

PAPER HEALTH REGISTERS PROJECT CASE STUDY:

SOUTH AFRICA'S 3-TIERED ANTIRETROVIRAL TREATMENT MONITORING SYSTEM

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EXECUTIVE SUMMARY

South Africa has the largest population of individuals on antiretroviral treatment (ART) for human immunodeficiency virus (HIV) in the world. There was a large scale-up of ART programs in 2004 and no standardized method to track or monitor key indicators related to ART distribution and use. In 2010, renewed political commitment to improving ART monitoring and evaluation, led by a new minister of health, catalyzed the move toward a standardized ART monitoring system. Against this backdrop, South Africa developed a 3-Tiered ART Monitoring Strategy in alignment with the World Health Organization's (WHO) monitoring recommendations. After being piloted in the Western Cape, this system was refined and implemented nationally in 2011.

The 3-Tiered Strategy uses registers exclusively as reporting tools, not as clinical tools. The register collects six monthly indicators and 27 quarterly indicators from standardized clinical stationery. Tier 1 of the system is a paper health register, designed for facilities with fewer than 500 patients or without capabilities to support an electronic system. Tier 2 (TIER.Net) is a non-networked electronic system for facilities with fewer than 2000 patients. Tier 3 is a networked electronic medical record and register, and is designed for large facilities with networking capacity. This tiered system collects the same indicators from all three tiers, regardless of their platform. This case study focuses on the paper registers in Tier 1.

The 3-Tiered Strategy is currently in its implementation stage, with 835 Tier 1 facilities using paper registers as of March 2014. The high level of political engagement has been a key contributor to the successes of this system. Lessons learned include: (1) collecting only a minimum data set improves efficiency of the system, (2) adequate workforce capacity is critical to register implementation and sustainability, and (3) political support at all levels encourages smooth transitions. This case particularly speaks to other countries that may be considering the WHO's Tiered Patient Management System, or where varying levels of health infrastructure call for a mixed paper and electronic health register system

COUNTRY PROFILE: SOUTH AFRICA

Population (2012): 52,386,000

GNI (PPP int. \$ 2012):
\$11,010

Life expectancy at birth (2013):
(M/F) 57/60 years

Fertility rate (2011):
2.4

Top causes of under-5 mortality (2010):

1. HIV/AIDS
2. Prematurity
3. Other non-communicable diseases

HIV Prevalence (per 100,000) (2013):
11,087

(WHO 2014)



PURPOSE

The Bill & Melinda Gates Foundation's Vaccine Delivery Team engaged the University of Washington's Global Health Strategic Analysis, Research and Training (START) Program in the *Paper Health Registers Project* in September 2013. Even as many health information systems worldwide move toward electronic and mobile models, paper health registers continue to be relevant tools in many low-resource settings. The project team hypothesized that sub-optimal paper register systems likely detract from patient care and produce poor data quality, but there is lack of evidence around optimizing paper register systems. Case studies were identified to fill gaps in knowledge about best practices for implementation and use of paper health registers. Innovative register systems in Ethiopia, Ghana, South Africa, Uganda, and Uruguay illuminate opportunities for improving paper health register systems and identify approaches to both strengthen support for patient care and optimize reporting mechanisms. This case study is one of five case studies developed as a part of this effort.



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BACKGROUND

THE GLOBAL HIV EPIDEMIC

Human immunodeficiency virus (HIV) causes acquired immunodeficiency syndrome (AIDS), a disease of the human immune system. HIV is an infectious disease transmitted through sexual contact; from mother to child during pregnancy, delivery or breastfeeding; and through blood transfusions or hypodermic needles. When an individual is infected with HIV, after an initial period of flu-like symptoms there is generally a long period without symptoms. As the disease progresses, it weakens the host's immune system making the host susceptible to infections, including opportunistic infections that do not affect healthy individuals.

The U.S. Centers for Disease Control and Prevention (CDC) first identified AIDS in 1981 and identified HIV shortly thereafter. The disease spread quickly throughout Sub-Saharan Africa, South and Southeast Asia, and through certain populations in the United States, including men who have sex with men and communities of color. HIV/AIDS-related stigma has been a serious public health concern. AIDS denialism – disputing the connection between HIV and AIDS or the validity of antiretroviral treatment – has also been a challenge in fighting the global epidemic.

By 2012, there were about 35.3 million people living with HIV throughout the world (UNAIDS 2013). The 2010 Global Burden of Disease Study estimates that HIV/AIDS was the fourth leading cause of disease burden and death (morbidity and mortality) in 2010 and was the sixth leading cause of death globally (Sidibé et al. 2012). Incidence of new HIV infections has fallen by 33% since 2001, and global AIDS-related deaths have been on the decline since they peaked in 2005 (UNAIDS 2013; Sidibé et al. 2012). In southern and eastern Africa, AIDS remains the leading cause of death (Sidibé et al. 2012). In particular, sub-Saharan Africa is home to 71% of people living with HIV; almost all countries in sub-Saharan Africa have a generalized HIV epidemic (Kaiser Family Foundation 2013).

HIV MONITORING AND EVALUATION

In the face of this enormous public health challenge, tracking the epidemic and people living with HIV has been a critical part of the public health response. Routine surveillance is an essential part of HIV policies and programs worldwide. The World Health Organization (WHO) and the CDC both have classification systems for diagnosing and staging HIV disease. In global HIV surveillance programs, less developed countries generally use the WHO's classification system, which relies on CD4 count to stage HIV disease.

Importantly, the growing HIV/AIDS epidemic prompted numerous different global, national, and local organizations to implement solutions. These programs provide key resources including testing, education, treatment, and support to their communities. However, these groups do not have a uniform way of measuring their programs and progress of their patients. HIV monitoring and evaluation systems are complicated by multiple funding requirements. Though 96% of national monitoring and evaluation plans for HIV programs are endorsed by key partners, only 30% of countries reported that all key partners aligned and harmonized their monitoring and evaluation requirements (Peersman et al. 2009).



ANTIRETROVIRAL TREATMENT

Treatment for HIV is antiretroviral therapy (ART) to fight the virus itself, alongside treatment for the myriad opportunistic infections that can accompany HIV. Combination ART was first introduced in 1996 and revolutionized HIV treatment (Hammer et al. 1996). ART generally refers to a combination of three or more antiretroviral drugs to achieve viral suppression ART can now be taken as a single, fixed-dose combination pill, which is safe, effective, and more acceptable to most patients.

For people living with HIV, ART decreases the likelihood of getting opportunistic infections and prolongs life (Palella et al. 1998). In addition, ART greatly decreases the risk of mother-to-child transmission of HIV, which has revolutionized antenatal care for HIV-positive women (Connor et al. 1994; Mandelbrot et al. 2001; Townsend et al. 2008). Evidence is also building to show that viral suppression from ART can also decrease the chance of sexual transmission of HIV (Quinn et al. 2000; Attia et al. 2009; Cohen et al. 2011). Thus, ART is becoming a cornerstone of both HIV treatment and HIV prevention policies.

In 1996, the United Nations established UNAIDS to serve as its coordinating body in the global fight against HIV. This marked the advent of a series of important policies and initiatives to prevent and treat HIV worldwide. In 2000, the Millennium Development Goals (MDG) included a commitment to halt and reverse the spread of HIV by 2015. In 2001, a UN General Assembly Special Session on HIV/AIDS (UNGASS) established the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) to fund efforts to prevent and treat HIV. A cornerstone to many of these policies was the encouragement of access to treatment for all people living with HIV.

Spurred by these international commitments and increasing urgency to quell the epidemic, countries began expanding their programs to provide ART to individuals living with HIV in the early 2000s. Programs that aimed to improve access to ART were eliciting increased commitment from outside donor groups. These programs are “naturally expensive” and their development, maintenance and expansion requires sustained commitment of numerous resources including funds, human resources and political will (WHO 2005). The cost and size of these programs make monitoring and evaluation essential to the fight against HIV.

An effective monitoring and evaluation system for treatment requires complete, accurate, and timely data flow from the moment of the first patient encounter through the clinic, to the hospital, and finally to the central information hub (Mate et al. 2009). ART programs generally require different indicators for making clinical, programmatic, and policy decisions. Important clinical indicators can include CD4 counts, transfers in or out of the cohort, deaths, changes in treatment regimen, TB screening and treatment, and pregnancies. Important programmatic indicators can include the number of patients starting on ART, the number of patients continuing on ART, and defaulters from the system. These types of indicators allow for planning for the amount of ART stock needed and staff time required, and inform other capacity-related decisions (South Africa NDoH 2011).

Part of the international response to the need for ART treatment included the WHO’s 2003 *3 by 5 Initiative*, which included recommendations related to monitoring and evaluating ART programs. This initiative aimed to achieve the “3 by 5” target of getting three million people in the world on ART by 2005 through encouraging universal access to ART for all who need it (WHO 2005). The WHO describes the role of national monitoring and evaluation programs:



National monitoring and evaluation of programs for increased access to antiretroviral drugs should allow programs to monitor their progress in implementation, identify problems, refine and adapt their implementation strategies, assess the effectiveness and impact of their interventions, and test strategies for optimizing their effectiveness, impact, cost-effectiveness and sustainability (World Health Organization 2005).

This initiative has particular links to South Africa's 3-Tiered ART Monitoring Strategy. When the *3 by 5 Initiative* was established in 2003, the initiative suggested a "tiered" approach to routine monitoring systems that would allow facilities to capture and report information on their patients based on their infrastructure and capacity, but did not specify a strategy for achieving this target. South Africa's 3-Tiered Strategy was one of the models that informed the further development of the WHO guidelines.

SOUTH AFRICA

GEOGRAPHY, DEMOGRAPHICS AND POLITICS

South Africa is the southernmost country in Africa, and shares borders with Namibia, Botswana, Zimbabwe, Mozambique, Swaziland, and Lesotho. South Africa is a parliamentary republic, divided into nine provinces and 52 districts. Currently home to more than 52 million people, about 62% of South Africans live in urban areas and about 23% live below the national poverty line (World Bank 2014).

South Africa's history has been characterized by racial discrimination, poverty, and conflict since the first European settlement in the Cape in 1652 (Coovadia et al. 2009). After periods of Dutch and British colonial rule, South Africa was established as the Union of South Africa in 1910. The period from 1910-1948 was a period of segregation in which labor migration intensified and poor urban working and living conditions increased (Coovadia et al. 2009).

Apartheid began in 1948 when the right-wing National Party came into power and codified the racial discrimination that had been growing in South Africa for years. This system racially classified individuals as European (white), Asian (Indian), Bantu (black), or colored (other non-white racial groups) and positioned white people at the peak of this racial hierarchy (Coovadia et al. 2009). These classifications determined where people could live and work, whether their children could go to school, and ultimately resulted in economic marginalization and political exclusion of non-white groups in South Africa (Coovadia et al. 2009).

The first democratic election occurred in 1994, ending apartheid and bringing Nelson Mandela to the presidency. The early post-apartheid years were characterized by both pro-poor policies and neo-liberal policies (Coovadia et al. 2009). Under Thabo Mbeki, the second post-apartheid president, social services and infrastructure improved even as income inequalities grew (Coovadia et al. 2009). The current president, Jacob Zuma, was elected in 2009.



HEALTH SYSTEM

The health system in South Africa has been greatly influenced by the country's history. The Health Act of 1919 established the first Unionwide Public Health Department (Coovadia et al. 2009). South Africa was a forerunner in community-based health services and established community health centers as early as 1945 (Coovadia et al. 2009). Despite these early commitments to public health, South Africa's health system suffered throughout apartheid. The Health Act in 1977 determined that curative services should be provided at a provincial, not the national level, further perpetuating the fragmentation of an already segregated system. The Alma-Ata Declaration of 1978, widely hailed as a pivotal policy in global community health efforts, did not affect South Africa as the country was increasingly isolated. In addition, in 1983 the Tricameral Parliament further codified discrimination in health services by establishing "own affairs" departments for white, colored, and Indian groups (Coovadia et al. 2009).

South Africa further decentralized its health system after apartheid ended in 1994 (Coovadia et al. 2009). The National Department of Health (NDoH) committed to a primary health care (PHC) model that focused on health prevention and promotion, rehabilitative and referral services, and emphasized both individual and family health (Republic of South Africa 2012). In 2004, the National Health Act legislated a national health system incorporating both private and public health services and established a district-level health system for delivering primary care (Coovadia et al. 2009). Unfortunately, the health system suffered under the presidency of Thabo Mbeki, whose unscientific health policies and failures to address the burgeoning HIV epidemic cost thousands of lives (Mayosi et al. 2012).

After President Mbeki's term ended in 2009, the newly-elected President Jacob Zuma appointed Aaron Motsoaledi as the Minister of Health. Motsoaledi's leadership has been widely recognized as key to South Africa's improved commitment to evidence-based health efforts (Mayosi et al. 2012). However, leadership at the highest level has yet to infiltrate lower-level leadership, and the health management bureaucracy has not changed a great deal (Mayosi et al. 2012).

DATA MANAGEMENT FOR HEALTH

South Africa's shift toward a decentralized model of health service management and delivery had enormous implications for data collection and management. This shift was the impetus for the development of the District Health Information System (DHIS), which was introduced in South Africa in 1996 (Garrib et al. 2008). The DHIS is intended to support decentralized decision-making and health service management by collecting aggregated routine data from public health facilities.

The decision to decentralize health management led some districts to review the data they were already collecting. The Eastern Cape Province, a remote district in northern South Africa, undertook an evaluation exercise to create an "essential data set" in the hope of consolidating and streamlining their reporting across health domains (Shaw 2005). An essential data set was defined as "a set of the most important data elements, selected from all primary health care vertical programs, that should be reported by health service providers on a routine basis, with the aim of being able to generate indicators that monitor the provision of health services in an integrated manner," (Shaw 2005). This essential data set was adopted by the DHIS in 2001 (Garrib et al. 2008). Note that the DHIS is not exclusive to HIV data and includes indicators gathered from all domains encompassed by primary health care. The DHIS grew



steadily in its first ten years, and by 2005 was considered to be a comprehensive primary health care information system (Shaw 2005).

HIV EPIDEMIC AND RESPONSE

As of 2013, there were 6.1 million people living with HIV in South Africa (UNAIDS 2014). South Africa has experienced one of the most devastating HIV epidemics and is still suffering the effects of this disease on its economy and society.

The first case of HIV in South Africa was confirmed in 1982 (Ras et al. 1983). From 1982 to 1994, the apartheid government did very little to contain HIV. In fact, the need to prioritize HIV was highlighted by outside groups in the Maputo statement on HIV, which was issued jointly by the exiled African National Congress (ANC) and other anti-apartheid organizations (Karim et al. 2009). The National AIDS Convention of South Africa's (NACOSA) AIDS Plan from 1993 was the first credible response to the HIV epidemic and was adopted by Mandela's government in 1994. Even still, South Africa's response to HIV included numerous setbacks. President Mbeki's response to HIV was characterized by public disputes about the cause of AIDS, the reliability of HIV testing, and the safety of ART. This caused many international organizations and community groups to criticize the government's response to the epidemic.

After significant international pressure and an early demonstration project on ART provision in the Western Cape, a national ART program was launched in South Africa in April of 2004. The Operational Plan for Comprehensive HIV/AIDS Care Management and Treatment was also established in 2004, which included a national monitoring and evaluation policy (Kawonga et al. 2012). This plan required 144 indicators related to HIV care and treatment to be reported to the national level, but did not include guidelines for how to gather and calculate these indicators. These indicators were gathered haphazardly due to the lack of established standards (Kawonga et al. 2012; White 2014).

ART programs in South Africa were steadily scaled up after 2004. The WHO estimates that 28% of South Africans in need of ART were receiving it in 2007, which increased to 56% in 2009 and 80% by 2013 (Hontelez et al. 2013; World Health Organization 2010). Due to this scale-up, the NDoH negotiated a significant reduction in the price of ART, which allowed the health sector to reallocate resources toward enrolling more people in the ART program (Republic of South Africa 2012). Current WHO guidelines recommend ART for patients with a CD4 count of less than 500 cells per μL (WHO 2013b). These guidelines, along with the increased commitment to provided ART to all who need it, present challenges to the capacity of South Africa's health system. South Africa currently has the largest ART program in the world; the NDoH estimated over 2.2 million South Africans accessing HIV treatment by the end of 2013 (UNAIDS 2014).

Unfortunately this scale-up was not accompanied by improved routine data systems. From 2004 to 2011, provinces, districts, and health facilities used various paper forms and electronic data systems to monitor ART services. There were many non-standard forms and definitions, making it impossible to ascertain how many people were receiving ART (McIntosh 2013). By 2009, facilities were required to manually record HIV treatment data on six different forms, including two different DORA reporting tools (Kawonga et al. 2012). An October 2010 review found over 40 patient management systems in South Africa alone, with various non-standard, non-networked ART data monitoring systems in the public



sector (Pillay et al. 2012). Even in a single facility, multiple monitoring systems could be in use. Conflicting monitoring systems make it very difficult to provide quality patient care and reporting.

3-TIERED ART MONITORING SYSTEM

DEVELOPMENT

MOTIVATING CHANGE

The impetus for improving South Africa’s ART monitoring systems originated in 2001 in the Western Cape where the first large-scale ART demonstration projects were beginning. The legacy of apartheid left the Western Cape better resourced in comparison to the majority of other provinces. This allowed the Western Cape to focus more on strategy and implementation, as the infrastructure required to implement ART services was already mostly available (Osler 2014). Medicins Sans Frontieres (MSF) in collaboration with the Provincial Department of Health (PDoH) of the Western Cape and the University of Cape Town led an ART demonstration project in Khayelitsha district. This project aimed to demonstrate that even countries with a high density of people living in poverty could offer ART in public health clinics and that patients could prove as adherent as those in developed countries (Coetzee et al. 2004; Osler 2014). The scale of the program required monitoring a large volume of patients using a cohort-based register system so their outcomes could be tracked over time.

Dr. Andrew Boule had strong ties with the MSF project which started in the Western Cape in 2001 and was a critical change agent in the evolution of the Three-Tiered Strategy, both at a provincial level and nationwide (Osler 2014). At this time, monitoring and evaluation of health services usually consisted of headcounts and aggregate counts of services rendered. Boule, Katherine Hilderbrand from MSF and others in the PDoH recognized the need for a simple, paper cohort-based register system to track patient outcomes in the ART demonstration project. Their “basics first” approach emphasized a paper system as a critical baseline tool for establishing a culture of monitoring and evaluation, and for fostering comprehension and use of cohort data (Osler 2014).

DEVELOPING THE REGISTER

Boule led efforts to improve the register system and his creativity and innovation were essential to the development process (Osler 2014). He aimed to develop a system that would be standardized across facilities with varying infrastructure and capacity, collect only essential data elements, and track cohorts of patients. The resulting 3-Tiered Patient Monitoring Strategy relies on standardized paper clinical stationery to track patient encounters and collects ART data into one of three monitoring tiers depending on the health facility size and capabilities (South Africa NDoH 2011). Notably, the register – whether paper or electronic – is designed solely to extract ART data from clinical stationery. The register can be used to enhance patient and service management as well as supply data to extract for nationally required reports, however it should not be used directly for clinical management by health providers. (White 2014; Franken 2014; Hurter 2014; Osler 2014).

The paper ART register system followed lessons learned from the TB paper registers, which represent the first use of longitudinal records for a patient as part of monitoring and evaluation in South Africa (Osler 2014). The register is designed to collect cohort-based data for easy assessment of ART outcomes. The clinical stationery, used as input into the register, includes a visit summary sheet with multiple rows



divided by five columns per page. Each column represents a clinical visit. Each row or section is clearly labeled for recording clinical plans and patient information, including key indicators such as ARV drugs prescribed, weight, height, family planning, and TB screening (see Appendix B). This format allows for health providers to offer improved continuum of care, because indicator trends, such as a CD4 count, can be easily tracked visually. The design of these patient records in the clinical stationery also allows for better capturing of data into paper or electronic registers, because key indicators are easily identified in the same location for every patient. The paper ART register is designed with columns that align with those in patient records to easily draw information from the record to the register for reporting purposes (see Appendix A) (Osler 2014).

Reducing the number of data elements that are collected by the registers was a major part of the redesign of the monitoring system. Boule advocated for greatly decreasing the number of data elements collected by ART facilities (Osler 2014). In alignment with the WHO's recommendations to collect monthly program-related indicators and quarterly clinical indicators, the register system was designed to capture the minimum amount of data elements possible to inform key decisions. Where there were previously 140 data elements tracked by disparate systems, there are now six monthly indicators and 27 quarterly indicators (Pillay et al. 2012). The monthly reports generated by the system include only counts of new adults and new children on ART, total new individuals on ART, adults remaining on ART, children remaining on ART, and total individuals remaining on ART (White 2014). Monthly and quarterly reports are required to be used locally and are supported by national standard operating procedures (Osler et al. 2014).

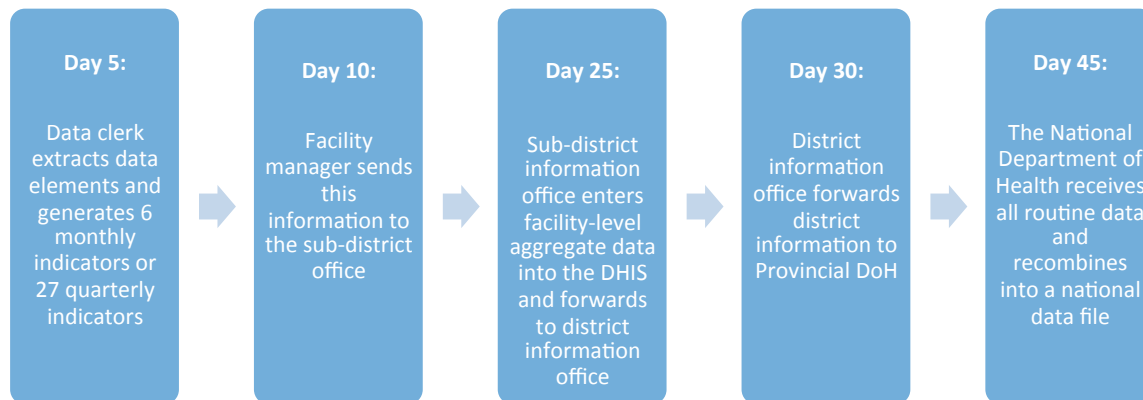
After the start of the free ART services in the public sector in 2004, Boule quickly realized that the paper register would grow too cumbersome as ART services matured and more individuals remained on ART. Stable networks required by electronic medical record systems were found within tertiary hospitals but not available in most resource-constrained countries. Therefore, Boule conceptualized a second, non-networked electronic tier that would allow for electronic registration of patient encounters, without requiring infrastructure for full, electronic medical records (Osler 2014). This tier would become known as "TIER.Net," and comprised the second tier of the 3-Tiered Patient Monitoring System. A third tier was also developed for large facilities that could support electronic medical records and networked systems. The electronic registers used in Tiers 2 and 3 were developed to collect the same elements that were collected in Tier 1.

This case study focuses on Tier 1, which is a paper-based system designed for use in facilities with 500 or fewer ART patients or in areas where electronic systems are not feasible. See Figure 1 for data flow details.

For facilities that are in Tier 1, data clerks abstract information from the standardized clinical stationery into the paper register for monthly and quarterly reports. Missed appointment lists can also be abstracted from the paper register, which can identify patients that are lost to care and can be used by community health workers to trace these individuals (Osler et al. 2014). For facilities in Tier 2, data clerks use the electronic register to collect identical information from clinical stationery; in Tier 3, transcription of data is the same but as the system is networked, patient movement can be more easily monitored. The three-tiered approach offers standardization, yet allows facilities to implement the system that is most appropriate to their own capacity. Program management by the facility is the main focus of this system (Osler et al. 2014).



Figure 1: Monthly and quarterly data flow. Monthly and quarterly data flow is similar for paper and electronic register systems. The major difference is the tool that is used by the data clerks to extract information from the clinical stationery – in Tier 1 this is paper register form, and in Tier 2 this is the TIER.Net system. The facility manager sends this to the sub-district as paper forms for Tier 1 or on a memory stick for Tier 2. The rest of the data flow is the same for both systems. In this diagram, days indicate the expected number of days after each monthly reporting period begins.



PILOTING THE SYSTEM

The Western Cape Province in South Africa has been home to numerous demonstration projects related to ART provision (Stinson et al. 2014; Coetzee et al. 2004b). The first of these types of projects began providing ART to adults in May 2001 in Khayelitsha, closely followed by a similar project in Gugulethu in September 2002 (Boulle et al. 2008; Boulle et al. 2010). The study in Khayelitsha enrolled 7,323 ART-naïve adults between 2001 and 2007. After adjusting for individuals that were lost to follow-up, mortality was 20.9% at five years, demonstrating substantial benefit to providing routine ART at the community level (Boulle et al. 2010). Rigorous tracking and monitoring of this high volume of patients was an important part of demonstrating the operational potential of this type of program.

As previously described, this demonstration project served as the inspiration for the development of the 3-Tiered Strategy. The PDoH of the Western Cape implemented the Tier 1 paper registers throughout the Western Cape, which resulted in a baseline of understanding around monitoring and evaluation concepts for cohort data among facility staff (Osler 2014). At the same time, an electronic medical record software called eKapa (Evaluation of the Khayelistsha AIDS Program), developed by MSF and UCT, was being used at a few selected sentinel sites in the Western Cape. From 2004 to 2009, this province's HIV monitoring system was essentially two tiers. This two tier system successfully monitored the full cohort from 2004 until 2008 when paper registers were overburdened by the size of the cohorts accessing ART per facility (Osler et al. 2014). It was clear that an electronic medical record (EMR) system was not feasible for all ART facilities and that a paper register alone would grow too cumbersome as more patients lived longer lives on ART (Osler 2014). The newly developed TIER.net software formed the middle tier.

A 2008 analysis of the Western Cape's monitoring system and outcomes highlighted some of the key strengths and challenges of implementing a paper-based strategy complimented by an EMR system at sentinel sites (Boulle et al. 2008). The study found that the essential dataset and streamlined reporting in this system enabled tracking the performance of individual sites without overburdening sites with



unnecessary data collection activities. The ability to report cohort outcomes with a paper-based system was considered a major success of this program and demonstrated that this basics-first model was feasible (Boulle et al. 2008).

BUILDING SUPPORT

Support for the 3-Tiered Strategy grew as the NDoH searched for new monitoring and evaluation solutions for their burgeoning ART system. The 3-Tiered Strategy was proving to be highly successful in the Western Cape by 2010. Of facilities on the 3-Tiered Strategy, 100% were completing monthly reports, and the majority (87%) were complying with quarterly cohort reports (Osler 2014). The fact that the Western Cape built a foundation for understanding monitoring and evaluation with a paper system was critical to its overall success. In other provinces, disparate software solutions were spreading, as many “computer evangelists” hoped to solve monitoring and evaluation challenges with electronic systems (Osler 2014). No single software proved to be a strong solution, because of a lack of infrastructure, support on the ground, and a “culture of data” that really values accurate data collection and data-driven decision making. Thanks in large part to Boulle’s insistence on grounding the 3-Tiered Strategy with a strong paper system, the Western Cape was able to build an ethic of understanding monitoring and evaluation principles in facilities of all types, regardless of their capacity to support a computer-based system (Osler 2014).

The Global Fund released a new request for proposals in 2009. The University of Cape Town submitted a proposal for financial support for a nationwide ART monitoring and evaluation system (Osler 2014). Around this time, the NDoH was building interest in a monitoring and evaluation system that could be standardized across the country. The NDoH searched for solutions that included both paper and electronic components, calling together a panel of public health, monitoring and evaluation, HIV, and information technology experts to evaluate possible strategies in late 2009. Staff at the NDoH invited key individuals from the PDoH in the Western Cape to discuss the merits and modifications of the paper register with the national HIV team. Simultaneously, the NDoH conducted a survey to identify and score possible software solutions. Then, software solutions that received the top scores had site visit assessments of their system. The ten top-performing systems were then invited to present to a panel of clinicians, IT experts, researchers, program managers, and monitoring staff (Osler 2014).

This process resulted in the selection of eKapa for the third tier, and TIER.Net as the second tier in December 2010, and the 3-Tiered Strategy was announced as the national monitoring and evaluation strategy for HIV with funding provided by the Global Fund for implementation (South Africa NDoH 2011). Standardized clinical stationery to support a standard register system had been officially adopted by the National Health Council (NHC) in May 2010. This clinical stationery is a standardized paper health record at the individual level that was developed during the pilot in the Western Cape, and remains the standard for documenting care in South Africa (Pillay et al. 2012). In March 2011 the NDoH released the Implementation Plan for this strategy (South Africa NDoH 2011; McIntosh 2013). At that time the National Health Information System of South Africa (NHISSA) approved a revision of the ART data elements in the National Income Dynamics Survey (NIDS) to align with the data produced by Tier 1 and Tier 2. These changes went into effect in June 2011 (South Africa NDoH 2011). In April 2012, the DHIS was aligned with the revised data elements as well (White 2014).

Strong political support from Aaron Motsoaledi, Minister of Health, was enormously important to the interest in improving ART monitoring and evaluation systems. After years of AIDS denialism from leadership in South Africa’s ministry of health, the shift in priorities led to a palpable change in spirit



around provision of ART and care for people living with HIV (Hurter 2014). Motsoaledi cultivated a very strong commitment to implement an improved monitoring and evaluation system and to simplify tracking and monitoring of patients. Importantly early in the development stage, implementation teams acquired a letter of support from Motsoaledi and a memo co-signed by the U.S. Agency for International Development (USAID) and the U.S. Centers for Disease Control and Prevention (CDC), which demonstrated their commitment to the new 3-Tiered Strategy (White 2014). As this system moved from development to implementation, these documents proved to be essential in cases where local level providers and implementers were less certain of the approach.

It is important to note that the Western Cape has more financial resources and infrastructure than other provinces in South Africa and also has a lower burden of HIV (Stinson et al. 2014). As such, there is a sense that this province is different than the rest of the country, and there is some concern that the region's results may not be replicable across South Africa (Stinson et al. 2014). In addition, there is a concern that national initiatives are more acceptable to other leadership when they are branded as coming from places other than the Western Cape (Osler 2014). The paper register and clinical stationery are adapted from tools from the WHO. South Africa's 3-Tiered Strategy has been branded as originating from the WHO's *3 by 5 Initiative*, though in reality it was one of three models requested by the WHO team to showcase possible tools to monitor and evaluate ART services (Osler 2014).

IMPLEMENTATION

PLANNING STAGE

The NDoH released a detailed "Tier T1 and T2 ART Monitoring and Evaluation Implementation Plan" in early 2011. This plan was written by a consultant in partnership with the NDoH and lays out a detailed plan, defining responsibilities of funders and in-country partners (White 2014; South Africa NDoH 2011). After the Implementation Plan was released key staff members at the NDoH and supporting PEPFAR partners went on a "roadshow" to give an overview of the new strategy, address any misconceptions about the new systems, and get province- and district-level buy-in early on (White 2014).

The Implementation Plan calls for the development of provincial and district implementation teams (PITs and DITs, respectively) to manage the system's scale-up. The Implementation Plan also details district-level planning activities, which include: organizing engagements within sub-districts, identifying ART providers at the sub-district level, holding a buy-in meeting to provide information about the new system, performing a situational analysis to select the appropriate tier, planning strategy for Tier 1 or Tier 2 implementation, communicating procurement needs to the PIT, identifying a data clerk to manage ART data, identifying an individual from the DIT to conduct training, and creating a formal roll-out plan for the district based on the aforementioned activities (South Africa NDoH 2011). The NDoH, Global Fund, and PEPFAR all financially support the procurement of hardware, human resources, and trainings for this new system (South Africa NDoH 2011).

The Implementation Plan stipulates a facility-level buy-in meeting to be run by the appropriate DIT. The goals of this meeting are standardized in the Implementation Plan released by the NDoH. Unfortunately, buy-in meetings do not consistently occur (White 2014). Securing early buy-in was challenging from partners who had already invested a great deal of time and resources in their own monitoring and evaluation systems, particularly when their own systems were electronic (Osler 2014). For example, Right to Care, a PEPFAR partner, had created software that performed similar functions, including simple data input and reporting. However, this was a commercially owned and developed system with limited



access to the collected data and potentially expensive maintenance fees, making the solution infeasible for the NDoH (Osler 2014). In these cases, having the support of the Minister of Health and USAID was a key leverage point for bringing other ART providers on board with the 3-Tiered Strategy (White 2014). When the initial buy-in meeting does not occur, it is difficult to garner management support at the facility level to effectively implement the new register.

IMPLEMENTING AT A DISTRICT LEVEL

In January 2012, trainings for DIT were established. At the district level, PEPFAR partners played a critical role in supporting the implementation of this strategy. PEPFAR partners (such as Broadreach Health Care, Right to Care, Anova Health Institute, and many others) provided a full-time monitoring and evaluation manager for each of their district to support and drive implementation activities (Osler 2014).

Trainings and supporting materials for the paper register were designed by the University of Cape Town (UCT) in collaboration with the PDoH in the Western Cape. Notably, there are no manuals that accompany the paper register. Instead, instructions on filling out the register are included in the very front of the register, and at the very back there are instructions on how to extract monthly reports and quarterly cohort reports (Franken 2014; South Africa NDoH 2011). Materials for TIER.Net workshops and master training sessions were largely supplied by the UCT team with modifications made for a national context by the NDOH with support from the Clinton Health Access Initiative (CHAI) (Osler 2014, White 2014). These trainings were provided to two key facility-level staff per district at the beginning of the implementation stage and PowerPoint “training decks” concerning all aspects of the system’s use were provided through an online portal (Osler 2014; White 2014). These decks can be easily accessed by DITs and be modified for internal trainings for staff, including data capturers, facility managers, or others who may come in contact with the system (Osler 2014). There is an initiative to incorporate some of these training materials into a pre-service toolkit for data capturers, making it part of their job training. This effort was initiated in 2013 and is still underway (White 2014).

The NDoH is responsible for supplying clinical stationery and registers for provinces, who are then responsible for distributing materials to their districts (South Africa NDoH 2011). When the 3-Tiered Strategy was initiated in 2011, the NDoH did one large print of all the clinical stationery and registers and shipped them via trucks to the districts. This was important in getting everything started right away but may have taken some of the ownership away from the provinces, who would subsequently be responsible for this supply chain (Osler 2014). It is recommended that facilities always have at least two months of clinical stationery (and paper registers, if they are a Tier 1 facility) on hand. It is the responsibility of the facility-level information officer to report low stock of registers to their district, when required. Anecdotally, it seems that this system has worked well in the Western Cape, but in some other provinces there is evidence that stationery and registers are not always in supply (Osler 2014).

The back-capture process was an especially lengthy part of the implementation of the 3-Tiered Strategy (White 2014; Hurter 2014). Because this register relies on longitudinal, cohort-based data, back-capturing data on patients that are continuing ART care into the new register system has been critical for properly tracking patient history. Throughout the pilot in the Western Cape, back-capture of data into any tier of the 3-Tiered System involved systematically recording data from every single patient folder (Osler 2014). This strategy would not be feasible at the national level where ten years of free ART service data needed to be captured. As the other provinces did not implement paper registers at the start of the free ART services, they had back-capture from past systems, which often included handwritten clinical notes. Capturing data from ten years of hand-written notes would have been too overwhelming to implement. To reduce this burden, the recommended national scale-up strategy



suggests that data-capturers open a patient folder, capture their baseline ART visit, and then check the patient's current information. If the treatment regimen is the same, it is safe to assume that the individual has stayed on the same regimen from baseline to present. Therefore, data-capturers can indicate the same regimen for each month, without having to review multiple pages of notes. This adjustment decreased back-capture time from 10-40 minutes per patient to about 5 minutes per patient (Osler et al. 2014).

PRELIMINARY EVALUATION OF IMPLEMENTATION

The 3-Tiered Strategy is still deeply entrenched in its implementation stage and efforts have been focused on the logistics of setting up this system. These efforts have been monitored by dedicated NDoH staff and supported by staff at CHAI and implementing PEPFAR partners (White 2014; McIntosh 2013). Indicators monitored include counts of facilities implementing each system, stage in the implementation process, amount of time spent in back-capture, and other programmatic indicators (White 2014; McIntosh 2013). As of March 2014, only 65 facilities in South Africa are using non-standard systems (systems fully outside of the 3-Tiered Strategy); of these, just 11 facilities in the country are unable to report their data to DHIS in the standard form. About 835 facilities in South Africa use the paper register as part of Tier 1. Tier 2 of the system has been fully implemented in 1,408 facilities, with 1,352 facilities in the process of back-capturing data toward full implementation of TIER.Net. There are 12 facilities in Tier 3 (White 2014).

In 2013, PEPFAR funded a conference to foster dialogue around the ways that facility managers can use data to improve care and programming (Murphy et al. 2013). This conference included 160 delegates from districts across the country and highlighted the importance of data completeness, quality, and ownership. This conference was focused on TIER.Net, not the paper component of the register system, though many of the main messages are applicable to both systems (Murphy et al. 2013).

Some quality improvement and routine data use has been occurring at the district level. For example, PEPFAR partners and PDoH colleagues in the Cape Winelands district discovered that facilities in the district had initiated ART in more under-2-year-olds than had been offered PMTCT services, simply using routine data collected (Murphy et al. 2013). Data from the register is used to track individuals that are "lost to care," that is, people who do not maintain their clinical appointments or fall out of contact with their health facility. This is an important function of the register system. Anecdotally, it appears that most facilities are not currently using information generated by the 3-Tiered Strategy to make decisions as much as had been hoped (Hurter 2014). A culture of using data from the register system for other facility-level decisions is still being developed.

It appears that this register system lessens the time burden on clinical staff and data clerks, in comparison with the old disparate systems (Hurter 2014). However, this is only the case in facilities where the new system has truly replaced older, non-standard systems. There are a few facilities across the country that are not exclusively using the 3-Tiered approach. For these facilities, it is likely that this strategy increases the time burden on staff simply because it is adding to their workload without replacing the data collection activities for which they are already responsible (White 2014).

Experts suggest that it is normal for a new monitoring and evaluation system to focus on logistics and implementation for a few years, before shifting focus to monitoring and support improvements in data quality. This particular system also took some time to implement in the Western Cape. The paper registers were developed by 2004, and the TIER.Net system's HIV module was fully developed by late 2010 and is currently fully implemented throughout the province. Yet efforts only shifted toward



evaluating data quality and the impact of the system in late 2013 (Osler 2014). Implementing a system of this scale requires a great deal of resources, so evaluation is realistically not a top priority early in implementation.

A few studies have been undertaken to evaluate the effect this strategy has had on data quality in the Western Cape, but results from these studies are not yet available as of March 2014 (Hurter 2014).

LOOKING AHEAD

MAINTAINING SUPPORT FROM KEY STAKEHOLDERS

Once the 3-Tiered Strategy is fully scaled to the national level, maintaining political, financial, and human resource support for this system will be critical to its ongoing success. The goal is to move all facilities to Tier 2, the non-networked electronic system, in the near future (White 2014).

A 3-Tiered Technical Working Group was established later in the implementation process to better engage leadership from national partners, including members from NDoH, CHAI, UCT/CIDER, and Western Cape DoH (Franken 2014). This group was brought together for the first time in 2013, and continues to meet to discuss challenges and solutions to support this strategy. The 3-Tiered Strategy is currently led by two monitoring and evaluation staff at the NDoH, supported by Catherine White at CHAI (White 2014).

The Global Fund's grant to support the 3-Tiered Strategy will be in effect until 2015. A costing analysis was recently completed to assess the potential costs of maintaining this system after the Global Fund's support is no longer in place. Preliminary costing assessments by the TIER.Net Costing Calculator suggest that the cost of consumables and maintenance trainings will be around 15 million Rand per year (about \$1.4 million USD). This estimate does not include staff salaries required to support the system (White 2014).

PEPFAR partners will continue to be invaluable in the support of the implementation of this strategy at the district level – particularly as the system matures and moves toward assessing data quality, using data from the system to drive decision making, and supporting system updates. Key informants have indicated that the presence of a workplace culture that encourages data collection, reporting, and use greatly improves the sustainability of a register. In South Africa, this “culture of data” is growing, and implementation teams are working very hard to foster this by training managers and district staff to utilize data generated by the registers to inform their work (White 2014).

ONGOING MONITORING AND EVALUATION

Monitoring and evaluation strategies are in development in preparation for the longer-term maintenance of this system. Tools that have already been developed include a standard audit tool to evaluate data quality, as well as guidelines for district monitoring forums to discuss more qualitative needs of the register. The responsibilities of the provincial and district implementation teams are gradually shifting away from implementation activities and toward ongoing monitoring and evaluation activities, to focus on optimizing the utility of the system. These teams will be responsible for utilizing monitoring tools and communicating the importance of this data back to the facilities (White 2014).

The standard audit tool was internally developed as part of the register system and is to be implemented by district-level supervisors on a quarterly or biannual basis. The main function of the



audit tool is to assess whether information from the clinical stationery is correctly captured in the registers and the DHIS. Though the tool has been introduced to facilities in the implementation stage, most facilities have not yet begun to implement standard audits in a systematic way.

Preliminary results from facilities that have used the audit tool show it is already identifying areas for improvement. Meg Osler notes that, in the audits she has been a part of in the Western Cape, data capturers nearly always receive a score in the mid-90s out of 100, indicating that they do an excellent job transcribing data and make very few mistakes. In comparison, clinicians receive average scores in the low 80s out of 100 when evaluated for how well they fill out the patient clinical record. These results indicate that data that are available are transcribed well in TIER.Net and the paper registers but may not be complete or accurate because of how the clinicians are filling out the patient records. These audits led to the development and implementation of record keeping trainings for clinicians (Osler 2014). In contrast, audits in Mopani, Limpopo Province showed wide variation and disagreement between each of the three data points (the register, facility report, and the DHIS). When these results were shared at the 2013 conference on data quality, attendees from other districts confirmed that these patterns were consistent with their own experiences (Murphy et al. 2013). These differing experiences show that the audit is likely capturing some real challenges faced by the register system. The audits have been implemented sporadically thus far, but once this register system enters the maintenance phase in earnest, these will be performed regularly (White 2014).

Guidelines have also been internally developed for district monitoring forums, in which district-level staff and leadership gather regularly to discuss their experiences with the register system and their data. A major goal of these forums is to encourage a “culture of data.” A sample forum agenda includes semi-structured discussions around both monthly and quarterly data (White 2014). These discussions are intended to engage leadership from facilities across the district in exploring the data, looking for variance among facilities, discussing challenges with data quality or system management, and sharing experiences. Early forums held based on this agenda identified challenges such as high numbers of defaulters and an inability to trace patients due to a lack of community support staff. The forums also found that some facility managers were unaware of the reporting abilities of the system (White 2014). Broad implementation of these forums is expected to occur in 2014 (White 2014). These forums will not be unique to the paper-based system and will continue as facilities move toward Tier 2.

UPDATING THE SYSTEM

The Tiered Patient Monitoring System recommended by the WHO includes TB and Maternal Child Health (MCH) monitoring in addition to ART. There is a move underway to integrate the ART clinical stationery with TB stationery and with broader chronic disease stationery in South Africa (Franken 2014). The Tiered ART Monitoring Strategy began piloting an expansion to include TB monitoring in March 2014 (White 2014; Hurter 2014). Notably, this integration is planned to apply only to TIER.Net – Tier 1 facilities that use the paper register will be transitioned to the electronic system and integration with TB registers will only occur with TIER.Net (Franken 2014). There is no plan to use a fully paper-based system to integrate TB data into the system.

It is hoped that the infrastructure built around the ART monitoring system, particularly human resources such as engaged DITs and well-trained data capturers, will facilitate this update. However, it is anticipated that updating the system to include a TB component will be challenging (Hurter 2014). The current TB register is a four-page paper register filled out by nurses, which includes a page that is torn off and sent to the sub-district level for reporting. Nurses have taken ownership of this system and feel responsible for this data collection. Under the new system nurses would record TB data from patient



encounters in the standard paper clinical stationery, but responsibility for collating the data would move to data capturers. It is anticipated that nurses will be resistant to this change and that this shift in responsibilities may not be well-received (Hurter 2014; White 2014).

LESSONS LEARNED

The 3-Tiered ART Monitoring Strategy in South Africa offers an example of a system that standardizes indicators while maintaining some flexibility of reporting platform to account for variation in facility capacity. This case study highlights key challenges and solutions in the implementation stage of a register's life cycle. This register strategy aligns with the WHO's recommended Tiered Patient Monitoring System; lessons learned from this case could be applied to any country seeking to implement this system.

IDENTIFYING STRENGTHS

This is the first cohort-based tracking of ART data at this scale in South Africa – a huge achievement.

These paper registers represent South Africa's first effort to track cohort-based data on a large scale, which is an enormous undertaking (Osler 2014). This proved very challenging as there is generally a major gap in understanding what cohorts are and how to interpret cohort data. In practice, the quarterly cohort reporting from the paper registers has only been fully implemented in the Western Cape and has yet to take hold in other provinces (Franken 2014). However, the fact that a cohort-based paper system was at all successful is considered a great achievement.

Key “change agents” were in positions of influence and able to develop and support this innovation.

Expert interviews revealed that the development and success of the 3-Tiered Patient Monitoring Strategy in South Africa was greatly influenced by a few key “change agents,” at various stages of the system's design and implementation. These individuals were particularly innovative and strategic and were highly invested in the success of this system. Their work catalyzed the momentum and success of project and continues to be a major factor in the ongoing support of this work.

Near-universal roll-out is occurring quickly. Universal adoption has occurred, though the implementation process has been lengthy (White 2014). This roll-out process is addressing the problems of numerous non-standardized registers (mostly handwritten counters or tally books), and inconsistent, unreliable, and incomplete monthly data (Franken 2014). As of March 2014, all facilities that have fully implemented TIER.Net consistently report data. This high level of adoption is due to concerted efforts of the NDoH, PEPFAR partners, and key change agents who support this system (White 2014). Facilities that are still in process do not yet report regularly.

The paper registers paved the way for electronic systems. Implementation of the paper registers set the stage for the rollout of the TIER.Net, both in terms of the relationship-building between NDoH and partners as well as laying the foundation of more reliable patient-level data and buy-in for standardized systems (Franken 2014).



IDENTIFYING CHALLENGES

Back-capture took a very long time with the paper system. Because this system is cohort-based, capturing retrospective data into the system is critical to its accuracy and utility. Unfortunately this is very time consuming with a fully paper register system. The back-capture process is slightly more automated with TIER.Net and does not take nearly as much time (Hurter 2014). However, some facilities that cannot yet support an electronic system will still have to undergo the time-consuming exercise of paper back-capture.

The lengthy back-capture time has been slightly mitigated by encouraging data capturers to streamline the process by matching baseline ART regimens to current ART regimens. Key informants indicate that the back-capture stage is very important to the value of the paper register system; it gives data capturers a familiarity with the register and builds the cohort-style record. Though this stage can be made more efficient, it should not be eliminated.

Clinical stationery is not always properly filled out. Numerous expert interviews revealed that one of the biggest challenges with this register system is that health workers are not filling out paper clinical stationery properly, which makes accurate data capture impossible (Hurter 2014; Franken 2014). In addition, anecdotal evidence and results of early audits from the Western Cape suggest that poor clinical recordkeeping is one of the greatest barriers to data quality (Osler 2014; Hurter 2014; White 2014).

In the South African context, there are many new health providers (doctors and nurses) cycling through all the time, so even with frequent training not everyone is trained on the current stationery (Hurter 2014). It is not currently part of medical training for doctors, though individuals on the ground acknowledge that it should be (White 2014). The results of recent audits in the Western Cape that showed poor clinician recordkeeping have been leveraged to develop and implement trainings for clinical record keeping (Osler 2014).

Human resources are not sufficient to support the system. Results from key informant interviews suggest that a lack of sufficient human resources (data capturers and dedicated staff for the DITs and PITs) has negatively impacted implementation, and may continue to constrain the effectiveness of this system in the maintenance stage (White 2014). Having dedicated staff to support this system is critical, especially during time-consuming activities such as training data capturers and performing back-capture.

In addition to challenges with the quantity of human resources, quality of human resources is also a major challenge for this register system. Anecdotally there is concern that data capturers in particular have poor job performance, though results from the few internal audits that have been conducted suggest otherwise (Franken 2014; Osler 2014). There are high-performing individuals in a few facilities, but by and large there is a problem with poor workplace motivation and poor accountability within facilities (Franken 2014).

Replacing systems that already exist has proven to be very difficult. There has been some resistance to implementing yet another monitoring system, especially in facilities that have strong attachments to their own system (White 2014). Garnering support for replacing these disparate register systems is perhaps the greatest challenge faced by this system. Effective training and smooth implementation will encourage uptake of the new register system at the facility level. Catherine White notes that in some facilities, securing buy-in for the new system has been unsuccessful:



“Because of the nature of ART programs in South Africa, there are a number of facilities where they use a non-standard monitoring system. It is more difficult to convince people to switch where a lot of money has been invested in a non-standard system. They don’t want to let it go. If these facilities are very politically connected, they’ve been able to sway that province’s receptiveness of the 3-Tiered Strategy. It’s a real challenge,” (White 2014).

Theunis Hurter, Monitoring and Evaluation Manager at Anova Health Institute in Cape Winelands, reports that in Cape Winelands the new system has fully replaced “unofficial” registers, but that some other districts use their own reporting systems. In particular, he notes that PEPFAR-funded programs often report using a separate system. The timing of PEPFAR reporting was not aligned with the timing of national reporting with the 3-Tiered Strategy until early 2014; it is hoped that now that PEPFAR is on the same reporting schedule, the national system will be used for reporting and old PEPFAR reporting systems will be abandoned (Hurter 2014).

Resources are being diverted from the paper system to TIER.Net. The paper register was rolled out alongside many sites that were implementing the non-networked electronic tier (TIER.Net). Barbara Franken, Monitoring and Evaluation Specialist at Right to Care, says:

“Once TIER.Net roll-out started, it was considered by almost everyone (NDoH and partners) as more ‘sexy’ and almost all the resources – training, mentoring, data quality checks, computer equipment – started flowing into the TIER.Net rollout, whilst the paper register started being neglected. It started being seen as a ‘temporary’ tool for sites that were due to TIER.Net conversion... The success and attractiveness of TIER.Net seems to be the unraveling of the paper register,” (Franken 2014).

Many view the paper register as a mere step in the process toward an electronic system, for facilities where implementing Tier 2 or 3 was not an option, paper was an added value that resulted in consistent data collection in all ART facilities.

KEY LESSONS

Collecting a minimum dataset made the register system much more efficient. Previous to the 3-Tiered ART Monitoring Strategy in South Africa, 144 different indicators related to ART were required for reporting, with no standards for how to collect and report these indicators. By contrast, the new 3-Tiered Strategy only collects six monthly data elements and 27 quarterly indicators. This change alone greatly reduced the time and administrative burden of the system.

Workforce capacity is a critical determinant of the success of a new register system. In this case study, the implementation plan included well-defined plans for staffing roles. In order to support the rollout of this strategy, PEPFAR partners were utilized with each district to supplement the capacity of health workers in the public sector. The collaborative efforts of the NDoH, PEPFAR partners, and CHAI have greatly strengthened this system.

Back-capture of historical data into the paper register systems was a particularly time-consuming task. This case study demonstrates that one full-time staff member and one part-time staff member in each district was the minimum acceptable to complete this task in a timely manner. Back-capture was streamlined a bit for the non-networked electronic tier (Tier 2) as key information could automatically populate the electronic form. However, a significant time investment was still required, and the electronic system will not be acceptable in all contexts. Staff members with early roles in back-capture of data and setting up infrastructure for the system are now shifting their responsibilities toward reporting and assessing data quality and encouraging use of the data within facilities. This task shifting



was very intentional, aiming to reduce turnover and keep well-trained staff in contact with the register system.

The quality of the workforce is as important as the quantity of staff members. It is hoped that tools such as the standard audit and the district monitoring forums will encourage accountability at all levels.

Political support at the highest level facilitates rapid roll-out and reduces resistance to a changing system. Key informant interviews revealed that one of the most critical reasons for the rapid adoption of the 3-Tiered Strategy at a national level was display of high-level political support, via the Deputy Director General, Dr Yogan Pillay and the memorandum from USAID and the CDC. These pieces were leveraged in conversations with provinces and districts, and were especially critical for those that were reluctant to accept the new system.

This support will continue to be important as the system moves toward its maintenance phase. The 3-Tiered Strategy is now the national standard, and its success will be dependent on its leaders continuing to support its growth and optimization. South African leadership invested in identifying a homegrown solution to its data challenges and the results will pay off with continued engagement.



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3. CLINICAL ASSESSMENT: FIRST VISIT AT THIS CLINIC

Use this section during your patient's first encounter with HIV / ART services to help decide whether they need HIV or ART care

Presents from: TB clinic / PMTCT / VCT / GP / other ART clinic / primary care clinic / in-patient / correctional / work / other

WHO CLINICAL STAGING:

If your patient has, **OR HAS EVER HAD**, any of the illnesses below, and none in stage 4, and a CD4 count > 200, they need HIV care

If your patient has, **OR HAS EVER HAD**, any of the illnesses below, or their CD4 count is < 200, they need HAART

Clinical Features		Date	Clinical Features		Date
WHO Stage 1	Persistent generalised lymphadenopathy		WHO Stage 4 Severe disease (AIDS)	Herpes simplex virus lesions > 1 month	
	Other:			Oesophageal candidiasis	
WHO Stage 2	Weight loss <10% body weight			Pneumocystis jiroveci (formerly PCP)	
	Minor mucocutaneous conditions			Kaposi's sarcoma	
	Recurrent URTI			HIV wasting syndrome	
	Uncomplicated herpes zoster			HIV encephalopathy	
	Other:			Recurrent pneumonia	
WHO Stage 3 Moderate disease	Weight loss >10% body weight			Cytomegalovirus	
	Diarrhoea > 1 month			Isosporiasis / Cryptosporidiosis	
	Oral candidiasis			Bedridden > 50% / day for most of last month	
	Severe bacterial infections including Pneumonia		Cryptococcal meningitis		
	Oral hairy leukoplakia		Cervical cancer		
	Prolonged fever		Lymphoma		
	Bedridden < 50% / day for most of last month		Extra-pulmonary TB		
	Pulmonary TB (current or in the last year) *		Clients with MDR/XDR-TB irrespective of CD4 count or		
	Other:		*Clients with CD4<350cells/mm3 who have TB/HIV or who are pregnant		
	Other:		CD4 result		

REPRODUCTIVE HEALTH

Pregnant	Y / N	Trimester	1	2	3	Grav	Para	Date:
Contraception:	Date last used:							
none / condom / injection / pill / other								
Signs and symptoms of STI today?	1) Urethral discharge / dysuria Y / N	2) Vaginal discharge Y / N	3) Genital ulcers Y / N	4) Y / N	5) Lower abdominal pain Y / N	RPR (date)	Result	Treatment completed Y / N

TUBERCULOSIS SCREEN

Ever had TB before?	Y / N	If YES	Year	tra-pulmonary or pulmonary	Treatment outcomes	
Current TB	Y / N	Pulmonary or extra-pulmonary				
TB symptoms today	1) Cough > 2 w ks Y / N	2) Weight loss Y / N	3) Fever Y / N	4) Night sweats Y / N	5) Haemoptysis Y / N	6) Fatigue Y / N
Smear date		Culture / sensitivity date		Clinical indication of TB Y / N		
Result		Result				

NUTRITIONAL SCREEN (Note: if BMI is less than 18.5 must refer to dietician and nutritional programme)

Date of assessment:	/ /	A. Weight: (kg)	B. Height (meters)	C. BMI = $\frac{\text{Weight (A)}}{\text{Height (B)} \times \text{Height (B)}}$
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HISTORY AND EXAMINATION:

Temperature:		PLAN: CD4 > 200 AND stage 1-3 (except TB) <input type="checkbox"/> CD4 < 350 AND TB or Pregnant <input type="checkbox"/> CD4 < 200 OR stage 4 <input type="checkbox"/> Cotrimoxazole Fluconazole Other:
Heart Rate:		
Blood Pressure:		
Respiratory Rate:		

Screened for IPT:	Y / N	Qualifies for IPT	Y / N	Started IPT	Y / N
Date:		Date:		Date:	
Screened for cotrimoxazole:	Y / N	Already on cotrimoxazole	Y / N	Qualifies / started	Y / N
Date:		Date:		Date:	
Screened for other / fluconazole	Y / N	Already on other / fluconazole	Y / N	Qualifies / started	Y / N
Date:		Date:		Date:	

Print name: _____ Signature: _____ Date: / /



4. CLINICAL EVALUATIONS FOR HAART OR TO RE-START HAART

If HAART is indicated for your patient, use this section to help decide whether there are any medical contra-indications to starting

PRIOR HAART HISTORY

If your patient has ever had previous HAART, detail the period when taken, treatment changes and the reasons they stopped treatment:

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BASELINE SAFETY BLOODS

Test	Date	Result	Other tests	Date	Result	Notes
ALT			Creatinine Clearance			
Haemoglobin						
CD4						

TB WORK-UP

Symptoms suspicious of TB?	Y	N	If YES: Perform TB work-up, record results in visit summary sheet
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NUTRITIONAL ASSESSMENT

Symptoms Nausea / Vomiting / Diarrhoea / Severe loss of weight / Difficulty swallowing	Baseline BMI
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CLINICAL NOTES

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CLINICAL FACTORS INFLUENCING REGIMEN CHOICE

1. On TB treatment? Y / N	5. Has had more than 1 month of HAART? (excluding PMTCT or PEP) Y / N	PLAN: ARV 1 ARV 2 ARV 3 Cotrimoxazole Fluconazole IPT
2. Pregnant? Y / N	6. BMI > 27.5 Y / N	
3. Has severe peripheral neuropathy? Y / N	7. Other Y / N	
4. Has a history of psychiatric illness? Y / N	8. Other Y / N	

COMMENCING HAART

Psychosocial readiness (see section 7) Y / N	Clinically ready
Regimen factors (clinical factors influencing choice) Y / N	Regimen

ASSESSMENT OF OVERALL READINESS FOR HAART

Signature:	Date: / /
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