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HIV and Patient Monitoring in Malawi

Brian Williams

South African Centre for Epidemiological Modelling and Analysis,
University of Stellenbosch, South Africa: williamsbg@me.com

This document[i] provides background information for Malawi in support of the WHO Consolidated Guidelines for Person Centered HIV Patient Monitoring and Case Surveillance[ii]

Key words: Malawi, HIV, tuberculosis, anti-retroviral therapy, surveillance, patient monitoring, epidemic trends, drug supply, unique patient identifiers, data analysis

i This document: http://tinyurl.com/BGW0042
ii WHO Consolidated Guidelines: http://tinyurl.com/BGW0043

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Summary

Malawi has an excellent, nation-wide system for monitoring patients found to be infected with HIV, keeping records of individual patient outcomes, providing support to clinic managers and keeping track of programme performance. Of all those infected with HIV, 73% know their status, 89% of these are on treatment and 91% of these are virally suppressed[1,2,iii] close to the *90-90-90* target set by UNAIDS to end AIDS by 2030. Malawi's success may be attributed to agreement, from the start, on the overall strategy and key priorities.[3]

- The strategy was: start simple and build it up slowly; put the Ministry of Health in charge; ensure clear funding streams; train local staff; ensure no drug interruptions; start with paper based recording and computerize data systems as the number on treatment rises.
- The priorities were (roughly in order): Secure the drug supply; ensure adherence; expand treatment; monitor patients monthly; report individual patient outcomes; provide quarterly feedback and support to clinics.

The *sine qua non* of good patient monitoring is being able to uniquely identify individual patients and track them over time and one might argue that Malawi has been a victim of its own success. They currently (2016 Q4[1]) have 679k people alive and on ART and, on average, 30 people starting ART in each quarter in 732 clinics. Keeping track of individual patients and using the data to determine aggregate outcomes including alive, dead, transferred-out, lost to follow-up, on ART, virally suppressed and other opportunistic infections by age, gender and clinic is a massive task and it is these issues of data collection, management, analysis and interpretation to which Tyler Smith drew attention in his recent Landscape Analysis (Appendix 1).[4,iv]

Over the next seven years the emphasis will shift from finding new people infected with HIV to making sure that those on ART are fully compliant and healthy. Eventually, Malawi is going to have to manage about one million people and keep them alive and on ART for several decades to come or until a cure for HIV is found.

The key challenges facing the patient monitoring system in Malawi are to:

1. Develop a strong analytical unit in the Ministry of Health.
2. Adapt key recommendations from the World Health Organization (WHO) on ART for everyone infected with HIV[v] as appropriate.
3. Establish trends in incidence and mortality as well as individual outcomes by district, age and sex to identify places and groups where the system is working more or less well and where the data are stored electronically. Follow-up on specific programme outcomes such as improved retention, viral suppression and toxicity monitoring
4. Use the data to project future epidemiological trends to assist in forward planning.
5. Use these models to assess the impact, cost and cost-effectiveness of different interventions and to plan future financial, personnel, and infra-structural resource needs in

iii Integrated HIV Programme Report: http://tinyurl.com/BGW0046
iv Smith 2016 Achieving a Unified ME System: http://tinyurl.com/BGW0045
v Case Based Surveillance Toolkit: http://tinyurl.com/BGW0047

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order to do effective long-term, forward planning as the country approaches the *End Game*.

6. Make sure that a structure is in place within the Ministry of Health to coordinate and manage donor funds and support.
7. Ensure that the quarterly feed-back, support to clinics and data quality reviews are maintained.
8. Expand the electronic monitoring and recording system to clinics which are currently using paper based recording and reporting but only as the infrastructure, facilities, training and demand are in place.

The most important lesson from Malawi is that good patient monitoring made it possible to provide support to clinical staff, leading in turn to good treatment coverage and high rates of compliance, and to a decline in transmission. Good epidemic control starts from good patient monitoring, treatment, prevention and support.

Introduction[vi]

Malawi has developed an excellent, nation-wide system for monitoring people infected with HIV and keeping track of key epidemic markers. Their success lies in two things: the focus on simplicity and the use of data collection not only to track the epidemic and identify problems but also to give regular feedback and support to every clinic in the country. This achievement is the more remarkable given that Malawi is one of the poorest countries in the world, ranking 190 out of 194 countries by GDP,[vii] but has one of the most severe epidemics of HIV in the world, ranking 9th out of 168 countries by HIV prevalence.[viii]

We first discuss the current state and likely future epidemic trends in Malawi: unless we know where we are and where we are going we cannot decide what to do or how to do it to in order to achieve a better outcome. We then discuss the history and development of Malawi's patient monitoring system, as reported in their Integrated HIV Program Reports,[ix] which have been published quarterly since the beginning of 2004. We consider the current state of patient monitoring and support as reflected in the most recent report for the third quarter (Q3) of 2016[1] and comment on some of the questions that this raises. Finally, we consider ways in which the current system could be improved by strengthening Malawi's analytical capacity and making better use of this unique data set.

The focus here is on HIV in adults[v] because if ART is initiated early in all adults living with HIV this should include testing all pregnant women for HIV and starting them on treatment immediately. However, PMTCT is especially important and care must be given to reducing MTCT and identifying the long-term child survivors of mother-to-child transmission[5-9] and this demands a complementary assessment.

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vi For a list of acronyms see Appendix 4.
vii Countries by GDP: http://tinyurl.com/BGW0048
viii Countries by HIV Prevalence: http://tinyurl.com/BGW0049
ix Quarterly Reports 2004 Q2 to 2016 Q4: http://tinyurl.com/BGW0050

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There is an ongoing debate about the relative merits of treatment and prevention in reducing transmission and it should be made clear that the primary reason for starting people on treatment early is that it is in the best interest of the individual patient to start treatment as soon as possible after becoming infected. Allowing a person's immune system to deteriorate to any degree is not consistent with the clinician's commitment to 'first do no harm' and even those with the highest $CD4^+$ cell count are at a substantially increased risk of death.[10] What matters, therefore, is to get as many people as possible onto ART, ensure that they remain virally suppressed, and consider prevention in this context.

The epidemic of HIV

The epidemic of HIV in Malawi started early[11,12] (Figure 1). In 1987 thirty thousand men working on Anglo-American's gold-mines in South Africa were tested for HIV. The men in the study came from Botswana, Lesotho, Malawi, Mozambique, Swaziland and South Africa but not from what was then Rhodesia and is now Zimbabwe.[13] The prevalence among mine-workers from Malawi was 4%, while among those from all other countries, including South Africa, it was 0.03% or less. This led the South African Chamber of Mines to stop recruiting novices from Malawi[14] and the number employed on the South African gold-mines fell from 13,090 in 1988 to 2,212 in 1989.[15]

These data are important for two reasons. First, they show that Malawi experienced the epidemic of HIV before most other countries in southern Africa. Second, while the exclusion of Malawian nationals from working on the gold-mines affected the economy of Malawi in the short term, it almost certainly mitigated the spread of HIV in the long term. The spread of both HIV and TB in southern Africa is largely attributable to the system of oscillating migrant labour, introduced in the early 20th century to ensure a steady supply of cheap labour to the expanding gold mines while allowing them to avoid taking responsibility for the long term health of their workers.[16,17]

As shown in Figure 1A, the prevalence of HIV among adults in Malawi over the age of 15 years peaked at about 17% in 1998 and fell to about 12% in 2008, before ART became widely available, implying a 70% decline in the risk of infection[12] as a result of changes in behaviour and/or the structure of the sexual networks for reasons that are not well understood. The roll-out of treatment in the public sector began in 2004 and has reached an estimated 69% of all those infected with HIV.[x] The combination of the decline in transmission before ART became available and the roll out of ART after 2005 has led to an overall decline in the risk of transmission of about 90% since the start of the epidemic. As shown in Figure 1A continuing the current rate of treatment scale-up should end AIDS in Malawi by 2040 (2030–2050).[xi] The reduction in the prevalence of HIV has led to a decline in TB-notification rates[18] starting in 2000 as the prevalence of HIV began to fall and accelerating as ART was rolled out (Figure 1B).

x Quarterly Reports 2004 Q2 to 2016 Q4: http://tinyurl.com/BGW0051

xi We define *Ending AIDS* as having less than one new case and one death per 1,000 adults *p.a.*

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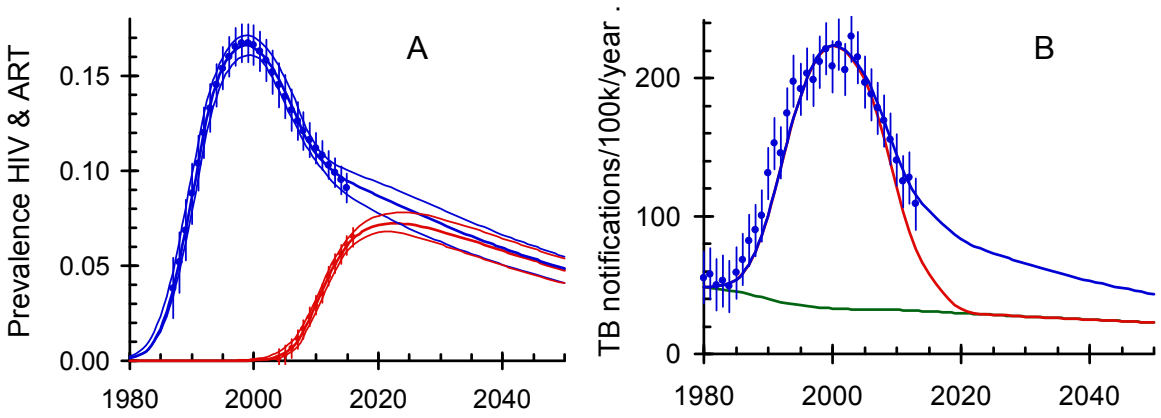

Figure 1. A. Adult (15 years or more) prevalence of HIV and ART in Malawi. Data: UNAIDS 2017 Spectrum/EPP.[19],[xii] Fits: SACEMA model.[12] Blue: HIV; Red: ART. B. TB notification rates (all forms) per 100k population. Green: HIV–; Red: Green plus HIV+ not on ART; Blue: Red plus HIV+ on ART.

Scaling-up ART and patient monitoring[20]

In a series of papers Harries and co-workers[3,21-30] discuss the development of the Malawi programme to monitor, treat and support those infected with HIV, drawing on their experience in managing TB[24,31] and the lessons are discussed in a recent paper.[3] The scale-up of ART in the public sector began in earnest in 2004 when 13k people were started on ART; by the end of December 2016,[1] 679 thousand people, or 69% of the estimated 979 thousand HIV positive adults, were on ART.[x] Several factors contributed to this successful expansion of treatment in a poor country with a substantial epidemic of HIV:[3]

1. From the beginning, the emphasis was on simplicity and standardization.
2. The Malawi Ministry of Health, through the director and staff officers of the HIV Department, took clear leadership and assumed responsibility for national scale up.
3. Financial support for ART scale-up was from one source only: The Global Fund for AIDS, TB and malaria.
4. As clinics were brought on board clinic staff received an intensive course of training.
5. Every quarter the HIV Department and its partners conducted supportive supervisory and monitoring visits to all ART sites in the country and the data, results and lessons are published on a regular basis in the 'The Quarterly Reports'.[vii]
6. Maintaining uninterrupted drug supplies was a top priority. Knowing cumulative outcomes every quarter gave the number of people who were alive and needing ART; knowing how many people were starting ART every quarter gave the number of new people needing ART. This was the basis for a drug-forecasting system that gave accurate estimates of the next quarter's drug needs and drug interruptions were rare.
7. Initially a dedicated clerk was employed at each clinic to enter patient information retrospectively from patient treatment cards to an ART paper-based register, and clerks and staff were trained to do quarterly and cumulative cohort analysis from the data. Two to three years after starting ART, Malawi introduced a computer-based touch-screen,

xii AIDS Info: http://tinyurl.com/BGW0052

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point of care system for busy sites with over two thousand patients; most sites still use paper-based systems. The Electronic Reporting and Monitoring system (ERM) was designed by the Baobab Health Trust, a local non-governmental organization: healthcare workers use simple, robust, touch-screen computers to enter patient information during clinical encounters at the point of care (Appendix 2).

8. All patients now have a health passport, a document that the majority (~90%) carry when they are seen at hospital or health centers and health passports can be bought at a token price. Computer terminals are used to register patients, from whom basic demographic information is collected, and if a new patient, a unique barcode identifier is generated. Duplicate registrations are largely avoided through a well-validated cross-checking algorithm using critical personal variables including name, age, sex, and location.[29]
9. Key challenges that needed to be overcome included: 1. Low computer literacy among target users; 2. The need for unique patient identifiers; 3. Maintaining clean and reliable electrical power; 4. Managing the transition from paper to electronic-based records; 5. accurately back-entering large numbers of paper-based treatment cards and registers.

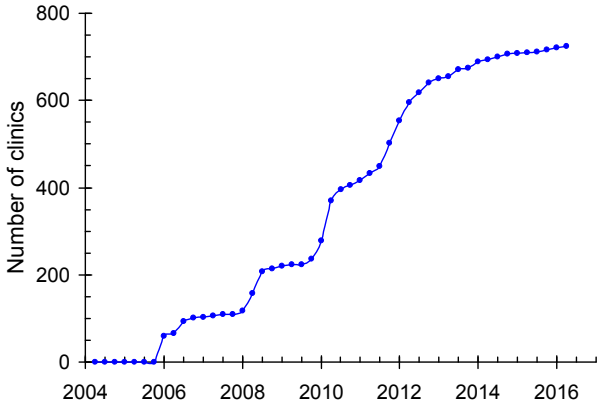

Figure 2. The number of static ART clinics that were operating in each quarter.

What can we learn from the routine data collection?

The Quarterly Reports[x] give the number of static ART clinics that were operating over time and this is shown in Figure 2. The number increased at about 78 new clinics per year or about one new clinic every six weeks from 2005 to 2014. There was a burst in activity 2006, 2008, 2010 and 2012 and the number of clinics has now reached saturation.

Figure 3 shows the trends over time in the cumulative number of people in Malawi who have ever started ART and the number who are alive and on ART. At the end of 2016 Q4,[1] 1,004,596 people had been started ART while 679 thousand people were alive and on ART. Figure 4 gives the number of people that started ART in each quarter. From 2004 to 2008 the number of people starting ART each year increased linearly reaching 80 thousand in 2009. The rate at which people started ART then remained fairly constant until 2011 when the criterion for starting ART was changed from a $CD4^+$ cell count of 100/μL to 350/μL and

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when Option B+ for HIV-infected pregnant and breast-feeding women started. In 2012 there was an initial backlog to be made up after which the rate at which people started ART settled down to about 104k new people per year. With an adult population of 9.7M adults in 2016 this suggests that the incidence of ART is of the order of about 1.1% per adult *p.a.*

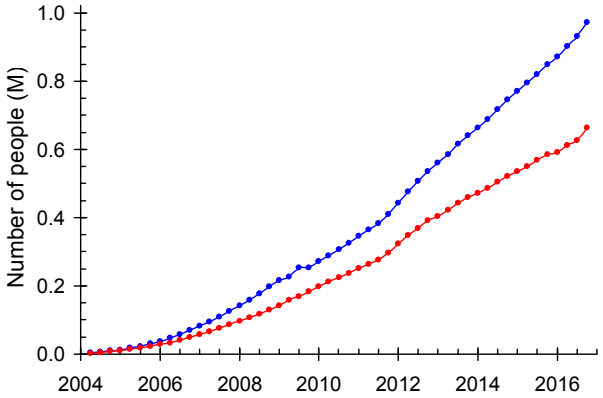

Figure 3. The cumulative number of people who ever started ART (blue) and who were alive and on ART (red) for each quarter.

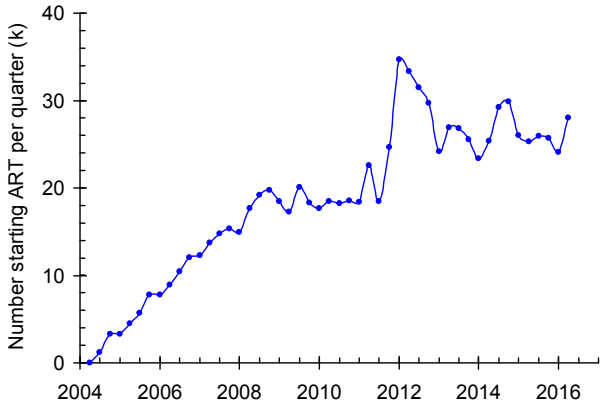

Figure 4. The number of people starting ART in each quarter

From the number of people reported to be alive and on ART and the number of people starting ART in each quarter one can calculate the number of people expected to be alive and on ART in the next quarter. The recorded number in successive quarters is always less than the expected number giving us the lost-to-follow up (LTF) rate which will include those that stopped taking ART and those that died while on ART. Figure 5 shows that the number that were lost to follow up rose sharply over the first two years to a peak rate 5.0% (±0.6%) *p.q.*[xiii] as the programme got underway but then fell to an asymptote of 0.83% (±0.6%) *p.q.* in 2012, since when it has remained constant. This is similar to the data shown in the Quarterly Report for 2016 Q4, Figure 5,[1] which gives a peak drop-out rate of about 5.0% *p. q.* falling to an asymptotic rate of about 1.6% *p. q.*[xiv] It is important to note that the Quarterly Report for

xiii Here and elsewhere *p.q.* indicates *per quarter*.
xiv The total drop-out rate in the quarterly reports appears to about double the rate calculated here.

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2016 Q4[1] suggests that the drop-out rate remained fairly constant at about 2% to 3% per quarter over this whole period while the mortality rate fell from about 3.5% per quarter to about 0.5% *p.q.* However, it is suggested that the drop-out rate in the Quarterly Reports includes those that transferred out suggesting that about 1% of patients transferred out each quarter.

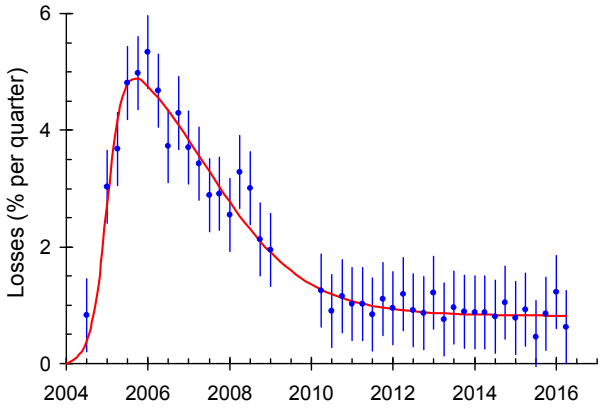

Figure 5. The proportion of those on ART that are lost-to-follow up in each quarter. Outlying points between 2009 and 2010 have been excluded. The final asymptote is 1.2% per quarter or 4.8% (±0.7%) *p.a.*

Since the life-expectancy of those not on ART is about 10 years, but falls from 16 years for those infected at age 4 years, to 4 years for those infected at age 70,[32] one would expect that in a steady state, and without ART, the mortality of people infected with HIV should be about 10% *p.a.* while the mortality of 30 year-old men and women in Malawi, not infected with HIV, is about 1% *p.a.*. The initial rate of about 20% *p.a.* reflects that fact that when the control programme began, people were starting treatment with advanced infection. The current loss rate is about 3.3% *p.a.*, and the estimated mortality rate is about 2% *p.a.* I would be interesting to explore the relationship between mortality and the $CD4^+$ cell count at which people started treatment.

In Figure 6 we compare the estimated rate at which people start ART with the values from the model[12] that was used to fit the data in Figure 1. In order to estimate the incidence from the reported data[x] we add to the increase in the number of people starting ART each year an assumed annual mortality of those on ART of 3.3% *p.a.* The model suggests that in 2018 the number of people starting ART each quarter will begin to fall and by 2024 will be close to zero. Over the next seven years the emphasis will shift from finding new people infected with HIV to making sure that those on ART are fully compliant and healthy.

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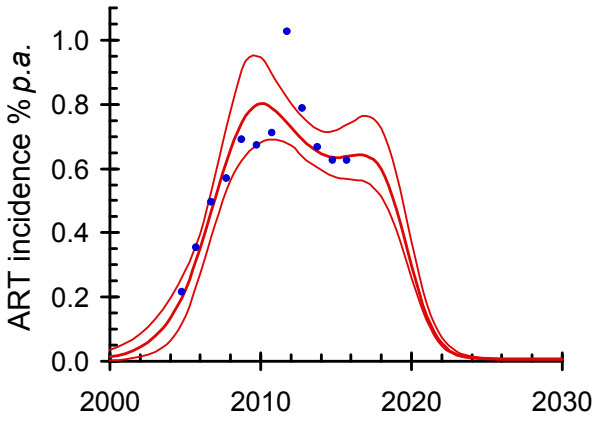

Figure 6. The incidence of ART calculated from the routine data (see text) and from the model fit presented in Figure 1.

Where are we now?

The most recent Quarterly Report (2016 Q4)[1] provides important lessons while raising new questions. There are currently 912 HIV testing and counselling (HTC) sites serving an average of 18k people site. In 2016 Q3[1,x] 872 thousand people were tested for HIV, an average of 956 people per site or about 12 people per site per day. Interestingly, 71% of those tested were repeat testers, presumably having tested negative on a previous occasion. It would be interesting to know what motivated people to be tested and the times since their last test. Altogether, 36 thousand people tested positive giving a case detection rate of about 4% so that 25 tests were done for each case found. With random testing[xv] and an adult prevalence of people infected with HIV but not on ART of about 6% one would expect to do 16 tests to find one case so that the case detection rate is close to expectation.

Of the 872k people tested for HIV in 2016 Q3[1]

- 253k (29%) were tested for the first time and 36.3k were positive giving a case-detection ratio (CDR) of 14.3%;
- 619k (71%) were repeat testers and 40.4k were positive giving a CDR of 6.5%.
- 147k (17%) were women tested at ANC clinics and 11.2k were positive for a CDR of 7.6%.
- 132k (15%) were women tested 'at maternity' and 9.7k were positive for a CDR of 7.3%.

Almost three quarters of those tested had been tested previously and one assumes that they were then HIV-negative. If data were available on the date of the previous test it should be possible to estimate the incidence of HIV but one would like to know why so many people were coming back for testing. The overall case-detection rate is 8.8% so that 11 people were tested to find one case. The number that started ART, 42.0k, is in excess of the number that had a positive confirmatory test apparently because of the large number of patients transitioning from pre-ART to ART under the Test-and-Treat policy many of whom will have received their confirmatory test when enrolling in pre-ART (2016 Q3 Report,[1] p. 11.)

xv Consolidated Guidelines on HIV Testing Services: http://tinyurl.com/BGW0054

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In 2016 Q3[1] 872k people were tested for HIV, 97.6k people (8.7%) tested positive and, of these, 22.3k people (23%), were in WHO Clinical Stage 1 showing the importance of starting all HIV-positive people on treatment. However, only 42.0 k people, or 43%, were started on ART. There is, of course, a cascade of steps after testing positive and starting ART including being referred for treatment, group and individual counselling, and being registered to start ART, all of which takes time, and people can drop out each step. This does warrant further investigation. If the ANC and maternity women were a sub-group of the others then there were 76.7k positive tests which cannot be the case since this is less than the number that started ART. Indeed, the number starting ART is only slightly higher than the number of repeat testers who were then positive suggesting that people only started ART after a confirmatory test.

Out of those tested and counseled 37% were men and 63% were women. However, 36% of women were pregnant and if these are excluded 48% were men and 52% were women. Furthermore, 21% of those tested accessed HTC with their partners.

In 2016 Q3[1] an estimated 68% of those infected with HIV were on treatment. Since this corresponds to the first two '90s' the target coverage should be 81% so that Malawi is close to the target rate.[xvi,33] At the same time 76% of adults were retained alive on ART at 12 months after initiation and the actual retention rates may be up to 10% higher due to misclassification of 'silent transfers' as defaulters in clinic-based survival/retention analysis. A total of 83k viral load tests were done and of these 74k, or 89%, were below 1000/μL (2016 Q3 Report, p. 33[1]) but it would be more informative if the proportion below 100/μL and 400/μL were also reported[34] or, better still, the full distribution of viral load measurements by age and sex was reported.

The physical-stock count carried out during supportive supervision in October 2016 confirmed that 734 (99.6%) of all 736 ART sites with patients on this regimen had sufficient stocks (2016 Q3 Report, p. 37[1]).

Of all 644k patients who were both retained on ART and screened for TB, 2,007 were confirmed to have TB giving a prevalence of 312/100k just less than the reported national prevalence of TB of 334 (156–578)/100k[35] whereas one would have expected it to be significantly higher.

The proportion of patients on second line treatment was 1.4%, 1% of those on ART had documented side effects, and compliance was, apparently, in excess of 95% although the 2016 Q3 Report (p. 11)[1] does not define 'compliance'.

Patient monitoring[xvii]

The patient monitoring currently works as follow:

xvi A recent briefing by the Presidents Emergency Plan for AIDS Relief (PEPFAR) suggests that in Malawi 73% of those infected know their status, 89% of these are on treatment and 91% are virally suppressed. Combining the first two 90s suggests that 65% of those infected with HIV know their status close to the value estimated here. PEPFAR 2016 Malawi Zambia Zimbabwe: http://tinyurl.com/BGW0055

xvii Information provided by Oluyemisi Akinwande: yemisiakinwande@gmail.com

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1. If a patient decides to seek ART care at a different clinic the patient is provided with his/her records: the yellow card, which is the facility based ART card, and their health passport which is kept by the patient. These provide the UID (unique identifier: a three-letter clinic code and a sequential patient number) and the patient's history of visits, care, ART, and so on.
2. If a patient resumes treatment at another clinic and reports a history of having been on ART but has neither the yellow card nor the health passport the patient is re-tested for HIV and given an ART registration number for the new clinic. It is recognised that a patient who transfers out from one clinic and transfers in at another is double counted in the national figures and this is taken into account in the national reporting. If the person does not report at a clinic for 2 consecutive months the patient is categorized as default.
3. The complete history of a patient on ART is available in the facility based ART card and the register. If a patient goes to a new clinic and loses their ART card their history is lost.
4. Viral load records are available on the yellow card which is the facility based record. But a new viral load register was recently introduced.

Strengthening the health management information

The intention is to expand the electronic monitoring system to cover some of the smaller clinics and not just the larger clinics which already have electronic recording systems in place. While Malawi recognizes the need for disaggregation of data, care must be taken not to overwhelm the facilities where the current capacity may be limited. Malawi already has one of the most effective health management information systems in the world and the data are used to great effect in providing regular, quarterly feedback to clinics throughout the country and it will be important not to overwhelm the system with too many reporting requirements. The system already in place allows clinic staff to monitor the key treatment outcomes: retention on care, viral load suppression and toxicity, and the data produced in a timely way each quarter allows for accurate and timely drug forecasting.

The World Health Organization has publishing new consolidated guidelines on person-centred HIV patient monitoring and case surveillance (Appendix 3).[xviii] These guidelines discuss the building blocks, governance and partner engagement and human resources needs. The intention is to update, standardize and simplify data systems, policies and procedures; establish buy-in and support from donors, further improve patient monitoring, use patient identifiers to harmonize and collate health records and link health service usage to individual patients. Implementing the key recommendations[xviii] (Appendix 2 and Appendix 3) will require substantial resources. Although Malawi already a very effective patient monitoring and support system, increased capacity at both facility and district levels to generate, manage, analyse, interpret and use the data for decision making will strengthen it further. The KUUNNIKA project, intended to streamline the priorities as outlined in the COP17 implementation plan[xix] Malawi, will need to continue with their current monitoring and

xviii Case Based Surveillance Toolkit: http://tinyurl.com/BGW0057
xix Not available at the time of writing.

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evaluation system while expanding, cautiously, the electronic monitoring and recording system while ensuring sustainability in the long run.

Need to strengthen analytical capacity in the Ministry of Health[xx]

In 2016 Tyler Smith[4,xxi] carried out an extensive review of monitoring and evaluation (M&E) in the Health Sector in Malawi focussing on HIV, TB and malaria but the current status and staff compliment for analyzing and interpreting the data in the Ministry of Health (MOH) is not clear from Smith's report. Without people in the MOH who can assemble, synthesize, analyze, model and interpret data it will not be possible to draw useful conclusions concerning progress in controlling the epidemics. Smith[4,xxi] (p. 23) recommends 'a mechanism by which data system users can access support when needed, which could not be found in the health sector.' This can only be a stop-gap measure; what is needed is local analytical capacity. Smith (p. 23)[4,xxi] also notes that 'up to US$1M had been allocated to training health surveillance assistants (HSAs) on use of the District Health Information System (DHIS2) this should easily cover the development of local analytical capacity. However, the current situation is that (p. 32) 'current Central Monitoring and Evaluation Division (CMED) human resources are not adequate and do not reflect the optimal skill mix for providing extensive analytical support'.

Smith suggests (p. 45)[4,xxi] that 'much of the data collection and reporting requirements are donor driven' but discussions with programme managers suggest that this has not, in fact, been the case until now. The primary aim of collecting data should be to:

1. Ensure that the needs of individual people infected with HIV are met (access to drugs, compliance, viral load, regular health checks).
2. Inform clinic staff about the effectiveness of their programme and to alert them to problems (stock-outs, resistance, mortality, patient retention).
3. Enable districts to evaluate their performance and to identify clinics that may have problems so that support can be provided.
4. Inform government of overall progress in managing the epidemic, identify districts that may have problems and need support, advising on how to improve interventions, and for forward planning as the epidemic comes under control.
5. Inform donors about how their funding is being used, how successful it has been and the impact of their funding and likely future funding needs.

While donors are rightly concerned to evaluate the impact of their funding and to justify their support and investment this should not be the primary reason for collecting data which is to inform the country and the programme about on-going progress and provide data on which to base accurate forecasting for drugs, consumables and human-resource planning.

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xx The role of the analytical unit within the Department of Health is critical. Rose Nyirenda, pers. comm..

xxi Smith 2016 Achieving a Unified ME System: http://tinyurl.com/BGW0045

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Smith[4,xxi] refers to the 2015 *Malawi National Health Information Policy*[xxii] which notes that 'evidence-based management decisions' are needed to 'achieve … efficiency in the provision of … essential health.' In the view of the authors of this report, emphasis should be on science-based, not evidence-based, management; the former includes the latter but makes it clear that not all evidence is equal. In this context donors should advise on and support data collection, synthesis, analysis and interpretation but data collection and reporting requirements should not be donor driven. While the policy document referred to by Smith[xxii] is comprehensive it was largely focussed on process not on outcomes. This is of particular concern as Smith (p. 57)[4,xxi] notes that: '…no mechanism exists for systematic tracking of training and capacity building efforts in Malawi [although] the USG provided over 11 million USD for in-service training between 2012 … and 2014'. In the 'current grant cycle' (Smith, p. 64)[4,xxi] TGF invested $2.7M in M&E systems in Malawi but only US$5.4k, or 0.2%, in training.

A strong analytical unit should be able to direct and harmonize the myriad data collection systems that are currently active in Malawi leading to much better reporting, data synthesis and analysis and, of course, better feedback to patients, clinics, CBOs, NGOs, GOM, donors and other organizations. There is an urgent need to improve and develop the capacity at both facility and district level to generate, manage, analyze, interpret, and use the data for decision making. As a matter of urgency, it will be necessary to work with KUUNIKA project to streamline the priorities as outlined in the COP 17 and KUUNNIKA project implementation plan.[xxiii]

The End Game

In 2011 a Triangulation Report[xxiv] demonstrated the significant impact the roll-out of ART had had in Malawi. Between 2002 and 2010 adult mortality fell by about 30%, mortality of those on ART fell from 13% *p.a.* to 3% *p.a.* ART coverage had reached 80% of eligible adults but only 26% of eligible children. During this time TB notifications fell[12] while TB cure rates increased. ART coverage for pregnant mothers had risen from 3% to 49% in 2010 while infant mortality fell from 104 to 66 per 1,000. Under-5 mortality fell from 189 112 per 1,000. Since then the ART programme has expanded greatly and, if this continues, there is every reason to believe that Malawi will *End AIDS* by 2030.

As Malawi approaches the *End Game*, the way in which they find, treat and manage patients will change. First, there will be less emphasis on finding large numbers of new patients while the challenge of keeping one million people on ART for the rest of their lives, or until a cure is found, will remain. The new cases that still arise are likely to be in relatively small, isolated, groups of people at high risk and they will have to be found, treated, helped and supported. Furthermore, those that remain at high risk, even as the overall prevalence of those not on ART falls, will need access to the best possible methods of prevention. In a

xxii Malawi National Health Information System Policy: http://tinyurl.com/BGW0058
xxiii Rose Nyirendra, *pers. comm.* nyirendarose@gmail.com
xxiv Triangulation Report 2011: http://tinyurl.com/BGW0060

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recent study[36] the prevalence of HIV among MSM varied from 4·1% (2.2–7.6) in Mzuzu to 24·5% (19.5–30.3) in Mulanje with an overall average of 18·2% (15·5–21·2) giving a prevalence ratio of 2·5 (±0.4) as compared to the overall adult male population. In those aged 21–30 years the prevalence was 62·2% (58·9–65·4). Among HIV infected MSM only 0.9% (0.4%–2.5%) reported having been diagnosed with HIV infection and 0.17% (0.07%–0.27%) had initiated antiretroviral treatment. As the prevalence declines contact tracing (CT) of spouses and other contacts of index cases will become increasingly effective as a way of finding people in need of treatment.[37]

Over a three year period in Mzuzu Central Hospital, Malawi, all of the patients who started on ART and 'transferred out' were identified from the ART register and master cards.[38] Clinic staff then attempted to trace these patients to determine whether they had transferred in to a new ART facility and their outcome status. There were 805 patients (19% of the total cohort) who transferred out, of whom 737 (92%) were traced as having transferred in to a new ART facility, with a median time of 1.3 months between transferring-out and transferring-in.

In 2014 Malawi was able to provide ART at a cost of US$137 *p.a.* of which $72 was for drugs, $23 for personnel, $8 for laboratory tests and $34 for other costs including drugs for opportunistic infections, nutritional support, training, equipment and supplies, vehicle and building maintenance and miscellaneous administrative costs.[39] Viral load testing rates were very low in 2014 with only one test per ten patients per year;[39] ideally those on ART should be tested annually and if this were the case the long term cost of keeping about one million people on ART will be of the order of US$137 M *p.a.* It would be interesting to know what the current cost of the Malawi patient monitoring system is but even 1% to 2% of the current total cost of the HIV programme should be sufficient to maintain a first-class patient monitoring and support system and a strong analytical team.

Conclusions

Malawi has made excellent progress in starting and then maintaining people on ART, keeping track of patients, providing feedback to clinics and collecting good monitoring data. The key to their success lies in keeping it simple and building it up slowly with strong leadership and coordination from the MOH. Because Malawi is a poor country with a substantial epidemic of HIV they have had to rely on external funding for much of their work but the leadership shown by the Ministry of Health[20] has meant that donor support has been well spent and directed to where it is most needed. Treatment coverage is high, adherence to ART is good, drug-stock outs are rare,[30] incidence is falling rapidly[12] and there is every reason to believe that Malawi is in a position to end AIDS by 2040.[12] A critical component of the Malawi programme is the quarterly feedback to clinics in which each clinic's data and progress are discussed, problems can be identified and support can be given immediately.

HIV-programmes must first ensure the best outcomes for individual patients. Malawi has a good system of unique patient identifiers which is the *sine qua non* of good follow-up and support and provides the basis for analyzing epidemic trends and for making future

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projections. While only about 8% of ART sites have an electronic recording and reporting system, these include most of the bigger sites with the largest number of patients and in the smaller sites paper based recording and reporting works well.

There is still room for improvements in Malawi to further develop their analytical capacity so as to facilitate better access to data, the analysis and interpretation of data, and the use of models to make estimates of current trends in incidence and mortality and to make future projections which are essential for forward planning. The problem that Malawi faces, like most countries in the region including South Africa, is the lack of people with the necessary analytical, mathematical and numerical skills to make best use of the data that they already have and to carry the analysis forward. More and better analyses could be done with the data that are available and in those sites with good electronic recording and reporting one could investigate trends in particular places and clinics by age, sex and treatment outcomes as well as the impact of control in more detail. The risk is that without sufficient local capacity overly ambitious plans can easily compromise the quality of the data that are collected. If unrealistic demands are made on the level, extent and detail of the data that should be collected the end result may be that few data are collected, there are multiple gaps, and the data that are collected are of lower quality. In the short term, some of this work could be done with external support but in the long term it will only be sustainable and effective if Malawi is able to train and develop a strong analytical unit within the Ministry of Health. Such a unit could assist not only the HIV Department in their very extensive quarterly data collecting and reporting exercise but also other departments that collect and need to analyse and interpret large quantities of data.

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Appendix 1. Achieving a Unified System for Monitoring and Evaluation of the Health Sector in Malawi

In 2016 Tyler Smith[4,xxv] carried out an extensive review of monitoring and evaluation (M&E) in the Health Sector in Malawi focussing on HIV, TB and malaria.[4] He noted several problems that he felt should be addressed.

1. Data collection and the reporting burden is excessive.
2. Data transfer between levels is a problematical.
3. There is too much duplication across data systems.
4. The data quality is not satisfactory.

xxv Smith 2016 Achieving a Unified ME System: http://tinyurl.com/BGW0045

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5. There are inadequate data visualization tools.
6. Resources not linked to results.
7. Feedback to Community based Organizations (CBOs) should be improved.

To which one might add:

8. In-country analytical capacity needs to be strengthened.
9. The data are not being used to get a sense of the overall impact on the epidemic and to do forward planning.
10. What is needed are not 'visualization tools' but analytical capacity.

One year after Smith's report and landscape analysis it would be advisable to assess the extent to which the recommendations have been carried out. However, two broad areas of importance are coordination among donors and developing local analytical capacity.

Need for coordination among donors

It is not immediately clear from Smith's analysis how the multitudinous donors and technical partners co-ordinate their support. If the World Health Organization were to convene quarterly or biannual meetings of the various international donors at which to report on their activities, outcomes, funding and successes this could greatly improve coordination and lead to more efficient use of resources.

Developing local analytical capacity

The Malawi Quarterly Reports that have been published regularly since the beginning of 2007 contain a wealth of information and provide the basis for providing support to individual clinics. However, much more analysis could be done using these historical data and, as the roll out electronic monitoring and recording continues it will be possible to break down the analysis by age, sex, clinic and other variables that are in the data base. While these analyses could be contracted out this provides an ideal opportunity to build analytical capacity in the Ministry of Health which would be a sound long-term investment for the country and could be expanded to include other infectious as well as non-communicable diseases.

Appendix 2. Data storage (2014)

Baobab Health Trust (BHT), a local NGO was contracted by CDC to work develop the EMR at health facilities in Malawi. In 2014 77 out of 723 facilities had the EMR system while about 10 private facilities used a different EMR. With funding from the BMGF under the Kunnuka Project, EMR will be expanded to over 100 facilities. In 2014 BHT had a MOU with MOH and was being considered for TB and malaria monitoring by the GF. Data belong to the facility and the MOH through CMED. The DHA has a separate customized Access database on ART, PMTCT, and HCT. The viral load data base is maintained by CHAI.

A recently published document [xxvi] describes the working of one of the busiest HIV/AIDS clinics which has an annual facility volume of approximately 13,957 patients

xxvi Success stories: http://tinyurl.com/BGW0061

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enrolled and receiving antiretroviral treatment (ART). Clients seamlessly transition from point to point as clerks and clinicians use bar-code scanners and touch-screen computers.

Health care workers query the EMRS to retrieve information from previous appointments and record new information. At the end of the visit, a label with information from the visit is affixed to the patient's health passport, which acts as a link for sharing information within or between health care facilities.

In 2006 the MOH Department of HIV/AIDS, CDC-Malawi, and Baobab Health Trust raised the possibility of electronic record keeping. Following a successful hospital-based pilot, the Malawi national EMRS was launched with funding from PEPFAR and other donors. Implementation of EMRS is done in collaboration with the MOH and the National Registration Bureau (NRB). Informatics, quality improvement, epidemiology, and surveillance, technical assistance are provided by the University of Pittsburgh, Maikhanda Trust, and CDC's Division of Reproductive Health and National Center for Health Statistics. The EMRS has grown from 19 facilities in 2012 to 50 HIV/AIDS health care providers in all regions of the country in 2014 providing care for 180,000 people, 41% of all those receiving care. By September 2014, the plan is to increase the number of EMRS sites to 54 health facilities out of a total of 85 HIV high burden sites. To date, more than 1,500 healthcare workers have been trained in using the national EMRS at the point of care.

Strategic priorities focus on capacity development, strengthening linkages with Ministerial programs, and optimizing EMRS use for public health research, learning and practice.

Appendix 3. Guidelines on person-centred HIV patient monitoring and case-based surveillance: 2017

The 2017 WHO *Guidelines on person-centred HIV patient monitoring and case-based surveillance* are intended to help countries implement WHO strategic information indicators for HIV and to provide guidance on the use of antiretroviral drugs for HIV treatment into routine HIV patient monitoring and health information systems. The guidelines support: definition of standard events along the cascade of services; linkage of key data sources to support the cascade of services; and development of routine, ongoing monitoring systems for improved patient care, programme management and reporting on most programme, national and global indicators.

Table 1. Recommendations for person centred HIV patient monitoring and surveillence[xxvii]

1. **Minimum dataset for patient care** Collect a minimum, standardized set of data necessary for the care and management of persons confirmed to be HIV-positive, a subset of which can be used to report on district, national and global indicators for programme monitoring and management. *WHO provides guidance on a minimum dataset for patient monitoring that reflects updates of the ARV guidelines.*

xxvii Person-centred HIV patient monitoring and case surveillance: http://tinyurl.com/BGW0063

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2. **Transitioning to 'treat all'** Consistent with 'treat all' and depending on national guidelines, once 90% ART coverage has been attained, countries should transition from using the pre-ART register and collecting HIV care indicators (e.g. indicators from the consolidated strategic information guidelines LINK.2 HIV care coverage, LINK.3 Enrolment in care) to using the ART register and dropping HIV care indicators from reporting requirements. *WHO provides guidance for this transition.*

3. **Simplification of tools.** For paper-based systems, patient monitoring tools (cards, registers and reports) should be simplified and standardized across facilities. *WHO provides generic tools that countries can adapt.*

4. **Integration and linkages.** Health workers should create a facility-based HIV patient card for every person who is confirmed HIV- positive and subsequently enters into care, regardless of the point of entry, and ART registers should be kept and used at all sites where ART is provided. The HIV card should form part of the facility-held patient folder or passport, and should be integrated with primary health care. *WHO provides a generic HIV patient card and ART register that countries can adapt.*

5. **Data quality review and use for quality of care.** Countries should carry out periodic review of the patient monitoring system to collect key additional national and facility-based indicators (for paper-based systems); monitor and assess the quality of data; monitor and improve the quality of care; and collect facility-level early warning indicators (EWI) for HIV drug resistance (HIVDR). *WHO provides guidance on carrying out an annual patient monitoring review and improving the quality of care.*

6. **Standardization of sentinel events and indicators.** Countries should collect core information on a standardized set of sentinel events and indicators, including at a minimum, the six key cascade events described in these guidelines. *WHO provides guidance on key indicators for primarily paper-based monitoring systems and additional indicators for electronic systems or periodic review, especially of patient monitoring tools.*

7. **De-duplication of records to support facilities and improve data quality.** HIV case surveillance should provide de-duplicated counts of diagnosed persons and people on treatment for reporting, to be shared with facilities. *WHO provides guidance on these approaches.*

8. **Country situation analysis.** Improvements to HIV surveillance, patient monitoring and unique identifiers should be based on a country situation analysis that identifies and costs incremental improvements. *WHO provides a tool for country situation analysis.*

9. **HIV diagnosis and building on patient monitoring.** HIV case surveillance should start with the diagnosis of HIV and build on existing patient monitoring systems. *WHO provides guidance on HIV case definitions.*

10. **Key population (KP) data.** Routinely collected data can be used to describe access by key populations to services; however, confidentiality and security issues are paramount when collecting data related to KP, whether in patient monitoring or HIV case surveillance systems. In most settings, patient monitoring records should not include the KP category and any information collected should be used to support patient management and referral to care. The probable route of transmission can be assessed at the point of diagnosis and used to disaggregate data in HIV case surveillance systems. *WHO provides guidance on how to address issues around KP data collection and reporting.*

11. **Promote and use unique identifiers** that replaces names in HIV patient records shared within the national HIV programme. This anonymous code should be linked to their health records. *WHO provides definitions and examples of unique identifiers.*

12. **Transition progressively from paper-based to electronic patient information systems.** Countries should use a tiered approach to when and how patient and case-monitoring data from paper tools will be entered electronically based on resource availability by site or setting, starting with high-volume sites, e.g. with more than 2000 patients. *WHO provides an example of a tiered approach.*

13. **Strengthen and establish different data security levels.** Assess and establish different security levels for data elements, and invest in robust databases and policies to protect security and confidentiality based on risks and benefits in individual settings. *WHO provides the major headings to be included and provides reference to additional specialized guidance.*

14. **Invest in data systems and ensure interoperability.** Countries should invest in robust and secure data systems. As this is being done, strengthen the interoperability of electronic databases and opt for open-source standards for data systems. *WHO recommends that 5–10% of the programme budget be used to strengthen monitoring and evaluation.*

15. **Use individual data to improve programmes and long-term chronic health care.** WHO recommends that data be linked to programme improvements and that evidence of these improvements be collected.

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1. Strengthen retention and transfer by supporting the routine sharing of information between clinics.
2. Ensure linkage by supporting the routine sharing of information between testing, treatment, laboratory, pharmacy and other health services.
3. Strengthen integration with long-term chronic health care by using unique identifiers to share information and link HIV and wider health services.
4. Invest in data analyst capacity, including central and district data analysts and routine dashboards to feed back data in real time for programme improvement.

Appendix 4. Partners, Donors, National Bodies and Acronyms

Coordinating Bodies

MANASO: Malawi Network of AIDS Service Organizations
UNAIDS: United Nations Joint Programme on HIV/AIDS
WHO: Coordinating Bodies World Health Organization

Donors

BMGF: Bill and Melinda Gates Foundation (funds the Kuunika Project)
DFID: U.K. Department for International Development
GFATM: Global Fund to Fight AIDS, TB, and Malaria
GTZ: German Society for International Cooperation
NORAD: Norwegian Agency for Development Cooperation
PEPFAR: President's Emergency Plan for AIDS Relief
TGF: The Global Fund to Fight AIDS, TB and Malaria
USG: United States Government
USAID: United States Agency for International Development
WV: World Vision

Technical Partners

BHT: Baobab Health Trust
CDC: U.S. Centers for Disease Control and Prevention
CHAI: Clinton Health Access Initiative
Dimagi
DREAM Programme
NGO: Non-government organizations
Village Reach

National bodies

ARTC: ART Coordinator
CMED: Central Monitoring and Evaluation Division
DHA: Department of HIV/AIDS
DNHA: Division of Nutrition, HIV and AIDS
EP&D: Department of Economic Planning and Development
GOM: Government of Malawi,
HMIS: Health Management Information System
HTTS: Health Technical Support Services

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ICTD: Information, Communication and Technology Department
MC: Malaria Coordinator
MHSP-TA: Malawi Health Sector Programme, Technical Assistance
MOF: Ministry of Finance
MOH: Ministry of Health
NAC: National AIDS Council
NMPC: National Malaria Control Programme
NRB: National Registration Bureau
NAC: National AIDS Commission
NSO: National Statistics Office
NTP: National Tuberculosis Control Programme
OPC: Office of the President and Cabinet
TBC: TB Coordinator

District

CBO: Community-based Organization
DAC: District AIDS Council
DC: District Council
DHMT: District Health Management Team
DHO: District Health Officer
HAD: Health Diagnostic Assistant
HCAC: Health Centre Advisory Committee
HRO: Human Resource Officer
HSA: Health Surveillance Assistants
VDC: Village Development Committee
VW: Vital Wave

Plans and reports

DDP: District Development Plan
DIP: District Implementation Plans

Systems

DHIS: District Health Information System
UID: Unique patient identifier

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