarter**

Total ART clinic registrations include patients who transferred between sites. This results in double counting of patients at the national level. For 'patients newly initiated on ART' every patient is only counted once.



Implementation of the 2011 Integrated Clinical HIV Guidelines started in July 2011 and the number of new ART initiations continued to increase to an unprecedented **24,638** this quarter (see **Figure 1**). Establishment of many new static sites continued to cause a growing wave of transfers between sites: **11,910** patients transferred between clinics (**25%** of the total **46,793** new ART clinic registrations). Among all new registrations **28%** were males and **72%** females. **7,599 (22%)** of all females were pregnant and **7,218 (95%)** of these were started under **Option B+** in WHO stage 1 or 2, independent of their CD4 count. The remainder of pregnant women were otherwise eligible for ART, either due to WHO stage 3 or 4 conditions or because of a CD4 count <350. A further **6,799** women in WHO stage 1 or 2 were started because of breastfeeding, bringing the total number of women started under **Option B+**<sup>3</sup> to **14,017**. The number of pregnant women started on ART is expected to increase further over the next few quarters, while the number of breastfeeding women is expected to increase initially and then decline as many sites will have caught up with initiating HIV positive breastfeeding women who delivered before the policy change.

A total of **26,071** patients (**56%**) started in WHO stage 1 or 2. This is the highest proportion of early ART initiations in any quarter since the start of the program resulting from the implementation of the new guidelines (raised 350 CD4 threshold, Option B+, universal ART for HIV-infected children aged 12-23 months). The on-going roll-out of the national pre-ART program with scheduled CD4 count monitoring is expected to lead to a further increase in early ART initiations. **16,817 (36%)** of

<sup>3</sup> Universal ART for all HIV infected pregnant and breastfeeding women in WHO stage 1 or 2, independent of CD4 count

patients registered in Q4 started in WHO stage 3 and **3,014 (6%)** started in stage 4 (a further decrease from 8% in Q3).

The total number of children registered increased from 2,986 in Q3 to **3,556** in Q4. **295** children were registered under the policy of universal ART for children aged 12-23 months in WHO stage 1 or 2, independent of CD4 count. A small increase was also noted for children with presumed severe HIV disease (from 152 in Q3 to **206** in Q4) and infants in WHO stage 1 or 2 with confirmed HIV infection through DNA-PCR (from 215 in Q3 to **231** in Q4). Paediatric ART access is expected to further accelerate as implementation of the new guidelines over the next few quarters continues.

**2,672 (6%)** out of all ART clinic registrations were patients with TB: **1,517 (3%)** had a current and **1,155 (2%)** a recent history of TB. **604 (1%)** of patients registered had Kaposi' sarcoma.

## 14.2 Cumulative ART Registrations up to December 2011

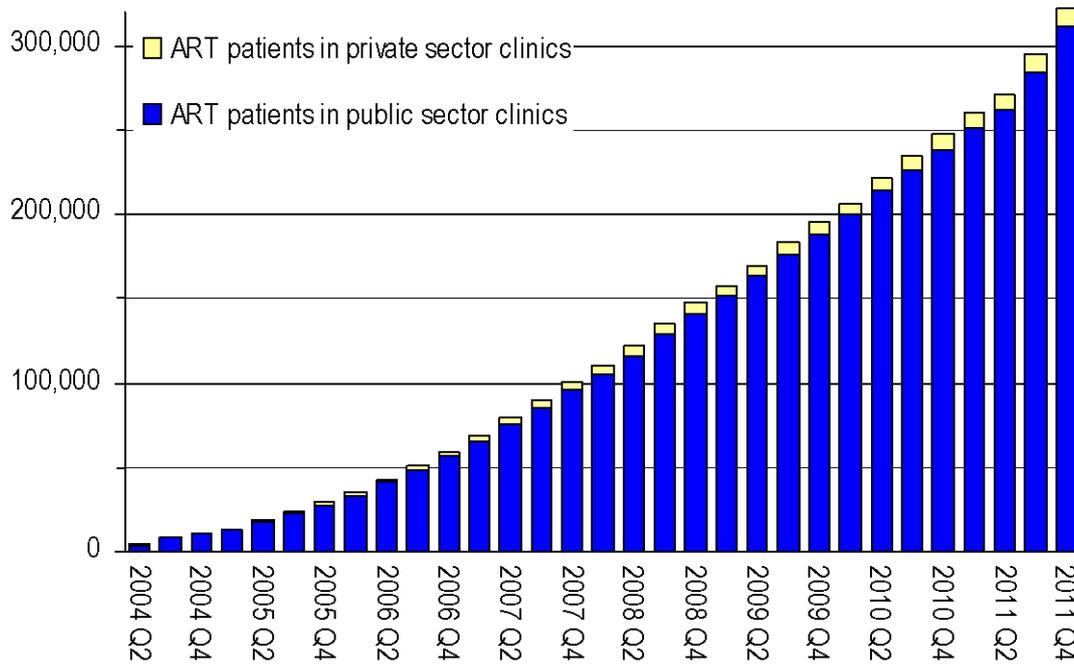
By the end of December 2011, there were a cumulative total of **535,483** clinic registrations, representing **443,594 (83%)** patients who newly initiated ART and **91,216 (17%)** patients on ART who transferred between clinics. **673 (<1%)** out of all clinic registrations were patients who re-initiated ART after treatment interruption. Out of all ART clinic registrations, **38%** were males and **62%** were females, **92%** were adults and **8%** were children (<15 years). Private sector clinics accounted for **18,998 (3.5%)** of total patient registrations.

## 14.3 ART Outcomes

By the end of December 2011, a total of **323,638 patients were alive on ART**. This number includes **1,429** patients who were assumed to be 'in transit' as of the 31<sup>st</sup> December 2011, based on the difference between **92,645** patients *transferred out* and **91,216** 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.

Out of the **443,594** patients ever initiated on ART, **323,638 (73%)** were retained alive on ART, **48,482 (11%)** had died, **70,207 (16%)** were lost to follow-up (defaulted) and **1,940 (<1%)** were known to have stopped ART. An estimated **294,585** adults and **29,053** children (<15 years) were alive on ART by the end of December 2011.

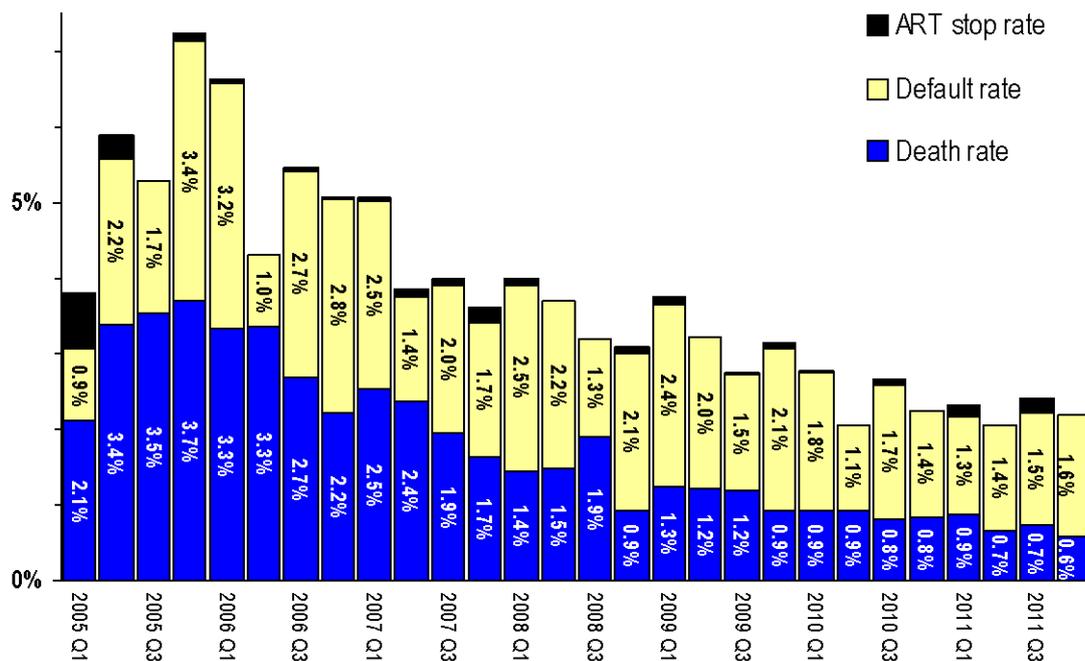
**Figure 2: Patients alive on ART in public and private sector clinics in Malawi**



**Figure 2** shows the increase of patients alive on ART by the end of each quarter. The number of patients alive on ART **increased by 27,676** in Q4 of 2011. This unprecedented growth is a result of the implementation of Option B+ for PMTCT and the raised CD4 count threshold for ART eligibility. Implementation of revised integrated PMTCT/ART guidelines is expected to further accelerate growth of the ART patient cohort. The workload at individual sites is expected to remain manageable due to the massive on-going decentralization to over 300 new sites.

**Figure 3: Quarterly rates of ART drop out (ART stop, defaulters and deaths)**

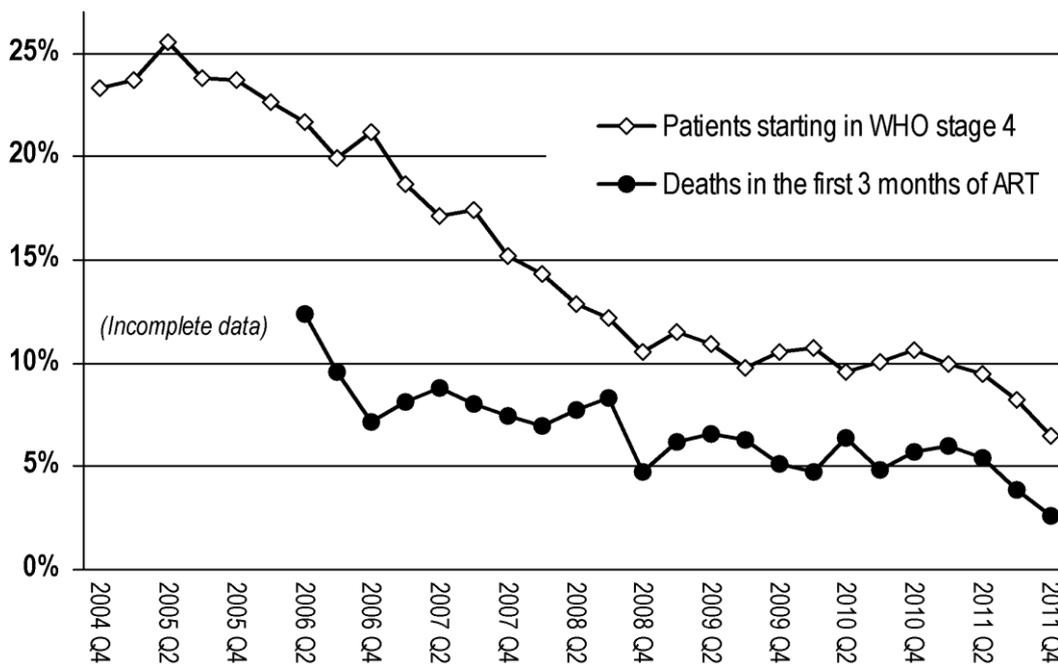
Numerator: new ART stops, new defaulters and new deaths in the respective quarter  
 Denominator: total patients retained alive at the end of the previous quarter plus new patients registered in the respective quarter)



**Figure 3** shows the considerable decrease of ART drop-out rates since the start of the national programme. During Q4 2011, there were **1,876** new deaths, **5,310** new defaulters, 0 new ART stops

(and **148** new ART re-initiations). This translates into a quarterly death rate of **0.6%** and a defaulter rate of **1.6%** among the patients alive and on treatment during this quarter. By end of December 2011, a cumulative **48,482 (11%)** patients were known to have died **70,207 (16%)** were lost to follow-up and **1,940 (<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.

**Figure 4:** 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)



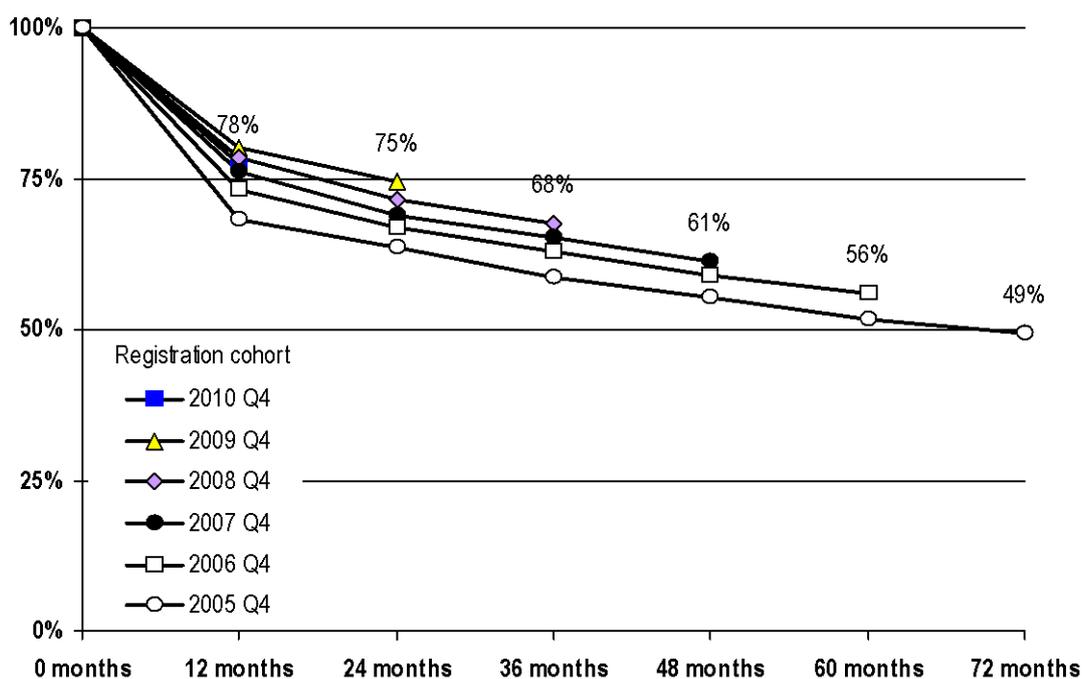
**Figure 4** shows the considerable decline in **early mortality** since the start of the program. In 2006 Q2, 11% of new patients died within the first 3 months after ART initiation. Early mortality has declined to the lowest value since the start of the program (**2.6%** in Q4 2011). This correlates well with the decline in the proportion of patients starting ART in WHO clinical stage 4 from 25% in 2005 Q2 to **6.4%** in Q4 2011. The decrease in early mortality is probably mainly due to earlier ART initiation (patients in WHO stage 2 with a CD4 count below the threshold or in stage 3). The new guidelines are expected to further reduce early mortality, as more patients will be started in WHO stage 1 and 2 (universal ART for HIV infected pregnant and breastfeeding women and children under 2 years).

At the time of publication of this report, revised epidemiological projections for the population in need of ART (based on the changed eligibility criteria) were not available and estimates for ART population coverage are therefore not presented.

### 14.3.1 ART Cohort Survival Analysis

A 12, 24, 36, 48, 60, 72 and 84-month 'cohort outcome survival analysis' was conducted for patients registered in Q4 of 2005, 2006, 2007, 2008 2009 and 2010, 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 2010. **78% of adults** and **77% of children** were retained alive on ART after 12 months on treatment. This is a slight decrease from 79% in children and from 79% in adults in the previous quarter. **Figure 5** 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 5:** Group cohort survival analysis: Proportion of patients retained alive on ART 12, 24, 36, 48, 60 and 72 months after ART initiation



### 14.3.2 Secondary outcomes of patients retained on ART

Secondary outcomes are known for the **322,209** patients alive on ART who remained at their sites at end of the quarter. They are not known for 1,429 patients *in transit*.

#### ART Regimens

**319,403 (99%)** of patients were on first line and **1,378 (<1%)** were on second line regimens; **1,428 (<1%)** were on non-standard regimens. Non-standard regimens are not necessarily substandard regimens and include patients continuing an ART regimen that was started outside Malawi, patients in research programmes and patients in specialist care.

Among patients on first line regimens, **18,290 (6%)** were on paediatric formulations and **13,109 (72%)** of these were on the new standard first line for children (regimen 2P: AZT/3TC/NVP). Over the next few quarters, it is expected that about 9% of all first line patients will be moved to paediatric formulations and over 90% of these will receive regimen 2P.

**244,561 (81%)** of 301,113 patients on adult formulation first line regimen were on regimen 1A (stavudine / lamivudine / nevirapine); **2,615 (8%)** were on regimen 2A (zidovudine / lamivudine / nevirapine), which is the main alternative regimen for patients with stavudine toxicity.

By the end of December 2011, **25,161 (8%)** of patients on adult first line were receiving regimen 5A (tenofovir / lamivudine / efavirenz). The majority of these were new initiations under Option B+ or because of concurrent TB treatment. Only a minority were substituted to regimen 5A due to confirmed lipodystrophy or other severe ART side effects.

### Adherence to ART

Pill counts and the number of missed doses were documented for **288,351 (89%)** out of all patients retained on ART and **260,991 (91%)** of these were classified as >95% adherent in Q4 2011. 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 has switched to a direct evaluation of doses missed in 2010. Most ART sites are now recording this measure consistently.

### ART Side Effects

**256,135 (79%)** patients on ART had information on drug side effects documented at their last clinic visit before end December 2011 and **8,386 (3%)** of these had side-effects. This is probably an under-ascertainment of the true rate of drug side effects, as an assumed 20-25% of patients develop at least mild side effects on regimen 1 (stavudine / lamivudine / nevirapine). Malawi continues to increase access to alternative first line regimens for such patients, and those with severe lipodystrophy are now moved to regimen 5A (tenofovir / lamivudine / efavirenz).

## 15 TB / HIV Management

Approximately **99%** of HIV infected TB patients were receiving ART in Q4 2011. This estimate is based on the following triangulation of TB and ART program data:

*TB Program Data:* A total of **5,332** TB patients were registered during Q4 2011. Assuming an average HIV prevalence of 67% among TB patients, **3,555** TB patients were estimated to be HIV positive and therefore in need of ART. Given that **1,526** TB patients registered were already on ART at the time of starting TB treatment,  $3,555 - 1,526 = \mathbf{2,029}$  TB patients needed to initiate ART.

*ART Program Data:* An estimated **1,983** patients<sup>4</sup> started ART with a current or recent episode of TB during Q4 2011. This is **99%** (1,983 of 2,029) of the TB patients who needed to start ART. This means that a total of  $1,526 + 1,983 = \mathbf{3,509}$  (**99%**) of the estimated 3,555 HIV infected TB patients were receiving ART in Q4 2011.

### TB / ART program triangulation

\*

#### HIV-burden among TB patients (estimated)

HIV negative (est. 33%)	1,777	33%
HIV positive (est. 66%) in need of ART	3,555	67%
Not on ART	46	1%
Total on ART (coverage)	3,509	99%
Already on ART (TB prog)	1,526	43%
Started ART within 24m of TB diagnosis (ART prog)	1,983	57%
ART initiations with current TB (ART prog)	1,126	57%
ART initiations after recent TB (ART prog)	857	43%

<sup>4</sup> 25% of the 2,672 ART patients who were registered with a recent or current episode of TB at the time of ART initiation were assumed to be transfers and were subtracted to adjust for double-counting.

## 16 STI Treatment

STI program reports remained incomplete and 3 out of 29 district-level reports could not be included in this quarterly report. The STI service data presented below are estimated to represent **85%** of the total national STI program outputs.

Detailed STI Program data are presented in the **Annex**.

### 16.1 STI Treatment Access and Coverage

Between October and December 2011, **35,262** STI clients were served at health facilities in Malawi, representing **36%** of the 98,600 expected quarterly STI cases in the population. Out of all clients, **14,368 (41%)** were male and **20,894 (59%)** were female. **3,078 (15%)** of female STI clients were pregnant. **22,196 (63%)** of clients were 25 years and above, **9,326 (26%)** were 20-24 years and **3,770 (11%)** were under 20 years old. Considering the estimated STI case burden in the population, access to STI clinics remained particularly low among under 20 year olds: **3,770 (22%)** of the expected 17,323 STI cases in this age group were seen at the health facilities during this quarter.

### 16.2 Client Type and STI History

**27,858 (79%)** of clients were index cases and **7,336 (21%)** were partners of index cases. **4,430 (60%)** of partners were asymptomatic. Considering that a total of **18,629** partner notification slips were issued, **45%** of those notified presented to the clinic. **24,314 (69%)** of clients presented with their first lifetime episode of STI, **7,968 (23%)** clients reported to have had an STI in over three months ago and **2,974 (8%)** of clients reported having had an STI within the last three months. Re-occurrence of an STI after a recent episode may be due to re-infection or treatment failure.

### 16.3 HIV Status

HIV status was ascertained for **18,058 (51%)** clients and **5,652 (31%)** of these were HIV positive. **1,635 (29%)** of positives were identified through a new test initiated at the STI clinic, while **4,017 (71%)** presented with a documented previous positive HIV test result. **2,174 (54%)** of clients with a previous positive HIV test result were on ART.

The rate of HIV status ascertainment remained low at STI clinics in Malawi. This is likely due to poor implementation of provider initiated testing and counselling, combined with weak back-referral systems which may lead to incomplete documentation of new HIV test results at the STI clinics. It is worth noting that a substantial proportion of clients who are aware of their HIV infection present with a new episode of an STI. This may suggest poor translation of positive living strategies promoted during counselling, but could also be due to the increased risk of recurrence of HSV-2 and balanitis among HIV-infected clients.

### 16.4 STI Syndromes

The most common syndrome was abnormal vaginal discharge (AVD) with **10,324 (28%)** cases. Similar to the previous quarter, balanitis, bubo, warts and neonatal conjunctivitis each accounted for 1 – 3% of cases.

## 17 Supply of HIV Program Commodities

**409,800** Determine, **48,400** Uni-Gold and **9,090** SD Bioline test kits were distributed to the district pharmacies for onward distribution to all sites in November/December 2011. These supplies were procured through UNITAID/CHAI to address the shortage of HIV test kits that had started to emerge during the previous quarter due to delayed procurement from Global Fund supplies. Unfortunately, this expedited consignment contained a faulty batch of SD Bioline (which is used as a tie-breaker for discrepant test results) and 6,360 (70%) of the 9,090 distributed SD Bioline were successfully recovered from the sites after the recall notification was received on 24<sup>th</sup> November 2011. It is assumed that at least some of the SD Bioline which could be recovered was used for HTC. However, an assessment of the affected batch by the national HIV reference showed no false positive or false negative results, making it likely that few - if any - clients would have been given wrong test results.

The regular quarterly distribution of ARVs which was scheduled for September could not take place due to procurement delays and the lack of a buffer stock. ARVs started running out at individual sites from October and a system of ad hoc allocations with weekly deliveries to all 3 regions was put in place to avert stock ruptures at the service delivery sites. However, remaining stocks at the warehouse (from the Q1 2011 consignment) started to be depleted by December. In spite of additional measures (such as reducing supply intervals for patients), several sites experienced complete stock ruptures of first line ARVs for 2-3 weeks.

An increased 6 month consignment of HIV test kits procured with GF resources (**1,450,000** Determine and **85,600** Uni-Gold tests) was distributed in Jan/Feb 2012 to the district pharmacies, for onward distribution to the sites. At the same time, the scheduled quarterly distribution of adult and paediatric ARVs was carried out directly to all facilities in the national program.

Physical stock counts for ARVs and drugs for HIV-related diseases were performed at all sites during the supervision visits in January 2012, which coincided with the distribution of ARVs and test kits. This means that the new consignment is partly included in the physical stock report. **Table 5** shows the total drug stocks found at the sites during the January 2012 site visits and the estimated consumption periods. Stocks of the adult first line regimens were expected to last until April 2012 and the new paediatric first line (regimen 2P: zidovudine / lamivudine / nevirapine) were expected to last until March 2012.

The actual number of patients alive on ART by the end of December (**323,638**) exceeded by 3,782 (**1.2%**) the number projected for the quantification for procurement of ARVs (**319,856**). **25,161** patients were on regimen 5A, which was only **1,567 (6%)** less than projected in the procurement plan for the end of this quarter. This confirms that mid-term ART program projections have a high degree of accuracy.

Procurement of drugs for HIV-related diseases has been delayed due to inadequacies of the in-country supply chain and many of these items were running out at the sites. Stocks of cotrimoxazole in packs of 60 tabs for CPT were low, with an estimated consumption interval of less than 2 weeks from stock taking in January. Cotrimoxazole in packs of 1,000 tabs is procured for treatment of HIV-related diseases rather than for CPT, but given the short supply of CPT, many sites had resumed to dispensing this instead.

**Table 5:** Total stocks of HIV program commodities at all sites visited during the 2011 Q4 supportive site supervision. Stock positions are from the date of the visit (between 1-4 weeks after the end of the quarter).

Inventory unit	Item	Total physical stock	Sites with any stock	Consumption per month *	Months of stock *	
<b>tins</b>	ABC / 3TC 60 / 30mg tins (60 tabs)	2,314	32	567	4.1	
	AZT / 3TC 60 / 30mg tins (60 tabs)	4,730	402	1,028	4.6	
	AZT / 3TC 300 / 150mg tins (60 tabs)	36,664	282	1,933	19.0	
	AZT / 3TC / NVP 60 / 30 / 50mg tins (60 tabs)	85,835	477	32,773	2.6	
	AZT / 3TC / NVP 300 / 150 / 200mg tins (60 tabs)	125,313	307	22,615	5.5	
	d4T / 3TC 6 / 30mg tins (60 tabs)	2,065	78	678	3.0	
	d4T / 3TC 30 / 150mg tins (15 tabs)	29,451	519	10,418	2.8	
	d4T / 3TC 30 / 150mg tins (60 tabs)	43,412	288	6,511	6.7	
	d4T / 3TC / NVP 6 / 30 / 50mg tins (60 tabs)	6,865	52	12,040	0.6	
	d4T / 3TC / NVP 30 / 150 / 200mg tins (15 tabs)	29,958	521	10,418	2.9	
	d4T / 3TC / NVP 30 / 150 / 200mg tins (60 tabs)	944,923	582	244,561	3.9	
	EFV 200mg tins (90 tabs)	1,884	26	201	9.4	
	EFV 600mg tins (30 tabs)	57,872	319	7,927	7.3	
	LPV / r 100 / 25mg tins (60 tabs)	2,541	25	567	4.5	
	LPV / r 200 / 50mg tins (120 tabs)	15,855	65	1,189	13.3	
	NVP 200mg tins (60 tabs)	8,285	122	849	9.8	
	TDF / 3TC 300 / 300mg tins (30 tabs)	11,651	275	1,733	6.7	
	TDF / 3TC / EFV 300 / 300 / 600mg tins (30 tabs)	164,442	577	25,161	6.5	
	<b>bottles</b>	NVP 10mg/ml bottles (10 ml)	2,171	19		
		NVP 10mg/ml bottles (25 ml)	58,025	516	17,627	3.3
NVP 10mg/ml bottles (100 ml)		153	3			
<b>vials</b>	Depo-Provera 150mg/1ml vials (1 each)	452,676	410			
	Bleomycine 15,000IU vials (1 each)	379	18			
	Ceftriaxone 1g vials (10 each)	23,759	90			
	Ganciclovir 250mg / ml vials (1 each)	973	6			
	Vincristine 1mg / 1ml vials (1 each)	8,871	54			
<b>tabs</b>	Aciclovir 400mg tins (500 tabs)	5,312,655	373			
	Ciprofloxacin 500mg blister packs (10 tabs)	1,411,653	343			
	Codeine 30mg tins (500 tabs)	74,732	23			
	Cotrimoxazole 100 / 20mg tins (100 tabs)	11,121,699	129			
	Cotrimoxazole 400 / 80mg blister packs (60 tabs)	5,420,915	103	20,456,696	0.3	
	Cotrimoxazole 400 / 80mg tins (1000 tabs)	44,270,621	496			
	Fluconazole 200mg tins (100 tabs)	292,501	93			
	Ibuprofen 200mg tins (100 tabs)	971,604	146			
	Isoniazid 300mg tins (1000 tabs)	69,016	25			
	Morphine 10mg blister packs (60 tabs)	138,889	35			
	Pyridoxine 25mg tins (100 tabs)	443,172	97			
	<b>tests</b>	Determine HIV1/2 boxes (100 each)	796,609	328		
Uni-Gold HIV1/2 boxes (20 each)		71,603	362			
SD Biotest HIV boxes (30 each)		13,740	194			
Determine syphilis boxes (100 each)		163,474	183			
<b>pieces</b>	Condoms male boxes (1 each)	12,711,812	465			
	Condoms female boxes (1 each)	1,304,466	373			

\* 'Consumption per month' and 'Months of stock' are only estimated for commodities that are directly related to patient-regimen groups in the standard service reports. Estimates are based on the number of patients on the respective regimen at the end of the quarter evaluated and do not account for potential (positive or negative) growth. 'Months of stock' is calculated from the day of the physical stock count, which is on average 1 month after the end of the quarter.

## 18 Trainings and Mentoring

### 18.1 HIV Testing and Counselling

In Q4 2011, **4 basic HTC training** sessions for **105** participants were conducted in 2 districts, organised by Lighthouse, Dignitas, Malawi Prisons and YONECO. **99 (94%)** of all participants passed their exit exam and were certified as new HTC counsellors.

### 18.2 PMTCT/ART

By June 2011, the Department for HIV and AIDS had developed a **5-day curriculum** for the (re)training of all health workers in the 2011 Integrated Clinical HIV Guidelines. **120 trainers were trained** by July 2011 who then went on to train health workers and clerks from all sites around the country. **839** health workers were trained in the new integrated PMTCT/ART curriculum between October and December, bringing the total number of health workers re-trained in the new guidelines to **4,205**. This initial wave of trainings aimed to establish at least 2 staff at each facility who were able to start implementing the new guidelines.

The HIV Clinical Mentoring Program was launched with the initial training of **306** mentors during Q4 2011. The clinical mentoring programme aims to provide hands on support for implementation of the new guidelines and strengthen systems particularly at the new sites.

This major national training exercise received critical budgetary, technical and logistical support from donors and implementing partners, including: USG / PEPFAR, UNICEF, MSH, CHAI, Dignitas, PIH, Lighthouse, Baylor, UNC, EGPAF, GAIA, JHPIEGO, COM. All training and participant details were captured in the new national HIV training data base (*TrainSMART*) at MOH.

### 18.3 STI

There was no basic STI training in Q4 2011.

## 19 Participants in Q4 2011 ART Supervision

Lloyd Chakwawa (CO, Malawi Defence Force)	Prosper Lutala (HIV Zonal Supervisor, MOH, UNV)
Lincy Chalunda (CO, MOH)	Mercy Magombo (Nurse, MOH)
Grace Chipanga (Nurse, Private)	Martha Majiya (Nurse, MOH)
Zengani Chirwa (TA, MOH, Department of HIV and AIDS)	Simon Makombe (ART officer, Department of HIV and AIDS)
Salome Chiwewe (Nurse, MOH, Ntchisi DH)	Chifundo Makuluni (Nurse, MOH)
Stephen Chu (HIV Zonal Supervisor, MOH, UNV)	Amos Makwaya (CO, MOH)
Stuart Chuka (CO, MBCA)	Kondwani P A Makwenda (CO, MSH)
Tawina Crusoe (Nurse, MOH)	Davie Maseko (CO, NGO)
Peter Donda (CO, Dedza DH)	Hannock Matupi (ARV clinician, MOH, Rumphi DH)
Michael Eliya (National PMTCT Coordinator, MOH)	Benjamin Mazalo (CO, SUCOMA Clinic)
Dominic Gondwe (Nurse, MOH Dedza DHO)	Loyna Mbewe (Nurse, MOH)
Suleiman Ibrahim (HIV Supervisor, Central West Zone Office)	Eustice Mhango (ART officer, Department of HIV and AIDS)
Elifa Jere (Nurse, MOH Kasungu DHO)	Dalitso Midiani (PMTCT Officer, MOH)
Lilian Kachali (Nurse, MOH)	Erik Mittochi (CO (ART coord), MOH)
Vera Kajawo (Nurse, MOH)	Everista Mkandawire (Nurse, MOH)
Mathilda Kamanga (Nurse, Army)	Christopher Mkwezalamba (CO, MOH)
Rhoda Jamu Kamoto (Nurse, CHAM)	Offrey Mnduwira (CO, Police)
Henry Kamwetsa (CO, MOH)	Damison Msiska (CO, Dwangwa)
Mercy Kapito (Nurse, Nurse)	Andraida Mtoseni (Nurse, MOH)
Oscar Kasiyamphanje (Nurse, CHAM)	Ekwala Mubiala (HIV Zonal Supervisor, MOH, UNV)
Joseph Kasola (CO, MOH, Chitipa DH)	Fainala Muyila (Nurse, MOH)
Catherine Kassam (, MOH)	Ruockia Mwachumu (Nurse, MOH Nsanje DHO)
Rodrick Kaulele (CO, CHAM (Sister Tereza))	Linda Mwafurirwa (Nurse, CHAM)
Absalom Kaunda (CO, MOH, Mzimba DHO)	Edward Mwale (CO, Lighthouse)

James Mwambene (CO, Diginitas)  
Musaku Mwenechanya (CO, MOH)  
Mapay Ngalala (HIV Zonal Supervisor, MOH, UNV)  
Stanley Ngoma (CO, MOH)  
Joseph Njala (HIV fellow, MOH, Department of HIV and AIDS)  
Grace Juma Nkhata (Nurse, MOH)  
Angela Nkhoma (Nurse, MOH)  
Patricia Nkhota (Nurse, Dr David Livingstone)  
Jonas Nyasulu (IT Fellow, MOH)  
Sabina Phiri (Nurse, MOH)  
Macleod Piringu (CO, MOH)  
Abdul Richard (CO, MOH)  
Monica Simfukwe (Nurse, MOH, Chintheche RH)  
Mark Suzumire (CO, MOH)  
Elizabeth Tamula (Nurse, Baylor)  
Dyson Telela (Nurse, MOH NkhataBay DHO)  
Cecelia Tenesi (Nurse, MOH)  
Lyson Tenthani (M&E Fellow, Department of HIV and AIDS)

Gerald Zomba (HIV Fellow, MOH)

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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.

**12<sup>th</sup> April 2012**

## 20 Appendix (Full National HIV Program Data)