

**Title**

An evaluation of the implementation of the 3-Tiered ART Monitoring System in South Africa

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## Abstract

**Background and Purpose:** South Africa has the largest public antiretroviral (ART) service in the world but until recently it was unable to report from primary sources the numbers of patients on ART and was unable to monitor the program outcomes using routine data. In December 2010 the South Africa National Department of Health adopted a standardized ART monitoring strategy referred to as the 3-Tiered Strategy. The System provides facilities with different options for cohort monitoring based on the resources and infrastructure available. The technical design of the three tiers is pragmatic and appropriate to the facility-level context. The process to implement the System was articulated through an implementation plan. The health management information system was aligned to collate data produced by the System and standard operating procedures were produced to guide system use.

**Methods:** The study comprised a mixed-methods approach to evaluate the implementation of the system in accordance with the implementation plan. Program data were analysed, program documents were reviewed and key informants were interviewed in order to capture the complex and multidimensional nature of the country-wide implementation activities.

**Results:** By October 2014 full implementation had been achieved in 2,139 ART facilities, of a total 3,772 facilities that report ART data. And, of facilities that had reached full implementation, 87% of facilities had submitted data. At the time of analysis, the outcome data available were representative of 55% of active patients on ART. Qualitative results elicited facility-level challenges as well as structural barriers to effective implementation. The study demonstrated that South Africa's introduction of the 3-Tiered Strategy for ART monitoring was championed by senior management in the NDOH who fostered a collaborative environment and structured implementation approach which resulted in wide-scale uptake of the recommended systems, predominantly the electronic register.

**Conclusions:** The implementation of a basics first health information system has yielded a complete set of enrolment and retention on ART data; however there are systemic and structural barriers to the sustainable production of these and additional cohort outcome data. The study has brought attention to the organizational restructuring and the holistic health system interventions required to implement such a system.

**Key words:** TIER.Net, Antiretroviral treatment, routine monitoring, implementation science, health systems strengthening.

## Introduction

The South African National Department of Health (NDOH) antiretroviral (ART) program commenced public ART services in 2004. The program initially grew slowly where, by 2009, the country offered ART in 500 facilities and treated approximately 678,550 patients.<sup>1</sup> Following the election of President Jacob Zuma and his appointment of Health Minister Dr Motsoaledi a renewed focus on the HIV response commenced and the ART program grew rapidly, expanding service delivery to over 3,700 facilities by 2014.<sup>2,3</sup>

Comprehensive, timely, and precise health information is essential for formulating health policy and for planning to meet the demand for appropriate health services and interventions.<sup>4</sup> However, whilst the benefits of ART at an individual level are incontrovertible in the early years of the national ART program South Africa depended on situational analyses, cohort studies at sentinel sites, and drug consumption data to estimate the numbers of patients initiating and retained on treatment.<sup>5-8</sup> A review of the NDOH ART Monitoring and Evaluation (M&E) systems in 2006 characterised the environment as one with no standardized system of data aggregation; no recording of individual patient visits over time; and no attempts at cohort analyses.<sup>9,10</sup> Additional reports have described challenges with the quality of routine data, management, and feedback indicating the ART program was a priority program with too many data elements, a data flow that bypassed the health information management structures, and inadequate data feedback.<sup>11-13</sup> This meant the country was unable to effectively monitor the services or the patient population enrolled onto ART. This affected the ability of the different levels of the health services to effectively manage the ART patient population, especially at the facility-level.

A country-wide evaluation of ART monitoring systems in October 2010 identified that more than 40 systems were in use.<sup>14</sup> By this time South Africa had the largest antiretroviral program in the world but was not able to document from primary sources how many patients were on treatment.<sup>3</sup> Following the review, in December 2010, South Africa's NDOH adopted a standardized ART monitoring strategy referred to as the 3-Tiered ART Monitoring and Evaluation (M&E) Strategy (herein referred to as the 3-Tiered Strategy or the Strategy). The 3-Tiered Strategy provided a facility with different options for cohort monitoring based on the resources available at a facility. The technical design of the three tiers is pragmatic and appropriate to the facility-level context. The introduction of the Strategy included the establishment of a new and reduced dataset reported monthly and quarterly. Each tier within the Strategy produces the same core set of indicators.

The Strategy includes standardized HIV/ART clinical records which are the foundation of the program and document clinical management. The clinical record also serves as data source for the M&E system.<sup>15,16</sup> Thereafter the Strategy includes a paper-based register (Tier 1), a non-networked electronic register (Tier 2), or a networked system (Tier 3) for patient monitoring. Osler et al describe a three-tiered framework in further detail and provide guidance on the practical considerations in determining appropriate systems.<sup>17</sup>

The implementation of a health information system in a context of an already mature health program where health information systems were pre-existing introduced a number of complexities. In 2010, following Minister Motsoaledi's announcement, the South African ART program expanded service delivery to all primary health care sites; services were initially offered at the better capacitated hospitals and large clinics. In turn patient enrolments increased.<sup>1</sup> The implementation meant facilities transitioned their data systems from one of the over 40 different electronic systems, and in many cases paper-based systems, to one of the three tiers comprising the 3-Tiered Strategy. Where paper-based systems were used, in order to establish the cohorts, this process required back capture of the existing patient population including all initiated and no longer in care patients. This necessitated training of staff to understand the technical design of the system, to train a core set of trainers to cascade the training to the end users, and to manage the in-facility change management. Additionally, training was required to capacitate clinicians on effective use of the HIV/ART clinical record and assist their understanding of the intrinsic role of complete documentation in effective patient and data management. This was a complex undertaking which consisted of behavioural, technological, and organizational interventions.

The study adopted three aims; the first to describe the process and system interventions taken to implement the standardized monitoring system at the facility level. These include the technical and human interventions to implement the in-facility M&E system. Analysis included qualitative data produced through document review and validated through key informant interviews. The second aim sought to evaluate whether implementation was achieved and aimed to identify barriers to it. The third aim sought to identify the enablers and barriers to the national scale-up. This study undertook a formative approach throughout to evaluate the on-going activities and challenges were shared with the NDOH allowing course correction where necessary. The findings are anticipated to be of value to organisations or countries considering the implementation of a standardized monitoring system at scale. Findings presented seek to support a health system strengthening approach to implementation.

## **Methods**

### **Setting**

South Africa is comprised of 9 provinces which are further divided into 52 districts with an approximate 4,000 primary care public health facilities nationally. In March 2011, South Africa had approximately 1,801 ART service points (DHIS December 2011). By October 2014, ART service delivery had expanded to 3,772 of 4,000 public health facilities (DHIS October 2014). South Africa adopted the 3-Tiered Strategy in December 2010 and commenced national standardization of the ART M&E systems in March 2011. Guidance for the implementation strategy was provided by the '*The T1 and T2 Implementation Plan*'.<sup>16</sup> This document described the facility- and district-level change management activities required to implement the Strategy.

## **Study Design**

The study consisted of a process evaluation to describe and evaluate the implementation of the standardized ART monitoring system used in South Africa. The study was based on a mixed-methods approach. Interviews and document review were employed to generate qualitative data. Quantitative data were retrieved from NDOH routine data comprising: cross-sectional implementation monitoring data, as well as cross-sectional monthly and quarterly cohort ART program data. The monthly and quarterly ART data are produced using the routine monitoring systems.

The study received ethical approval from the University of Cape Town and the NDOH approved the use of routine national data. Informed patient consent was not required as the study used aggregate data from national reports.

The aggregate data were complete to October 2014 and interviews were conducted in March and April 2015.

The methods are further described below in three subsections based on the different data sources and study components.

## **Implementation monitoring**

### ***Population and Sampling***

The study population for the descriptive quantitative analysis included all fixed public health facilities which offered routine ART services and had reported enrolment and retention on ART data to the end of October 2014. Facilities that offered antenatal services and offered Option B PMTCT only were excluded from the analysis as this was a new intervention added during the study period.

### ***Data collection and collation***

Implementation monitoring data were collated into a standardized database comprising all facilities reporting ART data, disaggregated by province, district, sub-district, and facility. Cross-sectional implementation data were universally reported from all fixed service points offering ART. This was completed to October 2014, the study censure.

Data reporting the implementation progress of the 3-Tiered Strategy were submitted to the NDOH quarterly. For the purposes of this study, data were used to describe the uptake and progress of the implementation. Data were produced by districts and submitted by provinces using a standardized MS Excel data collation tool referred to as the '*phases of implementation monitoring*' tool. The tool included mutually exclusive categorical variables to report implementation progress by facility and a free text section to record facility-specific comments. A list of definitions for each of the categories was contained within the tool. All facilities that reported ART data provided the basis for the list of facilities in the monitoring tool.

Qualitative data were retrieved from the free text comment section of the *phases of implementation monitoring* sheet. This provided contextual information relating to the facilities and included challenges pertaining to implementation. Additional qualitative data were retrieved through observations from document and report review as well as field notes. These documents included training materials and training reports, minutes from meetings, official correspondence and national reports. The review of all data followed a formative process whereby identified challenges were immediately communicated to key stakeholders at the NDOH to facilitate course correction.

### ***Analysis***

The explicit grading system utilized the concepts which framed the training sessions. These concepts were referred to as the 12 steps of implementation; these are further described by Myburgh et al.<sup>18</sup> The 7 phases of implementation (phase 0 to 6) were a grouping of these 12 steps of implementation into 7 phases.<sup>19</sup> These phases deconstructed the complex change management processes of implementation into easy to comprehend steps of implementation. This terminology was adopted by the NDOH in December 2012 to refer to the TIER.Net implementation.<sup>18,19</sup>

Implementation outcomes were collated by corresponding phase, province and district. They were presented as proportions of all facilities offering ART in October 2014. Full implementation is defined as *phase 6* and these were all facilities reported to have completed implementation and expected to submit data to the DHIS. Table 1 presents the implementation data used to in this study. Analysis included discrete metrics on phases achieved to demonstrate the progress of roll-out. To describe achievements of implementation data were combined with programmatic data to describe the proportion of facilities with implementation by phase and by facility volume (not shown). These data provided trends and identified variations in implementation between provinces, districts, and sub-districts.

Qualitative data comprising document review and from the implementation monitoring data were categorized into themes to contextualize the quantitative results. These data were used to describe the challenges and best practices with implementation and to document the experiences and perceptions of the teams at the district and provincial level. These data informed the process and system interventions as well as identifying the enablers and barriers to scale up; these framed the key informant interviews.

### **Key Informant Interviews**

#### ***Population and Sampling***

Five key informants interviewed were purposively sampled from the initial list of core trainers. The list was established in September 2011 at the time the first 3-Tiered Strategy trainings were conducted. The core training was referred to as the Master Training and in many documents individuals were referred to as Master Trainers.

This study shifts the term to 'Key Implementers' (KI). Five individuals still supporting the ART M&E activities at the time of the study were requested to participate in the study. KIs comprised two staff employed by department of health and three staff employed by development partner organisations. Four staff worked at the district level whilst one worked at the provincial level.

### ***Data collection and collation***

Key informants interviewed were invited to participate and were able to withdraw at any time and were able to refuse responses to any question. Participants were supplied with an information document containing emerging themes produced through document review. These were shared with them prior to the interview. All participants were requested to sign a certificate of consent prior to participation. Using prompted open-ended questions KIs were encouraged to respond honestly with no repercussions for their involvement and their confidentiality was assured. Telephone interviews took place in March and April 2015.

### ***Analysis***

The pre-circulated themes were reviewed in conjunction with the open-ended interview responses to further describe the additional contextual factors leading to the differences with implementation in districts and facilities. Interview notes were reviewed to identify newly emerging themes and corroborate pre-determined themes relating to the implementation activities.

## **Program Outcome Data**

### ***Population and Sampling***

The Strategy produces two datasets; the first are data reported monthly which comprise cross-sectional enrolment and total remaining on ART, disaggregated by adult and child less than 15 years of age. Monthly data were universally reported by facilities offering ART. The second dataset are the ART cohort data. Reported quarterly, it is comprised of 27 data elements. Data are aggregated by ART start date and include baseline characteristics, regimen, viral loads done and suppression as well as outcome at set durations on ART. Further detail of the data and use is described elsewhere.<sup>17,20</sup> The quarterly cohort data were limited to facilities that were reported to have achieved phase 6 and had complete data for the study period. Data were further limited to the adult population. This totalled 1,861 facilities as not all facilities with full implementation submitted data.

Both data form part of the national indicator data set (NIDS) and are reported to the District Health Information System (DHIS).

### ***Analysis***

The analysis combined both monthly and quarterly data sets, and included the implementation data previously described. Named facility list comparisons were done to compare facilities that were reported to have reached phase 6 and compared against the list of facilities that submitted cohort data. This was further referenced against

the list of all facilities that reported ART data to serve as the denominator for total expected implementation. Counts and proportions were produced to illustrate the completeness of quarterly reporting and also served as a benchmark for the coverage of implementation.

### **Role of the lead author**

The lead author was a key participant in the implementation processes. This contributed to the knowledge base of the implementation activities. All processes and results were cross-referenced against external sources and corroborated through the KI interviews.

## **Results**

### **Major components of the intervention**

The study sought to tease out the major interventions undertaken to implement the newly adopted 3-Tiered Strategy. This included the technical intervention to both implement the in-facility M&E system as well as the software interoperability with the HMIS. The study also explored the broader activities that enabled the intervention to occur at scale.

Synthesising all data sources described below are the dominant design and implementation characteristics of the intervention that emerged as critical enablers to the national scale-up. In each instance the evolution and detail of activities are described alongside reflections on why these were enablers for the implementation, as well as specific challenges.

#### ***Stewardship, leadership and clear policy direction***

Following the December 2010 decision, the 3-Tiered Strategy was launched by the NDOH HIV cluster through a consultation with national and provincial program and information managers on 31 March 2011. In addition to government it included partners from non-governmental organizations. The meeting provided an overview of the Strategy, the technical design of the standardized system, and the expectations for implementation. This provided clear expectations which channelled provincial, district, and partner efforts to achieve the national objectives. The Strategy was guided through an implementation guide directed at provinces, districts and facilities. The guide was used to evaluate the implementation achievements.

Figure 1 illustrates a timeline of milestone events as identified through the evaluation. This figure includes the major processes contributing to the implementation between December 2010 and October 2014. Supplementary table 1 provides additional detail to the identified activities deemed most strategic through the process evaluation.

#### ***Technical design and the tiered approach***

The adoption of the 3-Tiered Strategy introduced two standard data sets with accompanying definitions. The indicator data set was reduced to prioritize the minimum data required to monitor the ART service and was aligned to recommendations by the WHO.<sup>21</sup>

The 3-Tiered Strategy comprised three tiers which represented different options for monitoring based on the resources available in each local context. The three tiers consist of a paper-based register (tier 1), a non-networked electronic register (tier 2), and a centralized electronic medical record (tier 3).<sup>17</sup> Each ART patient has a standardized HIV/ART clinical record where clinical documentation is recorded. The clinical record supports continuity of care and information documented within it also serves as the source data for capture into one of the information systems comprising the three tiers.<sup>15</sup> Each tier provides increased sophistication and management support with paper registers providing the minimum information only. All three systems produce the same core set of data and aggregated indicators to monitor the performance of the ART program at facility level.

The Strategy was premised on interoperability across the tiers and with other systems. The tier 2 system provided openly available data exchange standards (DES) allowing for the take on of existing electronic data, the production of data aligned to the national data definitions, and a standard export of data to the DHIS. Where infrastructure allowed, the tier 2 system facilitated future migration to a networked EMR.<sup>17</sup>

It emerged through document review that the decision taken to emphasize the implementation of tier 2 was instrumental in simplifying the strategy and contributing to rapid scale up. This was because a large number of facilities had existing infrastructure and a digitized population of ART patients that could be transitioned to the tier 2 system. Facilities would therefore benefit from the automated reports. This would assist with reporting in line with the standard definitions as well as patient centred management to assist with patient recall. This required an expansion of computer equipment at facilities that otherwise relied on paper-based data collection systems. This avoided the risks and dependencies inherent in large network- and infrastructure-dependent solutions.

### ***Clear standard operating procedures (SOPs)***

The ART M&E SOP served as a reference tool which established expected actions and processes to support effective data management and supported the maintenance of the system. The SOP articulated the intrinsic role of key role-players within the different departments within health, and at all levels from the facility to the NDOH. All actions had a clear and demonstrable link to enhanced patient management and data quality. This was considered at the outset to be a key component of the implementation.

The SOP provided a single authoritative and nationally endorsed reference document against which all role players could be held accountable. This facilitated the institutionalization of the 3-Tiered Strategy. It emerged through the evaluation that despite this clear guidance, adherence to the ART M&E SOP was weak as evidenced by non-reporting of data to the DHIS. Facility-level processes designed to enhance patient and service management were infrequently adhered to. This was due in part to weak accountability and a lack of clarity regarding the roles and

responsibilities involved in data management. Key informant interviews further elaborated on the challenges, citing facility managers who were not orientated to the ART M&E SOP and a general lack of familiarity with the available reports in TIER.Net to support their management. Additional challenges emerged where facility managers expressed uneasiness with an electronic system or had weak computer literacy and hence were unable to engage with the system. These challenges emerged with facility-level staff and also staff at subnational levels. Challenges related to the use of reports at facility level (a key aspect of the SOP) are discussed below in the section on facility-level support.

### ***Establishing appropriate management structures***

Project and implementation management structures were established to support the 3-Tiered Strategy. These were the Provincial and District Implementation Teams, referred to as PIT and DITs respectively. Recommended composition of the teams was inclusive of program, information management, development partners and IT. These teams were tasked with overseeing the coordination and management of the implementation, including in-facility change management processes. The PITs were responsible for project management to ensure the required systems were in place to support the 3-Tiered Strategy. These included: human resources, IT and equipment, capacity building initiatives, and support to the DITs. The DITs were the operational centres responsible for implementation of the 3-Tiered Strategy in the facility. This included coordination of implementation, capacitation and in-service training, quality improvement initiatives, monitoring adherence to SOPs, routine data engagement, and finally, leading the implementation of the 3-Tiered Strategy and monitoring progress.

The PIT and DITs, respectively, served as the coordination structures to drive the implementation of the Strategy as well as a focal point for the NDOH to engage with regarding implementation process, progress, and challenges. Where the teams comprised the recommended composition, including district representation on the PIT, it was identified that implementation was more often supported. However, where the teams excluded recommended members, accountability structures were weakened. This was reflected in stilted implementation. Key Informant interviews further highlighted that turnover of PIT and DIT leadership with individuals unfamiliar with the 3-Tiered Strategy and its technical design, or departure of leadership with no replacement, meant PIT and DITs ceased to function or function effectively. Data demonstrated varied implementation in each district and demonstrated that facility volume was not an indicator of complete implementation (data not shown). KIs indicated variation was attributed to the differing levels of understanding by district management, weak ownership of the system, infrequent meeting of the DITs, and attrition of KIs which resulted in a breakdown of knowledge transfer to new district staff. Poor functioning PIT and DITs contributed to weak collaboration between the NGO partner and the government counterparts thus resulting in inadequate facility mentorship, stalled implementation, and weak system maintenance.

KIs were enthusiastic to share best practices which included improved data quality and completeness. This was enhanced where the HIV program staff had frequent access to, and ownership of, the data. A respondent working

at provincial level aimed to strengthen the DITs by inviting chairs from other districts to attend all hosted DITs. The objective was to cross pollinate and share best practices to facilitate capacity building. It was reported where clinical and government staff was orientated to the technical design of the system and understood it, the operationalization and maintenance of the system was more consistent.

### ***Alignment with the HMIS***

The health management information system (HMIS) used in South Africa is referred to the District Health Information System (DHIS). It serves as a central repository for aggregate routine data from all public health facilities. The HMIS has an intrinsic link to the health system as a whole; it exists to produce information for use in planning and management.<sup>22,23</sup> It is a critical tool to support decentralized decision-making and health service management and creates a national data set.<sup>12,24,25</sup> The DHIS is aligned to the National Indicator Data Set (NIDS) and it undergoes revision every two years as program needs change.<sup>24</sup>

The alignment of the DHIS to accommodate the data required for reporting on ART emerged as a major component of the intervention. The new and reduced dataset were incorporated into the DHIS. The realignment of the HMIS necessitated the reorientation of the flow of routine ART data to it. The operationalization of this was articulated through the ART M&E SOP.

The result of the HMIS alignment meant the data and reporting expectations merged with the health information systems data management processes as defined by the South African National District Health Information Systems (DHMIS) Policy. Figure 2 provides a hierarchical description of the health system alignment activities adopted to actualize the 3-Tiered Strategy.

The establishment of the standardized in-facility information system, the reorientation of the data to the DHIS, the development of the SOP, and the establishment of the management structures all facilitated the institutionalization of the system. Fewer systems and standard guidance assisted the management structures to implement and support the standard M&E system. This enabled information and program managers to share the responsibility of implementation and maintenance rather than the responsibility resting on a single vertical program.

### ***Partnerships with non-governmental organizations (NGO)***

An essential component of the stewardship role previously described related to the management of the partner environment. Whereas previously the multitude of support partnerships contributed to the fragmentation and proliferation of information systems, a key enabler of the scale-up of the 3-Tier Strategy was the harnessing of non-governmental resources in support of a government-led initiative.

This harnessing of NGO resources supported the escalated implementation of the 3-Tiered Strategy. This was facilitated by a national moratorium on the further development or deployment of non-standard electronic ART

systems. Document review elicited a request by Government, and reciprocal commitment by PEPFAR-SA leadership (Presidents Emergency Plan for AIDS Relief), to support the initiative.

Partnership facilitated the fast-tracked implementation of the 3-Tiered Strategy and funding through Global Health Initiatives (GHI) such as PEPFAR, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and other partner agencies. These financial investments bolstered staff at the National, Provincial and District offices and also channelled support to a single objective. Direct service delivery through employment of facility based staff assisted provincial and district staff with coordination, driving the implementation, capacity building and support initiatives as well as data capture at the facility. Funds also helped procure necessary IT equipment to facilitate the roll out of the tier 2 system. Challenges emerged where equipment procured by donor agencies was different to government equipment fragmenting desktop support efforts.

It emerged through the KI interviews that, while the partner relationship assisted the scale-up, so too did it come with challenges. At times the additional capacity resulted in a perception the system implementation was a partner system and hence there was weak ownership by government officials. In addition, due to limited government capacity, a dependency on partners emerged. The secondment of partner funded human resources resulted in challenges with line management, accountability, and sustainability. Further challenges emerged where a high need for reporting redirected partner efforts to focus on reporting to funders rather than focused effort to establishing sustainable systems. A further challenge was attributed to the deployment of equipment which was cumbersome and provinces did not always have capacity to support the varying computer infrastructure deployed.

### ***Training and support***

Training emerged as an important process to operationalize the Strategy. It was through this that the teams of key implementers (KI) in the provinces and districts were capacitated to operationalize the initiative. The first capacitation training was referred to as the Master Training. KIs comprised government and partner staff. They were oriented to the technical design of the systems and tasked with driving the implementation in each district. They were responsible for fostering the change management processes at the facility- and district-level and were recommended to be members of the DIT. KIs were nominated based on a set of eligibility criteria. Document review revealed comprehensive materials which aimed to address the complex nature of the implementation. These included the tools and processes framed within a series of steps that aimed to structure and standardize implementation practices across all South African districts.<sup>18</sup>

This evaluation identified the master training as a central process to disseminate and operationalize the Strategy. Standardized training materials were made available on a central document portal updated as the processes and software evolved. It also emerged the KIs were the focal individuals with whom important implementation decisions were communicated. They were responsible for cascading and implementing the nationally communicated decisions and interventions to their districts. A challenge identified when selecting key implementers for interview was a high turnover of key implementer staff. More than half of individuals trained in

the master training had left the services at the time of the study. Staff vacancies at the subnational and facility-level posed a risk to system sustainability.

Whereas the cascading training was key to the scale-up of the system, the KIs frequently cited challenges with data use at facility-level due to weak understanding and interpretation of the reports available in TIER.Net. The lack of knowledge of the reports, and their intended purpose, demonstrated facility staff did not receive sufficient support or mentorship to gain full utility of the system. The following quote from a KI interview articulates the balancing act of implementing the system and fostering ownership of the system and sustaining support at the facility level.

“Most operational managers (OM), though aware of the LTF reports, refuse to coordinate with Data Capturers to manage LTF clients using missed appointment reports (early, late and unconfirmed lost to follow-up reports). Where the OMs are using these lists, the lack of printers or toner result in writing by hand of the lists. Often not done, it is considered too much work by some.”

This quote also demonstrates the complex nature of implementation which is reliant on many ‘pieces of the puzzle’ fitting together, and the challenge in developing and sustaining pro-active management at facility-level.

#### ***Explicit grading and tracking of implementation progress***

The implementation monitoring progress provided a source of the unstructured and quantitative data. The explicit and graded implementation monitoring data provided implementers and managers with a tool and targets to track the implementation of the Strategy. The grading assisted tracking the introduction of the new system, the back capture, data clean-up processes, and the expected reporting to the DHIS. This also provided the NDOH a tool to nationally monitor implementation and adherence to the overall Strategy, including reporting of data to the DHIS. Phase 6 was defined as the final step of implementation whereby patient files had been captured, data clean-up completed, facility staff were orientated to the reports produced by TIER.Net, and a baseline data quality audit had been conducted. Phase 6 was therefore used to measure complete implementation and expected adherence to the ART M&E SOP. This gained widespread acceptability as an outcome milestone within the provinces. In addition to highlighting the importance of this system as a key ingredient of the intervention, it is also the basis of the description of program implementation progress described in the next section.

It was noted that the strong emphasis on the target to reach phase 6, or full implementation, sometimes overshadowed the importance of phase 0 and the foundation-building activities. This resulted in an abbreviated phase 0, inadequate support to change management, an insufficient understanding of the system and often a perception of imposition by the system.

## **Description and analysis of the uptake of the implementation**

Table 1 includes data on the M&E systems used comprising 3-Tiered Strategy. The majority of facilities are categorized as phase 0 – 5 and phase 6. These are facilities using the tier 2 system; TIER.Net. The table includes data on the tier 1 (T1) paper register. The table demonstrates the progressive phasing out of the T1 register. The table also includes National Total Remaining on ART data (TROA) alongside the number of ART reporting sites. This serves to demonstrate both the growth of the National ART program in terms of patient volume as well as the number of facilities offering ART. This provides context to the burden of support the KIs were tasked with. The ART program was growing; both in terms of patients entering the services as well as the expanding number of ART service points.

### ***Measurement of the adherence to ART M&E SOP; data submission***

It became apparent through the evaluation there are two measures of success for implementation of the Strategy. The first was the local availability of data at the facility-level; this supported the management of the patient and the facility. This was measured by interrogating the number of phase 6 facilities as reported through the implementation monitoring. The second measure of success was the availability of data in the DHIS; the availability of both monthly and quarterly cohort data. The program outcome data completeness was assessed by comparing named lists of facilities that reported cohort data to the DHIS in October 2014 against the facilities reported phase 6, using the implementation monitoring data. The facilities that were reported to be phase 6 at study censure, and had submitted cohort data to the DHIS, served as the marker for expected data submission. Figure 3 presents provincial totals of cohort data submitted alongside the total number of facilities that reached phase 6, by province. Figure 3 includes a third variable which presents the total number of ART reporting facilities, by province. This comparison aims to demonstrate the penultimate achievement, complete implementation and the collation of this data within the DHIS. The third variable demonstrates how many facilities should optimally report outcome data to the DHIS were all facilities fully implementing the 3-Tiered Strategy.

In October 2014 68% of all facilities using TIER.Net (n=3,112) had completed implementation (phase 6 n=2,139). This was 58% of all facilities offering ART with a fully digitized patient population (n=3,772). At this time, 87% of all phase 6 facilities submitted cohort outcome data to the DHIS (n=1,861). The data completeness is diluted when compared against all facilities offering ART. These data accounted for 51% of all facilities offering ART; the third variable in Figure 3. The total number of patients included in the cohort data equated to data reported for 1.4 million adult patients. These data are complete from April 2004 to October 2014.

Figure 4 demonstrates the coverage of the available data in October 2014, by province. This has been interpreted as a proxy for data representivity, by province. These data are derived by comparing the total number of adults included in the cohort data divided the total number of adults reported to have initiated ART during the same 12 month period through the monthly ART data submitted to the DHIS. Despite the variable completion of

implementation and data submission as described in figure 3, these data accounted for 55% of the total ART population reported in April 2013 to March 2014.

## **Discussion**

This study aimed to undertake a detailed review of the scale-up of the ART M&E system and describe the health system alignment activities South Africa undertook to implement the 3-Tiered Strategy. The study demonstrated that, notwithstanding the challenges and perceived delays with implementation, as of October 2014, 1.4 million patients on ART in South Africa were reflected in the routine data reported to the national government through the DHIS. As such, this is the largest public health cohort of ART data in the world managed through routine information systems.

The implementation of the Strategy, and specifically TIER.Net, was a complex intervention supported by a number of initiatives, design characteristics and strategies identified by the study together with specific challenges to implementation in some instances.

### **Information system alignment was instrumental in unlocking involvement at all levels**

The launch of the Strategy served as a catalyst to simplify the facility-level M&E systems and standardize data management processes within health facilities and the sub-national levels. The incorporation of ART data into the HMIS facilitated the establishment a national repository of all ART data, including cohort outcome data, thus supporting program management in line with well-established information practices in district health systems.<sup>26,27</sup> These activities served to address previously described challenges with ART data,<sup>11</sup> and repeatedly emerged as a key enabler in the design of the system.

### **The dedicated management structures varied in their contribution to implementation**

The establishment of dedicated management structures (PITs and DITs) was identified as a key strategy for deconstructing the siloes of data and program management in order to achieve the “inclusivity, collaboration and collective responsibility” identified by Nash.<sup>28</sup> However the failure of management and facility-level support was also one of the main weaknesses identified, including the support of information use for program management.<sup>29,30</sup> The findings highlight the importance of a local champion and providing supervisory oversight to support holistic institutionalization of the health information system.<sup>31,32</sup> This includes routine meetings and support visits to facilities.<sup>33,34</sup> Collaborative forums provide an opportunity for timely engagement with data to inform program management. This further provides an opportunity to use data to understand best practices and identify challenges whilst also directing support activities.<sup>28</sup> Simple and visible implementation success metrics were invaluable in initial scale-up.

A tension emerged between the value of implementation success metrics as a tool for driving and monitoring scale-up of the system, especially in the roll-out phase, and the fostering of a utilitarian perspective that the system was a means for reporting rather than a tool to support patient management. Critical in routine maintenance of an information system is to ensure users fully understand the utility of the system for patient care. Partner organisations were critical enablers of roll-out but less successful in capacitating management.

There was interplay between the drive for initial scale-up and the stronger contribution of partner organisations in this phase than in supporting on-going use of information and system sustainability and resilience. The health system building blocks intrinsically built within the 3-Tiered Strategy implementation were often compromised.<sup>18,35–37</sup>

### **Local utility in assisting patient and facility management is the ultimate success criterion for an information system**

Prior to the introduction of the Strategy ART data were not locally available, were of limited completeness and quality, were not centrally available, and were not locally available for decision-making.<sup>11,38</sup> The study demonstrated that data became available at the facility and within the HMIS to potentially support patient-management, decision-making, and program improvement. As discussed above, the use of data were not adequately supported, and yet the available success metrics as described in this study point to a successful implementation and scale-up. This highlights the need for health system strengthening success measures related to information systems to incorporate the use of data at all levels, and not just the submission of data.

Further threatening the utility of the system for patient and facility management are potential data weaknesses. In this study data completeness was thought to be compromised where adherence to the ART M&E SOP was weak. Comprehensive SOPs that articulate roles and responsibilities and describe expectations serve as a reference document and assist to strengthen accountability,<sup>39</sup> but also in ensuring the completeness and fidelity of the data itself. The study demonstrated nevertheless that despite the identified challenges with implementation, clear and defined data flow provided a foundation on which to build improvement initiatives.

### **Digitisation is only one component of information system implementation**

Beyond the introduction of the software which became the dominant model (tier 2), facility-level changes included the introduction of a standardized HIV/ART clinical record to clinicians, the realignment of in-facility data systems and data flow, and the daily capturing from patient files into a patient information system as a work-flow. Change management is an essential component of implementation, and at times more challenging than establishing software and data capturing capacity where these did not previously exist.

## **Strengths and limitations of the study**

The size and scope of the implementation are a strength of the study, ensuring that the context studied is an appropriate one from which to draw lessons for system-wide implementations. This might be off-set by the unique characteristics of the South African context which might not fully align with health systems in other high-burden countries in the region.

A further study limitation is that the KI sample was small and responses may not be generalizable. The lead author was also a participant in the implementation process and had extensive insight into the processes, which was likely both a strength due to the contribution of this experience to the study, and had the potential to limit objectivity in some of the analysis, notwithstanding the efforts taken to verify interpretations with KIs.

This study identified areas of operational research that were beyond the scope of the study, but which could be highly informative to implementers elsewhere. These include research into optimal data capture norms and standards to integrate administrative management, and learnings from data quality assessments. Additional work on mentorship, especially where this has been successful in developing facility-level use of data, would also be contributory.

## **Conclusion**

High-quality data are essential to inform HIV prevention, care and treatment, policy development, resource planning, and to strengthen accountability. The study demonstrated that South Africa's introduction of the 3-Tiered Strategy for ART monitoring was championed by senior management in the NDOH who fostered a collaborative environment and structured implementation approach which resulted in wide-scale uptake of the recommended systems, predominantly the electronic register (tier 2). The study has identified important considerations for implementation of large-scale routine monitoring systems for priority health conditions, together with substantial challenges to subsequent support and optimal use of the systems.

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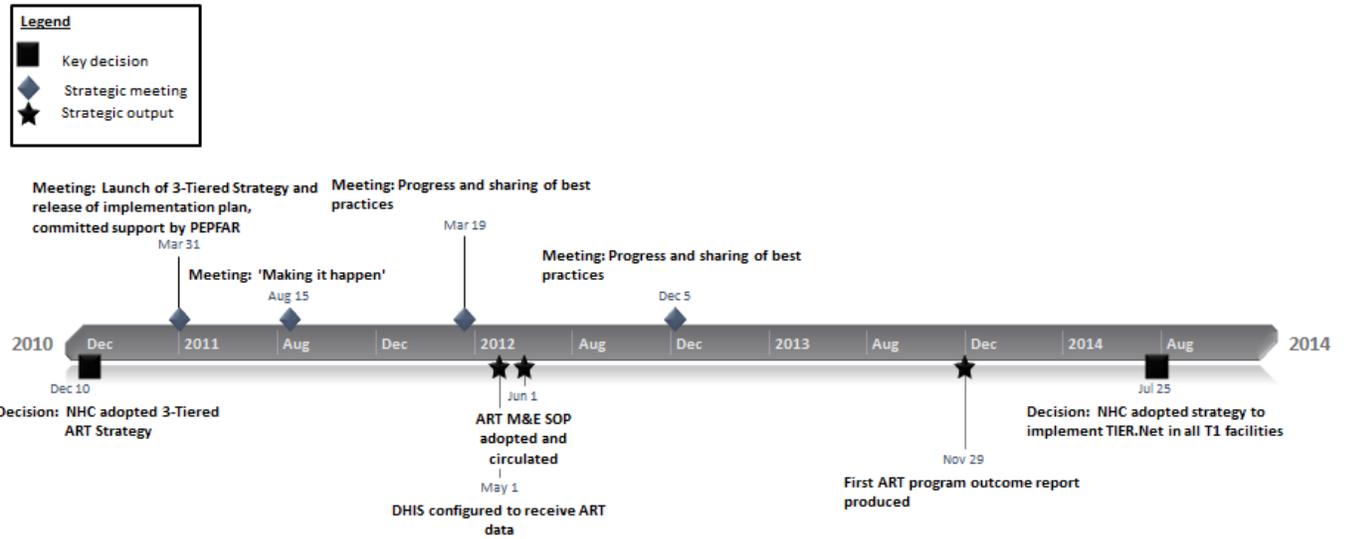
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**Table 1: Total patients on ART (TROA), number of ART facilities, and implementation progress to October 2014**

	<b>April 2013</b>	<b>December 2013</b>	<b>March 2014</b>	<b>June 2014</b>	<b>October 2014</b>
<b>Number of patients on ART (TROA)<sup>1,2</sup></b>	2,321,301	2,620,692	2,664,727	2,742,222	2,903,958
<b>Number of sites reporting ART data by M&amp;E system<sup>1</sup></b>	3,662	3,645	3,709	3,743	3,772
<b>Total number of facilities using TIER.Net (all phases)<sup>3</sup></b>	1,933	2,690	2,808	2,990	3,112
<b>Completed implementation Phase 6</b>	500	1,296	1,551	1,779	2,139
<b>Facilities Implementing TIER.Net<sup>4</sup> Phase 0 – 5</b>	1,433	1,394	1,257	1,211	973
<b>Facilities using paper register (T1)</b>	1,623	879	824	691	596
<b>Non-standard M&amp;E system<sup>5</sup></b>	96	65	65	50	50
<b>Standard electronic medical record (tier 3)</b>	10	11	12	12	14

1. ART – Antiretroviral Treatment
2. TROA – Total remaining on ART
3. TIER.Net - The tier 2 non-networked electronic system
4. Phase 0 – 5 – Describes the sequential progression to implement TIER.Net
5. Non-standard system is a system falling outside the three tiers of the 3-Tiered Strategy

## Timeline of milestone events



## Multi-day key events



Figure 1: Timeline of key activities in 3-Tiered Strategy implementation from December 2010 to December 2014

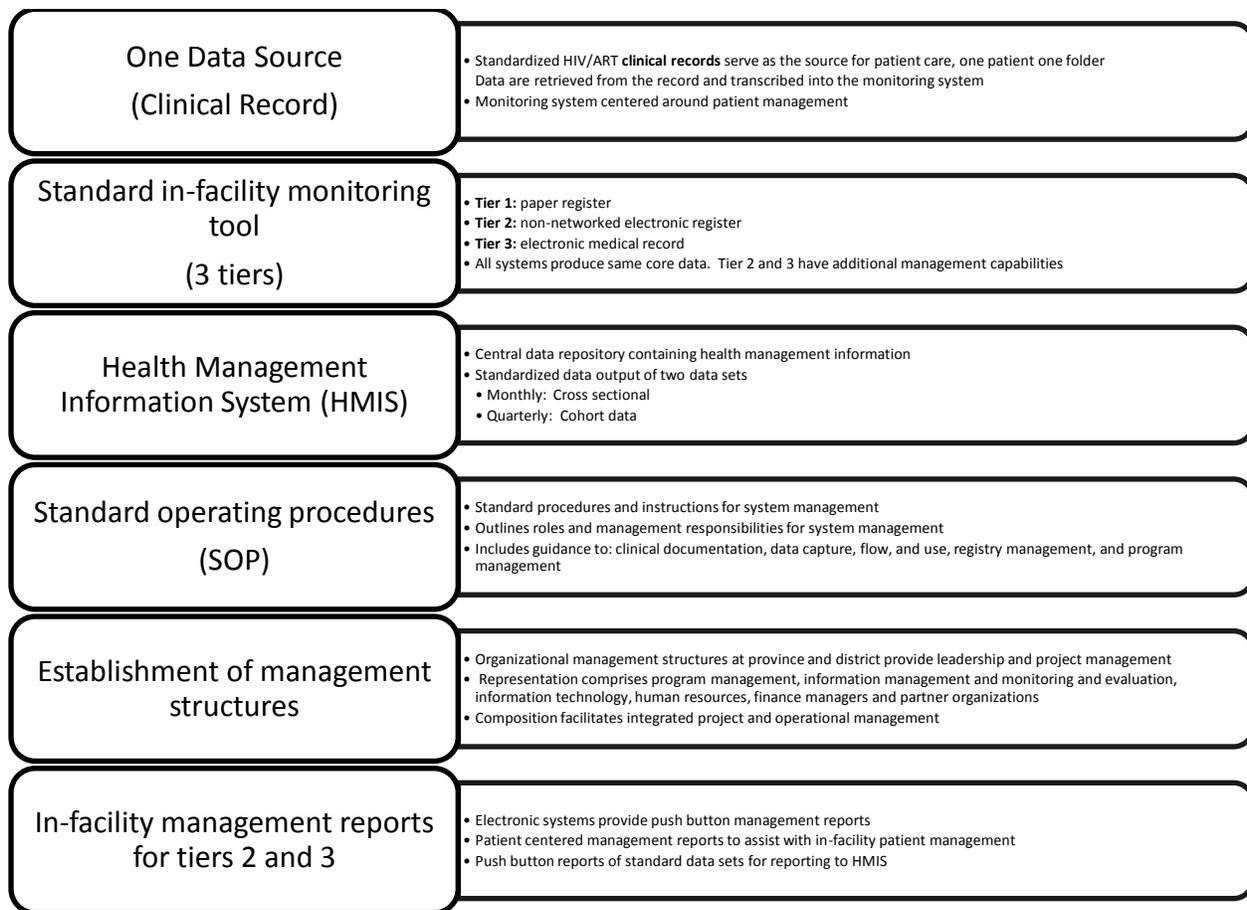


Figure 2: Health system alignment activities to implement 3-Tiered Strategy

### Total facilities submitted data in October 2014 With total number of ART facilities per province

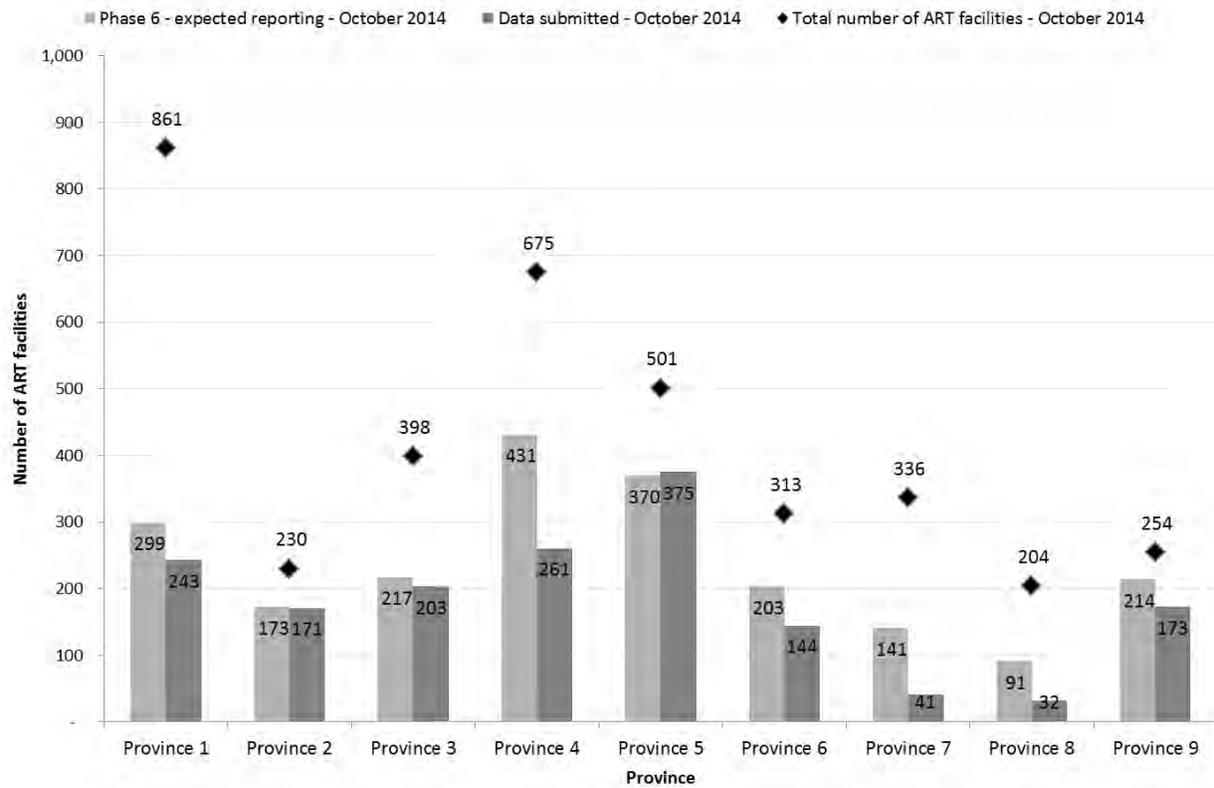
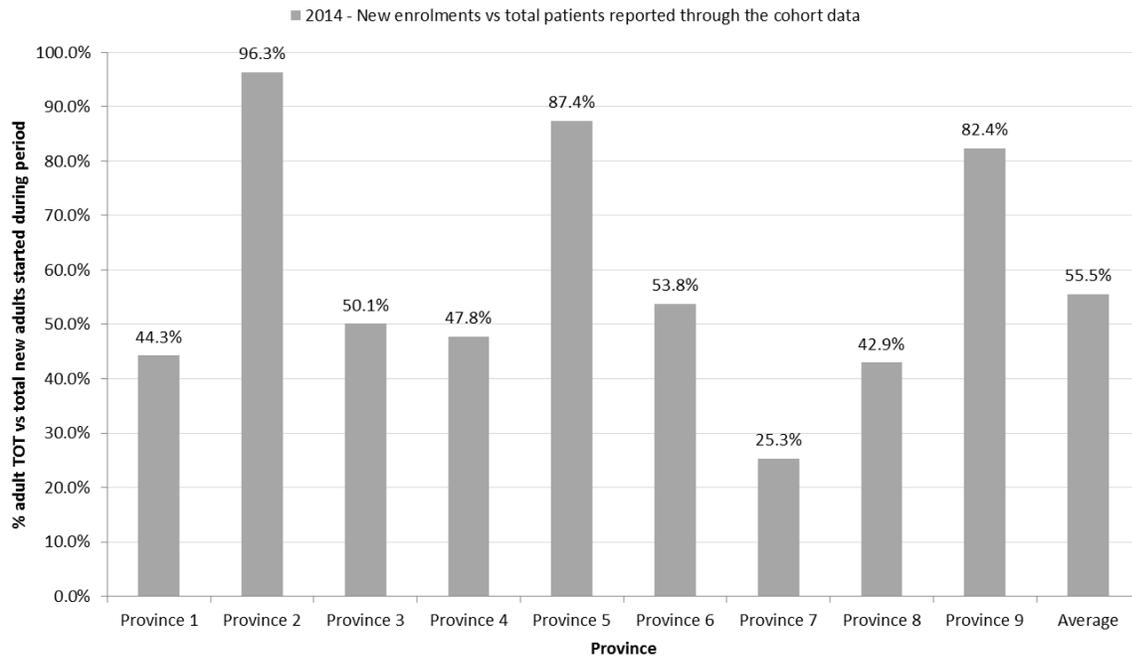


Figure 3: Expected reporting (phase 6) versus total number of facilities that submitted cohort data, reported alongside total number of facilities reporting ART data, October 2014

**Comparison of total patients included in cohort in April 2013 to March 2014 versus total number of adults started ART during same period**



**Figure 4: Coverage of cohort data, total enrolled into ART versus total patients included in data**

Supplementary Table 1: Strategic activities undertaken throughout the implementation of 3-Tiered Strategy

Activity	Additional details of key activity
NHC adopted 3-Tiered ART Strategy	<p>3-Tiered ART Monitoring Strategy presented to the NHC in December 2010. This was adopted by the council and presented to NHISSA in March 2014.</p> <p>[source: ppt]</p>
Strategy dissemination meeting	<p>Launch of 3-Tiered Strategy to government and partners. A meeting was held on March 31, 2011 which included provincial HAST representatives, information managers, as well as development partners together to ensure a common understanding of the System, the processes and the role of partners.</p> <p>[source: letter]</p>
PEPFAR commitment to support 3-Tiered Strategy	<p>Government requested support from the Development Partners to support provinces to plan and implement the 3-Tiered Strategy.</p> <p>PEPFAR reciprocated with commitment to support the 3-Tiered Strategy.</p> <p>[source: letter from Government and PEPFAR]</p>
Provinces establish PITs. National consultation meetings. Release of Implementation Plan	<p>T1 and T2 Implementation plan v4 [source: the plan]</p> <p>Establishing the PITs [source: NDOH communication to provinces 30 March 2011]</p> <p>Meetings held with each province to share the content of the System to all key stakeholders in the provinces and to provide a forum for questions as well as sharing recommendations. These meetings aimed to establish the PITs as well as to guide the establishment of the DITs.</p>
Pilot training	<p>Phase zero pilot. This session included only district individuals as well as partners who supported the district, as way to demonstrate the implementation processes. A report was produced which includes an overview of the first TIER.Net implementation workshop held in Bushbuckridge Mpumalanga from 25-29 July 2011. The focus is on lessons learned and feedback from the workshop participants. These activities informed further implementation processes</p> <p>[Source: report 25 - 29 July 2011]</p>
Meeting: Making it Happen	<p>Sharing of lessons learned from the pilot, shared additional details to enable implementers to further prepare for implementation following the master training - which was held the following in September and October 2011</p> <p>[source: ppt from conference]</p>
Master Training	<p>Each Province was requested to nominate one Master Trainer per district and a provincial representative. Partners working within the districts were requested to nominate one individual working within the ART monitoring program in the district.</p> <p>The Master training aimed to train key implementers and ensure all provinces and districts had representation. Identified individuals were required to identify their area of experience to ensure relevant candidates were selected</p> <p>[source: nomination form]</p> <p>The training consisted of system overview, 12 steps of implementation, guidance of change management activities, data analysis and interpretations, use of management reports to strengthen facility level management and patient recall</p> <p>[source: training slides]</p>

Progress Meeting and sharing of best practices	Progress meeting to seek assistance from partners to expedite implementation to all eligible sites and to provide roving data capturers to support digitization activities. [source: invitation]
DHIS alignment completed and disseminated	NIDS 2013 rolled out country-wide and included the ART M&E cohort dataset [source: ppt slides]
Progress Meeting and sharing of best practices	Meeting held to review the progress made and challenges and best practices including national, provincial HAST and partners. [source: meeting report]
Updater training and release of 1.5.7	Updater training included overview of new functionality, overview of data analysis, implementation progress, and new functionality.  The aim was for releases to be done annually to limit time spent in the manual dissemination of the software.  The updater training also provided an opportunity for key implementers to share challenges and best practices.  [source: training slides]
First ART Program report produced with results from implementation	ART Indicator III report [source: reference in works cited list]
TIER.Net Costing done and decision to scale all T1 facilities to T2  Commencement of district level data use trainings	TIER.Net costing calculator (TCC) produced to quantify costs of implementation, guide funds, and staff required to scale up TIER.Net to all sites. This was presented to NHC and guided decision to scale up TIER.Net to all T1 facilities  [source: TCC report and letter by Dr Pillay to provinces announcing escalation to T1 facilities]  District level trainings were conducted by the NDOH to guide data use and further institutionalize the TIER.Net implementation and escalate the move to phase 6  [source: consolidated training report June - Sept 2014]
Software release 1.8.3	Release September 2015  Release was disseminated through VULA with accompanying slides to guide installation and new content.  [source: email release, VULA, support materials, and letter to provinces]
2,139 Facilities fully implemented (phase 6)	October 2014 TIER.Net implementation progress report  [source: TIER.Net implementation progress]
Second ART program report produced	December 2014 ART program report produced including outcome data to March 2014. Report awaiting peer review process, finalization, and circulation.  [source: report reviewed, awaiting release]

