



Government of Malawi Ministry of Health

Integrated HIV Program Report October -December 2014

- *Integrated HIV Program Supervision*
- *HIV Testing and Counselling / Early Infant Diagnosis*
- *Blood Safety*
- *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 | 1 |
| 2 | INTEGRATED HIV PROGRAM OVERVIEW | 2 |
| 3 | SUPPORTIVE SITE SUPERVISION | 3 |
| 3.1 | METHODS..... | 3 |
| 3.2 | SUPERVISION OUTCOMES..... | 3 |
| 4 | INVENTORY OF SITES AND SERVICES | 5 |
| 5 | HIV TESTING AND COUNSELLING PROGRAM OUTPUTS | 6 |
| 5.1 | HTC ACCESS TYPE | 6 |
| 5.2 | AGE AND SEX DISTRIBUTION AMONG HTC CLIENTS..... | 6 |
| 5.3 | FIRST TIME, REPEAT AND CONFIRMATORY TEST RESULTS..... | 6 |
| 6 | DNA-PCR TESTING FOR EARLY INFANT DIAGNOSIS OF HIV (EID)..... | 8 |
| 7 | BLOOD SAFETY | 9 |
| 8 | POST EXPOSURE PROPHYLAXIS (PEP)..... | 9 |
| 9 | PROVIDER-INITIATED FAMILY PLANNING (PIFP)..... | 9 |
| 10 | COTRIMOXAZOLE PREVENTIVE THERAPY (CPT)..... | 10 |
| 11 | TB / HIV INTERVENTIONS | 11 |
| 11.1 | INTENSIFIED CASE FINDING (ICF)..... | 11 |
| 11.2 | ISONIAZID PREVENTIVE THERAPY (IPT)..... | 11 |
| 12 | HIV-RELATED DISEASES | 11 |
| 13 | HIV-EXPOSED CHILD FOLLOW-UP | 12 |
| 13.1 | METHODS AND DEFINITION OF INDICATORS | 12 |
| 13.2 | HIV EXPOSED CHILD REGISTRATION DATA | 12 |
| 13.3 | BIRTH COHORT OUTCOMES | 13 |
| 14 | PRE-ART | 13 |
| 14.1 | PRE-ART REGISTRATION DATA | 13 |
| 14.2 | CUMULATIVE PRE-ART FOLLOW-UP OUTCOMES | 14 |
| 15 | PMTCT / ART | 14 |
| 15.1 | DATA SOURCES AND REPORTING METHODS..... | 14 |
| 15.2 | ARV COVERAGE AMONG PREGNANT / BREASTFEEDING WOMEN AND EXPOSED INFANTS | 16 |
| 15.3 | HIV SERVICES AT ANC..... | 17 |
| 15.4 | HIV SERVICES AT MATERNITY..... | 17 |
| 16 | ART ACCESS AND FOLLOW-UP OUTCOMES..... | 18 |
| 16.1 | NEW ART REGISTRATIONS DURING Q4 2014..... | 18 |
| 16.2 | CUMULATIVE ART REGISTRATIONS UP DECEMBER 2014..... | 20 |
| 16.3 | ART OUTCOMES | 20 |
| 16.4 | ART COHORT SURVIVAL ANALYSIS..... | 22 |
| 16.5 | VIRAL LOAD (VL) MONITORING | 26 |
| 17 | TB / HIV MANAGEMENT..... | 27 |
| 18 | STI TREATMENT..... | 27 |
| 18.1 | ACCESS TO STI TREATMENT AND COVERAGE | 28 |
| 18.2 | CLIENT TYPE AND STI HISTORY | 28 |
| 18.3 | HIV STATUS..... | 28 |
| 18.4 | STI SYNDROMES..... | 28 |
| 18.5 | REFERRALS..... | 29 |
| 19 | SUPPLY OF HIV PROGRAM COMMODITIES | 30 |
| 19.1 | QUANTIFICATION AND PROCUREMENT PLANNING | 30 |
| 19.2 | QUARTERLY DISTRIBUTION OF HIV COMMODITIES | 30 |
| 19.3 | QUARTERLY LOGISTICS MONITORING AND SUPPLY CHAIN TRAIL FOR Q4 2014 | 30 |
| 19.4 | NATIONAL STOCK STATUS OF HIV COMMODITIES..... | 31 |
| 20 | TRAINING AND MENTORING..... | 33 |
| 21 | PARTICIPANTS IN Q4 2014 SUPERVISION (SITE VISITS 12 – 30 JANUARY 2015)..... | 34 |
| 22 | APPENDIX (FULL NATIONAL HIV PROGRAM DATA)..... | 34 |

1 Executive Summary

This is the 14th quarterly HIV Program report after implementation of the 2011 Integrated Clinical HIV Guidelines in July 2011. A summary of the key achievements between **October and December 2014** is provided below:

- Scale-up of integrated HIV services had reached the following number of sites:
 - **724** static (579 within and 145 outside of health facilities) and 188 outreach HTC sites
 - **713** (static) ART sites
 - **615** PMTCT sites (Option B+, all included in ART sites above)
 - **655** Pre-ART sites
 - **644** sites with HIV-exposed child follow-up
- **464,292** persons were tested and counselled for HIV; **139,602 (30%)** accessed HTC for the first time; **324,690 (70%)** were repeat testers and **9,854 (3%)** of these received confirmatory testing (after having tested positive in the past). This is equivalent to **38%** confirmatory testing coverage among 26,060 patients initiating ART this quarter. **28,465 (6%)** clients received a positive result for the first time.
- **19,606 (97%)** of 20,244 blood units collected were screened for (at least) HIV, hepatitis B and syphilis.
- **134,985 (89%)** of 151,118 women at ANC had their HIV status ascertained; **10,550 (8%)** of these were HIV positive. **129,821 (96%)** of 138,024 women at maternity had their HIV status ascertained **9,785 (8%)** of these were HIV positive.
- **26,060** patients started ART this quarter.
- **536,438** patients were alive and on ART by end of December 2014. This means that **54%** of the estimated 1 million HIV positive population was on ART. ¹ Estimated ART coverage among people in need for treatment¹ was **42%** (46,410 / 111,000) for children (<15 years) and **71%** (489,775 / 687,000) for adults.
- **76%** of adults and **77%** of children were retained alive on ART at 12 months after initiation. Actual retention rates are thought to be about **10%** higher due to misclassification of 'silent transfers' as defaulters in clinic-based survival/retention analysis. (see section 16.4)
- **470,048 (93%)** of 504,494 patients on first line adult ART were on regimen 5A (TDF/3TC/EFV).
- **11,053 ² (85%)** of an estimated **13,317 ¹** HIV infected pregnant women in Malawi were on ART this quarter. **6,288 (57%)** of these were already on ART when getting pregnant and **4,765 (43%)** started ART during pregnancy/delivery.
- An additional **1,593 ²** breastfeeding women started ART due to **Option B+** (in WHO stage 1/2)
- **78%, 72%, 68%** and **71%** of women started under **Option B+** were retained on ART at **6, 12, 24** and **36 months** after initiation, respectively.
- **8,851 (7%)** of infants discharged alive from maternity were known to be HIV exposed, **8,305 (94%)** of these received ARV prophylaxis (nevirapine). **7,006 (65%)** were enrolled in exposed child follow-up before age 2 months.
- A total of **10,797** HIV exposed children and **6,483** pre-ART patients were enrolled for follow-up in *HIV Care Clinics (HCC)* during this quarter.

¹ 2014 Spectrum estimates based on 2014 definition of eligibility for ART in Malawi (CD4<500, Option B+, UT for U5).

² Adjusted for double counting due to patient transfers / 'failed ART initiations' among women lost to follow-up within 6 months of ART registration.

2 Integrated HIV Program Overview

Malawi implemented a revised HIV Program in all health facilities following the release of the **2011 Malawi Integrated Clinical HIV Guidelines**. The second edition of these guidelines was published in March 2014 and implementation of revised policies commenced in April 2014. Key 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 should be integrated with maternal ART follow-up (*Option B+*) to improve retention and adherence.
- **Early ART initiation**: universal ART for children under 5 years (confirmed HIV infection, CD4% no longer required), children over 5 years and adults with a **CD4** count ≤ 500 , patients with HIV and hepatitis B co-infection.
- Transition to a **new 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 5A was completed by end 2013.
- Standardized **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 (500) through scheduled CD4 count monitoring.
- 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 and to reduce TB transmission in HIV clinics.
- 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 in June 2011 to currently 713 sites.

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 implementation of 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 in urgent need of clinical mentoring
- Semi-structured feedback and performance rating for the supervision teams by facility staff

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. A growing number of health workers from sites all over the country participate as supervisors in this quarterly exercise and this has strengthened the national HIV Program identity and has greatly facilitated communication between program staff at the national, zonal, district and facility level.

The HTC Program usually 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

719 public and private sector facilities were visited for **clinical HIV program supervision** between 12th and 30th January 2015. This round of supervision was disrupted by the severe flooding that affected several districts, mainly in the Southern Region of Malawi. 8 sites in Chikwawa and Nsanje

could not be reached at all (most had closed temporarily) and service reports are therefore not 100% complete for this quarter.

The large number of sites was covered by **95** supervisors working in **23** teams that spent a total of **2,042 working hours** at the sites. Each site visit lasted on average **2.9** hours, but up to 2 days were spent at the busiest sites. **321** sites were awarded a *Certificate of Excellence* for **excellent performance**. The number of sites with excellent performance is similar to previous quarter despite a more rigorous application of performance criteria being maintained. **72** sites had significant weaknesses and were rated to require **intensive mentoring**. The capacity to provide site mentoring will need to be further expanded.

Table 1: Outcomes of integrated HIV services supervision for 2014 Q4

| Zone | Total facil. visited* | Supervision hours spent at facilities | | Performance (# and % of sites) | |
|---------------|-----------------------|---------------------------------------|------------------|--------------------------------|------------------|
| | | Total | Average per site | Excellent perform. | Mentoring needed |
| NZ | 125 | 339 | 2.8 | 55 44% | 14 11% |
| CEZ | 99 | 257 | 2.6 | 47 47% | 15 15% |
| CWZ | 160 | 436 | 2.7 | 58 36% | 11 7% |
| SEZ | 166 | 528 | 3.2 | 96 58% | 19 11% |
| SWZ | 169 | 482 | 3 | 65 38% | 13 8% |
| Malawi | 719 | 2,042 | 2.9 | 321 45% | 72 10% |

* 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. **124** sites had cumulatively registered more than 2,000 ART patient and **43** of these had registered more than 5,000. **49 (40%)** of these high burden sites were using electronic data system for ART (EDS). Some NGO supported sites were using custom tools compatible with the national standard reporting requirements.

4 Inventory of Sites and Services

A total of **724** static sites reported HTC service provision in Q4 2014 and **145** of these were outside of health facilities. **188** outreach HTC sites.

Table 2: Facilities with integrated HIV services in the 5 Zones. Availability of services defined by performance (at least 1 patient enrolled) during 2014 Q4

| Zone | Total fac.(1) | Facilities providing HIV services | | | | CD4 count machines (2) | | |
|---------------|---------------|-----------------------------------|----------------|----------------|----------------|------------------------|----------------|---------------|
| | | Exp. child | Pre-ART | PMTCT B+ | ART | Installed | Functional | Results |
| NZ | 128 | 114 89% | 114 89% | 104 81% | 121 95% | 30 23% | 27 90% | 2,667 |
| CEZ | 99 | 92 93% | 91 92% | 90 91% | 97 98% | 18 18% | 16 89% | 1,350 |
| CWZ | 162 | 133 82% | 132 81% | 129 80% | 158 98% | 27 17% | 22 81% | 3,553 |
| SWZ | 168 | 145 86% | 159 95% | 135 80% | 163 97% | 39 23% | 34 87% | 11,069 |
| SEZ | 165 | 160 97% | 159 96% | 157 95% | 164 99% | 50 30% | 47 94% | 5,846 |
| Malawi | 722 | 644 89% | 655 91% | 615 85% | 713 99% | 164 23% | 146 89% | 24,485 |

(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.

Table 2 shows the distribution of the **722** sites designated to provide clinical HIV services in Q4 2014, by zone. At the national level, there were **713** (static) sites with at least one patient on ART, **615** sites had enrolled women under PMTCT Option B+; **655** sites were providing pre-ART services. **644** had enrolled HIV exposed children for follow-up. ART services were now available at almost all designated sites in the 5 zones. The SE had reached 99% of designated sites with ART services and 95% of designated sites with Option B+.

CD4 count machines (including 'point of care' machines) were installed at 164 sites, and 146 (89%) of these had produced at least 1 result during Q4 2014. 24,485 CD4 results were produced in this quarter. The total number of CD4 results produced decreased from 31,558 in Q3 to 24,485 during Q4. 45% of these outputs were generated with 34 machines in the SW zone, implying that many CD4 machines continued to experience down-time or to be running considerably below capacity. The raised CD4 count threshold for ART eligibility may have also resulted in a decrease in the number of pre-ART patients requiring CD4 count monitoring as a large proportion will now be started on ART after an initial CD4 test.

5 HIV Testing and Counselling Program Outputs

HTC protocols were revised in 2013 and a new HTC register was implemented in the course of a national re-training campaign for all HTC providers between May and November 2013. Protocol revisions include:

- Clear recommendations for re-testing based on the client's test result and risk assessment
- Proper documentation of confirmatory testing for clients with a prior positive result (usually performed at enrolment into care).

This is the second HTC report based on the 2013 HTC register. The full national HTC data are presented in the **Appendix**.

464,292 people³ were tested and counselled for HIV between October and December 2014. **449,130 (98%)** of these tests were performed at health facilities and **15,162 (2%)** were done outside of health facilities. **23,443 (5%)** of the facility based test were in facilities providing HTC only. Out of a total of **28,465** people newly diagnosed with HIV this quarter, **26,555 (93%)** were tested at health facilities, **1,623 (6%)** at stand-alone HTC sites and **287 (1%)** in community-based testing.

5.1 HTC access type

254,389 (55%) of people tested were patients receiving provider-initiated testing and counselling (PITC); **207,456 (45%)** accessed voluntary counselling and testing, door-to-door, community-based testing, etc. **2,451 (<1%)** came for testing with a *Family HTC Referral Slip* (FRS) that was issued to a family member at a prior HTC encounter. Based on a total of **15,222** FRS issued to index clients this quarter, the successful referral rate for family members was **16%** (2,451 / 15,222). This is similar to previous quarter (16%). Referral slip issuance and utilization has remained low.

5.2 Age and sex distribution among HTC clients

Out of **464,292** people tested and counselled, **34%** were males and **66%** were females. **49%** of females were pregnant. The proportion of males (50%) and non-pregnant females (50%) was very similar, implying gender balanced access to HTC services. Pregnant women have to be excluded from the comparison of male and female access to HTC because testing among pregnant women is almost entirely provider-initiated and there is no comparable access route targeting males.

51% of all people tested and counselled were 25 years and above, **41%** were between 15-24 years and **8%** were children below 15 years. **109,507 (24%)** accessed HTC with their partners (as a couple).

5.3 First time, repeat and confirmatory test results

The 2011 and 2014 Malawi Clinical HIV Guidelines stipulate: *All patients need a confirmatory HIV test to rule out any possibility of mix-up of test results or fraudulent access to ART: either at enrolment into pre-ART follow-up, or before starting ART if the test to confirm was not done in pre-ART. Children under 12 months starting ART with a positive DNA-PCR do not need another confirmatory test before starting ART, but all need a confirmatory rapid antibody test at age 12 and 24 months.* This is the second quarter reporting on confirmatory test results as a proportion of those who are classified as repeat testers.

³ Reports from the HTC register are based on client encounters. It is not possible to de-duplicate people who access HTC multiple times in the reporting period. However, very few individuals come for repeat testing in less than 3 months and the number of HTC encounters in one quarter is therefore assumed to represent individuals.

139,602 (30%) accessed HTC for the first time and **324,690 (70%)** were repeat testers. Based on the cumulative number of people who accessed HTC for the first time, a total of **5,565,620** people have been tested since introduction of the *first time HTC access* indicator in July 2007.

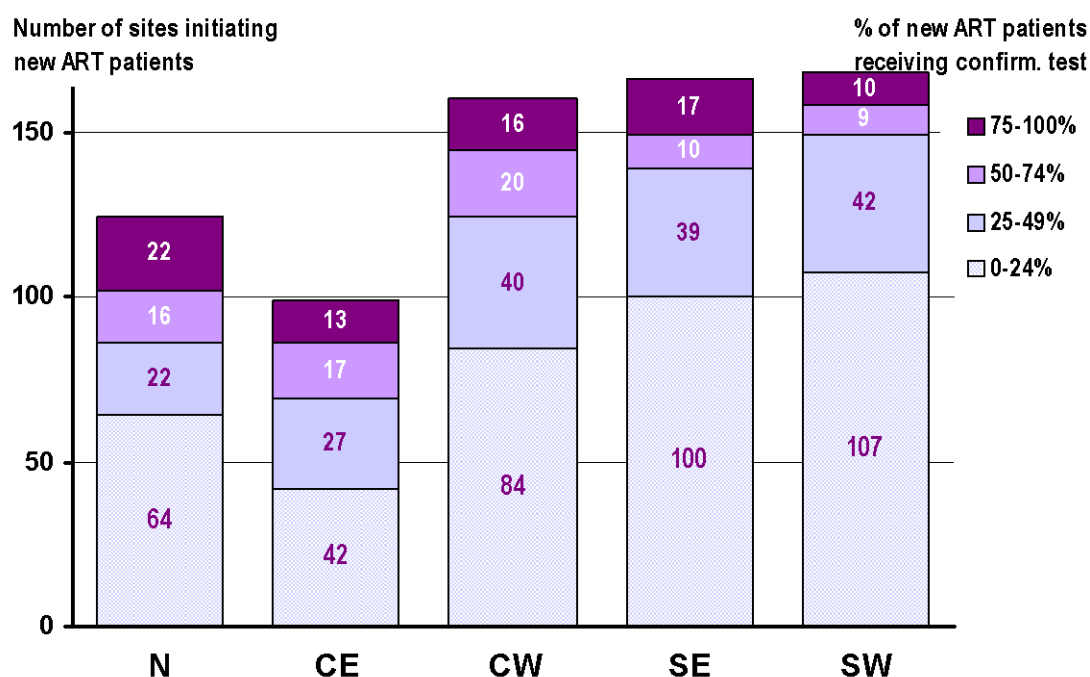
28,465 (6%) out of all clients received a positive result for the first time. Positive rapid test results among infants (**1,053**) and inconclusive test results (**1,632**) both accounted for **<1%** of new results given to clients.

312,120 (96%) of 324,690 repeat testers reported a *last negative* result. **9,854 (3%)** were reported as *previous positives* and all of these should have been classified as receiving a confirmatory test. For most of the **9,854 previous positives**, testing was probably initiated by a health worker before enrolment into care. However, *confirmatory test results* accounted for only **8,630 (88%)** of *previous positive* clients. The remainder (1,224) may have been misclassified as *new positive* or *new inconclusive* because they were among clients who independently sought confirmation of their positive status. **7,925 (80%)** of 9,854 confirmatory tests were concordant positive and **705 (7%)** were classified as *confirmatory inconclusive*. This category includes parallel concordant negative and discordant test outcomes (Determine HIV1/2 and Uni-Gold HIV1/2 are used in parallel for confirmatory testing). This relatively high proportion of clients who did not have a concordant positive confirmation may be explained by selective confirmatory testing among clients with doubts about their previous positive status, but it underscores the importance of both routine confirmatory testing before ART initiation as well as the need to continue strengthening HTC quality assurance processes.

The 9,854 confirmatory test results documented this quarter indicate that only **38%** of the 26,060 patients initiating ART this quarter received confirmatory testing and **Figure 1** shows that confirmatory testing coverage was low in all 5 zones. Only **78 (11%)** of facilities throughout the country had performed confirmatory testing for $\geq 75\%$ of patients newly initiated on ART. Implementation of the confirmatory testing policy will be further reinforced over the next quarters.

Figure 1: Confirmatory HIV testing coverage at ART sites in the 5 zones

Num.: total confirmatory HIV tests documented in HTC registers. Denom.: total new patients initiating ART at the site



6 DNA-PCR testing for Early Infant Diagnosis of HIV (EID)

DNA-PCR testing is performed at 7 labs (Mzuzu Central Hospital, Mzimba District Hospital, Kamuzu Central Hospital, Queen Elizabeth Central Hospital, DREAM Blantyre, Zomba Central Hospital and Partners in Hope, Lilongwe). EID counsellors collect infant blood samples as dried blood spots on filter paper. Health facilities are requested to maintain a standard EID DNA-PCR logbook to document EID samples and to track results. The logbook includes the dates of collection, dispatch, receipt of result from the lab and communication of the result to the mother. Supervision teams were asked to collect basic data from these logbooks.

516 (80%) of 644 sites with HIV exposed children in follow-up had collected and recorded at least 1 DNA-PCR sample during Q4 2014. A total of **8,369** DNA-PCR samples were collected and recorded. By the time the logbooks were reviewed (between 2 and 4 weeks after the end of the quarter), results had been received at the sites for **4,728 (56%)** of these specimens and **2,541 (54%)** of these results had been communicated to the mother. The proportion of results received at the sites was **78%, 56%** and **29%** for samples collected in October, November and December, respectively. A total of **248 (5%)** results received at the sites were positive.

The **7 laboratories** dispatched DNA-PCR test results for **8,470** children in Q4 2014. This is 101 (1%) more than the number of samples recorded in the DNA-PCR logbooks at health facilities during this quarter. This discrepancy is likely due to the difference in sample collection and result dispatch dates. **6,402 (76%)** of the dispatched results were from samples collected in Q4 2014, while 2,068 (24%) were from samples collected in the previous quarters (for 3 results the collection date was missing). The median time between sample collection and dispatch of the result was **23 days**; 75% of results were dispatched between 15 and 32 days after sample collection.

4,176 (49%) of all results were from infants under 2 months old at the time of sample collection. 3,048 (36%) were 2-5 months, 972 (11%) were 6-11 months and 129 (1%) were 12 months or older when the sample was collected (date of birth was missing for 145).

| Age at sample collection | Tot. Results | Positives | |
|--------------------------|--------------|-----------|------|
| <2 months | 4,176 | 38 | 0.9% |
| 2-5 months | 3,048 | 65 | 2.1% |
| 6-11 months | 972 | 43 | 4.4% |
| 12 months + | 129 | 6 | 4.7% |

156 (1.8%) of all results dispatched were positive. The age-specific number (%) of positive results is shown on the left. Receipt of the DNA-PCR result at the health facility is a prerequisite to updating

of patient records and for appropriate clinical management. Considering the delays between sample collection and dispatch of the test result from the lab, the child's age at the time of dispatch of the result from the lab is a useful indicator for the process of early infant diagnosis and early initiation of ART for confirmed infected infants. The table below shows the distribution of ages when results were dispatched from the lab.

| Age when result disp. from lab | Tot. Results | (Col %) | Positives | (Col %) |
|--------------------------------|--------------|---------|-----------|---------|
| <2 months | 1,106 | 13% | 15 | 9% |
| 2-5 months | 5,801 | 68% | 79 | 51% |
| 6-11 months | 1,223 | 14% | 50 | 32% |
| 12 months + | 198 | 2% | 8 | 5% |
| (missing date) | 142 | 2% | 4 | 3% |
| Total | 8,470 | 100% | 156 | 100% |

Out of 156 positive results dispatched, only 15 (9%) were sent before the child was 2 months old. A total of 84 (60%) positive results were sent before the child

was 6 months old and 134 (92%) were sent before the child was 12 months old. A total of 106 infants were started on ART in WHO stage 1 or 2 on the basis of confirmed HIV infection (see ART section below). This is equivalent to **79%** of the positive DNA-PCR results dispatched for children <12 months this quarter.

7 Blood Safety

The Malawi Blood Transfusion Service (MBTS) is striving to provide blood products for the entire country using voluntary non-remunerated donors and quality assured screening for transfusion transmissible infections (TTIs). For the last years, MBTS has not been able to meet the national demand and several hospitals continue to supplement or rely entirely on blood units collected from replacement donors. Complete reports from MBTS have been available throughout, but blood safety reports from health facilities have not been consistently available and it has been challenging to compile national reports relying on the data passively submitted by the sites. Therefore, the PMTCT/ART supervision teams were tasked with active collection of blood donor and cross-matching data from all visited health facilities. Some of the visited laboratories were not using the standard MOH registers and the aggregation of data for reporting may have been affected by incomplete documentation at some sites.

A total of **20,244** blood units were collected in Malawi during Q3 2014. MBTS collected **15,327 (65%)** of these, **100%** of which were screened comprehensively for the relevant TTIs (HIV, Hepatitis B, Hepatitis C, syphilis, malaria). In addition, **54** hospitals in Malawi collected a total of **4,917** units from replacement donors. **4,279 (87%)** of these units were screened for at least the 3 key TTIs (HIV, HepB and syphilis) and **1,374 (32%)** of these were also screened for HepC and malaria. This means that a total of **19,606 (97%)** of all 20,244 units collected by MBTS and from replacement donors this quarter were screened at least for HIV, HepB and syphilis. Based on the blood donor registers at the sites that collected blood from replacement donors, 139 units were screened for HIV and HepB only and 27 were screened only for HIV. 472 were screened with any other combination of tests for TTIs.

A total of **7,022** potential replacement donors were documented in the blood donor registers at the facilities and 4,917 (70%) of these ended up donating. Facilities may have used different screening algorithms and potential donors may have been excluded on the basis of different criteria, including TTIs, blood group, haemoglobin concentration and/or clinical conditions. Testing for less prevalent TTIs may have only been carried out for donors who passed the screening for more common conditions. In total, 81% of potential donors were tested for HIV, 79% for HepB, 79% for syphilis, 53% for malaria and 32% for HepC. Detailed data on individual test outcomes among all potential blood donors are presented in the Appendix.

8 Post Exposure Prophylaxis (PEP)

A total of **1,409** persons received PEP during Q4 2014. This is 27% increase from the previous quarter (1,106).

9 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 offered 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 to women who received an injection of Depo-Provera in pre-ART and ART clinics during the last quarter. The report does not account for family planning need nor does it include women who accessed family planning services outside of HIV clinics.

Table 3: Number and % of women retained in HIV care * who were on injectable contraceptives (Depo) by the end of 2014 Q4.

| Zone | Pre-ART | | ART | | Both patient groups | |
|---------------|---------------|------------------|----------------|-------------------|---------------------|-------------------|
| | Tot. women | On Depo | Tot. women | On Depo | Tot. women | On Depo |
| NZ | 807 | 238 29% | 30,835 | 9,547 31% | 31,641 | 9,785 31% |
| CEZ | 516 | 114 22% | 24,883 | 5,444 22% | 25,400 | 5,558 22% |
| CWZ | 2,967 | 469 16% | 62,799 | 9,511 15% | 65,766 | 9,979 15% |
| SEZ | 2,682 | 1,087 41% | 95,919 | 35,913 37% | 98,601 | 37,000 38% |
| SWZ | 4,860 | 1,839 38% | 103,244 | 33,775 33% | 108,103 | 35,615 33% |
| Malawi | 11,832 | 3,747 32% | 317,680 | 94,190 30% | 329,511 | 97,937 30% |

* 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 **97,937 (30%)** of 329,511 women in care received Depo-Provera from HIV clinics in Q4 2014. The SE Zone had achieved the highest coverage among women in pre-ART and ART. Patient coverage and stock availability had further improved this quarter and 548 (80%) of ART/PMTCT sites had stocks of Depo-Provera in January

2015.⁴ This was mainly due to inclusion of Depo-Provera in the quarterly distribution of ARVs and other HIV commodities.

10 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 **622,741 (94%)** of 664,506 all patients in care were on CPT at the end of Q4 2014.

Table 4: Number and % of patients retained in HIV care who were on cotrimoxazole and isoniazid preventive therapy (CPT, IPT) by the end of 2014 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 | 7,846 | 5,942 76% | 3,018 | 2,884 96% | 54,474 | 50,793 93% | 65,338 | 59,618 91% | 3,018 | 2,598 86% |
| CEZ | 7,537 | 6,045 80% | 2,182 | 1,996 91% | 43,256 | 42,464 98% | 52,975 | 50,505 95% | 2,182 | 1,745 80% |
| CWZ | 15,945 | 13,925 87% | 9,279 | 8,057 87% | 108,672 | 101,315 93% | 133,896 | 123,296 92% | 9,279 | 7,233 78% |
| SEZ | 30,133 | 26,983 90% | 10,200 | 9,948 98% | 153,953 | 150,088 97% | 194,286 | 187,019 96% | 10,200 | 8,856 87% |
| SWZ | 26,171 | 23,480 90% | 15,757 | 15,294 97% | 176,083 | 163,527 93% | 218,011 | 202,302 93% | 15,757 | 13,920 88% |
| Malawi | 87,632 | 76,375 87% | 40,436 | 38,178 94% | 536,438 | 508,187 95% | 664,506 | 622,741 94% | 40,436 | 34,352 85% |

⁴ Many Mission hospitals do not provide family planning.

11 TB / HIV Interventions

11.1 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.

523,186 (98%) of all patients retained on ART were screened for TB at their last visit before end of December 2014. As of that visit, **2,855 (<1%)** patients were new TB suspects and had presumably been referred for examination by a clinician and for TB investigations. **1,314 (<1%)** patients had confirmed TB (clinical or lab based). Out of these, **1,094 (83%)** were confirmed to be on TB treatment and **220 (17%)** had not yet started or had interrupted TB treatment. An excerpt from the data in the **Annex (Cumulative ART outcomes)** is shown below.

Current TB status among ART patients (ICF)

| | | |
|----------------------------------------------------|---------|-----|
| ICF not done (Current TB status unknown/ not circ) | 13,252 | 2% |
| ICF done | 523,186 | 98% |
| TB not suspected | 519,017 | 99% |
| TB suspected | 2,855 | 1% |
| TB confirmed | 1,314 | 0% |
| TB confirmed, not on treatment | 220 | 17% |
| TB confirmed, on TB treatment | 1,094 | 83% |

11.2 Isoniazid Preventive Therapy (IPT)

All pre-ART patients with a negative screening outcome for TB symptoms are eligible for IPT. The first (large scale) distribution of isoniazid and pyridoxine for the HIV programs reached the sites during July 2012. **38,178 (94%)** of 40,436 patients retained in pre-ART were on IPT by the end of December 2014. Isoniazid was in stock at 632 facilities during the January 2015 supervision visit.

12 HIV-Related Diseases

Table 5 shows the number of patients treated for key HIV-related indicator diseases. **4,204** patients were started on TB treatment this quarter and HIV status was ascertained for **3,989 (95%)**. **2,103 (53%)** of these were HIV positive and **1,546 (74%)** of all HIV positives were already on ART when starting TB treatment. The Diflucan (fluconazole) donation program has received renewed attention and significant stocks of fluconazole were distributed to all sites in November 2012. In Q4 2014, **475** and **663** patients received Diflucan for acute cryptococcal meningitis and oesophageal candidiasis, respectively. **336** patients with Kaposi sarcoma were registered for ART in this quarter.

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 |
| 2014 Q1 | 4,342 | 3,903 90% | 2,103 54% | 1,431 68% | 361 | 414 | 690 |
| 2014 Q2 | 4,258 | 3,773 89% | 2,130 56% | 1,619 76% | 312 | 408 | 774 |
| 2014 Q3 | 4,692 | 4,368 93% | 2,149 49% | 1,460 68% | 310 | 368 | 640 |
| 2014 Q4 | 4,204 | 3,989 95% | 2,103 53% | 1,546 74% | 336 | 475 | 663 |

13 HIV-Exposed Child Follow-Up

13.1 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 / postnatal ward; 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 infection through DNA-PCR or 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 HIV uninfected by the age of 24 months.

13.2 HIV Exposed Child Registration Data

This is the 14th quarterly report from the standard follow-up program for HIV exposed children. **10,797** HIV exposed children were newly enrolled into follow-up during Q4 2014; **7,006 (65%)** of these were under the age of 2 months. This represents timely enrolment for **79%** of the 8,851 known HIV exposed children discharged from maternity this quarter. The total number of new enrolments (10,797) exceeds by 1,946 (21%) the total number of known HIV exposed children discharged from maternity (8,851). This apparent discrepancy may be explained by delayed enrolment of infants born in previous quarters; by double-counting of infants who transferred between sites; or by

identification and enrolment of additional HIV exposed infants after birth. Overall, enrolment into follow-up for known HIV exposed infants appears to be almost complete.

The documentation of follow-up outcomes, particularly the updating of DNA-PCR results on patient cards, remained incomplete at several sites. This has led to an underreporting of ascertainment of HIV status among the 2 month old cohort.

13.3 Birth Cohort Outcomes

There were **8,296** infants in the **2 month age cohort**. **3,152 (38%)** had received a DNA-PCR result. **89 (3%)** of these were confirmed HIV infected. An additional **15** infants were diagnosed with *presumed severe HIV disease*, which means that a total of **104** infants were eligible for ART. **92 (88%)** of these had started ART. The proportion of positives starting ART has increased from the previous quarter (36%). Out of the entire 2-month age cohort, **7,518 (92%)** were retained in exposed child follow-up, **92 (1%)** had started ART and **26 (<1%)** were discharged confirmed uninfected⁵. **25 (<1%)** were known to have died and **529 (6%)** had been lost to follow-up.

There were **8,806** children in the **12 month age cohort**. Current HIV infection status was known for **3,551 (40%)** children (DNA-PCR or rapid antibody test) and **161 (5%)** of these were confirmed HIV infected. **8 (<1%)** additional children had been diagnosed with *presumed severe HIV disease*, which means that a total of **169** children were eligible for ART. **150 (89%)** had started ART. Out of the entire age cohort, **6,361 (74%)** were retained in exposed child follow-up, **150 (2%)** had started ART and **51 (<1%)** were discharged confirmed uninfected.⁵ **1,941 (23%)** were lost to follow-up and **61 (<1%)** were known to have died.

There were **8,895** children in the **24 month age cohort**. Current HIV infection status was known for **3,799 (43%)** children (DNA-PCR or rapid antibody test) and **231 (6%)** of these were confirmed HIV infected. **14** additional children had been diagnosed with *presumed severe HIV disease*, which means that a total of **245** children were eligible for ART. **229 (93%)** of these had started ART. Out of the entire age cohort, **1,058 (12%)** were retained in exposed child follow-up, **229 (3%)** had started ART and **3,391 (39%)** were discharged confirmed uninfected. **3,850 (45%)** were lost to follow-up and **77 (1%)** were known to have died.

Confirmed HIV-free survival at age 24 months in this quarter was only **39%**, which was implausibly low and related to the fact that only 43% in this cohort had a known HIV status. 5,096 (57%) children were classified as '*current HIV infection status unknown*' and many of these may be among the 3,850 children lost to follow-up and the 77 children who had died. However, 1,058 (12%) were retained in follow-up beyond age 24 months and a final rapid test was not available for these children, possibly due to continued breast feeding. There are still problems with scheduled HIV testing (and documentation of test results) at 6 weeks, 12 and 24 months of age.

14 Pre-ART

14.1 Pre-ART Registration Data

A total of **6,483** patients were newly registered for pre-ART follow-up in Q4 2014. **485 (8%)** of these were children aged 5-14 years. The number of new pre-ART enrolments continued to decline from the previous quarter (6,942 total, 546 children) due to the introduction of relaxed ART eligibility

⁵ 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.

criteria in April 2014. Several sites had already established pre-ART services before July 2011 and the cumulative number of pre-ART patients ever registered was **181,298**.

14.2 Cumulative Pre-ART Follow-up Outcomes

40,436 (23%) of all patients ever registered were retained in pre-ART follow-up by the end of December 2014; **89,700 (51%)** had started ART; **43,136 (25%)** had been lost to follow-up; **1,749 (1%)** were known to have died. The proportion of patients starting ART is bound to increase in the cumulative pre-ART cohort analysis over time. Based on a subtraction of cumulative outcomes from the previous quarter, **2,853** pre-ART patients started ART during Q4 2014. There were inconsistencies in the number of patients lost to follow-up and who died between this and the previous quarter.

CPT coverage among pre-ART patients was **94%** in Q4 2014 while IPT coverage increased from 81% to **85%**. **3,747 (32%)** of 11,832 women had received Depo-Provera from their pre-ART clinic. Further details on CPT, Depo-Provera and IPT are presented in **Tables 3** and **4** in the sections above.

15 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 in 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 ANC at the earliest opportunity to take home with instructions how to give it to the new-born.

15.1 Data Sources and Reporting Methods

New standard M&E tools for ANC and maternity were implemented in January 2010 and revised in Q2 2012 to reflect the Option B+ policy. ANC and maternity clinic registers and reporting forms include patient management information and all relevant data elements for 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.

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 getting pregnant. Implementation of *Option B+* will further increase ART coverage in this group. **Maternal ART coverage** is estimated from the number of pregnant women who were already on ART when getting pregnant (**maternity reports**) *plus* those who newly started ART when pregnant (**ART reports**).

Maternity reports capture ART status at the time of delivery (up to the time of discharge from the postnatal ward). The timing of ART initiation is categorized into: (any time) before pregnancy; during

1st / 2nd trimester; during 3rd trimester; during labour. About 97% of pregnant women in Malawi attend ANC, but only 83% of women in the general population deliver at a health facility in Malawi. Maternity reports therefore have the potential for undercounting the number of mothers and infants receiving ARVs. However, there is evidence from ANC and maternity reports that almost all of the known HIV infected women deliver at health facilities. ARV coverage among known positives is therefore reliably calculated from maternity reports. Women admitted at maternity who are referred to another facility before / after delivery are double-counted in aggregated maternity data. Assuming the probability of referral is independent of ART status, the number of women already on ART when getting pregnant is therefore **adjusted** by the overall proportion of referrals among women admitted to maternity.

ART program reports capture pregnancy (and breastfeeding) status at the time of *ART initiation*, providing information on the number of new women starting ART while pregnant (or while breastfeeding). ART reports do not capture women who become pregnant after starting ART. For the estimation of maternal ART coverage, the number of women starting ART in pregnancy is **adjusted for**:

a) Double-counting of women starting ART in pregnancy and subsequently transferring to another site. These women are counted multiple times as ‘pregnant at the time of starting ART’ in the quarterly ART cohort reports because the disaggregation of age, sex and reason for starting ART applies to all patients newly registered in the quarter, including transfers in. Separate *ART ‘survival’ analyses* are collected each quarter for women started under Option B+. The proportion of women transferred within 12 months of registration is used to adjust the quarterly number of pregnant women starting ART for transfers.

b) Failed ART initiation is thought to be the main underlying reason for early loss to follow-up among the Option B+ cohort. Patients are recorded on patient cards and in clinic registers when the first supply of ARVs is dispensed and all new entrants are counted as ART initiations in the quarterly ART cohort report. Recent operational studies indicate that most pregnant women lost to follow-up within the first 6 months never return after this first dispensing visit and many of these may have never actually started taking ART. The proportion of women lost to follow-up in the 6-month survival analysis is therefore used to adjust the number of pregnant women starting ART in the quarterly ART cohort reports for *failed initiations*.

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.

Coverage is calculated by dividing the number of patients served by population denominators. The denominators are derived from expected pregnancies based on population projections and HIV prevalence from epidemiological surveillance (source: 2014 Spectrum model for Malawi). There are an estimated 13,317 HIV infected pregnant women in the population per quarter (1/4 of 53,268 in 2014).⁶

⁶ 2014 Spectrum estimates based on 2014 definition of eligibility for ART in Malawi (CD4<500, Option B+, UT for U5).

15.2 ARV Coverage among Pregnant / Breastfeeding Women and Exposed Infants

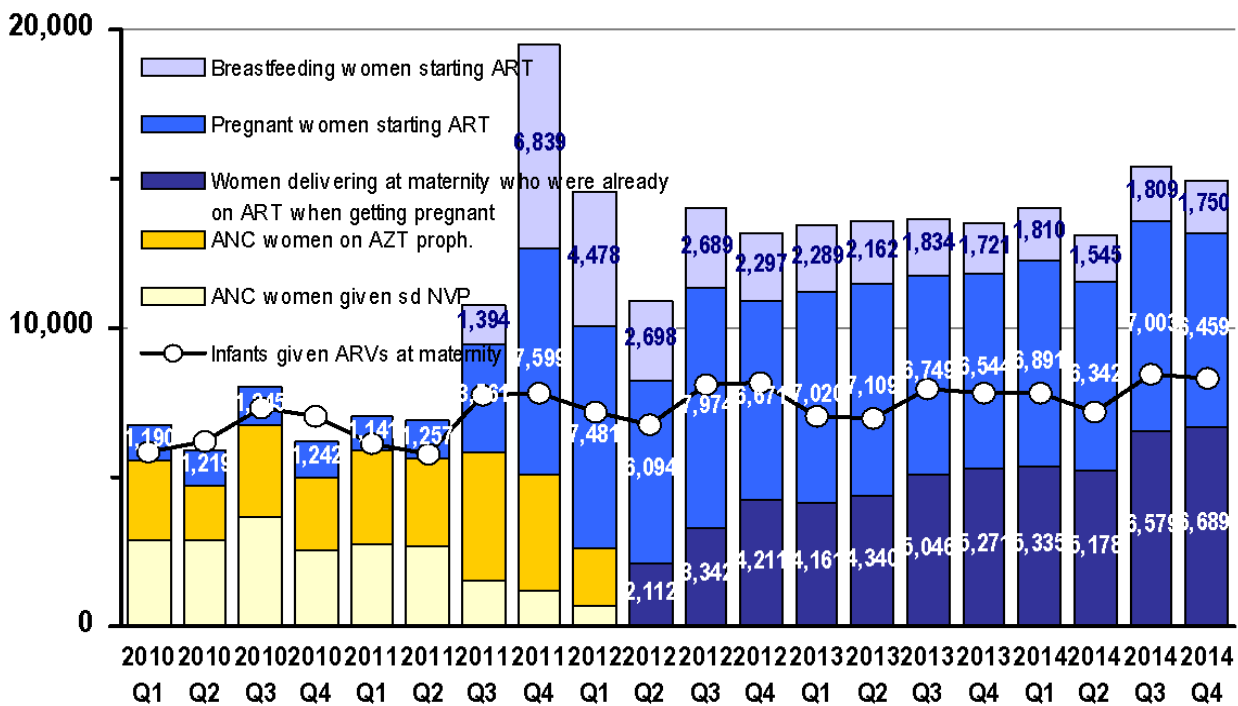
11,053 (83%) of the estimated 13,317 HIV infected pregnant women in Malawi this quarter were on ART. This is based on **6,288**⁷ women at maternity who were already on ART when getting pregnant and **4,765**⁸ women who newly initiated ART in pregnancy.

An additional **1,593**⁹ breastfeeding women started ART due to **Option B+** (in WHO clinical stage 1 or 2), bringing the total number newly started on ART under **Option B+** to **6,358**. Most women starting ART while breastfeeding were probably identified late in maternity or early in the postnatal period, but this group may also include some women who re-initiated after interrupting ART in pregnancy. **8,305** infants were confirmed to have started NVP prophylaxis at maternity.

Figure 2 shows the transition from prophylactic ARV regimens for HIV infected mothers to universal ART under **Option B+** (registration data; not adjusted as above). The (less effective) single dose NVP regimen and AZT combination prophylaxis had been phased out by April 2012. The average number of pregnant women registered for ART each quarter **increased almost 6-fold** from **1,221** in the 12 month period before introduction of Option B+ to an average of **7,000** since Q4 2011.

Figure 2: Transition from prophylactic ARV regimens for PMTCT to Option B+ in Malawi

Women who moved to Option B+ from sdNVP / AZT were double counted between Q3 2011 - Q1 2012. It is likely that <12,000 total women were on ARVs during these quarters. Data on women already on ART when getting pregnant are only available from Q2 2012.



⁷ 6,689 women who started ART before pregnancy admitted at maternity; reduced by 6% to adjust for double-counting of 7,802 referrals among 138,024 total admissions.

⁸ 6,612 women registered at ART clinics who were pregnant at the time of starting ART; a) 9% are discounted to adjust for double-counting of transfers based on 668 of 7,678 women who transferred within 12 months of registration (12 month Option B+ survival analysis); b) 20.8% are discounted to account for presumed failed ART initiations based on 1,514 of 7,287 women lost to follow-up within 6 months of registration (6 month Option B+ survival analysis).

⁹ 1,750 women registered at ART clinics who were breastfeeding at the time of starting ART; reduced by 9% to adjust for double-counting of transfers based on 668 out of 7,678 women who transferred within 12 months of registration (12 month Option B+ survival analysis). Failed ART initiations are thought to be less common among this group, so no further adjustment is made.

15.3 HIV Services at ANC

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

151,216 women attended ANC for their first visit between October and December 2014. This is 89% of the estimated 170,732 pregnant women in the 2014 population during one quarter.¹⁰

The following report covers the outcomes of the **151,118** women who started ANC between April and June 2014 and who had finished ANC between October and December 2014. **12,939 (9%)** of these started ANC in their first trimester. **6,576 (4%)** were tested for syphilis at ANC and **389 (6%)** were syphilis positive. The low testing rate probably explains the higher (6%) than expected proportion (<1%) of positives as the testing was likely selective of those suspected to be positive. Only **35,231 (23%)** of women in this cohort attended the minimum of 4 focussed ANC visits.

15.3.1 HIV Ascertainment at ANC

134,985 (89%) of ANC attendees had their HIV status ascertained. This is similar to the previous quarter (89%). Out of all women whose HIV status was ascertained, **11,676 (9%)** presented with a valid documented previous HIV test result and **123,309 (91%)** received a new HIV test result at ANC. A total of **10,550 (7.8%)** women were found HIV positive. This is lower than the estimated 11% HIV prevalence among pregnant women in the 2010 ANC sentinel surveillance survey but consistent with the latest Spectrum projections (7.8% HIV prevalence among pregnant women in 2014).⁶

15.3.2 ARV Coverage at ANC

9,674 (92%) of (known) HIV infected women attending ANC received ART. This represents **73%** coverage of the estimated 13,317 HIV positive pregnant women per quarter at the population level.

Of the **9,674** ANC women who were known to receive ART, **4,500 (47%)** were already on ART when starting ANC, **4,039 (42%)** initiated before 28 weeks of pregnancy and **1,135 (12%)** initiated during the last trimester of pregnancy. **9,598 (91%)** of HIV infected women at ANC were on Cotrimoxazole Preventive Therapy.

8,500 (81%) of known HIV infected women attending ANC received the infant dose of ARVs (nevirapine syrup) to take home.

15.4 HIV Services at Maternity

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

Between October and December 2014, **130,222** women were admitted for delivery to maternity; **7,802** of these were referred to another facility before delivery, resulting in **138,024** total admissions to maternity during Q4 2014. Out of all admissions, **129,789 (95%)** delivered at health facilities, while **6,048 (5%)** had already delivered before reaching a facility. The **129,789** facility deliveries represent **76%** of the estimated 170,732 quarterly deliveries in the population in 2014 which is less than the 83% reported in the Integrated Household Survey Report of 2010-2011.

A total of **120,368 (95%)** deliveries were conducted by skilled birth attendants, **746 (<1%)** by paramedical staff and **6,003 (5%)** were not attended by any of the above (probably mainly among women who delivered before reaching maternity). **16,374 (12%)** of women developed obstetric

¹⁰ Estimated as ¼ of 682,926 births projected for 2014.

Malawi National Statistics Office. (2008). Malawi Population Projections 2008-2030.

Retrieved from http://www.nsomalawi.mw/images/stories/data_on_line/demography/census_2008/MainReport/The_maticReports/Population_Projections_Malawi.pdf

complications. The most common leading complications were obstructed / prolonged labour (5,474 cases) and post-partum haemorrhage (1,821 cases). A total of 129,789 babies were born, 125,712 (97%) were singletons and 4,077 (3%) were twins/multiples. There were 127,428 (98%) live births and 2,361 (2%) stillbirths. 126,007 (99%) of babies born alive were discharged alive and 1,421 (1%) died before discharge. 127,001 (>99%) of women were discharged alive and 116 (<1%) women died before discharge, which is equivalent to a maternal mortality ratio of 91 per 100,000 live births among women attending maternity.

15.4.1 HIV Ascertainment at Maternity

129,821 (96%) women had their HIV status ascertained at maternity. Out of these, 127,013 (98%) presented with a valid previous HIV test result and 2,808 (2%) received a new HIV test result. A total of 9,785 (8%) women were HIV positive and 120,036 (92%) were negative. The 129,821 women whose HIV status was ascertained at maternity represent 76% of the expected 170,732 women delivering in the population.

HIV exposure status was ascertained for 121,829 (97%) out of 126,007 babies born and discharged alive. 8,851 (7%) of these were born to a known HIV positive mother.

15.4.2 ARV Coverage at Maternity

A total of 9,566 (98%) of known HIV infected women admitted to maternity received ART. Out of these, 6,689 (70%) had started ART before pregnancy, 1,483 (16%) initiated ART during the 1st or 2nd trimester, 1,164 (12%) initiated during the 3rd trimester and 230 (2%) initiated ART at maternity.

A total of 8,305 (94%) of 8,851 infants who were known HIV exposed and discharged alive started daily NVP prophylaxis at maternity. This represents 62% coverage of the estimated 13,317 HIV exposed infants born in the population in this quarter.

16 ART Access and Follow-Up Outcomes

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

16.1 New ART Registrations during Q4 2014

By the end of December 2014, there were 713 static ART sites in Malawi, managed by government, mission, NGOs and the private sector. Out of these, 95 were ART facilities in the private sector, charging a nominal MK500 per monthly prescription of drugs per patient.

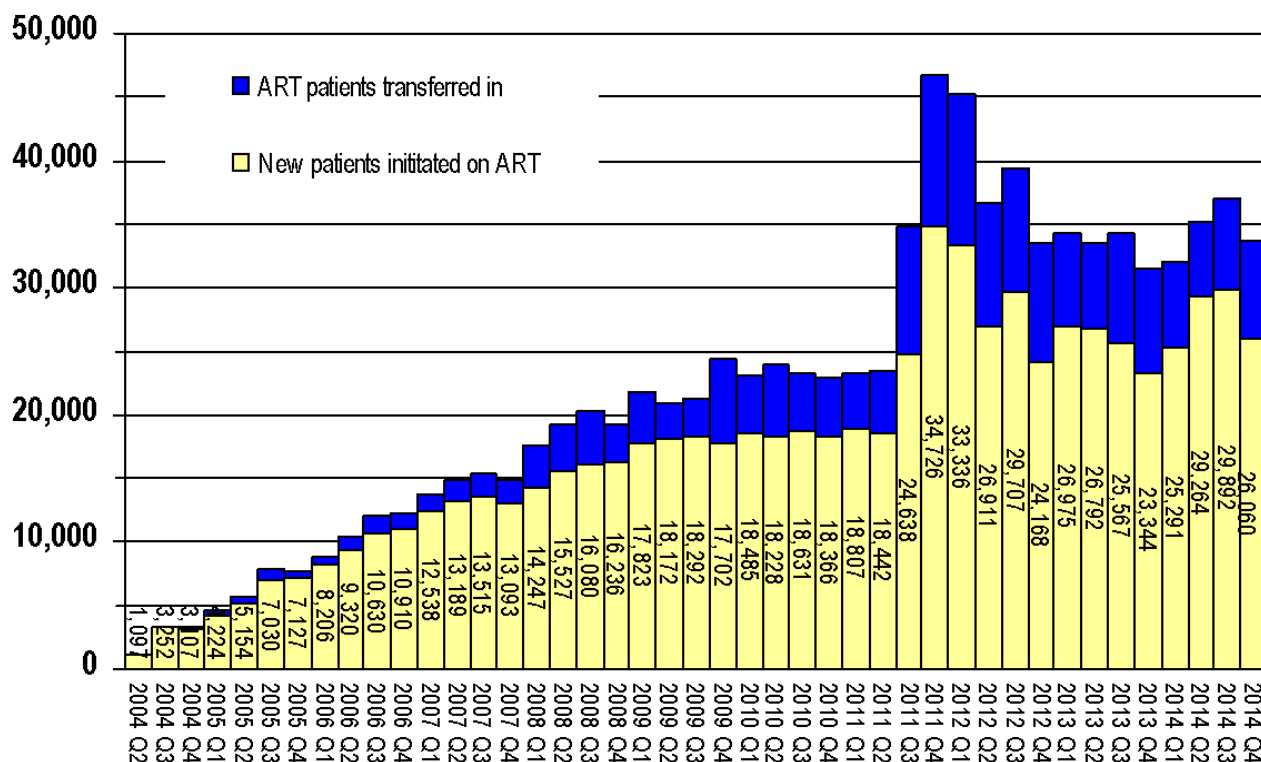
Implementation of the Malawi Integrated Clinical HIV Guidelines started in July 2011, triggering a massive surge in new ART initiations (see **Figure 3**). 26,060 patients initiated ART in Q4 2014 and 7,220 patients were registered as a transfer in (already on treatment; 21% out of all 33,740 clinic registrations). The number of new ART initiations was 13% lower than in the previous quarter.

Among all new registrations 36% were males, 64% were females and 6,459 (30%) of females were pregnant. For some of the 6,612 who had started under **Option B+** and who transferred to sites with electronic medical records system, the status at registration was updated to 'no longer pregnant', leading to an apparent discrepancy with the number of women recorded as pregnant. An additional 1,750 women in WHO stage 1 or 2 were started because of breastfeeding, bringing the total number of women registered as started under **Option B+**¹¹ to 8,362.

¹¹ Universal ART for all HIV infected pregnant and breastfeeding women in WHO stage 1 or 2, independent of CD4 count

Figure 3: 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.



A total of **22,113 (66%)** of all patients registered started in WHO stage 1 or 2 and **13,021 (59%)** of these started due a low CD4 count. **9,607 (29%)** of patients registered started in WHO stage 3 and **1,600 (5%)** started in stage 4.

2,791 children were registered at ART sites in Q4 2014. **612** of these were registered under the expanded policy of universal ART for children aged 12-59 months in WHO stage 1 or 2, independent of CD4 count. **136** children started ART with presumed severe HIV disease, which was higher than the previous quarter (113). **106** infants in WHO stage 1 or 2 who started due to confirmed HIV infection through DNA-PCR, which is slightly lower than the previous quarter (123). Early paediatric ART access has remained below expectations, but the relatively low number is consistent with reduced transmission rates due to Option B+: considering that 8,851 HIV exposed infants were identified at maternity and assuming a 2% transmission rate among the 94% of HIV positive mothers at maternity who received ART (and 20% transmission in the 6% who did not receive ART)¹², only about 275 of these known HIV exposed infants may have been infected perinatally during Q4 2014. However, considering the projected 1,025 new infant HIV infections in the 2014 population per quarter⁶, early infant treatment coverage remains low at an estimated **10%** (106 / 1,025). The most significant bottleneck for early infant treatment remains the identification of HIV infected pregnant / breastfeeding women.

1,012 (3%) out of all ART clinic registrations were patients with TB: **660 (2%)** had a current and **352 (1%)** a recent history of TB. **336 (1%)** of patients registered had Kaposi's sarcoma.

¹² UNAIDS Reference Group on Estimates Modelling and Projections (2011). Working paper on mother-to-child-transmission rates for use in Spectrum. Geneva, UNAIDS.

16.2 Cumulative ART Registrations up December 2014

By the end of December 2014, there were a cumulative total of **962,783** clinic registrations, representing **770,369 (80%)** patients who newly initiated ART and **182,272 (19%)** patients who transferred between clinics. **10,142 (1%)** out of all clinic registrations were patients who re-initiated ART after treatment interruption. Out of all registrations, **36%** were males and **64%** were females, **91%** were adults and **9%** were children (<15 years). Private sector clinics accounted for **29,252 (3.0%)** of total patient registrations.

16.3 ART Outcomes

536,438 patients were alive on ART by the end of December 2014. The omission of sites that could not be visited due to flooding led to an inconsistency among patients recorded as ‘in transit’ between sites: the total cumulative number of transfers in exceeded the number of transfers out this quarter.

Out of the **770,369** patients ever initiated on ART, **536,438 (69%)** were retained alive on ART, **73,434 (9%)** were known to have died, **167,669 (21%)** were lost to follow-up and **3,010 (<1%)** were known to have stopped ART. An estimated **489,775** adults and **46,410** children (<15 years) were alive on ART by the end of December 2014.

Figure 4 Patients alive on ART at the end of each quarter, stratified by size of facility (number of patients alive on ART)

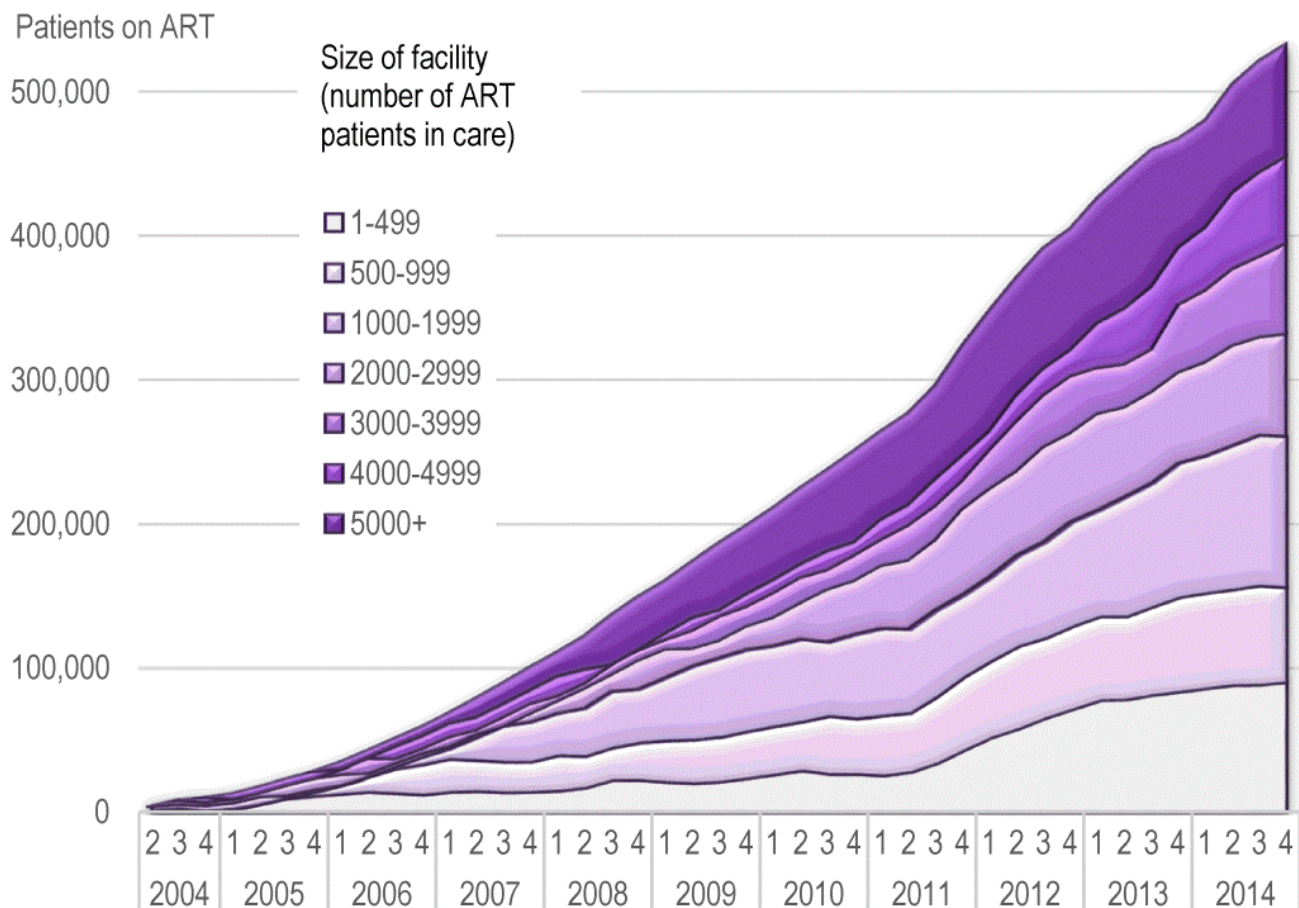


Figure 4 shows the increase of patients alive on ART by the end of each quarter. The number of patients alive on ART **increased by 15,109** in Q4 of 2014. **Figure 4** also illustrates the ongoing decentralization of Malawi’s ART program. From Q3 2011, the greatest increase in ART patient numbers was seen at sites with fewer than 500 patients alive on ART. By the end of December 2014, **49%** of the national ART patient cohort was in care at sites with fewer than 2,000 patients.

Figure 5: 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)

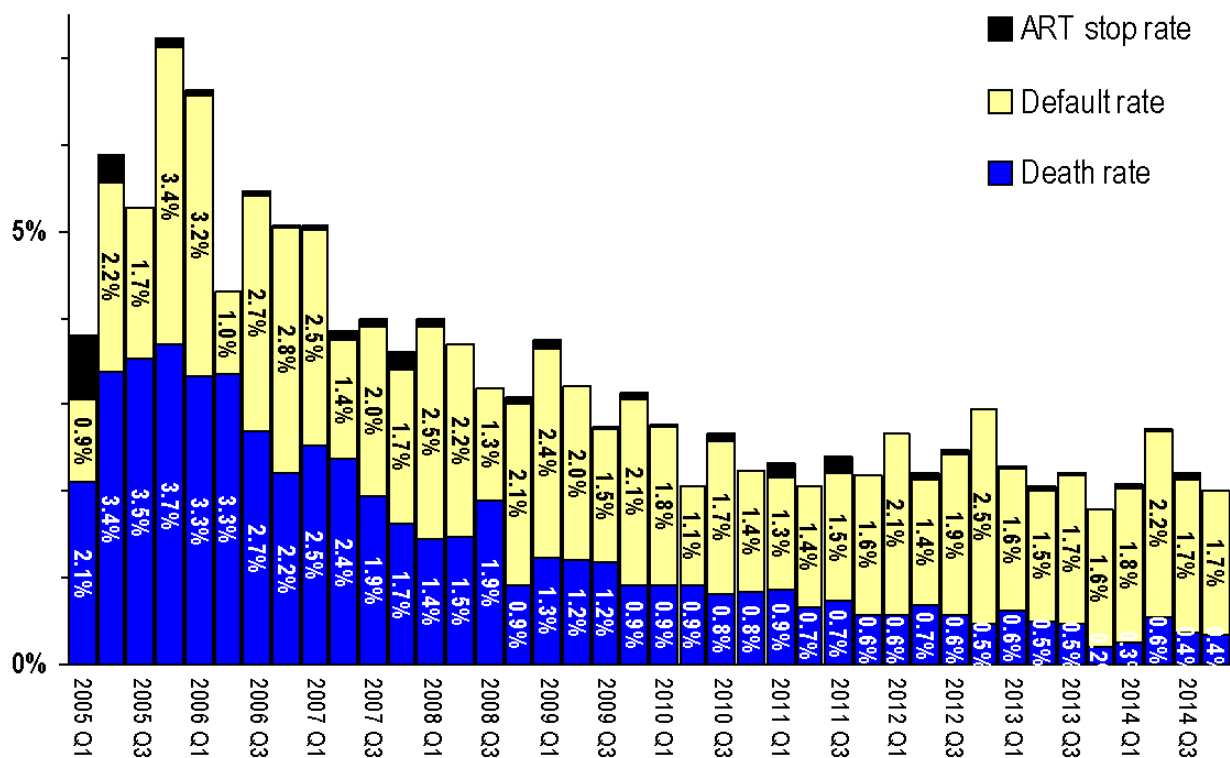


Figure 5 shows the considerable decrease of ART drop-out rates since the start of the national program. There were **1,909** new deaths, **9,089** new defaulters in Q4 2014. This translates into a quarterly death rate of **0.4%** and a defaulter rate of **1.7%** among the patients alive and on treatment in this quarter. These rates were similar to the previous quarter. Based on previous operational studies, about half of the patients in stage 3 and 4 who are classified as lost to follow-up are thought to have died. There is also an indication that 10-15% of pregnant women who were registered as ‘initiated on ART’ under Option B+ may have never actually started taking ARVs due to inadequate preparation at ANC. Importantly, the ascertainment of loss to follow-up requires updating of patient treatment cards after analysis of the most recent dispensing visit. Any lack in rigour in this process will lead to a misclassification of patients who have been lost to follow-up as ‘retained alive on ART’. The cumulative total number of patients known to have stopped declined from the previous quarter, probably due to missing data from flood-affected sites.

By end of December 2014, a cumulative **73,434 (9%)** patients were known to have died **167,669 (21%)** were lost to follow-up and **3010 (<1%)** were known to have **stopped ART**.

Figure 6: 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)

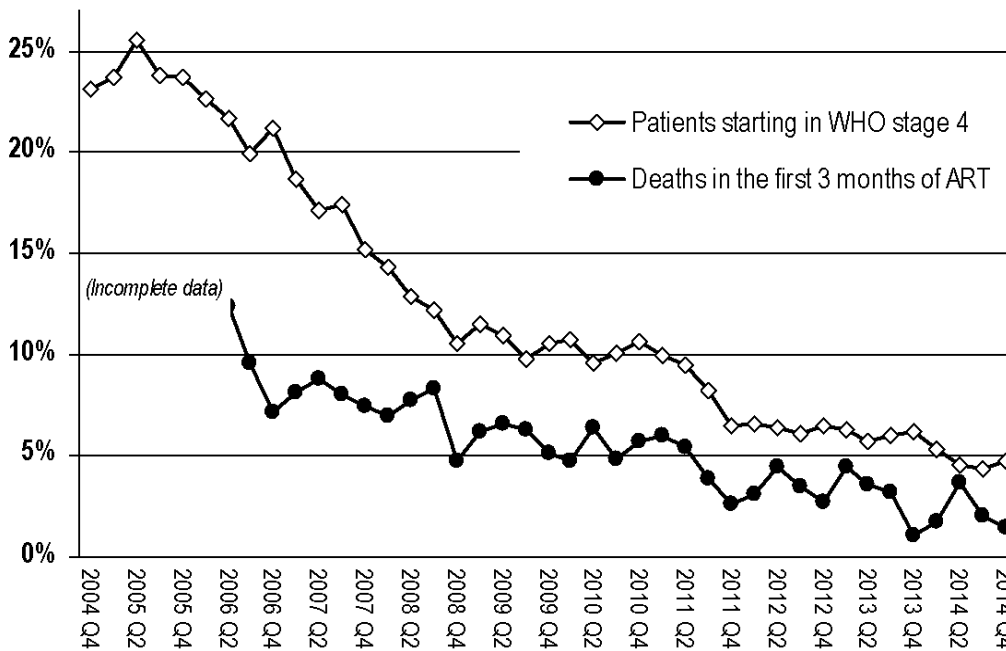


Figure 6 shows the considerable decline in **early mortality** since the start of the program. In Q2 of 2006 11% of new patients died within the first 3 months after ART initiation. There has been a remarkable decline in early mortality and the lowest point thus far has been reached in Q4 2013. The decrease 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). It correlates well with the decline in the proportion of patients starting ART in WHO clinical stage 4 from 25% in 2005 Q2 to **5%** in Q4 2014. Slight fluctuations in the calculated early mortality rates are mainly due to inconsistent classification of month of death at the sites with electronic patient record systems. The 2014 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 5 years).

16.4 ART Cohort Survival Analysis

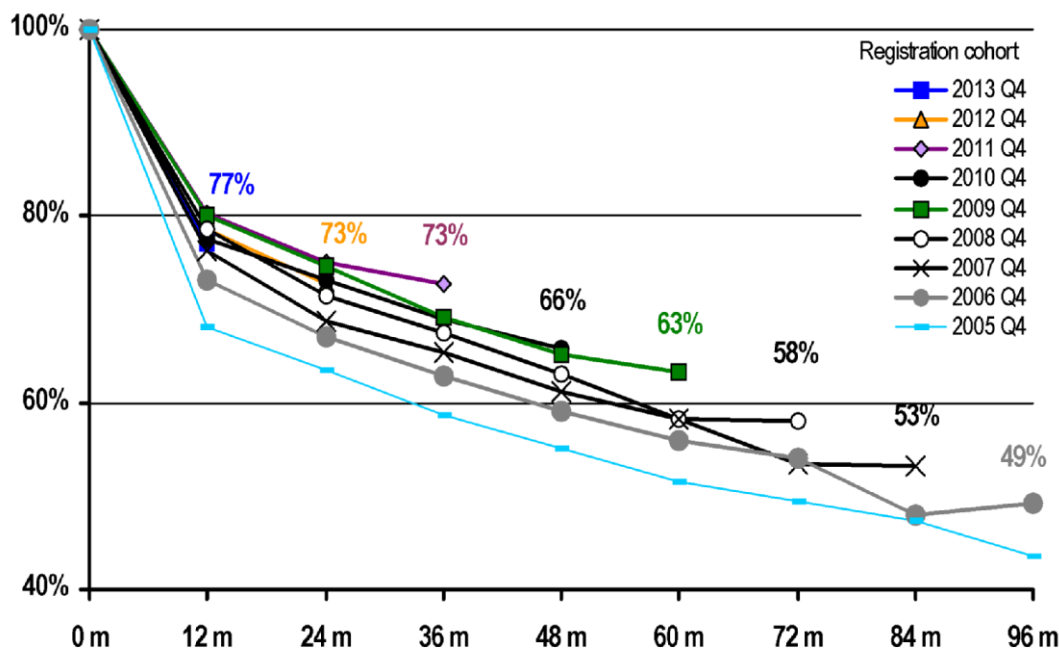
A 12, 24, 36, 48, 60, 72, 84, 96 and 108-month **'cohort outcome survival analysis'** was conducted for patients registered in Q4 of 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012 and 2013, respectively. A separate 12-month cohort outcome analysis was conducted for children who were under 15 years at the time of ART initiation and who registered for ART in Q4 2013. For the 11th time, a further subgroup analysis was done for women who started ART under **Option B+** during Q4 2012, Q4 2013 and Q2 2014. **76% of adults** and **77% of children** were retained alive on ART after 12 months on treatment. This is slightly lower than the previous quarter and remains below the WHO target of 85%.

The majority of patients classified as lost to follow-up are likely to have stopped/ interrupted ART, but others will have transferred to another facility without notifying the previous site. Actual retention rates are thought to be about **10%** higher due to misclassification of 'silent transfers' as 'defaulters' in clinic-based survival/retention analysis. A population-based study in Karonga district

with individual linkage showed that **92%** of patients started in 2011-2012 were retained after 12 months on ART while routine monitoring data showed **79%** retention rates for the same period.¹³

Figure 7 shows the continuous improvement of long-term treatment outcomes over time. **58%** and **52%** of patients registered 5 and 7 years ago had been retained alive on ART.

Figure 7: Group cohort survival analysis: Proportion of patients retained alive on ART 12, 24, 36, 48, 60, 72, 84 and 96 months after ART initiation



6-month group cohort survival outcomes were known for **7,766 (99%)** of the 7,855 women registered as having started ART under *Option B+* in Q2 2014.¹⁴ This number represents 479 (6%) women who transferred out and are therefore double counted and **7,287 (94%)** patients not transferred. **5,720 (78%)** of these were retained at 6 months after registration. **1,514 (97%)** of those not retained were lost to follow-up, **18 (1%)** were known to have stopped ART and **35 (2%)** were known to have died.

12-month group cohort survival outcomes were known for **7,678 (97%)** of the 7,906 women registered as having started ART under *Option B+* in Q4 2013.¹⁴ This number represents **668 (9%)** women who transferred out and are therefore double counted and **7,010 (91%)** patients not transferred. **5,035 (72%)** of these were retained at 12 months after registration. **1,848 (94%)** of those not retained were lost to follow-up, **36 (2%)** were known to have stopped ART and **91 (5%)** were known to have died.

24-month group cohort survival outcomes were known for **8,244 (95%)** out of the 8,646 women registered as having started ART under *Option B+* in Q4 2012.¹⁴ This number represents **896 (11%)** women who transferred out and are therefore double counted and **7,348 (89%)** patients not transferred. **5,017 (68%)** of these were retained at 24 months after registration. **2,201 (94%)** of those

¹³ Koole, O., Houben, R. M. G. J., Mzembe, T., Van Boeckel, T. P., Kayange, M., Jahn, A., Crampin, A. C. (2014). Improved retention of patients starting antiretroviral treatment in Karonga District, northern Malawi, 2005-2012. *Journal of Acquired Immune Deficiency Syndromes* (2014), 67(1), e27-33. doi:10.1097/QAI.0000000000000252

¹⁴ Group cohort survival analyses were not available from some sites with electronic data systems. 'Reason for starting' may be reclassified for some patients, leading to minor inconsistencies in patients included in group cohort survival analyses.

not retained were lost to follow-up, **42 (2%)** were known to have stopped ART and **88 (4%)** were known to have died.

2,297 (27%) of the women in the 24 month Option B+ survival cohort had initiated ART in the breastfeeding period and **2,581 (30%)** started in the third trimester / in labour; considering the 24 month median breastfeeding period in Malawi (2010 MDHS), more than half of the women in this cohort can be assumed to have stopped breastfeeding. The **68% and 71% retention rate at 24 and 36 months** after ART initiation confirms that a high proportion of women started under Option B+ **remain on ART beyond the cessation of breastfeeding.**

The 6-month retention rate is the same as in the previous quarter. These are satisfactory results. Most of the women lost to follow-up failed to return after their first visit and many of these may have never actually started ART due to inadequate counselling and preparation in the initial phase of implementation. The program is examining the different modes of delivery closely to further improve uptake and retention on *Option B+*.

6 month survival OptionB+

Survival and retention in ART program

*

ART cohort registration group outcomes

| | | |
|------------------------------------------------|-------|------|
| Total ART clinic registrations | 7,766 | 100% |
| Transfers out (double counted) | 479 | 6% |
| Total not transferred out (patients in cohort) | 7,287 | 94% |
| Total alive on ART | 5,720 | 78% |
| Total not retained | 1,567 | 22% |
| Defaulted | 1,514 | 97% |
| Stopped ART | 18 | 1% |
| Died | 35 | 2% |

12 month survival OptionB+

Survival and retention in ART program

*

ART cohort registration group outcomes

| | | |
|------------------------------------------------|-------|------|
| Total ART clinic registrations | 7,678 | 100% |
| Transfers out (double counted) | 668 | 9% |
| Total not transferred out (patients in cohort) | 7,010 | 91% |
| Total alive on ART | 5,035 | 72% |
| Total not retained | 1,975 | 28% |
| Defaulted | 1,848 | 94% |
| Stopped ART | 36 | 2% |
| Died | 91 | 5% |

24 month survival OptionB+

Survival and retention in ART program

*

ART cohort registration group outcomes

| | | |
|------------------------------------------------|-------|------|
| Total ART clinic registrations | 8,244 | 100% |
| Transfers out (double counted) | 896 | 11% |
| Total not transferred out (patients in cohort) | 7,348 | 89% |
| Total alive on ART | 5,017 | 68% |
| Total not retained | 2,331 | 32% |
| Defaulted | 2,201 | 94% |
| Stopped ART | 42 | 2% |
| Died | 88 | 4% |

36 month survival OptionB+

Survival and retention in ART program

*

ART cohort registration group outcomes

| | | |
|------------------------------------------------|--------|------|
| Total ART clinic registrations | 13,180 | 100% |
| Transfers out (double counted) | 1,702 | 13% |
| Total not transferred out (patients in cohort) | 11,478 | 87% |
| Total alive on ART | 8,119 | 71% |
| Total not retained | 3,359 | 29% |
| Defaulted | 3,053 | 91% |
| Stopped ART | 72 | 2% |
| Died | 234 | 7% |

16.4.1 Secondary outcomes of patients retained on ART

Secondary outcomes are known for the **536,438** patients alive on ART who remained at their sites at end of the quarter.

ART Regimens

530,361 (99%) of patients were on first line and **5,700 (1%)** were on second line regimens; **377 (<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, **25,867 (5%)** were on paediatric formulations and **24,947 (96%)** of these were on the new standard first line for children (regimen 2P: AZT/3TC/NVP). By the end of December 2014, **470,048 (93%)** of patients on adult first line were receiving regimen **5A** (tenofovir / lamivudine / efavirenz). **26,506 (5%)** were on regimen 2A (zidovudine / lamivudine / nevirapine), which was the main alternative regimen for patients with stavudine side-effects before transition to regimen 5A and **1,294 (<1%)** were on regimen 1A (stavudine / lamivudine / nevirapine).

Adherence to ART

Pill counts and the number of missed doses were documented for **523,732 (98%)** out of all patients retained on ART and **471,978 (90%)** of these were classified as >95% adherent in Q4 2014. Manual estimation of adherence from pill counts is practically difficult and classification can be misleading. The ART program has switched to a direct evaluation of doses missed in 2010 to improve on accuracy of adherence assessment and plausible adherence levels are recorded with this method. However, there have also been persistent challenges with the analysis of adherence levels at sites with Electronic Data Systems (EDS) and adherence data from several of these sites could not be included in this report.

ART Side Effects

523,154 (98%) patients on ART had information on drug side effects documented at their last clinic visit before end of December 2014. **3,727 (1%)** of these had side-effects. The prevalence of side effects seems to have stabilized at very low levels following the full transition to regimen 5A (tenofovir / lamivudine / efavirenz) that started in July 2013.

16.5 Viral Load (VL) Monitoring

The National Treatment Program has started rolling out routine VL monitoring for patients on ART to facilitate early detection of treatment failure and timely switching to second line ART. Routine VL monitoring is scheduled at 6 months after ART initiation, at 2 years and every 24 months thereafter. Additional targeted VL testing may be carried out for patients with clinically suspected treatment failure. During Q4 2014, **8** laboratories in the national program provided VL testing for patients enrolled at the 8 respective facilities and associated sites. A total of **17,364** VL results were produced at these labs between October and December 2014. The number of VL results per lab was: Thyolo District Hospital: 4,589; Partners in Hope (Lilongwe): 3,978; Kamuzu CH (Lilongwe): 3,551; DREAM (Blantyre): 1,831; Zomba CH (Zomba): 1,268; Mzuzu CH (Mzimba): 970; Mzimba DH (Mzimba): 824; QECH (Blantyre): 540.

| Reason | 0-999 | | 1000-4999 | | 5000+ | | Total |
|------------------|---------------|------------|------------|------------|--------------|------------|---------------|
| Routine | 14,215 | 85% | 637 | 4% | 1,807 | 11% | 16,659 |
| Targeted | 233 | 60% | 25 | 6% | 131 | 34% | 389 |
| Other/unk | 183 | 58% | 31 | 10% | 102 | 32% | 316 |
| Total | 14,631 | 84% | 693 | 4% | 2,040 | 12% | 17,364 |

16,659 (96%) of all VL samples were classified as *routine scheduled*. This is equivalent to **24%** of the

estimated 70,000 ART patients passing a VL monitoring milestone this quarter. **389 (2%)** of samples were classified as *targeted (suspected treatment failure / repeat)* and for **316 (2%)** the reason for the sample was other or not specified. **14,631 (84%)** of all results were undetectable / below 1,000 copies/ml. The proportion of results with 5,000+ copies was higher among targeted samples (34%) than among *routine* samples (11%). VL monitoring outputs are expected to increase significantly over the next quarters.

17 TB / HIV Management

Approximately **92%** of HIV infected TB patients were receiving ART in Q4 2014. This estimate is based on the following triangulation of TB and ART program data:

TB Program Data: A total of **4,204** TB patients were registered during Q4 2014. Assuming an average HIV prevalence of 60% among TB patients, **2,522** TB patients were HIV positive and therefore in need of ART. Given that **1,546** TB patients registered were already on ART at the time of starting TB treatment, $2,522 - 1,546 = 976$ TB patients needed to initiate ART.

ART Program Data: An estimated **782** patients¹⁵ started ART with a current or recent episode of TB in Q4 2014. This is **80%** (782 of 976) of the TB patients who needed to start ART. This means that a total of $1,546 + 782 = 2,328$ (**92%**) of the estimated 2,522 HIV infected TB patients were receiving ART in Q4 2014.

TB program report

*

TB clinic registrations

| | | |
|------------------------------|-------|------|
| Total TB patients registered | 4,204 | 100% |
|------------------------------|-------|------|

HIV status ascertainment

| | | |
|---------------------------------------|-------|-----|
| HIV status not ascertained | 215 | 5% |
| HIV status ascertained | 3,989 | 95% |
| HIV negative | 1,886 | 47% |
| HIV positive | 2,103 | 53% |
| Already on ART | 1,546 | 74% |
| Not on ART when starting TB treatment | 557 | 26% |

TB / ART program triangulation

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HIV-burden among TB patients (estimated)

| | | |
|---------------------------------------------------|-------|-----|
| HIV negative (est. 40%) | 1,682 | 40% |
| HIV positive (est. 60%) in need of ART | 2,522 | 60% |
| Not on ART | 195 | 8% |
| Total on ART (coverage) | 2,328 | 92% |
| Already on ART (TB prog) | 1,546 | 66% |
| Started ART within 24m of TB diagnosis (ART prog) | 782 | 34% |
| ART initiations with current TB (ART prog) | 510 | 65% |
| ART initiations after recent TB (ART prog) | 272 | 35% |

18 STI Treatment

STI reports were actively collected during the Integrated HIV Program Supervision exercise for the 7th time this quarter. This decision was taken due to the persistent challenges with 'passive' reporting based on data aggregated by the district STI coordinators. This quarter, supervision teams collected

¹⁵ 21% of the 1,012 ART patients who were registered this quarter 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.

STI data from 697 out of 928 facilities offering STI management according to the *2013-14 Service Provision Assessment*¹⁶ in Malawi. The site-level reports included here may therefore only represent 73% of all STI services in Malawi. The supervision teams re-emphasized the importance of complete and accurate documentation at the sites and the data quality is expected to improve with resumption of regular site supervision for the STI program. The complete set of STI program data collected is included in the Appendix.

18.1 Access to STI treatment and coverage

Based on the data collected at the facilities, a total of **60,856** STI cases were treated in Q4 2014. Considering the 73% site-level completeness of reporting, this number is estimated to represent a total of **83,173** STI cases treated. This is equivalent to **84% STI treatment coverage** of the expected 98,600 STI cases in the population.

Out of **60,856** documented clients treated, **24,496** (40%) were male and **36,360** (60%) were female. **4,071** (11%) of female STI clients were pregnant. **40,804** clients (67%) were 25 years and above, **14,448** (24%) were 20-24 years and **5,604** (9%) were under 20 years old.

18.2 Client Type and STI History

53,413 (88%) of clients were symptomatic and **7,443** (12%) were asymptomatic (treated as partners). Among symptomatic clients, **48,748** (91%) of were index cases and **4,675** (9%) were partners. A total of **19,821** partner notification slips were issued, equivalent to an average of 0.41 slips per index case. Considering the 19,821 partner notification slips issued, **61%** (12,118) of those notified presented to the clinic. **45,638** (75%) of clients presented with their first lifetime episode of STI, **9,838** (16%) clients reported to have had an STI in over three months ago and **5,380** (9%) 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.

18.3 HIV Status

HIV status was ascertained for **30,806** (51%) clients and **7,985** (26%) of these were HIV positive. **1,766** (22%) of positives were identified through a new test initiated at the STI clinic, while **6,219** (78%) presented with a documented previous positive HIV test result. **4,464** (72%) of clients with a previous positive HIV test result were on ART.

The rate of HIV status ascertainment at STI clinics remained low. 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.

18.4 STI Syndromes

The most common syndrome was abnormal vaginal discharge (AVD) with **19,259** (30%) cases, followed by urethral discharge (UD, **15,017** cases), genital ulcers (GUD, **10,570** cases) and lower abdominal pain (LAP, **10,485** cases). Similar to previous reports, balanitis, bubo, warts and neonatal conjunctivitis each accounted for 1 – 2% of cases.

¹⁶ Ministry of Health, & ICF International. (2015). Malawi Service Provision Assessment (SPA) 2013-14. Lilongwe, Malawi and Rockville, Maryland, USA. Retrieved from <http://dhsprogram.com/pubs/pdf/SPA20/SPA20.pdf>

18.5 Referrals

Given the high risk of recent HIV infection among STI clients, all clients with unknown status and those with a new negative test result should be referred for (repeat) HIV testing and counselling. **19,596 (37%)** of the 52,871 STI clients with unknown or new negative test result were referred for repeat HTC. **1,171 (66%)** of 1,766 clients who were newly tested HIV positive were referred for ART eligibility assessment.

19 Supply of HIV Program Commodities

19.1 Quantification and procurement planning

The quarterly quantification and procurement plan for all HIV commodities was reviewed and updated. This formed the basis for the December 2014 order for ARVs, OI medicines and selected laboratory commodities estimated at 35.5 million USD.

During Q4 2014, there was a marked improvement noted with the procurement and delivery of 5A (tenofovir / lamivudine / efavirenz) resulting into **5** and **4** months of stock in the warehouse and health facility levels respectively. By the end of December 2014, **470,337 (93%)** of 530,361 patients receiving first line adult formulation ART were on this preferred regimen.

Continuous healthy supply chains for co-trimoxazole 960mg at most sites (651) enabled the program maintain a CPT coverage of 94% among pre-ART and 95% among ART patients.

During Q4 2014, ARVs and medicines for opportunistic infections worth \$23.2 million were received by the Central Medical Store Trust warehouse dedicated for HIV Program commodities. This included Tenofovir/Lamivudine/Efavirenz 300/300/600mg (Regimen 5A; 84% of the value of adult ARVs) and other ARV formulations (16% of the value for all medicines received during the period).

To maintain adequate stocks in the pipeline and hence ensure uninterrupted supply for subsequent orders, the Ministry has continued processing HIV commodity orders for ARVs, OI, RDTs and other related commodities through Partnership for Supply Chain Management (ARVs and RDTs) and IDA Foundation (laboratory commodities and medicines for opportunistic infections). The second order for the transition funding was placed in Dec 2014 to maintain central level stocks in Q3 & Q4 2015 (July-Dec 2015).

19.2 Quarterly distribution of HIV Commodities

The scheduled quarterly distribution of HIV commodities (**Distribution Round 20**) took place from November to mid-December 2014. This was the first consolidated distribution for HIV and Malarial commodities. **49** HIV and malaria program commodities (anti-malarials, ARVs, OI, STI medicines and laboratory commodities) were distributed **726** health facilities. Rapid test kits for HIV and malaria were also distributed to individual health facilities to ensure adequate stocks and uninterrupted testing services at all sites.

During Q4 2014, the logistics team at the Department of HIV and AIDS also coordinated a total of **1,247** individual commodity transactions between ART sites to avert expiries and/or stock outs. All transactions are all managed using the HIV Department Supply Chain Hot Line, a toll free facility that was set up to facilitate communication between the health facilities and the central level. Health workers are able to communicate supply chain and other HIV commodities related issues that need to be resolved by the technical team at the department in a timely manner.

19.3 Quarterly logistics monitoring and supply chain Trail for Q4 2014

Logistics monitoring and supply chain trail of HIV commodities post-distribution for Distribution Round 19 was conducted in Salima, Kasungu, Mchinji and Lilongwe at 21 ART sites with the aim of monitoring distribution and conducting a supply chain trail for HIV commodities. No deviations were noted from the verified delivery notes reviewed by the team and health facility staff during the supply chain trail visit. There was a marked improvement in the logistics management of ARVs and medicines for opportunistic infections. Health care providers continued to use RDT daily activity registers and relocation books for registration of redistributed commodities to health facilities for

which authorization codes must be obtained as a commodity tracking measure. This enables the program foster accountability before commodities are relocated between any sites.

19.4 National Stock Status of HIV Commodities

Physical stock counts for ARVs and other medicines for HIV-related diseases were performed at all sites during the supervision visits in January 2015. **Table 6** shows the total medicine stocks found at the sites and the estimated consumption periods. Health facility stocks of the key adult and paediatric regimens were estimated to last until May 2015.

Minimum stocks of TDF/3TC 300/300mg and AZT/3TC 300/150mg are maintained at all sites for post-exposure prophylaxis (PEP) and the total stocks at the sites therefore far exceeds the actual consumption from patients using this regimen in alternative ART regimens or as PEP.

Large volume commodities include stavudine and efavirenz containing regimens at all levels mainly driven by the transition to tenofovir based regimens. The program continues to monitor the trend of patients on stavudine and efavirenz containing regimens to inform future procurements.

470,337 patients were on regimen 5A, which was **4,546 (1%)** lower than projected in the previous forecast for the end of this quarter (474,883). The national ART program forecast and quantification was updated in December 2014 to inform procurement planning and budgeting for HIV commodities.

Table 6: Total stocks of HIV program commodities at all sites visited during the 2014 Q4 supportive site supervision. Stock positions are from the date of the visit (between 1-4 weeks after the end of the quarter). Warehouse stock positions are from 26/01/2015

| Inventory unit | Item | Sites with any Stock | Total Physical Stock | | Consumption/ Month | Months of Stock * | |
|---------------------------------------|-------------------------------------------------------|----------------------|----------------------|--------------|--------------------|-------------------|--------|
| | | | At Sites | In Warehouse | | At Sites | Wareh. |
| tins | ABC / 3TC 60 / 30mg tins (60 tabs) | 130 | 18,223 | 21,181 | 2,697 | 6.8 | 7.9 |
| | ABC / 3TC 600 / 300mg tins (30 tabs) | 22 | 275 | | | | |
| | ATV / r 300 / 100mg tins (30 tabs) | 153 | 8,042 | 21,183 | 5,001 | 1.6 | 4.2 |
| | AZT / 3TC / NVP 300 / 150 / 200mg tins (60 tabs) | 599 | 108,907 | 398,026 | 26,565 | 4.1 | 15.0 |
| | AZT / 3TC / NVP 60 / 30 / 50mg tins (60 tabs) | 617 | 305,872 | 568,892 | 62,368 | 4.9 | 9.1 |
| | AZT / 3TC 300 / 150mg tins (60 tabs) | 562 | 17,032 | 12,173 | 2,049 | 8.3 | 5.9 |
| | AZT / 3TC 60 / 30mg tins (60 tabs) | 586 | 21,712 | 15,521 | 2,221 | 9.8 | 7.0 |
| | d4T / 3TC / NVP 30 / 150 / 200mg tins (60 tabs) | 132 | 17,624 | 88 | 1,294 | 13.6 | 0.1 |
| | d4T / 3TC 30 / 150mg tins (60 tabs) | 213 | 18,582 | 97 | 124 | 149.9 | 0.8 |
| | d4T / 3TC 6 / 30mg tins (60 tabs) | 199 | 3,379 | | 256 | 13.2 | |
| | EFV 200mg tins (90 tabs) | 130 | 3,251 | 1,367 | 323 | 10.1 | 4.2 |
| | EFV 600mg tins (30 tabs) | 209 | 14,743 | 15,117 | 824 | 17.9 | 18.3 |
| | LPV / r 100 / 25mg tins (60 tabs) | 52 | 7,603 | 9,870 | 2,097 | 3.6 | 4.7 |
| | LPV / r 200 / 50mg tins (120 tabs) | 67 | 1,846 | 222 | 412 | 4.5 | 0.5 |
| | NVP 200mg tins (60 tabs) | 373 | 21,078 | 52,562 | 5,343 | 3.9 | 9.8 |
| | NVP 50mg tins (60 tabs) | 124 | 9,505 | 13,350 | 500 | 19.0 | 26.7 |
| | TDF / 3TC / EFV 300 / 300 / 600mg tins (30 tabs) | 694 | 1,937,618 | 2,402,319 | 470,337 | 4.1 | 5.1 |
| TDF / 3TC 300 / 300mg tins (30 tabs) | 585 | 92,802 | 56,753 | 9,935 | 9.3 | 5.7 | |
| bottles | Fluconazole (Diflucan) 50mg / 5ml bottles (35 ml) | 15 | 286 | | 80 | 3.6 | |
| | Gentian violet 25g bottles (1 each) | 458 | 8,382 | | 1,159 | 7.2 | |
| | NVP 10mg/ml bottles (25 ml) | 562 | 97,663 | 154,751 | 16,218 | 6.0 | 9.5 |
| vials | Benzathine Penicillin 1.44g vials (50 each) | 588 | 201,040 | | 37,309 | 5.4 | |
| | Bleomycine 15,000IU vials (1 each) | 26 | 12,183 | | | | |
| | Ceftriaxone 1g vials (50 each) | 467 | 190,424 | | 100,704 | 1.9 | |
| | Depo-Provera 150mg/1ml vials (25 each) | 548 | 487,469 | 1,287,050 | 279,030 | 1.7 | 4.6 |
| | Gentamicin 80mg / 2ml vials (50 each) | 585 | 375,542 | | 94,767 | 4.0 | |
| | Vincristine 1mg / 1ml vials (1 each) | 54 | 74,402 | 50,458 | 4,032 | 18.5 | 12.5 |
| tabs | Aciclovir 200mg blister packs (25 tabs) | 610 | 5,464,961 | 3,114,250 | 607,043 | 9.0 | 5.1 |
| | Amitriptyline 25mg tins (500 tabs) | 254 | 665,149 | | 111,810 | 5.9 | |
| | Azithromycin 500mg blister packs (3 tabs) | 342 | 85,602 | | 10,018 | 8.5 | |
| | Ciprofloxacin 500mg blister packs (100 tabs) | 360 | 1,333,713 | | 287,141 | 4.6 | |
| | Clotrimazole 500mg boxes (1 each) | 418 | 160,016 | | 36,909 | 4.3 | |
| | Codeine 30mg tins (100 tabs) | 165 | 2,255,649 | | 47,523 | 47.5 | |
| | Cotrimoxazole 100 / 20mg blister packs (1000 tabs) | 589 | 33,538,431 | 49,703,000 | 6,044,991 | 5.5 | 8.2 |
| | Cotrimoxazole 400 / 80mg tins (1000 tabs) | 631 | 57,787,118 | 21,774,000 | 15,919,602 | 3.6 | 1.4 |
| | Cotrimoxazole 960mg blister packs (1000 tabs) | 651 | 43,791,302 | 20,936,000 | 16,960,095 | 2.6 | 1.2 |
| | Doxycycline 100mg tins (1000 tabs) | 572 | 16,716,649 | 998,000 | 4,254,538 | 3.9 | 0.2 |
| | Erythromycin 250mg tins (1000 tabs) | 455 | 7,268,667 | 1,498,000 | 3,806,115 | 1.9 | 0.4 |
| | Fluconazole (Diflucan) 200mg tins (28 tabs) | 325 | 335,141 | 291,760 | 42,435 | 7.9 | 6.9 |
| | Fluconazole (generic) 200mg tins (100 tabs) | 32 | 38,862 | | | | |
| | Ibuprofen 200mg tins (100 tabs) | 261 | 4,475,151 | | 813,756 | 5.5 | |
| | Isoniazid 100mg blister packs (100 tabs) | 143 | 767,450 | | 147,511 | 5.2 | |
| | Isoniazid 300mg tins (1000 tabs) | 632 | 11,569,324 | 14,663,000 | 1,079,641 | 10.7 | 13.6 |
| Metronidazole 200mg tins (1000 tabs) | 538 | 10,240,100 | | 4,621,809 | 2.2 | | |
| Morphine 10mg blister packs (60 tabs) | 151 | 880,271 | | 207,375 | 4.2 | | |
| Pyridoxine 25mg tins (100 tabs) | 140 | 2,736,570 | | 1,152,426 | 2.4 | | |
| Pyridoxine 50mg tins (1000 tabs) | 506 | 8,575,699 | 12,119,000 | 1,152,426 | 7.4 | 10.5 | |
| sheets | ART pat. card adult (yellow) bundles (100 sheets) | 645 | 299,609 | 23,900 | 10,316 | 29.0 | 2.3 |
| | ART pat. card paed. (blue) bundles (100 sheets) | 605 | 122,473 | | 930 | 131.6 | |
| | Exposed child card (pink) bundles (50 sheets) | 592 | 87,333 | 49,250 | 3,599 | 24.3 | 13.7 |
| | Polythene sleeve bundles (100 sheets) | 495 | 110,989 | 294,600 | 17,007 | 6.5 | 17.3 |
| | Pre-ART pat. card (green) bundles (100 sheets) | 601 | 148,671 | | 2,161 | 68.8 | |
| tests | DBS kit (filter paper, lancet, etc.) bundles (20 eac) | 398 | 20,490 | 440 | 4,319 | 4.7 | 0.1 |
| | Determine HIV1/2 boxes (100 each) | 625 | 627,734 | 590,000 | 147,638 | 4.3 | 4.0 |
| | Determine syphilis boxes (100 each) | 313 | 50,792 | 90,200 | 50,322 | 1.0 | 1.8 |
| | Uni-Gold HIV1/2 boxes (20 each) | 595 | 72,342 | 14,060 | 12,196 | 5.9 | 1.2 |
| pieces | Condoms female boxes (1000 each) | 423 | 876,519 | | 178,204 | 4.9 | |
| | Condoms male boxes (144 each) | 560 | 12,100,709 | 11,557,152 | 4,057,270 | 3.0 | 2.8 |

* 'Consumption per month' and 'Months of stock' for ARVs, CPT, INH and HIV test kits are based on the respective 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. Facility stock positions for OI and STI drugs include HIV Program and other supply sources. Total national consumption and MoS estimates are used for these commodity groups. '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.

20 Training and Mentoring

Viral Load orientation trainings

1,350 providers were orientated in routine and targeted viral load testing using the capillary DBS sample technique.

ART/PMTCT refresher trainings

A cumulative total of **4,850** clinicians and nurses have been refreshed in the new 2014 National guidelines by the end of the quarter.

STI training

21 STI trainers of trainers (TOT) participated in a refresher training. 16 were clinical officers and 5 were nurses. A total **156** providers were trained in 9 sessions during this quarter. 5 sessions were conducted by the private sector and 4 by the public sector.

HIV Testing and Counselling trainings

12 participants were trained in the 2014 HTC Skills Intensive Training this quarter. A team of HTC master trainers and officers from the HIV Department monitored and supervised the intensive skills trainings in all the districts.

21 participants were trained and certified in initial HTC training during this quarter.

21 Participants in Q4 2014 Supervision (Site visits 12 – 30 January 2015)

| | | |
|-----------------------------------------------------------------|-------------------------------------------------------|---------------------------------------------------------|
| Absalom Kaunda (CO, MOH, Mzimba DHO) | Everista Mkandawire (Nurse, MOH) | Michael Eliya (PMTCT Program Officer, MOH) |
| Afred Kamoto (Logistics Fellow, MOH) | Ezra Majoni (Nurse, MOH) | Miriam Chigwiya (CO, MOH) |
| Agnes Kalitsiro (Nurse, Mlambe Mission Hospital) | Fainala Muyila (Nurse, MOH) | Miriam Thindwa (Clinician, Limbe H/C) |
| Alefa Fikira (CMT, MOH) | Felix Chinguwo (CO, Ntcheu DH) | Monica Simfukwe (Nurse, MOH, Chintcheche RH) |
| Allan Nkhata (MA, MOH) | Frazer Mkawa (Nurse, MOH) | Offrey Mnduwira (CO, Police) |
| Allison Zakaliya (, MSH) | Gabriel Layout Kachere (clinician, MOH) | Oscar Kasiyamphanje (Nurse, CHAM) |
| Amos Makwaya (CO, MOH) | George Sankhulani (CO, Dignitas) | Overtone Ndhlovu (CO, MOH) |
| Andraida Mtoseni (Nurse, MOH) | Gerald Zomba (Program Officer, Dept for HIV and AIDS) | Paul Nyasulu (CO, Dept of HIV & AIDS) |
| Andrew Mgaga (, I-Tech) | Grace Chipanga (Nurse, Private) | Pax Mkupani (Logistics Fellow, MOH) |
| Andrew Mganga (M&E Fellow, Dept for HIV and AIDS) | Hannock Matupi (ARV clinician, MOH, Rumpi DH) | Peter Chimphero (CO, MOH) |
| Angela Nkhoma (Nurse, MOH) | Harrison Tembo (CO, MOH) | Peter Donda (CO, Dedza DH) |
| Annie Biza (Nurse, MDF) | Janet Chikonda (Nurse, MOH) | Rhoda Ching'ani (Community Nurse, Lighthouse) |
| Beatrice Malonje (Nurse, MOH) | Jean Kayamba (Nurse, MOH) | Richard Abuduo (CO, MOH) |
| Blessings Mvula (, MOH) | Jesse Lobeni (Nurse, MOH) | Rodrick Kaulele (CO, CHAM (Sister Tereza)) |
| Catherine Kassam (, MOH) | Jones Morra (, MOH) | Rose Kalinde (Nurse, Lighthouse) |
| Cecilia Manyawa (Nurse, MOH) | Josephy Mwanyongo (, MOH) | Rose Maviko (Nurse, Limbe HC) |
| Cecilia Mphika (, MOH) | Josephy Thole (, MOH) | Roseby Malombe (Nurse, CHAM) |
| Chifundo Makuluni (Nurse, MOH) | Judith Ntopa (Nurse, Cobbe Barracks) | Ruth Deula (Nurse, CHAM) |
| Chikayiko Majamanda (Nurse, MOH) | Juliana Soko (ARV nurse, MOH, Livingstonia MH) | Sabina Phiri (Nurse, MOH) |
| Chikumbutso Pendame (MA, MOH) | Kelvin Jobo (CO, Lighthouse) | Salome Chiwewe (Nurse, MOH, Ntchisi DH) |
| Chimwemwe Francis Mkandawire (IT Fellow, Dept for HIV and AIDS) | Kingsley Mbewa (CO, MOH) | Sidder Hambisa (ENM, MOH) |
| Chrissy Lizengo (, MOH) | Lameck Mlauzi (, NTP (MOH)) | Simon Makombe (ART officer, MOH, Dept for HIV and AIDS) |
| Christopher Mkwezalamba (CO, MOH) | Lilian Kachali (Nurse, MOH) | Stanley Ngoma (CO, MOH) |
| Dalitso Midiani (PMTCT Officer, MOH) | Limbani Kadzuwa (Nurse, MOH) | Stanley Phombo (Nurse, MOH) |
| Davie Maseko (CO, SOS) | Lindiwe Zaina (Logistics, HIV Dept) | Stony Mbiriyawanda (, MOH) |
| Dominic Gongwe (, MOH) | Louis Mkwatula (, Dignitas) | Stuart Chuka (CO, MBCA) |
| Domminic Gondwe (Nurse, MOH Dedza DHO) | Louis Pota (, MOH) | Thom Chaweza (CO, Lighthouse) |
| Edith Taulo (Nurse, MOH) | M V Cheonga (Nurse, MOH) | Timothy Mwenyedini (MA, MOH) |
| Edith Thaulo (Nurse, MOH) | Macleod Piringu (ART CORDINATOR, MOH) | Yusuf Bhamu (HIV Fellow, HIV Dept) |
| Eliza Mahimanya (Logistics Officer, MOH) | Magaret Mkusa (, MOH) | Zione Mchikaya (, MOH) |
| Elizabeth Chatsika (CO, CHAM) | Margaret Katumbi (Nurse, MOH) | |
| Emmanuel Chiweta (, MOH) | Martha Kamphanda (MA, MOH) | |
| Erik Mittochi (CO (ART coord), MOH) | Martin Katanga (CO, MOH) | |
| Eustice Mhango (ART officer, MOH, Dept for HIV and AIDS) | Mary Gosten (MA, MOH) | |
| | Mathilda Kamanga (Nurse, Army) | |
| | Mercy Makaika (Nurse, MOH) | |

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We thank all facility staff for their sincere welcome and co-operation with the HIV Department and its partners during these supportive visits. We congratulate all staff for their excellent work.

12 May 2015

22 Appendix (Full National HIV Program Data)