

**DEVELOPING A LABORATORY BASED CCMT PROGRAMME STATUS
REPORTING SYSTEM IN THE EKURHULENI HEALTH DISTRICT**

By

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Submitted in fulfilment of the requirements for the degree of

Master of Public Health with specialisation in Medical Informatics

at the

University of South Africa

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November 2013

DEDICATION

I dedicate this dissertation to my late parents Fatima Jassat and Abdool Hay Cassim, my dear wife Zarina Khan and our sons Muhammed Rashaad and Rameez Cassim.

DECLARATION

Student number: 0-641-867-8

I declare that DEVELOPING A LABORATORY BASED CCMT PROGRAMME
STATUS REPORTING SYSTEM IN THE EKURHULENI HEALTH DISTRICT is my
own work and that all the sources that I have used or quoted have been indicated
and acknowledged by means of complete references.



SIGNATURE

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22/11/2013
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ACKNOWLEDGEMENTS

I want to convey my gratitude to the following persons for their respective contributions to this dissertation:

- A special thank you to my supervisor Prof. D.K. Glencross, for her continued guidance, support and encouragement.
- Dr. Lindi Coetzee in the National Priority Programme Unit for her willingness to edit the various versions of this dissertation and her support to keep persevering.
- Mr. Clive Moody who kept motivating me to register for a master's degree.
- Mr. Bahule Motlonye the NHLS Business Manager of the laboratories where the study took place.
- The Gauteng Province: Department of Health for granting permission to conduct the study. In particular, I would like to thank Nobantu Mpela for her continued support of the study and Dr. Zuki Pinini for her assistance with the Gauteng DOH Research Committee application.
- Clinicians and nursing staff in the Ekurhuleni Health District for participating in the study. In particular, I would like to thank Sr. Zulu at Tambo Memorial, Sr. Gumede at Far East Rand and Sr. Ramalepe at Tembisa.
- The laboratory staff at the three sites including amongst others Rene Cooks (laboratory manager at Tambo Memorial), Sello Matsho (laboratory manager at Tembisa) and Mapaseka Mnisi (acting laboratory manager at Far East Rand)
- To my aunt, Ms. Sabera Jassat, a retired educator for her critical and keen eye for detail.
- The phlebotomists at the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) blood Room for the pre-testing. In particular I would like to thank Sr. Lilly Matsetse who manages the phlebotomists at CMJAH.
- Mr. Danzil Poonen from Forms Media that generously printed the request forms as part of a social development programme for health upliftment (refer to Addendum G). I would also like to thank Mr. Sam Jainarain for his assistance with the procurement of the request forms.

- The team involved in the development of the new NHLS request forms that included the new CCMT request form, especially Dr. Helena Vreede, who led this project.
- The IT support team that created the test methods to capture the CCMT programme status information and ensured that they were available at the three study sites. In particular I would like to thank Mr. Floyd Olsen from the National Priority Programme (NPP) Unit and Ms. Happy Mashigo from the NHLS IT Department.
- The Corporate Data Warehouse team for extracting the data required for the study.

PUBLICATIONS OR PRESENTATIONS

The findings of this study were disseminated to the Gauteng provincial CCMT unit and to the study sites where the hospital management and staff involved in the study were present. Presentations were done at the study sites as follows: -

- Tambo Memorial: 1st and 26th of March 2013
- Tembisa: 6th of March 2013
- Far East Rand: 1st of March 2013

Additionally the findings of this study was presented at the 14th World Congress on Medical and Health Informatics (MEDINFO 2013) conference in Copenhagen (Cassim, Coetzee, Motlonye, Mpele and Glencross 2013:1).

DEVELOPING A LABORATORY BASED CCMT PROGRAMME STATUS REPORTING SYSTEM IN THE EKURHULENI HEALTH DISTRICT

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ABSTRACT

The purpose of this study was to develop a laboratory based Comprehensive Care, Management and Treatment of HIV and AIDS (CCMT) programme status reporting system using a methodological research study design. Quantitative data was collected using a request form and qualitative data was collected using structured questionnaires. For the study 1190 eligible CD4 samples were received, of which 1004 (84%) had a valid CCMT programme status. Overall 32% of the CD4 samples had a pre-ART status (n=383) and 52% had an ART status (n=621). The remaining 16% of CD4 samples (n=186) did not have a valid CCMT programme status. A pre-ART register was generated and assessed using a structured questionnaire. Based on the study findings a recommendation has been made to adopt the two-tick design for all NHLS request forms where programmatic data is collected. Additionally the CCMT programme status reporting system is recommended for rollout to other health districts.

KEY CONCEPTS

CD4 count; monitoring and evaluation; comprehensive care, management and treatment of HIV and AIDS (CCMT) programme; laboratory register; programme status; pre-ART register; laboratory request form; laboratory management information system; antiretroviral therapy; indicator.

ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
CCMT	Comprehensive Care, Management and Treatment of HIV and AIDS
CDW	Corporate Data Warehouse
CEO	Chief Operating Officer
CHW	Community health care worker
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
DHIS	District Health Information System
EDR	Electronic Drug Resistance System
HER	Electronic Health Record
ETL	Extraction, Transformation and Loading
HCW	Health care worker
HIPAA	Health Insurance Portability and Accountability Act
HIS	Health Information System
HIV	Human Immunodeficiency Virus
HCT	HIV/ AIDS voluntary counselling and testing
HL7	Health Level Seven
HOD	Heads of Department
ICD	International Statistical Classification of Diseases and Related Health Problems
ICT	Information and Communications Technology

LIMS	Laboratory Information Management System
MDB	Municipal Demarcation Board
MPI	Master Patient Index
NHLS	National Health Laboratory Service
NDOH	National Department of Health
NHC	National Health Council
NHII	National Health Information Infrastructure
NHMIS	National Health Management Information System
NHIN	National Health Information Network
NIMART	Nurse-initiated and managed antiretroviral treatment
NSP	HIV & AIDS and STI Strategic Plan for South Africa
PMTCT	Prevention of Mother to Child Transmission
PRE-ART	Pre-Antiretroviral Therapy
PRISM	Practical, Robust Implementation and Sustainability Model
QAD	Quality Assurance Department
RTC	Regional Training Centre
SANAC	South African National AIDS Council
STI	Sexually Transmitted Infection
TB	Tuberculosis
VCT	Voluntary counselling and testing
WHO	World Health Organisation

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CHAPTER 1: ORIENTATION TO THE STUDY

Human Immunodeficiency Virus (HIV) infection and Acquired Immune Deficiency Syndrome (AIDS) are one of the main public health challenges facing South Africa. It is estimated that of the 33.3 million people living with HIV worldwide in 2009, 67% are from Sub-Saharan Africa (22.5 million), of which 25% (5.3 million or 11% of the SA population) reside in South Africa (Rehle, Hallett, Shisana, Pillay-van Wyk, Zuma, Carrara and Jooste 2010:1).

In 2003 the South African government initiated the Comprehensive Care, Management and Treatment of HIV and AIDS (CCMT) programme. The National Department of Health (NDOH) outlined its plans to extend the HIV & AIDS and STI Strategic Plan for South Africa 2007-2011 (NSP) (NDOH 2009:10) in 2007. The primary aim of the NSP was to reduce HIV incidence by 50% and to expand access to treatment, care and support to 80% of people who need it by 2011 and beyond (Rehle et al 2010:1).

In April 2010, to strengthen its response to the HIV epidemic, the NDOH launched an HIV Counselling and Testing (HCT) Campaign that aimed to test 15 million individuals by July 2011 (SANAC 2011). The objectives of the HCT campaign are to mobilise the South African population to know their HIV status, provide key prevention messages to promote healthy lifestyle choices irrespective of HIV status, increase the incidence of health seeking behaviour, and to increase access to treatment, care and support (Red Ribbon 2011). By December 2012, the DHIS reported that 2 million people were enrolled on ART in South Africa (Magoro 2013).

Indicators were developed to manage and generate reports on the roll out of ART in South Africa for the monitoring and evaluation (M&E) of the CCMT programme. These included the proportion of patients starting ART with a CD4 below 50 and the number of CD4 tests performed pre-ART as a percentage of HIV infected patients (NDOH 2009:113) The introduction of the Monitoring & Evaluation Framework for the NSP (NDOH 2009:105) further strengthened HIV M&E efforts. Specific M&E indicators have subsequently been routinely collected using a combination of a paper based (at facility

level) and aggregate reporting (at health district level) using the District Health Information System (DHIS). Despite the presence of electronic systems existing at facility level, data is not integrated into a national M&E reporting system. Sites using paper based data systems are even more difficult to manage as data completion is erratic with low data completion rates despite efforts to provide training (Garrib, Stoops, McKenzie, Dlamini, Govender, Rohde and Herbst 2008:550). There is no recorded formal NDOH database with ART enrolment data or patient follow-up records. Only limited data sources are available to correlate the data collected by the paper-based pre-ART registers e.g. the ART enrolment numbers related to the supply of ART medicines for examples.

According to Rosen and Fox (2011:7), in Sub-Saharan Africa, a median of 55% of patients that had a positive HIV test reached the study endpoint, which consisted of a repeat CD4 count, ART initiation, 12 month follow-up visit or data censoring. This study emphasized the importance of reporting tools to assist facility managers to identify potential pre-ART loss to follow-up. The high pre-ART loss to follow-up during CD4 screening poses a major programmatic challenge that could be addressed with improved pre-ART M&E reporting and programmatic interventions.

The National Health Laboratory Service (NHLS) developed a national database of laboratory results which has indirectly provided valuable information about the numbers of patients accessing the CCMT programme in South Africa. This is possible because each NHLS CD4 laboratory has a Laboratory Information Management System (LIMS) enabling capture of patient demographics, details of referring health facility and CD4 results. The LIMS at each laboratory replicates this information daily to the Corporate Data Warehouse (CDW) which is based at the NHLS corporate head office. This stored data currently provides the NDOH with specimen level laboratory data for the CCMT programme. However, CD4 laboratory records do not differentiate between CD4 testing performed at the time of HIV Voluntary counselling and testing (HCT) /pre-ART screening versus those same CD4 tests that are used to monitor patients already enrolled on ART. The ability to track individual patients, who are accessing HIV care for the first time versus those who are subsequently followed on wellness programmes or enrolled onto ART, would provide a valuable tool to review numbers of new patients accessing the public health care system, a means to provide

some information about loss to follow-up and give an indirect indication about programmatic performance.

Unfortunately the absence of unique patient identifiers (a unique number or code which would identify a single patient irrespective of where the patient presented him/herself for counselling or treatment) in the existing NDOH system makes identification of patient programme status and longitudinal review difficult.

Therefore, in the absence of such unique patient identifiers, this research study aims to establish a system whereby patients CD4 results can be identified as first or subsequent-visit CD4 counts linked to patient samples. Information including clinical data about the patients status in the CCMT programme on the laboratory request form would be invaluable e.g. HCT, first ever CD4 count, not yet on ARV's and on ART, will be collected on the LIMS, with the CD4 count, and accessible for data review within the CDW.

The aim of this report was to develop a system to characterise CD4 as described above. To achieve the objectives of this research study, the CCMT programme status information was incorporated into the laboratory request form linked to request for CD4 enumeration, with training provided to both health care workers (on how to complete the request forms) and laboratory data capturers (on the capture of the programme status information on the LIMS). Specific capture fields were set up on the LIMS to facilitate easy data capture of the CCMT programme status. Throughout the project, regular follow-up visits and feedback sessions with the health facilities and laboratories were conducted to ensure data quality. Data was extracted from the CDW and analysed using Excel and Stata software. To protect the identity of patients, patient identifiers were not included for the study.

1.1 Research problem

The absence of a national electronic HIV M&E system to monitor CD4 patient data characterised according to their pre-ART and ART status in the CCMT Programme prevents the NDOH from monitoring the impact of their HCT campaigns. A system is

needed which will facilitate monitoring number of patients accessing the system for the first time versus those enrolling onto ART or during follow-up. Meaningful analysis of this data will facilitate the analysis of CD4 data for both patients accessing the HCT campaign and those already enrolled in ART care (wellness programs or treatment).

1.1.1 The source of the research problem

No national M&E data system currently exists to monitor CD4 data for patients in the pre-ART and ART components of the CCMT Programme. While CD4 laboratory data is reported, the ability to report the data by CCMT Programme Status is not available.

1.2 Background to the research problem

The initiatives of the CCMT Programme have led to increased access to ART in South Africa. The rapid scale up of ART provision in South Africa resulted in two million HIV infected individuals being placed on ART by December 2012 (Magoro 2013). Despite the large scale HIV testing campaign initiated in 2010 to accelerate HIV diagnosis, as well as raising the CD4 treatment eligibility to 350 cells/ μ l, patients are still presenting at a very late stage of their illness for ART initiation (Rosen and Fox 2011:2). A local study utilising HIV treatment and care programme data, reported a median CD4 cell count 263 cells/ μ l at first presentation and 145 cells/ μ l prior to ART initiation (Lessells, Mutevedzi, Cooke, and Newell 2011:79). Another local study, conducted in the rural uMkhanyakude district, longitudinal population-based HIV and health surveillance was conducted to assess the variability of CD4 counts in the general population. This study reported that the median CD4 count was 775 cells/ μ l for HIV-uninfected individuals vs. 374 cells/ μ l for HIV-infected individuals (Malaza, Mossong, Barnighausen, Viljoen and Newell 2013:4)

Failure to link patients from HIV testing to HIV care (CD4 test, ART, etc.) is now recognised as the key factors leading to late presentation for ART enrolment (Rosen and Fox 2011:2).

The study by Clouse, Pettifor, Maskew, Bassett, Van Rie, Behets, Gay, Sanne and Fox (2013:39) reviewed retrospective clinical records at the Witkoppen health and welfare centre to compare the retention of patients at three stages of pre-ART care and two stages of ART care. The aim of their study was to identify when the greatest attrition occurred between HIV diagnosis and treatment on ART (Clouse et al 2013:39). Three stages of pre-ART care were defined. (i) The pre-ART stage one category was for patients that had completed CD4 staging within three months of HIV diagnosis (Clouse et al 2013:41). (ii) The next stage was pre-ART stage two category that included all patients that were not eligible for ART (based on their CD4 result) who completed their CD4 test within 12 months of the first CD4 staging date (Clouse et al 2013:41). (iii) The pre-ART stage three category was for patients that had been initiated on ART within three months of an eligible CD4 count. The patient retention rates for the three pre-ART categories were 69.8%, 57.4% and 36.9% respectively (Clouse et al 2013:41).

This study demonstrated the poor level of pre-ART retention in care. Retaining patients in HIV care from the time of testing HIV positive through to lifelong ART is critical for getting patients onto treatment promptly and preventing the morbidity and mortality associated with disease progression (Clouse et al 2013:41).

In 2008, the World Health Organisation (WHO) proposed the deployment of a pre-ART/ HCT register, in addition to ART register, to improve the linking of patients in HIV care (WHO 2006:58). Paper-based pre-ART/HCT and ART registers were introduced in South Africa in 2010 and data is reported at the health district level on the Department of Health Information System (DHIS). Data entry is however labour intensive on this existing system and is not integrated into a national database. Locally, results from a study at the Themba Lethu Clinic (TLC) in Johannesburg, reported that only 51.3% of HIV diagnosed patients eligible for ART had completed CD4 testing within 12 weeks of their initial HIV test (Larson, Brennan, McNamara, Long, Rosen, Sanne and Fox 2010:677).

A recent study by Mate, Bennett, Mphatswe, Barker and Rollins (2009:3) in the KwaZulu-Natal province found that the DHIS data was incomplete in approximately 50% cases and that critical PMTCT data elements being studied, including CD4 testing

of HIV positive pregnant women and HIV PCR test of babies born to HIV+ women at 6 weeks or later, were missing from the clinic registers in 5 to 41% of cases (Mate et al 2009:3).

The existing CCMT request form of the NHLS (Form 3 Page 95) was deployed in the Gauteng, North West, Limpopo, Mpumalanga and Free State provinces in 2006. This request form was designed to include a programme status data collection tool, however the implementation was mainly focussed on utilising this request form for billing purposes (conditional grant). The Western Cape and Eastern Cape provinces were using alternative versions of the current NHLS CCMT request form (Form 3 Page 95). In 2012, the NDOH and NHLS agreed to develop a national CCMT request form (Form 4 page 96) that would be used throughout the public health care system and would be designed to collect the CCMT programme status data in a standardised manner. Additionally, the LIMS used within the NHLS would utilise specially designed test methods to collect this programme status data using standardised LIMS codes.

The use of the new CCMT request form (Form 4 page 96) and the LIMS will provide a more robust and reliable M&E system to identify whether CD4 testing is being performed for pre-ART screening or ART monitoring. This data is required to track the linkage of care from HCT to CD4 testing and finally to ART provision. This information will provide the NDOH with valuable information on the number of patients being tested (CD4) following HCT versus those who are receiving ART.

The new CCMT request form (Form 4 page 96) was developed by the NHLS, in consultation with the NDOH, as part of a process to propose and design national laboratory request forms for use in the public health sector. The primary health care (PHC), hospital and national programme forms were developed. This study evaluated the new CCMT request form (Form 4 page 96) (national programme request form).

1.3 Aims of the study

1.3.1 Research purpose

The purpose of this study is to develop laboratory based CCMT Programme Status reporting system through the use of specific modifications to the current CCMT request form (Form 4 page 96) and thereafter, to the NHLS LIMS to enable appropriate capture of the CCMT programme status for CD4 samples. The information will be used to generate supplement exiting M&E reports to assist programme management at the health facilities. These reports will help the health personnel at the facilities to differentiate between CD4 counts taken before the patient commenced treatment (i.e. pre-ART screening) and those CD4 counts taken later during patient follow-up that are used to assess response to treatment (i.e. ART monitoring). The data generated by the study will help the facility manager to plan for and anticipate new patients who are likely to be eligible for enrolment onto ART programmes based on the CD4 median of the pre ART group. Once implemented across all health districts this data could be used at a national level to make relevant programmatic decisions about the extent of patients eligible for care and at which sites these patients are presenting.

1.3.2 Research objectives

The study will develop the laboratory based CCMT Programme Status reporting system to answer the following objectives in a limited cohort:-

- Establish the impact of use of the tick box system for the capture of the CCMT programme status.
- Establish the median CD4 for 'pre-ART' and 'ART CCMT' programme status groups as an indirect indicator of overall patient programmatic immune status.
- Establish the percentage of patients with pre-ART and ART programme status categories as a percentage of total CD4 samples received, to define eligibility for treatment.
- Establish the proportion of patients eligible to start ART with a CD4 count below 50.

- Establish the number of patients that were eligible for ART, but not yet enrolled onto treatment programmes.
- Establish the usefulness of the laboratory pre-ART register (assessed with a questionnaire).

The study will also provide insight on the provision and capture of the CCMT Programme Status information. This insight will enable the researcher to develop practical guidelines for the implementation of the CCMT Programme Status reporting system to other health districts.

1.4 Significance of the study

The outcomes of this study will improve how the CCMT programme is managed at the district and facility level by providing information on whether patients are accessing the system for first or subsequent visits during ART. Potentially, it can assist facility managers to improve the health facility utilisation and reduce loss to follow-up. Overall the ultimate outcome of the study will be improved patient care.

1.5 Definition of terms

Antiretroviral Therapy (ART): Standard antiretroviral therapy (ART) consists of the combination of at least three antiretroviral drugs to maximally suppress the HIV virus and stop the progression of HIV disease. Patients that are enrolled in the CCMT programme are receiving Antiretroviral Therapy.

Pre-Antiretroviral Therapy (Pre-ART): Patients that are diagnosed as HIV positive but not yet eligible for ART enrolment. The eligibility for ART enrolment is determined either through a clinical assessment or by a CD4 count below 350.

Register: A document used at the health facility to capture all the information about a patient's pre-ART care, for example. The Pre-ART register documents the basic demographic and clinical information about patients with HIV attending a health facility. The register will be kept in the health facility and allows the health care worker to

monitor the progression in the CD4 count for each patient, and the demand for ART to be anticipated.

Programme Status: is the status of a patient in the continuum of HIV care. The programme status aspects relate to the status of the patient once diagnosed with HIV. The programme status categories include HIV diagnosis (at an HCT or PMCTC service point), CD4 staging for ART enrolment and currently on ART treatment.

HIV counselling and testing (HCT) (also known as VCT): describes voluntary counselling and testing. An individual can on a voluntary basis decide to take an HIV test that is performed confidentially. The individual must receive counselling before and after the HIV test. The South African government launched an expanding access to HIV counselling and testing that is seen as a critical gateway to HIV prevention as well as providing appropriate treatment and care for people who are already infected. This massive testing campaign was initiated in April 2010 and aimed to test a total of 15 million people throughout South Africa by the end of June 2011.

Laboratory Information Management System (LIMS): A laboratory information management system (LIMS) is a series of computer programs that processes, stores and manages laboratory data at all stages of the testing procedure. This kind of information system is used in laboratories for the management of the data related to samples received, instruments used to test these samples and other laboratory functions such as recording quality control performed as well as management reporting and storing of patient results.

National Health Laboratory Service (NHLS): The NHLS is the largest diagnostic pathology service in South Africa with the responsibility of supporting the National and Provincial Department of Health in the delivery of healthcare. The NHLS provides laboratory and related public health services to over 80% of the South African population through a national network of 265 laboratories.

National Department of Health (NDOH): is a national department in the South African government with a mission to improve health status of the population through the prevention of illnesses and the promotion of healthy lifestyles. The NDOH aims to

consistently improve the healthcare delivery system by focusing on access, equity, efficiency, quality and sustainability through the delivery of health care services at public health care facilities across the country.

Health District: The nine provinces of South Africa are divided into 53 health districts. The health districts focus on issues related to the general health of the population at district and provincial level.

District Health System (DHS): is the organisation of health care according to geographic sub-divisions of a country (health districts), which are managed through a decentralised management structure.

CD4 Count: Along with other tests, the CD4 count indicates the status of the patient's immune system, the stage of HIV/AIDS disease, acts as a guide to determine eligibility for treatment and predicts how the disease may progress. The CD4 Count is a laboratory test performed on a sample of blood drawn by venepuncture, using the PanLeucogate (PLG) CD4 test method as standardized test (Glencross, Scott, Jani, Barnett and Janossy 2002:73)

1.6 Conceptual framework

The conceptual framework was derived from the published literature relating to the M&E systems required for the CCMT Programme. Various key concepts have been identified as elements that feature as central to the CCMT M&E system. A conceptual map was used to illustrate relationships between the different concepts (refer to Annexure K Page 157).

1.6.1 Key components of a CCMT Monitoring and Evaluation (M&E) System

An effective well-functioning CCMT M&E system relies on various inputs to determine what data will be generated as outputs. The inputs into the system guide what will be measured as well as how they will be reported. An example of such input is the tiered

ART M&E implementation plan that defined standardising ART monitoring at health facilities as well as district and provincial management, that would track and respond to the expansion of ART services (NDOH 2011e:7).

The CCMT M&E systems depend on clear government policies to direct health care interventions. For example the District Health Management Information Policy guides the long term M&E goals of the NDOH to develop a National Health Management Information System (NHMIS) (NDOH 2012a:10). The NDOH policies and guidelines determine the M&E data to be collected as well as the indicators to be reported. The NDOH, via the NIDS process, develops the health indicators and associated data elements that must be reported (NDOH 2012a:19). The health care workers are the enablers that implement the policies and guidelines into health care practices and facilitate the collection of data using the M&E data systems.

The CCMT programme regularly updates its clinical guidelines, which guide how health care provision is offered throughout the country by health care workers, i.e. the new antiretroviral treatment guidelines that were released in 2010 (NDOH 2010:1). This change introduced access to ART for all HIV-infected infants, pregnant women and people with TB and HIV at CD4 less or equal to 350 cells/ μ l (NDOH 2010:8). This guideline changes required the M&E system to modify indicators to reflect the changes in the ART enrolment criteria. Therefore guidelines facilitate the implementation of government policies into routine health care provision, whereby trained health care workers execute the new plans (such as ART provision). The M&E units also release new data tools, such as the pre-ART register, to update data reporting systems and cater for the new national indicator dataset (NIDS) reporting requirements (NDOH 2012a:19).

The M&E systems require competent and trained health care workers that are able to utilise the data tools such as the tiered ART system M&E framework, DHIS and pre-ART register to deliver the required data at the facility level. For the tiered ART M&E implementation plan the district implementation teams are required to perform a facility assessment prior to implementation. This assessment will establish whether there has been a delegation of responsibility from the facility manager to existing data staff to

support the data capturing. Additionally the plan requires that facility manager understands the process that is underway, the importance of folder flow, clinical stationery and its management, and the data that is generated from the monitoring tool (NDOH 2011e:11). Extensive training of health care workers is discussed in the tiered ART M&E implementation plan including “train-the-trainer” sessions, district implementation training, training for health care workers on the new standardised based systems, as well as training on how to use the information for both programme management and reporting (NDOH 2011e:21-27).

A data system comprising of paper based and electronic data collection systems form the next key component of a CCMT M&E system. The most common data system used is nurse or clinician based notes following a patient encounter. These clinical notes are captured by the health care worker during patient visits. The next level of data systems is the paper based register that has been designed for a specific purpose, e.g. pre-ART or malaria register. The pre-ART registers identifies all patients that had a HIV positive test result but are not yet eligible for ART enrolment. The next step is the move to an electronic system to collect patient data. These electronic systems are customised to meet a specific need. In a hospital setting, the Hospital Information System (HIS) would be employed, and in special disciplines within a hospital, data systems such as the Laboratory Information System (LIS) and Radiology Information System (RIS) may be used (Shortliffe and Cimino 2006:453). At a health facility level various electronic medical record (EMR) systems may be used (Shortliffe and Cimino 2006:503). The tiered ART M&E system is an example of an EMR. In many countries data from multiple electronic systems are integrated into an electronic health record (EHR) that integrates all patient data from multiple systems into a single system (Shortliffe and Cimino 2006:453).

The data collected from paper based and/or electronic systems is often aggregated and captured using a national district health information system (DHIS). All of the data systems described allow for the collection of data to facilitate M&E. The DHIS was introduced in the South African public health sector in 1994 as the national standard system for the capture, storage, analysis, and reporting of routine health data (NDOH 2012a:11). The DHIS provides a large proportion of the information used for planning,

budgeting, health service management, M&E at all levels of the South African health care system. This aggregated data is used for indicator and related target reporting (NDOH 2012a:11).

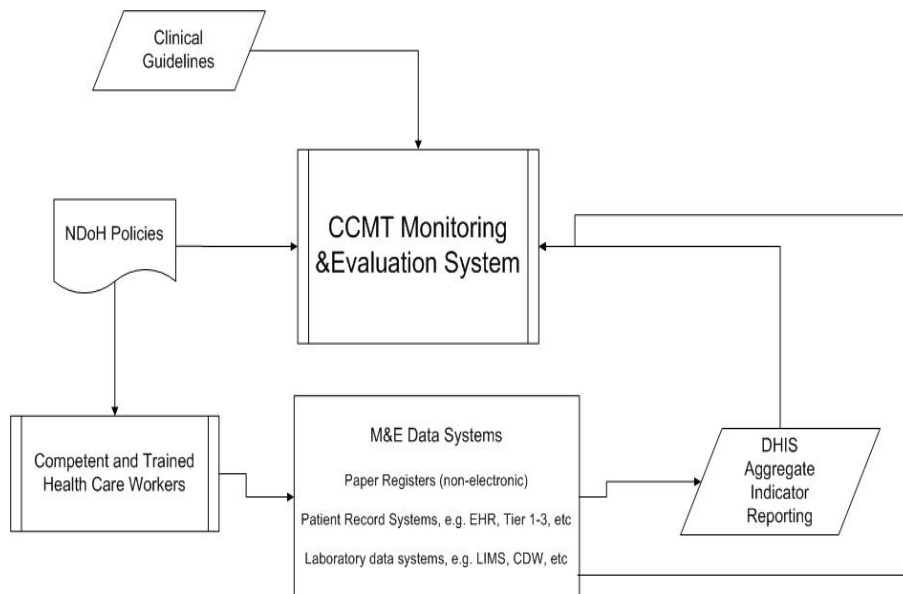


Figure 1.1: Conceptual framework for CCMT M&E Systems

All of the components of the conceptual framework for the CCMT M&E system contribute to determining the data to be collected. The conceptual framework described above represents the ideal CCMT M&E systems. The current South African CCMT M&E systems do not meet these ideals as current electronic patient record systems are not universally used by the majority of health facilities as they are either using paper based registers or non-networked current electronic patient record systems. Additionally data collected by the existing NHLS laboratory information system is not integrated into the CCMT M&E system. For the ideal CCMT M&E systems data needs to be available to flow from the M&E systems to the District Health Information System, and between the different M&E data systems.

1.7 Scope of the study

The study was undertaken in one health district in the Gauteng province. Three hospitals in the Ekurhuleni health district were selected based on CD4 test volumes. The study required health care workers to complete the new CCMT request form (Form 4 page 96) and submit them to their local laboratories. At each laboratory the

CCMT programme status was captured in the Laboratory Information System (LIMS) by data capturers.

This study was designed to develop an electronic M&E system to report the CCMT programme status for CD4 results using the new CCMT request form (Form 4 page 96). The CD4 results and CCMT programme status data was captured in the LIMS and then replicated to the CDW, from which data was extracted.

The candidate led the research project, planned and coordinated all the study activities such as designing the data collection instruments, providing training for health care workers and laboratory staff as well as conducting follow-up visits. The dissertation will provide quantitative data collected using the new CCMT request form (Form 4 page 96).

1.8 Structure of the dissertation

The dissertation is structured into chapters, the first being the orientation to the study (this chapter).

The literature review chapter (2) identifies and critically evaluates the available information in the form of journal articles, books and National Department of Health policies.

In the research design and methods chapter (Chapter 3), the research population and sample as well as the sampling approach used is described.

The next chapter (Chapter 4) describes the analysis, presentation and description of research findings. This chapter outlines the research findings of the study and data is presented by means of tables, graphs and histograms.

The final chapter (Chapter 5) is the conclusions and recommendations chapter that reports the findings of the research in relation to the research problem and problem statement.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter will discuss the related literature reviewed for this study which outline key the concepts.

2.2 Purpose of the literature review

The purpose of the literature review is to identify and critically evaluate the available information available at the time of writing this dissertation, in the form of journal articles, books and National Department of Health (NDOH) policies.

2.3 Scope of the literature review

The NDOH policies, reports and documents were searched to identify current and new HCT and ART M&E systems.

Additionally a literature search was requested from the UNISA library to identify literature sources for the following keywords; "HIV Programme Status", "Pre-ART Register", "First ever CD4", HIV Counselling and Testing", "Baseline CD4", "CD4 Median" and "Request form", "HIV M&E". The Google scholar search engine was also used to search for literature using the keyword "laboratory register". Additionally the Google scholar search engine was used to search for literature articles for the keywords above.

The literature review is presented according to the following headings:-

- development of a tiered ART M&E framework in South Africa
- the pre-ART register
- development of a National Health Information Network (NHIN)
- current challenges with collecting ART data using paper based systems

- current challenges with collecting ART data using electronic medical record systems
- the laboratory register
- development of a national laboratory based data repository

2.4 Development of a tiered ART M&E framework in South Africa

The NDOH set a goal in 2008 to integrate health record systems in the country by bringing together all the different health information systems facilitating access to health records within a province and across provinces (NDOH 2008:7).

In a review conducted by the NDOH in October 2010, over 40 different ART patient management systems and various non-standard non-networked M&E systems were identified in the public health sector (Pillay, White and McCormick 2012:77). This identified the lack of standardisation of data collection and reporting for ART provision in South Africa. The study further identified the use of multiple versions of clinical stationery. In May 2010, the NDOH adopted standardised registers and clinical stationery to assist with capturing and tracking ART patient information at health facilities (Pillay et al 2012:77).

On the 1st of March 2011, the NDOH HCT Campaign and ART Expansion update to provinces and districts announced that a three tiered ART monitoring strategy would be introduced that would comprise of a paper based system (known as Tier 1), a non-networked electronic register (known as Tier 2) and finally a fully networked electronic patient register (known as Tier 3) (NDOH 2011c:3-6).

According to the NDOH, this strategy would enable health facilities to manage their ART patient data with the system that best suits their context (2011c:2-4). Tier 1 consists of a non-networked, non-electronic paper based system that will utilise standardized clinical stationery and the standardized paper-based registers to collect information for the NDOH CCMT monthly and quarterly reports (NDOH 2011e:16).

The next tier, Tier 2, is a non-networked electronic stand-alone system that uses an electronic register identical to the paper-based registers used in Tier one (NDOH

2011e:17).The final tier, Tier 3, is a fully networked electronic patient management system that has some additional functionality such as the ability to import electronic patient information. This could be considered to be a module of the longer term EHR strategy (NDOH 2011e:15).

The NDOH identified that to implement this strategy they would have needed to consider the system requirements for space, infrastructure, networks, staffing, registry management and standardised clinical stationery (NDOH 2011e:15). In April 2011, the NDOH released the tier T1 and tier T2 ART M&E implementation plan (NDOH 2011e:1). This plan described how provincial and health district implementation teams would deliver a tiered ART monitoring strategy. It outlines the specific set criteria that will assist in selecting the appropriate monitoring systems based on number of patients on ART at a health facility, implementation of standardised clinical stationery, folder management and staffing (NDOH 2011e:15).

The NDOH tiered ART M&E implementation plan states that standardised clinical records are the most basic of clinical tools and they are the international standard of care in chronic disease management. Standardised records support the clinical management of patients and provide the source data to data capturers for the routine monitoring of patient enrolment and clinical outcomes (NDOH 2011e:14). The minimum set of standardized stationery that will be used for the tiered ART M&E system includes the patient summary, visit summary, patient card and laboratory results forms (NDOH 2011:14).

The DHIS in South Africa consists broadly of two parts, the first being data collection at the health facility level and followed by the analysis of the data (Garrib et al 2008:550). The DHIS aggregate data is collated at the sub-district or district level from reporting health facilities and entered using the DHIS software (Garrib et al 2008:550). The aggregate DHIS data was analysed, and reported at the district, provincial and national levels (Garrib et al 2008:550). In this way the three tiers of the tiered ART M&E framework generates data into the national DHIS data set used by the NDOH for M&E of health services (NDOH 2011e:23). According to the tier T1 and tier T2 ART M&E implementation plan, the DHIS is the primary repository for reporting routine health services data (NDOH 2011e:23).

The NSP 2012-2016 has set a target to complete the rollout of the tiered ART M&E system for ART 2013/14 (NDOH 2011d: 50). Furthermore the NSP calls for a clear M&E framework that would require a single national unique patient identifier that would facilitate improved M&E, seamless transfer of patient information, improved referral and tracking, decreased duplication of laboratory and radiological investigations, and harmonisation of information systems (NDOH 2011d:44).

By March 2013 the NDOH had 10 health facilities fully implemented at Tier 3 which is the fully networked electronic patient register (White 2013). In South Africa, 1361 health facilities offering ART are eligible to implement Tier 2 (non-networked electronic register) as they have 500-2000 patients currently enrolled on ART (White 2013). By March 2013, a total of 887 (52.9%) eligible health facilities were implementing Tier 2 (White 2013). Additionally there were 654 health facilities not eligible to implement Tier 3, that were allowed to start implementing Tier 2 (White 2013). All the health facilities implementing Tier 2 were classified into seven stages of implementation with “Tier Phase 0” indicating that these sites were preparing for implementation. To achieve the final phase of implementation, “Tier Phase 6”, health facilities should have completed data signoff to be considered as a live site (White 2013). By March 2013 of the 1361 Tier 2 eligible sites, 43.5% (n=593) had reached the final Tier Phase 6 level of implementation (White 2013). All the health facilities that have reached Tier Phase 6 would be able to utilise the application for cohort reporting whereby patients can be followed up over time (White 2013).

A major challenge for the tiered ART M&E strategy is that most health facilities in South Africa have only deployed either Tier 1 or Tier 2, with only 10 health facilities using Tier 3 (White 2013). A local study by Sorensen et al (2008:39-40) highlighted that with the exception of the major Health Information System (HIS) or Electronic Health Record (EHR) systems in South Africa, none of the ICT systems were ready to be deployed in the country as a whole. They (Sorenson et al 2008:40) concluded that paper based and ICT systems would coexist in South Africa for some time to come. Until the majority of health facilities offering ART have transitioned to Tier 3, it would be difficult to make the progression to a national EHR.

The NDOH tiered ART M&E framework, once fully implemented would achieve the standardisation of ART records for the routine monitoring of patient enrolment and clinical outcomes in South Africa. The tiered approach also allows health facilities to develop their exposure to M&E systems by transitioning from Tier 1 to Tier 3 in a phased approach.

2.5 Pre-ART Register

For patients not yet eligible for ART (pre-ART), the tiered ART M&E framework does not apply. Instead these patients will be monitored using facility based pre-ART paper registers. Some of the paper based monitoring systems used to capture health information for patients include the pre ART register, ANC register and TB card and registers (NDOH 2011b:24). The NDOH Clinical Mentorship Manual for Integrated Services was developed in 2011 (NDOH 2011b:1). This document lists that the HIV care/ART card, pre ART and ART registers are used for patient monitoring in HIV care (NDOH 2011b:25). The ART card will be replaced by the standardized stationery utilised by the tiered ART M&E system, however the pre-ART register will still be utilised by health facilities (NDOH 2011e:14).

The Pre-ART register should therefore be used by health facilities to record all patients who are enrolled in HIV care and counted as enrolled in HIV care (WHO 2006:58). Data will be recorded in the pre-ART register until the patient starts ART (WHO 2006:58). The ART register is only used when patients start ART (WHO 2006:58). The data from the pre-ART register will be collated and reported using the DHIS.

Patients may attend a health facility for more than one condition that requires tracking using several patient cards. Consequently linkages need to exist between information reported for HIV care and cards or records for family planning, TB treatment, antenatal care and PMTCT. This is achieved through the use of transfer forms to facilitate referrals between services (WHO 2006:58). The challenge with the pre-ART register is that it does not form part of an electronic M&E system as the data is collated from paper registers and reporting on the DHIS.

2.6 Development of a National Health Information Network (NHIN)

Early in 2012 the NDOH released an ambitious plan for the creation of National Health Management Information System (NHMIS) which builds on the tiered ART M&E strategy (NDOH 2012a:10). The NHMIS plans to integrate data from the source systems such as the tiered ART system and DHIS (NDOH 2012a:10). The NDOH envisages the NHMIS consisting of at least five key components: population-based information, health services based information, health resources records, vital registration data and finally transversal (government-wide) support systems (NDOH 2012a:10). To develop such a system, the health sector would have to collaborate with other government departments such as the Home Affairs Department, Statistics South Africa (STATSSA) and private health sector organisations (NDOH 2012a:10). They would also have to liaise with the suppliers of the existing public sector health information systems currently in use in South Africa (NDOH 2012a:10).

In order for the NDOH to deliver on the NHMIS strategy they would have to start developing the National Health Information Infrastructure (NHII). According to Detmer (2003:2), the NHII is the means by which the quality of health data, information and knowledge, used to support decisions at all levels and in all domains of the health sector, can be improved. Shortliffe and Cimino (2006:578) describe that the aim of a NHII is to provide access to anytime and anywhere health care information at the health facility level. To achieve NHII, electronic patient information needs to be collected and stored at each health facility (Shortliffe and Cimino 2006:485-486). With NHII, whenever a patient presents for care, the various existing electronic patient record systems can be located, collected, integrated, and immediately delivered to guide clinical decisions (Shortliffe and Cimino 2006:573).

There are significant barriers and challenges to the development of NHII which include ensuring the confidentiality of electronic medical records, lack of interoperable standards for health information systems (HIS) data interchange, funding for health care information systems as well as legal and regulatory barriers (Shortliffe and Cimino 2006: 575-576). Additionally an electronic health record system is not in place at every public health facility to provide the data to populate the NHIN.

Despite the complexity and cost of developing an NHII, the long term goal for the NDOH would be to develop the required infrastructure to deliver on the NHMIS strategy. In summary the NHII has the potential to transform health care by improving health care quality, reducing health care costs, preventing medical errors, improving administrative efficiencies, reducing paperwork, and increasing access to affordable health care (Sittig, Shiffman, Leonard, Friedman, Rudolph, Hripcsak, Adams, Kleinman and Kaushal 2005:1).

The majority of health facilities in South Africa would need to migrate to networked electronic patient record systems that would support HL7 data interchange and start using a national unique patient identifier to enable cohort analysis. Additionally the health care systems would need to be linked to systems such as the home affairs to validate national identity numbers. In South Africa it means that the health infrastructure would have to be substantially strengthened to support the NHII requirements for NHIN.

2.7 Challenges with collecting ART data using paper based systems

The quality of ART data collected for national priority programmes is critical as national policy changes are based on the analysis of the aggregated data reported by the DHIS. The decision by the national programme manager to increase the ART eligibility criteria, based on a CD4 count, must be based on good quality data. Incorrect decisions based on poor data could burden the entire public healthcare system.

In 2009 Mate et al (2009:1) conducted a study to assess the completeness and accuracy of data reported for six key PMTCT data elements at health facilities in three districts in the KwaZulu-Natal Province. The study reported large variations in the completeness of data reporting for each of six PMCTC data elements on the DHIS (Mate et al 2009:3). The analysis of data accuracy for all six elements revealed that the clinic registers were missing data between 4.5% and 41.0% of the time (Mate et al 2009:3). Their study highlighted the major flaws in the collection and reporting of PMTCT data at both the facility level (paper registers) and on the DHIS (Mate et al 2009:4).

Shortliffe and Cimino (2006:30-31) reported that any data collection system that relies on the manual capture of information onto datasheets that are later transcribed into computer databases for analysis, is both labour intensive and fraught with opportunities for error.

Another study by Mate et al (2009:4) demonstrates how the data collection of a small subset of the DHIS national data elements can go wrong at the health facility level. Mate et al (2009:4) highlighted that even though the accuracy and completion of this PMTCT data was suboptimal, national health systems still use this data for national reporting and for financial allocations (Mate et al 2009:4). Additionally they found that data was frequently not submitted by health facilities to their local district office to capture into the DHIS, worsening the problem (Mate et al 2009:4). Similar problems with paper based systems have also been noted elsewhere.

The Malawian Ministry of Health with partners conducted local supervisory visits in 2006 to assess the completeness and accuracy of key case registration and outcome data compiled by 89 ART clinics in Malawi (Makombe, Hochgesang, Jahn, Tweya, Hedt, Chuka, Yu, Aberle-Grasse, Pasulani, Bailey, Kamoto, Schouten and Harries 2008:311). The key case registration and outcome data was collected using the paper based WHO tools that are used for ART monitoring and consists of a master card for each ART patient and one patient register at each ART facility (Makombe et al 2008:311), similar to data collection in South Africa. In their assessment of data quality, the study found that 70% of health facilities had complete data for the six key case registration fields (Makombe et al 2008:311) , but case registration data was accurate in only 40% of the health facilities. The study recommended moving to an electronic system to include mechanisms to improve quality of data, i.e. including using validation checks, bounds (range) checking and alerts (Makombe et al 2008:313). Several contributing factors including a higher work load, lack of dedicated data clerks, poor district supervision and poorly resourced facilities were identified (Makombe et al 2008:311).

A data quality improvement intervention was conducted in 2008 that included three main components; training on data collection, monthly review of data and data audits at individual facilities (Mphatswe Mate, Bennett, Ngidi, Reddy, Barker and Rollins

2011:4). Data completeness improved from 26% to 64% following the intervention, This study highlights that with proper supervision and support it is possible to improve data quality using paper based registers (Mphatswe 2011:6).

The challenges with collecting ART data using paper based systems include low levels of incompleteness and inaccuracy. Where countries have the resources and skills to implement electronic data systems, substantial improvement in data quality can be expected. Shortliffe and Cimino (2006:89) states that not only will electronic data collection systems improve data quality, they also make it feasible to monitor the data collected, generate warnings or advice based on either a single observation or for logical combinations of observations, provide automated quality control that include flagging potentially erroneous data and providing feedback on patient-specific or population based deviations from desirable standards.

The additional limitation of paper based records is that the concentration of information is at a single location, which is at the health facility (Shortliffe and Cimino 2006:262). According to Shortliffe and Cimino (2006:262) this limitation prohibits the simultaneous entry and access of the information by multiple users.

In summary, while paper based system can be used to collect national data for ART management, there are significant challenges to collating this data at health facilities and aggregating this information at the district, provincial and national level using the DHIS. Additionally the challenges related to ensuring data quality makes it difficult at the national level to accurately allocate human and financial resources.

2.8 Challenges with collecting ART data using electronic medical record systems

There are many challenges in a developing country for establishing electronic medical record systems as described by Sood, Nwabueze, Mbarika, Prakash, Chatterjee, Ray and Mishra (2008:3). Some of the factors to consider when implementing electronic medical record systems in developing countries include security, confidentiality, reliability, technical infrastructure, accessibility, interoperability, cost, language and culture (Sood et al 2008:6-7).

The study by Forster, Bailey, Brinkhof, Graber, Boulle, Spohr, Balestre, May, Keiser, Jahn and Egger (2008:939) between 2006 and 2007, reviewed the use of electronic medical record systems in ART programmes in 15 countries in Africa, South America and Asia. Of the 21 health facilities surveyed only 18 routinely used an electronic database (Forster et al 2008:941). In 89% of these sites the clinicians used written charts during patient consultations that were then manually data captured (Forster et al 2008:941). The study assessed the percentage of missing data from the electronic medical record systems. They calculated a “missing data index” as the median of the percentages of missing data for six key variables that included the baseline and follow-up CD4 counts (Forster et al 2008:941). The missing data index for the study was 10.9% (Forster et al 2008:943). For the baseline CD4 percentage this missing data index increased to 19.8% (Forster et al 2008:943).

The study also highlighted that most of the databases used rely on software intended for personal or small business use and could not meet the data needs as the patient numbers increased exponentially (Forster et al 2008:943). Medical Record applications such as tier 2 of the tiered ART M&E framework are based on a non-networked Microsoft Access application with limited scope for growth.

The review of ICT used in South Africa for HIV/AIDS and antiretroviral treatment by Sorensen, Rivett and Fortuin (2008:39) in 2006 highlighted universal issues regarding the use of electronic medical record systems in South Africa prior to the decision to move to the tiered ART and evaluation framework (Sorensen et al 2008:39-40). One of the challenges noted by the study was that the implementation and support of health systems in South Africa is managed at a provincial level, which has resulted in different provinces implementing different systems based on their specific requirements (Sorensen et al 2008:39). The study also concluded that with the exception of the major Health Information System (HIS) or Electronic Health Record (EHR) systems none of the other ICT systems were ready to be deployed in the country as a whole (Sorensen et al 2008:39). The study concluded that paper based and ICT systems would still coexist in South Africa for some time (Sorensen et al 2008:39).

A major challenge for the tiered ART M&E strategy is that most health facilities have implemented tiers 1 and 2 (Magoro 2012). This leaves the majority of South African

health facilities using either paper based standardised stationery (Tier 1) or non-networked Microsoft Access based electronic records (Tier 2). Until the majority of health facilities offering ART services have transitioned to Tier 3, the full benefits for tiered ART M&E strategy will not be realised.

2.9 Using ART data collected on the DHIS to plan and manage health facilities

Garrib et al (2008:550) investigated the functioning of the District Health Information System (DHIS) in 10 clinics rural northern KwaZulu-Natal. There was good understanding of the data collection and collation process but little analysis, interpretation or utilisation of data (2008:550). In the 10 clinics, only 2.5% of indicator data values were missing (Garrib et al 2008:551). The study found that despite adequate training of the DHIS, health care workers and managers were not putting the data collected to good use (Garrib et al 2008:551). Several factors that affected the utilisation of DHIS data were identified. Some of these factors included poor skills transfer, high staff turnover and poor understanding of indicators (Garrib et al 2008:551). This study highlights the importance of moving the emphasis with electronic medical record system from data collection and reporting, to the utilisation of data for decision making.

2.10 The laboratory register

Where electronic medical record systems are not in place, the health authorities have no option but to rely on aggregate district based reporting using standardised clinical stationery and the DHIS. Where electronic medical record systems are in place the collection of data is much easier. However, the significant challenges with paper based and electronic medical record systems mitigate for the use of a laboratory register as an additional source of data to improve to quality of national reporting. The studies that will be discussed in this section demonstrate the usefulness of a laboratory register as an additional source of data as described in the conceptual framework.

In a retrospective study by Morrow, Munro, Wilke, Stark and Wood (2012:501) data was collected from 17 clinics in South Africa that included laboratory test data as well as clinical and demographic data files and regimen information. The patients in the data sets were matched using a patient identification number. Each patient's latest HIV Viral Load and CD4 prior to ART initiation were extracted. Additionally, the patients CD4 and HIV Viral Load results for routine ART monitoring were also included in the extract (Morrow et al 2012:502).

The authors stated that there were many advantages to using laboratory data as the data is collected at a more centralised location (such as the NHLS CDW), and can be accessed as a single download as opposed to collation of monthly or quarterly records from the DHIS (Morrow et al 2012:503). Laboratory results are reliable as they are used in clinical practice that has the required quality control in place to ensure data consistency and accuracy (Morrow et al 2012:503).

This study highlighted that it is possible to combine clinical and laboratory data using the patient identification number. This allowed the researchers to study the testing population. According to Shortliffe and Cimino (2006:517-518) the computer-based master patient index (MPI) is used to store patient identification information and basic demographic data that are acquired during the patient registration process, and simple encounter-level information such as dates and locations where services were provided. In South Africa where the majority of health facilities do not use a MPI system to ensure unique patient identification, one would have to resort to using probabilistic patient matching to achieve similar results.

The laboratory register concept was first introduced for TB microscopy testing as part of the essential set of TB M&E data to be recorded. In 1998 the WHO introduced the concept of a laboratory register for TB testing (WHO 1998:25). The TB laboratory register is a record book maintained by the technician or technologist at the laboratory that is responsible for performing TB testing (WHO 1998:25). For each tuberculosis suspect identified by the laboratory the tuberculosis laboratory register records the patient's demographic details (name, folder number, age, gender), date when the test was performed, smear and culture results as well as the results of confirmatory tests for M. Tuberculosis (WHO 1998:25). The latest requirements for a TB laboratory

register brought the recording and reporting forms into line with the revised 2013 case and treatment outcome definitions (WHO 2013a:1).

A retrospective study conducted by Mabaera, Lauritsen, Katamba, Laticevschi, Naranbat and Rieder (2008:294) collected data using TB laboratory register records for one calendar year from laboratories in Moldova (n=23), Uganda (n=30), Zimbabwe (n=23) and Mongolia (n=31). The TB laboratory register records were reviewed for completeness of recording age, gender and reason for examination (Mabaera et al 2008:294). Based on the data collected, the study authors concluded that surveillance of some of the basic laboratory indicators could provide a simple and locally based adjunct to the improvement of the TB laboratory network (Mabaera et al 2008:299). The study found that the information recorded in the TB Laboratory Register not only identified weakness and strengths in the laboratory, it also revealed weakness on a much broader scale in the TB control programme (Mabaera et al 2008:294).

The study highlighted the quality of data capture in four countries that attest to the very strong quality control over the collection and reporting of laboratory data. Laboratory staff is taught to work to very prescriptive standard operating procedures (SOP).

A study conducted by Botha, den Boon, Lawrence, Reuter, Verver, Lombard, Dye, Enarson and Beyers (2008:936) tested the hypothesis that the use of the TB laboratory register would identify the deficiencies in case detection among adults in a high TB incidence area in the Western Cape province (Botha et al 2008:959). This study compared data extracted from the NHLS LIMS and paper-based facility registers. Botha et al (2008:938) reported that of the 367 TB cases identified (by the laboratory registers) only 303 (83%) were recorded in the routine facility TB treatment register.

The benefits of using laboratory data is that it can utilise data stored on the LIMS, to generate the laboratory register to enable the health facility to correlate against data captured from paper-based register. An additional benefit would be the centralised storage of this data from each of the NHLS laboratories at the CDW would allow for the distribution of this data at the national, district, sub-district and health facility levels.

2.11 Development of a national laboratory based data repository

The NHLS developed a single national repository of all laboratory data within its Corporate Data Warehouse (CDW) making it possible to review public health laboratory data in South Africa. This has resulted in, for example, all public health sector CD4 laboratory data at the specimen level being available for extraction, analysis and reporting through the CDW (Grimett 2012). The specimen level data collected at the CDW includes information provided on the laboratory request form such as the patient demographic details and detail about the health facility requesting the test (Grimett 2012). This information is captured using the Laboratory Information Management Systems (LIMS) used at each NHLS laboratory (Grimett 2012). Each specimen is allocated a unique laboratory number. The LIMS then links the test results generated in the laboratory with the registration information captured from the laboratory request form using the laboratory number (Grimett 2012). The data collected by the LIMS at 265 laboratories within the NHLS network is consolidated at the CDW into a single national laboratory data repository (Grimett 2012). When the LIMS data reaches the CDW it is organised into logical reporting areas and structured according to data warehousing norms for reporting (Grimett 2012). This entire process is illustrated in Annexure D (Page 110).

In the NHLS annual report for the financial period 2010/11, it was stated that the function of the CDW is to support the information needs of the NHLS and that of the Information Management Unit (IMU) (NHLS 2011:14). The CDW team enhanced the provision of information to the NDOH by continued development of reporting to support the National Priority Programmes (NHLS 2011:30). This included the TB multidrug-resistant registers and early diagnosis of HIV infection in infants at 6 weeks. Monthly management summary reports by facility and province have been developed and are automatically circulated to the relevant recipients (NHLS 2011:30).

The ability of the NHLS to collate near real time data from each of the NHLS laboratories (n=265) using the LIMS makes this a perfect platform to pilot the collection of the CCMT programme status information. Not only can this be included for reporting

for the NDOH, this information can also be delivered electronically via a data interface to the multiple electronic medical record systems in use in South Africa.

The feature to feed laboratory data back to electronic medical record systems from the CDW has already been demonstrated. In the NHLS Annual Report for the financial period 2010-2011 the CDW unit states that in providing automated data interfaces to patient management systems to facilitate improved patient care, the CDW continued to interface data daily to the WamTech TB Electronic Drug Resistance system (EDR)(NHLS 2011:30). An interface to the Therapy Edge Patient Management System has been developed to provide a daily transfer of test results back to health facilities (NHLS 2011:30). In collaboration with the Desmond Tutu Tuberculosis Centre, an interface has been developed to transfer TB patient results to a patient management system developed for Cape Town City Health (NHLS 2011:30).

The development of a CDW that integrates all LIMS data within the NHLS can become the first step in the development of an NHIN in South Africa. As the tiered ART M&E strategy evolves to a stage where most health facilities are using Tier 3, the ability to deliver near real-time laboratory data to the NHIN and EHR systems becomes critical.

2.12 Conclusion

In this chapter, the tiered ART M&E framework, paper based pre-ART register, laboratory register, laboratory data repository, development of a NHIN in South Africa as well as challenges with using and implementing paper based and electronic M&E systems were explored. The available literature reviews the national initiatives to introduce an integrated national M&E data system for South Africa. To achieve this NDOH set a goal to integrate health record systems in South Africa by bringing together all the different health information systems facilitating access to health records within a province and across provinces through the NHIN (NDOH 2008:7).

The tiered ART M&E framework is an innovative system that will allow South Africa to migrate health facilities from paper based records to a non-networked M&E system

and finally to a fully networked and integrated patient record system that could lay the foundations for an electronic health record. The inaccessibility of paper based M&E systems as well as the poor quality of data has been described. There are many challenges that need to be faced when implementing electronic M&E systems in developing countries. The complexity of provincial budgeting for IT expenditure also makes it difficult to standardise electronic patient record systems. Developing a NHIN to integrate all health record data from source systems brings about challenges of confidentiality of data, developing data standards and funding to develop health IT infrastructure.

The use of laboratory registers where data from the LIMS is integrated into a national data repository hold great promise to provide national M&E data from a single data system. One of potential benefits of the laboratory registers is the ability to either replace or complement paper based and electronic M&E systems. When the final tier of the tiered ART M&E strategy is realised the ability to deliver laboratory results at the point of care in a comprehensive patient record offers the greatest potential to deliver on the NHIN strategy.

The next chapter describes the research design and methodology employed for the research study.

CHAPTER 3: RESEARCH DESIGN AND METHOD

3.1 Introduction

This study is a health systems research study aimed at developing new systems to deliver improved CD4 reporting with a CCMT patient programme status for better programme management.

3.2 Study Design

According to Eng and Siegelman (2007:653) the definition of the study design is a multi-step process that starts with defining a target population, i.e. the population for whom the study is intended. The next step is the definition of inclusion and exclusion criteria to specify who from the target population will be considered for the study (Eng and Siegelmen 2007:653).

The design of the study was descriptive (designed to describe and explore attributes) and cross-sectional (data collection was done once only). Descriptive designs are employed in studies where additional information is required in a particular field through the provision of a picture of the phenomenon as it occurs naturally (Brink, van der Walt and van Rensburg (2012:112). The additional question for the study was the CCMT programme status. Cross sectional studies are used to examine data at one point in time (Brink et al 2012: 115). For the study data was collected once only using the new CCMT request form.

3.3 Target population

The target population included patients who attended health facilities for CD4 testing in the Ekurhuleni health district.

3.4 Study population

The study population were patients who attend the Tambo Memorial, Far East Rand and Tembisa HIV clinics and who required CD4 testing in the Ekurhuleni health district, based in the towns of Boksburg, Springs and Tembisa respectively. All have busy ART and HIV counselling and testing wards. According to the DHIS classification, all three study sites are classified as regional hospitals (NDOH 2012c:36).

3.4.1 Selection of Study Population

A simple sequential sampling of public sector health facilities in the Ekurhuleni health district was undertaken using the CD4 test volume for 2011 from the NHLS Corporate Data Warehouse. The annual CD4 test volumes for this period was ordered in descending order, and the top three health facilities were proposed and adopted for study in consultation with the Gauteng Department of Health.

3.4.2 Inclusion Criteria

The inclusion criteria was also utilised to limit the study to a specific geographic area and time period. The table below describes the inclusion criteria for the study: -

Table 3.1: Inclusion criteria for study

Inclusion Criteria	Rationale
Patients between 18 years and older.	The study investigated the collection of the programme status for adults.
Patients presenting for CD4 testing at the Tambo Memorial, Far East Rand and Tembisa study sites.	The three study sites are based in the Ekurhuleni health district and were selected based on submitting the highest number CD4 samples per month in the 2011 calendar year (Coetzee 2012).
CD4 sample received on the new CCMT request form(Form 4 page 96)	The study collected data using the new CCMT request form (Form 4 page 96). The barcode sequence was used to identify CD4 results received on the new CCMT request form.

Inclusion Criteria	Rationale
Study Period: 1 October 2012 to 31 January 2013	Based on the number of samples submitted per day in 2011 by the three health facilities, the study was planned for one month (Coetzee 2012). However, the study was conducted for four months in order to reach the required sample size. Due to the implementation of HIV and ART services to the surrounding PHC facilities the study took longer to complete
CD4 sample request following HCT or for routine ART monitoring	The patient would be identified for CD4 testing following a positive HIV rapid test during HCT or during routine ART monitoring. Current ART guidelines prescribe CD4 testing following a positive HIV rapid test (NDOH 2010:3)

3.4.3 Exclusion Criteria

The table below provides a list of exclusion criteria as well as the rationale for each: -

Table 3.2: Exclusion criteria for study

Exclusion Criteria	Rationale
CD4 samples that are received on the existing CCMT request form (Form 3 Page 95).	All CD4 samples received on the Existing CCMT request form (Form 3 Page 95) were excluded from the study. This form uses a specific barcode sequence, e.g. ASFD1234B.
CD4 samples from other health districts in Gauteng received at the CD4 laboratories in the Ekurhuleni health district	Any CD4 samples received from outside the Ekurhuleni health district, tested at CD4 laboratories within the Ekurhuleni health district, were excluded (outside target population). Each CD4 sample recorded on the LIMS had a dedicated location code for the health facility, e.g. TEM for Tembisa Hospital. The specific location codes were used to identify study data from the three study sites. Additionally, the three location codes were used by the CDW to extract data for the study (refer to Annexure F Page 127).

3.4.4 Method of selecting health facilities

The health facilities were selected in conjunction with Gauteng provincial CCMT Unit as well as the Ekurhuleni district health management after reviewing the 2011 CD4 test volumes. The three study sites were selected on the basis that they provide HIV and ART services, are situated within 100km of an existing NHLS CD4 testing

laboratory, are already using the Existing CCMT request form (Form 3 Page 95) and submitted over 600 CD4 samples on average per month on average in 2011.

3.4.5 Method of selecting sample

For selecting the study sample, non-probability sampling was utilised to identify the health facilities where the study was conducted. For the selection of patients, convenience sampling was utilised as the patients (study subjects) would be attending the health care facility for routine HIV services making them easily accessible for the study. Convenience sampling is easy, fast and the least expensive sampling technique. However one of the weaknesses of convenience sampling is that sampling bias is likely to be introduced to the study. The sampling frame for this study would be the hospital, i.e. the three regional hospitals selected in the Ekurhuleni health district.

3.4.6 Size of sample

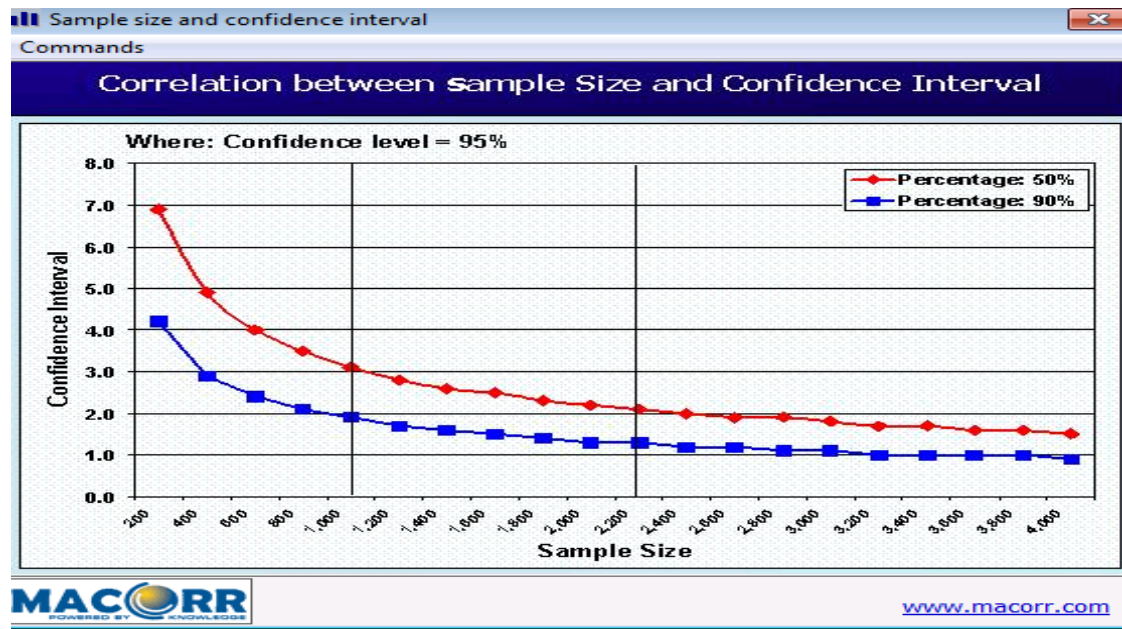
It is important to take into consideration the size of the sample required to achieve the study aims. The calculation of the sample size is determined by three main factors; p-value, statistical power and the size of the effect to be detected (Whitley and Ball 2002:336). Additional factors that must be taken into consideration when deciding on a sample size for a research study are: -

- Level of accuracy required
- Size and heterogeneity of the population
- Nature of the research design, e.g. qualitative or quantitative
- Financial resources

The use of the macorr sample size calculator (<http://www.macorr.com/sample-size-calculator.htm>) is recommended by Brink et al (2012:143). To compute the study sample size the following values were provided: -

Table 3.3: Variable used in the Macorr Sample Size Calculator

Variable	Value	Description
Population Size	16892	The population size is the average number of CD4 tests received per month from the Ekurhuleni health district during the calendar year 2011.
Percentage	50%	The worst case percentage of 50% was entered on the sample size calculator for the percentage of samples that did not tick the programme status box. According to the Macorr sample size methodology, when determining the sample size needed for a given level of accuracy one should use the worst-case percentage (50%).
Confidence Interval	2.7%	The confidence interval of 2.7% was used.
Confidence Level	95%	The confidence level of 95% was used.



Source: <http://www.macorr.com/sample-size-calculator.htm>

Figure 3.2: Output from the Macorr Sample Size Calculator

An adequate sample size as well as the appropriate research design are critical in allowing the study results to be generalised to the target population (Joubert and Ehrlicht 2009:94).

The sample size for the research study was calculated as 1200 by the macorr sample size calculator based on the values from table 3.3. Of the sample size of 1200, 500 samples were allocated to the Tambo Memorial study site. The Far East Rand and Tembisa study sites were allocated 350 samples each.

3.5 Data sources

A number of data collection methods as well as data collection instruments are used for this study.

3.5.1 Data collection Methods

The following data collection methods were employed for this study:-

- New CCMT laboratory request form (Form 4 page 96)
- Interview with professional nurses and clinicians
- Interview with laboratory staff at the week follow-up visits
- Self-administered pre-ART register questionnaire (Form 5 page 97)

3.5.2 Data collection instruments

A number of data collection instruments are used for this study. They are listed below in chronological order: -

- New CCMT Request Form pre-testing questionnaire (Form 1 page 91)
- Site follow-up visit form(Form 2 page 93)
- Existing CCMT request form(Form 3 Page 95)
- New CCMT request form (Form 4 page 96)
- Pre-ART laboratory register questionnaire (Form 5 page 97)

3.5.2.1 New CCMT Request Form pre-testing questionnaire (Form 1, page 91)

The reason for pre-testing a new data collection instrument for this research project was to evaluate whether the respondents interpret questions in a consistent manner as intended by the researcher. The pre-testing of the New CCMT Request Form (Form 4 page 95) involved asking the selected health care workers to review the form with regard to its flow and ease of completion.

3.5.2.2 Site follow-up visit form (Form 2, page 93)

In weeks two, four and seven of the study, the laboratories and study sites were visited to review progress. At the laboratory the percentage of CD4 requested forms completed with the required information were assessed. Additional aspects assessed included the form legibility, data capture accuracy and awareness. The follow-up visit forms (Form 2 page 93) were completed by the researcher based on the findings of the visits.

3.5.2.3 Existing CCMT request form (Form 3 Page 95)

The existing CCMT request form implemented by the NHLS in 2009, used by health facilities in the Ekurhuleni health district, forms part of the pre-study baseline data analysis. This laboratory request form is completed by health care workers at the health facilities and sent to their local CD4 laboratory.

3.5.2.4 New CCMT request form (Form 4, page 96)

The new CCMT request form design was based on the existing CCMT request form (Form 3 Page 95), and amended to meet the new HIV and TB programme status reporting requirements incorporate the current HIV and AIDS guidelines and reflect CCMT programme status. This new form is divided into multiple sections that are provided to capture the health facility details, patient demographics, specimen details, clinical information, laboratory tests requested and the CCMT programme status data collection tool. For the study, the new CCMT request form (Form 4 page 96) was used to collect the programme status for CD4 samples.

3.5.2.5 Pre-ART laboratory register questionnaire (Form 5 page 97)

This form was administered at the end of the study after the pre-ART register had been delivered by the researcher to the health facility manager. It was designed to be a self-administered questionnaire that consisted of two sections. The first section assessed

the quality and format of the laboratory-based pre-ART register. The second section assessed whether the laboratory based pre-ART register could reduce pre-ART loss to follow-up and improve record management and DHIS reporting.

3.6 Data Collection

The data for the study was collected using the forms described above and collected in a two-step process. In step one, the new CCMT laboratory request form (Form 4 page 96) was used by the health care worker to capture information about the health facility where the CD4 test originated, the patient's details, laboratory tests required and the CCMT programme status. In step two, the completed request forms (Form 4 page 96) were delivered with the patient's blood samples to the local laboratory where a laboratory data capturer would enter the information on the Disa*Lab Laboratory Information Management System (LIMS). Prior to the data collection, training was provided to the study sites and laboratory data capturers on data collection tools used in the study. Follow-up visits were conducted at week two, four and seven at the CD4 laboratory to assess the quality of data provision by the study sites and data capture at the laboratories. The findings of the follow-up visits were collected using the site follow-up visit form (Form 2 page 93).

Throughout the study data from the individual laboratories (LIMS) were replicated to the Corporate Data Warehouse (CDW) at the NHLS via wide area network (WAN). In this way the data collected for the study was routinely monitored.

3.6.1 Data collection method

The selection of the method for the data collection depended on a number of factors. The two key factors in making this decision were the information required to achieve the study objectives and the resources available.

3.6.2 Development and testing of the data collection instrument

The primary data collection instrument, i.e. the new CCMT request form (Form 4 page 96) was developed the NHLS in collaboration with Western Cape HIV clinicians and the Western Cape laboratory co-ordinator. This document was distributed by the NDOH Laboratory Co-ordinator to provincial laboratory co-ordinators, NDOH priority programme units (HIV & TB) and within the NHLS (refer to Annexure C) for additional input and approval.

The purpose of pre-testing the data collection instrument was to detect any possible flaws such as ambiguous instructions or wording and to determine whether the respondents understood what is required of them. The pre-testing was conducted on full time employed phlebotomists at the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) main blood room. This facility sees patients from the many wards at CMJAH for venepuncture and was selected because of their extensive exposure to the existing NHLS request forms.

3.6.3 Data collection process

After pre-testing, the pre-study baseline data was extracted using the existing CCMT request form (Form 3, page 95) prior to training the health facility on the new CCMT request form. This was done to assess the comprehensiveness and quality of data using the existing CCMT request form (Form 3 Page 95). By using the sequence of the barcode (e.g. ABCD 1234 B) on the existing CCMT request form, the number of CD4 samples received with a programme status was assessed.

Follow-up visits were conducted to review the data collected. Following the completion of the study, the CD4 and CCMT programme status data from the individual laboratories was extracted by the Corporate Data Warehouse (CDW) and analysed using Stata and Excel.

3.6.4 Ethical considerations related to data collection

The following ethical considerations apply to data collection. They are organised by the most common categories of responsibility that a researcher must comply with (Annexure M Page 161).

3.7 Reliability and validity of data sources

3.7.1 Reliability

The reliability of the research instrument used for the study can be assessed by the degree to which the instrument can be depended upon to yield consistent results if used repeatedly over time (Brink et al 2012:169). Reliability can be characterized by stability, internal consistency and equivalence reliability (Brink et al 2012:170). The following measures were taken in the design of the new CCMT request form (Form 4 page 96) to ensure that the data collection instrument could be relied upon to produce consistent results if used repeatedly:-

- The form was divided up into groups that collected data about a particular variable. For example the “LOC” box on the new CCMT request form was designed to collect information about where the sample originated. This design method was employed to ensure that each box or section on the new CCMT request form collected data about a specific group of variables. The flow from one box/section to the next was also designed to offer the user a logical flow for completing the form.

3.7.2 Validity

The validity of the data collection tool seeks to determine whether the instrument accurately measures what it is supposed to measure (Brink et al 2012:165). There are four common types of instrument validity; content validity, face validity, criterion-related validity and predictive validity (Brink et al 2012:166-167). The researcher used content validity to assess the data collection instrument. The content validity is an

assessment of how well the data collection instrument (new CCMT request form) represents all the components of the variables to be measured (Brink et al 2012:166). The following measures were taken in the design of the new CCMT request form to ensure that the data collection instrument measures what it purports to measure: -

- The CCMT programme status options for a CD4 test are mutually exclusive, which makes the data collection instrument more reliable, e.g. reduces the possibility of receiving two CCMT programme status values for a CD4 sample.
- Each programme status option was captured on the Disa*Lab Laboratory Information Systems (LIMS) to collect data in a standardised format, i.e. to avoid free-text entries.

These measures ensured that the data collection instrument (i.e. new CCMT form) is reliable.

3.7.2.1 Internal Validity

Internal validity relates to the degree to which the researcher has managed to eliminate confounding variables in the research design (Brink et al 2012:127). This study is a health systems research study aimed at evaluating whether the addition of a single new parameter, i.e. the programme status data on the NHLS request form can provide programmatic M&E data for meaningful application in the CCMT Programme. As such the study will use data collection instrument (i.e. laboratory request form completed by attending health care workers who collect the routinely requested CD4 sample from the patient). The following precautions were taken during the design of the study to improve the internal validity of the research design: -

- Use of a standardised data collection tool (new CCMT request form)
- Data collection was assessed through follow-up visits.

3.7.2.2 External Validity

A study that readily allows its findings to generalise to the population at large has high external validity (Brink et al 2012:111). The following precautions were taken during

the design of the scientific study to improve the external validity of the research design:

-

- The health care workers providing the CCMT programme status were trained prior to the study to ensure accurate and comprehensive provision of the CCMT programme status for CD4 testing.
- The new CCMT request form (Form 4 page 96) was developed following extensive consultation within the NHLS and the National Department of Health. Additionally the Virology Expert Committee, within the NHLS, validated the design of the data collection tool.

3.8 Bias and limitations

Bias is defined as an influence that can produce an error or distortion of the study results and can affect the quality of evidence in both qualitative and quantitative studies (Brink et al 2012:98).

Selection bias is introduced into a study when there are systematic or directional errors in how participants are sampled. Selection bias in a study results in the study sample being systematically different from the population they were drawn from (Joubert and Ehrlich 2009:160). Random selection and assignment or matching in the study design stage can decrease the potential for selection to be a threat to validity (Brink et al 2012:111).

Information bias occurs when systematic or directional bias in how measurements are collected from participants in the study (Joubert and Ehrlich 2009:163). An important step in reducing information bias is to ensure that variables are measured in the same way for all participants (Joubert and Ehrlich 2009:163).

The following measures were taken to reduce bias for this study –

- The study sites were provided with standardized operating procedures (SOP) for completing the new CCMT request form (Form 4 page 96). The laboratory

data capturers captured the information provided on the data collection instrument directly on the Laboratory Information management System (LIMS).

- Additional onsite training with standardised training guides was provided to the study sites to further reduce data capture variability.
- To minimise selection bias for the study, sequential sampling of health facilities was utilised. It was not anticipated that this method of sampling would bias the outcomes of the study.
- Through the use of the LIMS, data was captured in parameters that were specifically designed to include data validation checks. Additionally standardised LIMS codes were programmed into the parameter dictionary to limit what could be captured to a select list of programme status options.
- The results of the study were triangulated with other data sources. The CD4 test ranges for the study were triangulated with the national CD4 data reported from the CDW. Additionally age range reported for the study were triangulated with STATSSA published data.

3.8.1 Limitations of the study

This study is limited to hospitals based in the Ekurhuleni health district and may therefore not be generalised to the broader primary health care clinics in this district or broader application. In reality the ongoing intervention and training may not occur when implemented in other districts. It may therefore be difficult to generalise the findings of the research study.

3.9 Data analysis

The CD4 programme status data was extracted from the CDW using the Aginity workbench for Netezza tool. The data model in Annexure D describes the flow of information from the LIMS at the local laboratories to the CDW. The study data was analysed using Excel and Intercooled Stata 11. The data analysis included reporting the following data; median CD4 for pre-ART and ART programme status, percentage of CD4 samples in the pre-ART and ART programme status categories, percentage

accuracy of pre-ART electronic register (compared to paper based pre-ART register) and proportion of patients about to start ART with a CD4 count below 50 cells/ μ l.

3.10 Conclusion

This chapter provided a detailed description of the study methodology used. The ethical considerations relating to reliability, validity of the data and data collection instruments (CCMT forms) have been discussed. The next chapter will describe the results obtained from the analysis of the various sources of data.

CHAPTER FOUR: ANALYSIS, PRESENTATION AND DESCRIPTION OF THE RESEARCH FINDINGS

4.1 Introduction

This chapter outlines the research findings of the study. Data is presented by means of tables, graphs and histograms. The results are reported for the pre-testing, pre-study data analysis as well as the data collected for the study using the new CCMT request form (Form 4 page 96). Additionally, the feedback received for the pre-ART register is reported.

For the pre-study data collected using the existing CCMT request form (Form 3 Page 95) was analysed for CD4 samples submitted from the three study sites. For the study the information provided on the new CCMT request form (Form 4 page 96) by the study sites was captured on the LIMS.

The pre-study data analysis reports on the “as-is” data collection using existing systems. For the study the interventions included introducing a new request form, providing standardised materials and providing training.

4.2 Research results

The research results are presented under the following headings:-

- Pre-testing (using Form 1 Page 91)
- Pre-study baseline results (using Form 3 Page 95)
- Study follow-up visit findings (using Form 2 Page 93)
- Study results (using Form 4 Page 96)
- Pre-ART register (using Form 5 Page 97)

4.2.1 Pre-testing

The results of the pre-testing presented below include an assessment of the reliability and validity of the data collection instrument (new CCMT request form). For the assessment of the reliability (repeatability) of the data collection instrument, the completed forms were reviewed to assess whether the phlebotomist provided the same programme status on the two completed new CCMT request forms. In the pre-testing 75% of the phlebotomists provided the same CCMT programme status information (Figure 4.1).

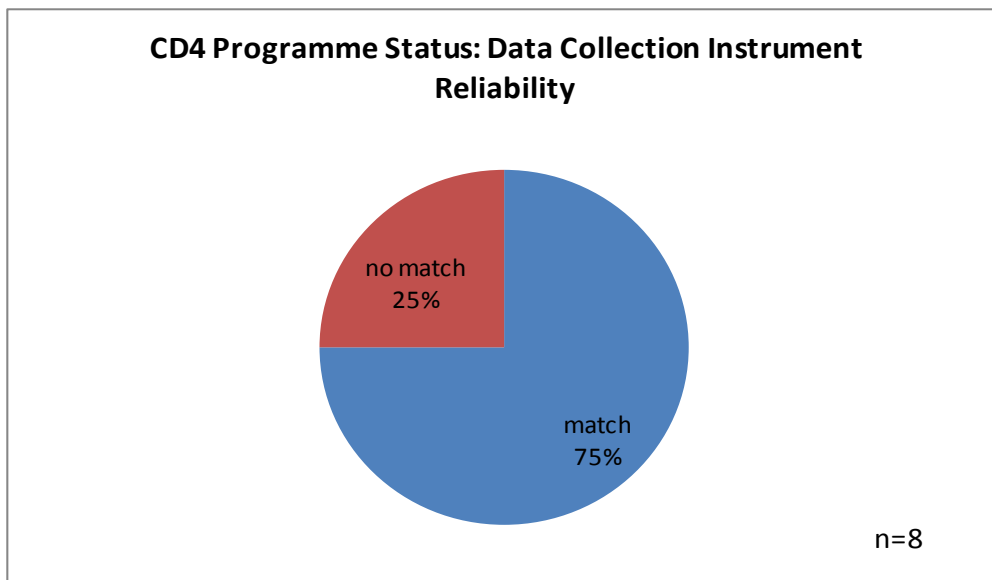


Figure 4.1: CD4 Programme Status reliability finding

To appraise the validity of the new CCMT request form, the pre-testing assessment form was evaluated using a standardised questionnaire. All of the phlebotomists (n=8) found that the new CCMT request form was easy to understand and had a logical flow that was suitable for health care workers. Two issues were raised. Firstly the completion of ICD 10 code (International Statistical Classification of Diseases and Related Health Problems, e.g. E10 used for Insulin-dependent diabetes mellitus) may be difficult to understand and secondly, that the completion of the clinical information ideally should be provided by clinicians. These concerns were noted. However, both are routine requirements for NHLS request forms as well as being a requirement by the NDOH as a diagnostic coding standard (NDOH 2012b:5). For certain laboratory tests, such as tissue samples for microbiological testing, the clinical diagnosis should

be provided on the laboratory request form according to the NHLS laboratory handbook (NHLS 2012:80). Therefore it was decided to leave these two elements on the new CCMT request form (Form 4 page 96) to comply with current standards.

The qualitative aspects highlighted by the phlebotomist provided in the more open-ended questions such as “please add any other information you would like to highlight” about the new CCMT request form, included comments such as “it is good to have to show who has collected the specimen so that you can track back”, “the form is simple and straightforward” and “I am satisfied with the new CCMT form”. In summary the pre-testing confirmed that the new CCMT request form was acceptable and not likely to be ambiguous based on the subjective responses of the phlebotomists attending (Figure 4.2).

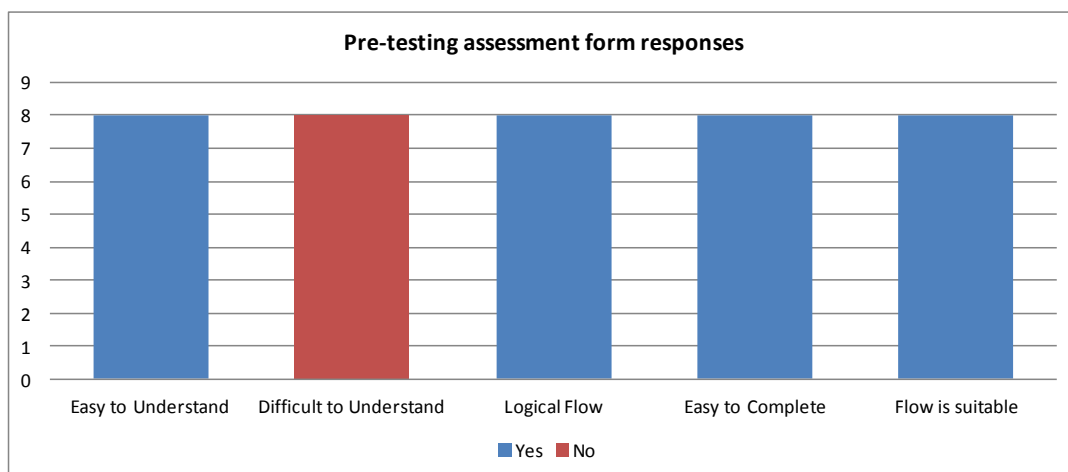


Figure 4.2: Pre-testing assessment form response summary

4.2.2 Pre-study baseline results

Of the 3168 CD4 samples received, over 97% (n=3103) were requested on the existing CCMT request form (Form 3 Page 95). At the Far East Rand study site, of the 863 existing CCMT request forms received (Form 3 Page 95), no CD4 samples had the CCMT programme status captured on the LIMS. In comparison, the Tembisa study site captured the CCMT programme status for 21.61% (n=250) of CD4 samples (Table 4.1). It is not clear whether this is due to poor implementation of standard operating procedures (SOP) or due to health care workers not providing this information. The

Tambo Memorial site had the highest rate of programme status provision on the LIMS at 57.53% (n=623). Overall the baseline analysis indicates that the existing systems could provide data to support a CCMT programme status reporting system but that the cooperation and response of health care workers in filling in programme status on the form was generally poor.

Table 4.1: (Baseline) CCMT Programme Status analysis on data entered on the existing NHLS request form

Health Facility	CCMT Form				Other NHLS request form		Grand Total	% Grand Total
	No Programme Status	Prog Stat Captured	Total	% Captured	No Programme Status	Prog Stat Captured		
FAR EAST RAND	863		863	0	9		872	27.53
TAMBO MEMORIAL	460	623	1083	57.53	10	5	1098	34.66
TEMBISA	907	250	1157	21.61	41		1198	37.82
Total	2230	873	3103	28.13	60	5	3168	100.00
% Total	70.39	27.56	97.95		1.89	0.16	100	

The CCMT programme status values captured in the LIMS (using coded comments) were categorised as ART, Pre-ART or No Data Supplied (where no information was provided by the health care worker). Some of the values captured were categorised as excluded as they included drug and PMTCT codes. Most of the CCMT programme status captured on the LIMS were from the ART category (55.2%), followed by pre-ART (33.9%). Only 6.7% of the data was categorised as excluded. Overall the CCMT programme status was provided by health care workers and captured on the LIMS in only 27.56% (n=873) of CD4 samples where the old CCMT form was used (Table 4.3). The median CD4 for the ART category was 361 cells/ μ l compared to 196 cells/ μ l for the pre-ART category. It was however not possible to identify the percentage of first ever CD4 samples for the baseline data as this information was not captured on the old CCMT form. For patients with a pre-ART CCMT programme status, 19% had a CD4 count below 50 cells/ μ l.

Table 4.2: CD4 count median and proportion of CD4 samples \leq 50 cells/ μ l for the CCMT programme status categories

CCMT Programme Status Category	n=	% Total	Median CD4	\leq 50 cells/ μ l	$>$ 50 cells/ μ l	% \leq 50
ART	485	56	361	14	471	3%
PRE-ART	297	34	196	56	241	19%
NO DATA SUPPLIED	32	4	214	6	26	19%
EXCLUDED*	59	7		1	58	
Total	873	100		77	796	

* PMTCT and Drug codes

4.2.3 Study follow-up visit findings

The new CCMT forms were delivered and training provided prior to the study. The research study commenced on 1 October 2013 and regular follow up visits were conducted to assess data provision. Follow up visits were conducted at weeks two, four and six.

4.2.4 Study results

At the follow-up visits, the number of new CCMT request forms received by the laboratory were manually counted. Additionally, the laboratory staff assessed the number of forms where the CCMT programme status was provided by the health care workers. Ten request forms were randomly selected by laboratory staff to assess whether the data capturers had entered the patients gender and programme status on the LIMS.

4.2.5. Week two follow-up visit findings

By the beginning of week two, 240 of the new CCMT request forms had been received for the study, the majority originating from the Tambo Memorial Site (66.67 %). Overall, at the time of the assessment, 20% of sample size had been achieved (Table 4.3). At the Far East Rand study site, most of the new CCMT request forms were received from the Osizweni ART ward, despite an agreement to distribute the request forms to other medical wards as well. The researcher informed Dr. Ncholo, who agreed to speak to other clinicians to start using the new CCMT request forms in the medical wards. The Tembisa and Tambo Memorial study sites did much better, as samples were received from the wards as agreed at the training sessions. The Tembisa study site agreed to increase the use of the new CCMT request form in other medical wards. It was noted that most of the new CCMT request forms originated from the Masakhane ART ward with only a few CD4 samples received from the medical wards.

Table 4.3: Number of new CCMT request forms received per site at the beginning of week two

Site	Date Assessed	n=	% Total	Target	% of Sample Size
Tembisa	09 October 2012	60	25.00	350	17.14
Tambo Memorial	11 October 2012	160	66.67	500	32.00
Far East Rand	09 October 2012	20	8.33	350	5.71
Total		240	100.00	1200	20.00

For this assessment of accuracy of the data captured, the laboratory staff randomly selected ten request forms and called up the LIMS registration screen for each laboratory number. Using a tick sheet, the laboratory staff placed a tick if the CCMT programme status provided on the new CCMT request form had been captured on the LIMS. The Tembisa and Tambo Memorial laboratories scored in excess of 90% for the random sample of ten request forms (Table 4.4). The Far East Rand site had not implemented the data capture requirements for the study despite receiving the same training as the other two laboratories. An intervention was planned for this laboratory with the acting laboratory manager to ensure that back capture was completed and that the information required was captured going forward.

Table 4.4: Percentage compliance with providing and capturing CD4 Programme Status information in week two

Site	Date Assessed	% Forms with CD4 Programme Status Provided	% gender correctly captured in LIMS (n=10)	% CD4 Programme Status correctly captured in LIMS (n=10)
Tembisa	09 October 2012	96.67	100.00	90.00
Tambo Memorial	11 October 2012	96.25	100.00	100.00
Far East Rand	09 October 2012	95.00	100.00	-
Total				

4.2.6 Week four follow-up visit findings

By the beginning of week four, 613 new CCMT request forms (Form 4 page 96) had been received for the study, the majority originating from the Tambo Memorial study site (50.57 %). Overall, 51.08% of the sample size had been achieved (Table 4.5). At the Far East Rand study site, the new CCMT request forms were received from various medical wards in addition to the Osizweni ART ward. The Tambo Memorial study site had reached 62% of their required sample size compared to 54.86% for Tembisa and 31.71% for the Far East Rand site (Table 4.5). This was a substantial increase from the two week follow-up visit where the sites had reached 32%, 17.14% and 5.71% respectively.

Table 4.5: Number of new CCMT request forms received per site at the beginning of week four

Site	Date Assessed	n=	% Total	Target	% of Sample Size
Tembisa	24 October 2012	192	31.32	350	54.86
Tambo Memorial	24 October 2012	310	50.57	500	62.00
Far East Rand	24 October 2012	111	18.11	350	31.71
Total		613	100.00	1200	51.08

When comparing the accuracy of the data capture on the LIMS at the three laboratories at the week four follow-up visit, the Tembisa and Tambo Memorial laboratories scored in excess of 90%, compared to 30% at the Far East Rand laboratory (Table 4.6). However 90% of the Far East Rand new CCMT request forms had a CD4 programme status captured on the LIMS, just not in the correct parameter on the LIMS. The data capturers at this laboratory were offered additional onsite training to populate the LIMS parameter specifically designed for the study.

Table 4.6: Percentage compliance with providing and capturing CD4 Programme Status information in week four

Site	Date Assessed	n=	% Total	Target	% of Sample Size	% Forms with CD4 Programme Status Provided (n=60)	% gender correctly captured in LIMS (n=10)	% CD4 Programme Status correctly captured in LIMS (n=10)
Tembisa	24 October 2012	192	31.32	350	54.86	96.88	100.00	80.00
Tambo Memorial	24 October 2012	310	50.57	500	62.00	97.74	100.00	90.00
Far East Rand	24 October 2012	111	18.11	350	31.71	98.20	100.00	30.00
Total		613	100.00	1200	51.08			

4.2.7 Week seven follow-up visit findings

A follow-up visit was planned for week six, however due to work commitments the researcher had to reschedule the follow-up visit to week seven. By the 16th of November 2012, 1037 forms had been received for the study, the majority originating from the Tambo Memorial Site (55.26%). Overall at the time of this assessment, 86.42% of sample size had been achieved (Table 4.7).

The Tambo Memorial site had reached 114% of their required sample size compared to 73.14% for Tembisa and 59.43% for the Far East Rand study site (Table 4.7). This was a substantial increase from the week four follow-up visit where the sites had reached 2%, 54.86% and 31.71% respectively.

Table 4.7: Number of new CCMT request forms received per site at week seven

Site	Date Assessed	n=	% Total	Target	% of Sample Size
Tembisa	16 November 2012	256	24.69	350	73.14
Tambo Memorial	16 November 2012	573	55.26	500	114.60
Far East Rand	16 November 2012	208	20.06	350	59.43
Total		1037	100.00	1200	86.42

The figure below (Figure 4.3) demonstrates how the Tambo Memorial site accelerated the uptake of the new CCMT request form to reach 114.6% of the required sample size by week seven. In contrast, the Tembisa and Far East Rand sites displayed a much slower increase in the uptake of the new CCMT request form. Telephonic discussions were arranged with these study sites to discuss interventions aimed at improving capture of the relevant programme status data. This included extending the study period.

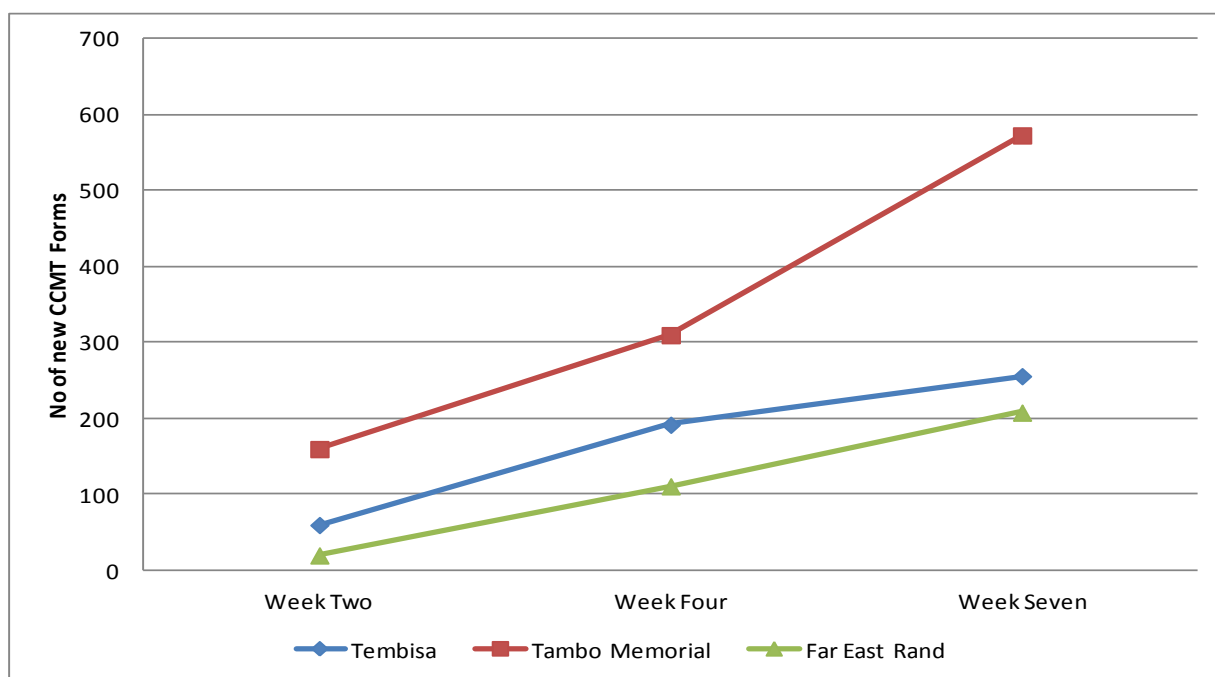


Figure 4.3: Number of new CCMT request form received per site at each follow-up visit

The assessment of the provision of the CCMT programme status information confirmed again that each study site provided the required information in 95% or more of all CD4 samples requested for the study (Table 4.8). The assessment of the data capture of the CD4 programme status information on LIMS confirmed that the three laboratories captured the required information in 70% or more of the CD4 samples requested for the study.

Table 4.8: Percentage compliance with providing and capturing CD4 Programme Status information in week seven

Site	Date Assessed	n=	% Total	Target	% of Sample Size	% Forms with CD4 Programme Status Provided (n=60)	% gender correctly captured in LIMS (n=10)	% CD4 Programme Status correctly captured in LIMS (n=10)
Tembisa	16 November 2012	256	24.69	350	73.14	97.20	100.00	80.00
Tambo Memorial	16 November 2012	573	55.26	500	114.60	98.00	100.00	100.00
Far East Rand	16 November 2012	208	20.06	350	59.43	97.10	100.00	70.00
Total		1037	100.00	1200	86.42			

4.2.8 Pre-ART register

During the study, a pre-ART register was printed for each study site. An extract of the pre-ART register delivered to Tambo Memorial study site is included in Annexure J (Page 150). This register listed all CD4 samples that were received with a “First ever CD4” programme status and where the CD4 count was below 350 cells/µl. A self-administered questionnaire was provided to the study sites to assess the laboratory based pre-ART register. Each study site was expected to review their laboratory based pre-ART register and complete the pre-ART questionnaire (Form 5 page 97) to assess the usefulness of the laboratory based pre-ART register.

In the first section of the pre-ART questionnaire the study sites were requested to rate the format and the quality of the pre-ART laboratory register compared to their existing paper-based records. The questionnaire utilised a five point scale to rate each question (excellent, very good, good average and poor). The responses were allocated a numerical score (1-5), with excellent scored as five and poor scored as one.

All three study sites rated the quality and format of the pre-ART laboratory register a score of four or five (excellent or very good) (Figure 4.4). This confirms that the study sites were satisfied with the content and format of the pre-ART laboratory registers.

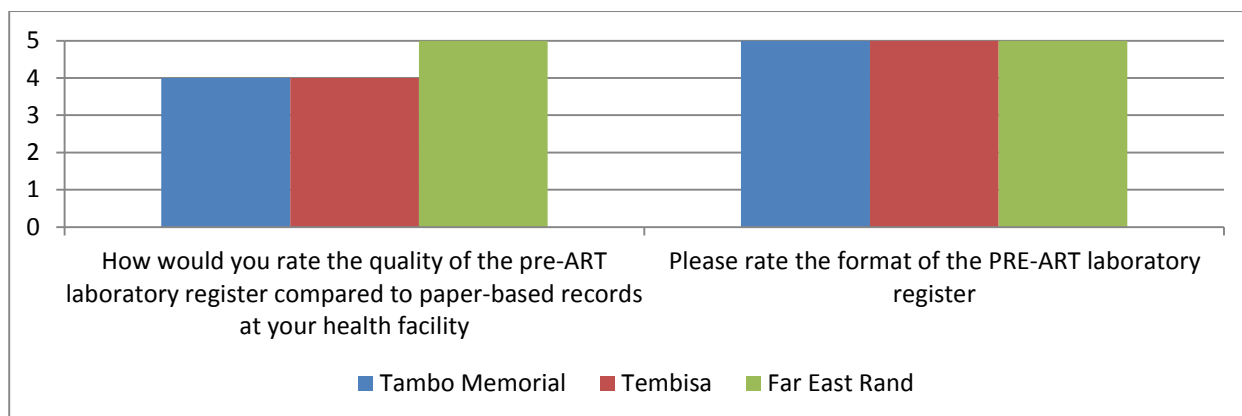


Figure 4.4: Study site assessment of the format and quality of the laboratory pre-ART register

In the next section of the pre-ART questionnaire the study sites were requested to assess whether the pre-ART laboratory register: -

- Made it easier to track patient to reduce loss to follow-up?
- Made it easier to ensure that the paper-based records are complete?
- Made it easier to report on the DHIS?
- Made it easier to manage the flow to patient being staged in your facility?
- Made it easier to follow-up patients that have not returned to the health facility after a CD4 test?

This section also utilised a five point scale to rate each question (great assistance, good assistance, partial assistance, only limited assistance and no assistance at all). The scale was also allocated a numerical score (1-5). For each of the questions assessed in this section, the study sites scored between four and five again (great assistance and good assistance) (Figure 4.5).

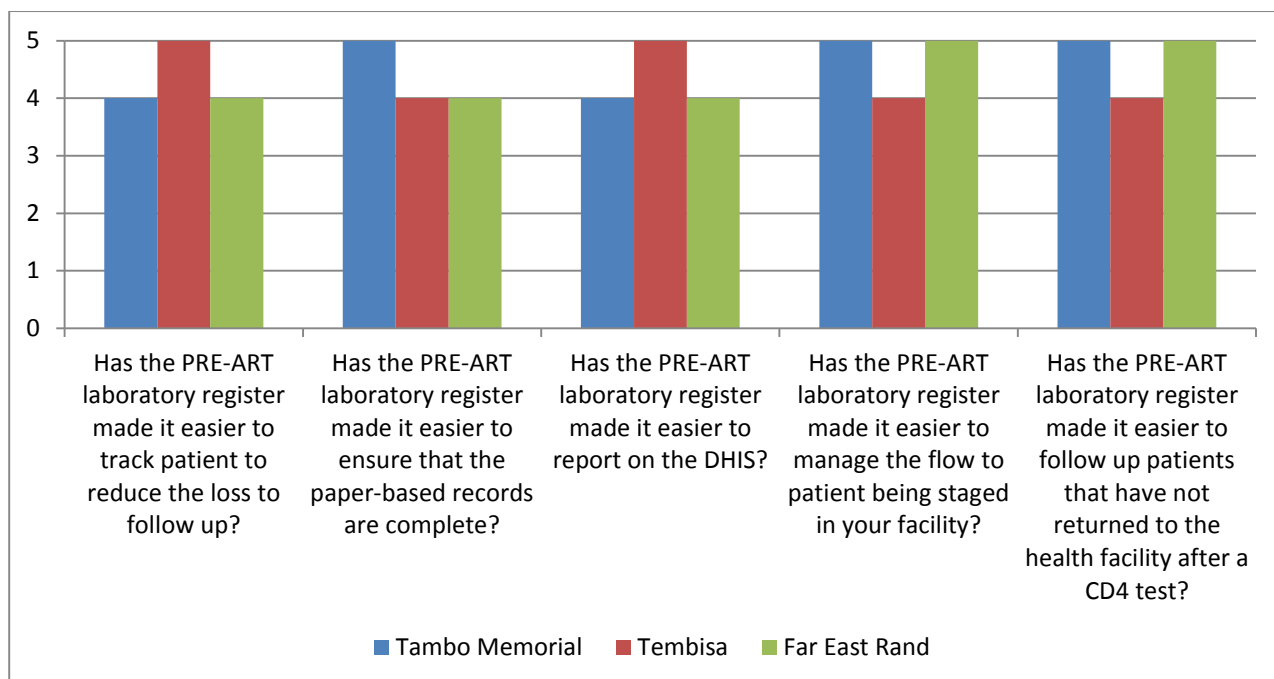


Figure 4.5: Study site assessment of the usefulness of the laboratory pre-ART register

4.3 Research Study results

After achieving the required sample size at each study site, the study data extract was obtained from the CDW. The data extract specification stipulated that CD4 data was required for the three study sites for the study period (1 October 2012 to 31 January 2013). The data was analysed using Microsoft Excel 2007 and Stata 11.

4.3.1 Samples that met the inclusion criteria

One of the inclusion criteria for the study was that CD4 samples should be submitted to the laboratory on the new CCMT request form (Form 4 page 96) as identified by the unique barcode sequence captured on the LIMS, e.g. INT1234. Based on the barcode sequence, CD4 samples were categorised as “New CCMT request form” or “Other forms”. The category “New CCMT request form” was allocated when the barcode sequence contained “INT” for a CD4 result. An additional criteria was that CD4 samples for the study should be from the adult population (≥ 18 years). The patient ages captured on the LIMS were categorised as <18 years, ≥ 18 years and unknown age (where no age was captured).

In the data extract provided by the CDW, 4513 CD4 samples were received of which 1266 (22.5%) were received on the new CCMT request form. The CDW data extract specification was designed to extract data for the study sites through the use of their LIMS location codes, e.g. BOK for Tambo Memorial. There were 76 samples requested on the new CCMT request form, where the patient ages did not meet the study inclusion criteria. The data set analysed for the study included 1190 eligible CD4 results with programme status information (Table 4.9).

Table 4.9: CD4 data that met the age and request form usage study eligibility criteria

Request Form	<=18	Unknown	>=18	Total	% Total
New CCMT request form	76	2	1188	1266	22.5
Other Form	996	46	3325	4367	77.5
Grand Total	1072	48	4513	5633	100
		# eligible forms	1190		

One of the criteria for the study was that the CD4 data generated by the study would include CD4 testing requested for pre-ART screening and routine ART monitoring. Therefore, at each study site, specific wards were utilised to ensure that the new CCMT request form were used at the wellness clinics (ART site) as well as HCT, antenatal and medical wards (pre-ART testing). Based on the LIMS location and ward codes, wards were categorised as ART ward and Pre-ART wards.

For the study data, 35% (n=419) of the samples were received from Pre-ART wards at the three study sites, whereas 65% (771) were collected from ART wards (Table 4.10). At each study site there was a single ART ward, but multiple non-ART wards. This confirms that the new CCMT request form (Form 4 page 96) was correctly deployed for the study.

Table 4.10: CD4 data that met the ward type study eligibility criteria

Ward type	n=	% Total
Pre-ART Ward	419	35
ART ward	771	65
Total	1190	100

4.3.2 Characteristics of study data

The characteristics of the research study data described included the number of CD4 samples submitted by each study site, a gender and age distribution as well as CD4 result range distribution.

The three study sites requested CD4 samples for the study from 1 October 2012 to 31 January 2013 using the new CCMT request form (Form 4 page 96) as noted in table 4.11. For the study, 1190 samples were received, with 47% (n=557) received from Tambo Memorial study site, 32% (n=378) from the Tembisa study site and 21% (n=255) from the Far East Rand site (Table 4.11). Therefore the study achieved 99% of the target study sample size.

Table 4.11: Study sites data uptake

Health Facility	n=	% Total
FAR EAST RAND HOSPITAL	255	21
TAMBO MEMORIAL HOSPITAL	557	47
TEMBISA HOSPITAL	378	32
Total	1190	100

The patient's gender was provided on the new CCMT request form by health care workers and captured on the LIMS at the laboratory. At each follow-up visit, the capture of gender on the LIMS for the 10 randomly selected request forms was 100%. This is consistent with the gender data collected for the study. Only 2 CD4 results did not have a gender captured in the LIMS (0.17%). For the study a valid gender was captured in the LIMS in 99.8% of all CD4 samples (Table 4.12).

Of the 1190 gender values captured on the LIMS, 686 were from female patients (58%) compared to 502 for males (42%).

Table 4.12: Study gender distribution

Gender	n=	% Total
Female	686	57.65
Male	502	42.18
Other	2	0
Total	1190	100

The age data collected indicates that the majority of patients were between the ages of 30 and 44 (59%). Only 13.9% of patients were between the ages of 18 and 29, whereas 26.9% of patients were older than 45 years (Table 4.13).

Table 4.13: Study age distribution

Age Category	n=	% Total
18-24	57	4.8
25-29	109	9.2
30-34	227	19.1
35-39	266	22.4
40-44	209	17.6
45-49	123	10.3
>49	197	16.6
Unknown	2	0.2
Total	1190	100

The CD4 absolute count data was extracted and categorised into various result ranges to enable the analysis of the percentage of samples with a CD4 value below 50, 100, 200 and 350 cells/ μ l. For the study, the data analysis revealed that 11% (n=128) of the CD4 results were less than or equal to 50 cells/ μ l, 19% were below 100 cells/ μ l, 36% were below 200 cells/ μ l and 60% were below 350 cells/ μ l (Table 4.14). The remaining 40% of CD4 results were greater than 350 cells/ μ l.

Table 4.14: CD4 test range distribution

CD4 Category	n=	% Total
<=50	128	11
51-100	99	8
101-200	198	17
201-350	286	24
>350	479	40
Total	1190	100

4.3.3 CCMT programme status data

For the study, the programme status captured on the LIMS was analysed. Where the programme status provided was not appropriate, e.g. NVP (nevirapine), the data was categorised as "Programme status not relevant to study". Where the data capturer had

captured the LIMS coded comment “NDS” (No Data Supplied) on the LIMS to reflect that the health care worker had not provided a programme status, the data was categorised as “No details provided by HCW”. Where no CCMT programme status data was captured on the LIMS, the data was categorised as “No data captured/provided”. The valid CCMT programme status options included “First ever CD4”, “CD4 taken previously, not yet in ART care” and “In ART care”.

To analyse the provision and capture of the programme status for the study, the percentage of samples received with a valid programme status was assessed. For the study, 84.4% (n=1004) of the CD4 samples had a valid programme status noted. This is a significant improvement from 27.56% reported for the pre-study baseline analysis (using Form 3 Page 95). The Tambo Memorial study site reported the highest rate of valid programme status provision on the LIMS (89%).

Only 14.2% (n=165) of the CD4 samples for the study did not have a programme status captured on the LIMS (unable to assess whether a programme status had been provided by the health care worker (Table 4.15).

A small number of samples of (n=17 1.43%) were categorised as “Programme status not relevant to the study”, e.g. NVP (nevirapine). For these samples the incorrect information was captured on the request form, i.e. drug status. However, this does not imply that these patients were not in ART or wellness care.

There were only 4 (0.34%) CD4 results where the programme status captured on the LIMS indicated that the health care worker had not provided a programme status, e.g. NDS (No Data Supplied).

Table 4.15: CCMT programme status distribution for CD4 results

CCMT Programme Status	n=	% Total
First ever CD4	309	25.97
CD4 taken previously, not yet in ART care	74	6.22
In ART care (please mark drugs)	621	52.18
No data captured/provided	165	13.87
No details provided by HCW	4	0.34
Programme status not relevant to study	17	1.43
Total	1190	100.00

The percentage of Pre-ART and ART programme status captured on the LIMS for each study site was assessed. To calculate these percentages only the valid programme status (highlighted in yellow) were included (n=1004). For the study 38% (n=383) of the CD4 samples with a valid programme status were received with a pre-ART programme status category, compared to 52% (n=621) for an ART programme status category (Table 4.16). For the Tambo Memorial and Tembisa study sites the proportion of CD4 samples received with a pre-ART or ART programme status were similar, at the Far East Rand study site samples were received mainly with an ART programme status (92%).

Table 4.16: CCMT programme status distribution for CD4 results at the three study sites

Programme Status Category	CCMT PROGRAMME Status	FAR EAST RAND HOSPITAL	TAMBO MEMORIAL HOSPITAL	TEMBISA HOSPITAL	Total	% Total
pre-ART	First ever CD4	13	162	134	309	26
	CD4 taken previously, not yet in ART care	3	44	27	74	6
ART	In ART care	192	288	141	621	52
Other	No data captured/provided	46	47	72	165	14
	No details provided by HCW	1		3	4	0.34
	Programme status not relevant to study		16	1	17	1
Total		255	557	378	1190	100
% Total		21	47	32	100	
% Valid CCMT Programme Status		82	89	80	84	
% Pre-ART Programme Status (of the valid CCMT Programme Status options)		8	42	53	38	
% ART Programme Status (of the valid CCMT Programme Status options)		92	58	47	62	

The ward codes captured on the LIMS for each study site were categorised as “ART ward” for wards that provided ART services or a “Non-ART” ward where the ward was not offering ART. The Far East Rand study site submitted only 5% (n=13) of their CD4 samples for the study from non-ART wards, compared to 38% (n=214) and 51% (n=192) for the Tambo Memorial and Tembisa study sites respectively (Table 4.17).

Table 4.17: New CCMT request form usage for the ward type at the three study sites

Ward Type	FAR EAST RAND HOSPITAL	TAMBO MEMORIAL HOSPITAL	TEMBISA HOSPITAL	Total	% Total
ART ward	242	343	186	771	65
Non-ART ward	13	214	192	419	35
Total	255	557	378	1190	100
% Non-ART ward	5	38	51	35	

One of the objectives of this study was to report the proportion of patients about to start ART with a CD4 count below 50 cells/µl. The CCMT programme status categories

for this study objective are the “First ever CD4” and “CD4 taken previously, not yet in ART care” results. The CD4 results for the study were categorised into two test ranges (≤ 50 and > 50 cells/ μ l). For this study, 11% of all CD4 samples tested were below 50 cells/ μ l. For the pre-ART CCMT programme status category, however this increased to 22% (Table 4.18). The percentage of CD4 samples with counts below 50 cells/ μ l was 24% for “First ever CD4” and 14% for “CD4 taken previously, not yet in ART care” programme status. Therefore one third of the patients with a CD4 count below 50 cells/ μ l were not yet in ART care.

Table 4.18: Proportion of patients about to start ART with a CD4 count below 50 cells/ μ l

CCMT Programme Status		≤ 50	> 50	Total	% ≤ 50
pre-ART	First ever CD4	75	234	309	24
	CD4 taken previously, not yet in ART care	10	64	74	14
	<i>Total</i>	85	298	383	22
ART	In ART care (please mark drugs)	11	610	621	2
Other	No data captured/provided	28	137	165	17
	No details provided by HCW	1	3	4	25
	Programme status not relevant to study	3	14	17	18
Total		128	1062	1190	11
% Total		11	89	100	

The current South African ART guidelines define the eligibility criterion to start ART at a CD4 count of 350 cells/ μ l (NDOH 2010:8). The study data pre-ART programme status was used to assess the number of patients that would be eligible for ART. For the study, 74% (n=282) of the patients with a pre-ART CCMT programme status were eligible for ART (current guidelines). This increased to 79% for CD4 samples with a “First ever CD4” programme status (current guidelines) (Table 4.19). The new WHO guidelines released in 2013 recommend that patients with CD4 count between 350 and 500 cells/ μ l should also be placed on ART irrespective of their WHO clinical stage (WHO 2013b:2). If these guidelines were to be adopted in South Africa, based on the study results, 87% (n=334) of these pre-ART patients would be eligible for ART.

Table 4.19: Proportion of patients with a pre-ART CCMT Programme Status that are eligible for ART

Pre-ART CCMT Programme Status	<=350	>350 <=500	>500	Total	% CD4 samples <= 350 cells/ul	% CD4 samples <= 500 cells/ul
First ever CD4	243	33	33	309	79%	89%
CD4 taken previously, not yet in ART care	39	19	16	74	53%	78%
Total	282	52	49	383	74%	87%
% Total	74%	14%	13%	100%		

The study CD4 mean was 323 cells/µl with a median of 288 cells/µl. For CD4 samples with a programme status of “First ever CD4” the median CD4 was 150 cells/µl, compared to a median CD4 of 346 cells/µl for samples with an “In ART” programme status (Table 4.20).

Table 4.20: CD4 Count mean and median for CCMT Programme Status codes

CCMT Programme Status	n=	Mean	Median CD4	%Total
First ever CD4	309	220	150	
CD4 taken previously, not yet in ART care	74	327	328	32
In ART care (please mark drugs)	621	379	346	52
No data captured/provided	165	309	274	
No details provided by HCW	4	261	267	
Not a CCMT Programme Status	17	293	267	
Total	1190	323	288	

4.4 Conclusion

The research findings have clearly described the number of CD4 samples for the baseline and study data at the three study sites as well as the median CD4. Additionally, the findings of the follow-up site visits identified some of the challenges encountered as well as the level of compliance for data collection and capture.

CHAPTER 5: CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter critically evaluates the results of the study and provides the conclusions for the findings as well as recommendations. The study results are discussed with available literature to relate findings to previous studies. This chapter assesses whether the intervention of the new CCMT request form provides comprehensive and accurate CCMT programme status data compared to the findings for the baseline study. Limitations inherent in the study will also be discussed in this chapter.

5.2 Research design and method

This was a quantitative research study that employed the methodological research design (empirical). Although one of the limitations of this study design is the applicability of results to other contexts, it is well suited for piloting the implementation of a new data collection tool.

The study population consisted of patients attending the Tembisa, Tambo Memorial and Far East Rand study sites in the Ekurhuleni district for HIV care. The health care workers at the study sites used the new CCMT request form when patients required CD4 testing during the study period.

Data was collected using the completed new CCMT request form and the LIMS at the study sites. Once the data was captured in the LIMS, it was replicated to the Corporate Data Warehouse and extracted without patient identifiers. The data was analysed to ensure that all CD4 results met the inclusion criteria for the study. Data analyses was done with Microsoft Excel and Stata 11, and included calculating the median CD4 for pre-ART and ART CCMT programme status categories, the percentage of CD4 samples in the pre-ART and ART programme status categories and the proportion of patients about to start ART with a CD4 count below 50, 350 and 500.

5.3 Summary and interpretation of research findings

5.3.1 The laboratory based CCMT Programme Status reporting system

The study was designed to address the following key issues:

- Establishing the impact of use of the tick box system to capture HIV ART programmatic status.
- Establishing the usefulness of the laboratory pre-ART register (assessed with a questionnaire)
- Establishing the median CD4 for 'pre-ART' and 'ART CCMT' programme status groups, at each of the health facilities, as an indirect indicator of overall patient programmatic immune status.
- Establishing the percentage of patients in the pre-ART and ART programme status categories as a percentage of total CD4 samples received, to define eligibility for treatment.
- Establishing the proportion of patients eligible to start ART with a CD4 count below 50 (specifically included for the study as the national M&E framework for the NSP 2007-2011, as an indicator to measure the proportion of patients with a CD4 count ≤ 50 on start (NDOH 2009)).
- Establishing the number of patients that were eligible for ART, but not yet enrolled onto treatment programmes.
- Contextualising the outcomes in light of the new NDOH guidelines for treatment.

In the baseline data analysis study a total of 3168 CD4 samples were requested between June and July 2012, of which 3103 (98%) were requested on the existing CCMT request form. However, only 873 (27.56%) had a CCMT programme status captured on the LIMS.

For this study, 1266 CD4 samples from the three study sites were received on the new CCMT request form between October 2012 and January 2013. Six percent (6%, n=76) of samples were excluded as they did not fulfil the study eligibility criteria. The study reached 99% of the target sample size (n=1190, original macorr calculation of 1200).

The study was conducted with minimal interruption to routine health care services at the three study sites with health care workers only required to place an extra tick when requesting a CD4 test on the new CCMT request form. During the follow-up visits in weeks 2, 4 and 7 of the study, the level of data provision by health care workers was high (well over 80% for all three visits). At the laboratory level, the data capture rate was poor only at one study site during week two and four follow-up visits, but improved with additional training. By the time the study data was extracted, all three laboratory sites had captured the CCMT programme status for 80% or more of the CD4 samples requested for the study.

The aim of the study was to develop a laboratory based CCMT Programme Status reporting system specifically to evaluate HIV patient programme ART status linked to the request for CD4 testing in the Ekurhuleni Health District. The study demonstrated that this reporting system was easily implemented into routine healthcare services delivery. Data was collected as part of the process of requesting a CD4 test by the health care workers and subsequently captured by the data capturer as part of registering the CD4 test on the LIMS. Lastly, the data transferred across to the NHLS Central Warehouse Database for data analysis.

There are a number of factors that facilitated successful collection of the data for the study. The LIMS test methods had already been designed to collect a specific set of information such as the CD4 results (CDARV) or in the case of the new CCMT form, the newly designated CCMT programme status (ARVID) linked to the request for CD4. Typically, within each test method, parameters are created to capture a specific data variable, e.g. CD4 absolute count, with drop down lists for categorical data such as the CCMT programme status. For continuous data, like entry of CD4 results, the LIMS provides the functionality to limit entries to valid number formats and ranges and to perform delta checking. These features make it easy for the data capturers to collect the information on the LIMS without transcription or other errors, different from a paper based system where data is manually entered into an electronic data system, often days later and frequently with transcription and other errors occurring.

The findings of the study demonstrate a dramatic improvement in the provision and capture of the CCMT programme status from 28% in the baseline data extract to 84%

for the study. This success can be attributed to interventions initiated through the study, including the design of the new CCMT request form (Form 4 page 96), simple tick box choices to indicate programme status, the provision of on-site training, standardisation of data captured on the LIMS and data review during the follow-up visits.

The percentage of CD4 samples with a pre-ART and ART programme status was assessed by using the CCMT programme status codes captured in the LIMS. Overall for this study 62% (n=621) of the CD4 samples had an ART CCMT programme status category, compared to 38% for pre-ART CCMT programme status category. This indicates that the CCMT M&E system can be used to assess the proportions of CD4 samples requested for routine ART monitoring as well as pre-ART CD4 testing following HCT. It therefore has the potential to report on how many CD4 samples were received following HCT as an indirect measure of HCT linkage to care. It is of concern that almost a third of the patients had a CD4 count but was not yet enrolled on ART. The study sites were satisfied with the quality of the data reported by the laboratory pre-ART register. They also rated the format of the register through a self-administered questionnaire either excellent or very good. The study sites indicated that the laboratory pre-ART register was useful to follow-up pre-ART patients as well as improve their reporting to the DHIS. These findings demonstrate the ability of the study to collect the data required to generate a pre-ART register. Although the laboratory based pre-ART register present challenges, it has the potential to improve how pre-ART services are offered in South Africa by providing a list of patients that need to followed-up and initiated on ART.

There were a number of interventions required to develop a laboratory based CCMT Programme Status reporting system in the Ekurhuleni Health District. The first intervention was the redesign of the new CCMT request form (Form 4 page 96). One of the key changes was to link the process of requesting a CD4 test using the “two-tick” principle which links the request of the CD4 test with the CCMT programme status options, prompting health care workers to add the required additional information. By associating the two elements in close proximity it was assumed that the CCMT programme status information would be provided more often, as the health care worker would not have to go and look for the CCMT data element elsewhere on the

new CCMT request form. Secondly the CCMT programme status options, provided on the request form, were limited to just three options that specifically related to CD4 testing. Finally, on the new CCMT request form the CD4, HIV viral load and EID tests were placed first as they the most frequently requested tests. These key changes all worked together to improve the comprehensiveness and quality of data collected for this study.

Training proved to be an important component of the success of these parameter changes and ensuring the capture of relevant programme status information. Training was provided to health care workers using a standardised presentation and training guide. During the health care worker training the “two-tick” system was emphasised and health care workers were required to complete the new CCMT request form. A more detailed training was provided for data capturers. The quality of training interventions was assessed during the follow-up visits where the provision and capture of the CCMT programme status on the new CCMT request form (Form 4 page 96) and LIMS respectively, was assessed. Only the Far East Rand study site required some follow-up training and support. This demonstrates that the combination of the training and follow-up visits are key to the integration of the CCMT programme status M&E system in other health districts. It also confirms that when data is being reviewed on a regular basis, the quality of the study data improved. Long term strategies and resources, however, need careful review and planning to ensure training programmes and support for users is sustained.

To implement the laboratory based CCMT Programme Status reporting system nationally would be a large undertaking and would need to be sustainable in the long term. For the study, most of the interventions were planned and executed by a small team led by the researcher. For a national rollout, a more sustainable implementation model would be required i.e. dedicated roll-out task team to do training and follow up visits.

Long term planning can be achieved through the use of the practical, robust implementation and sustainability model (PRISM) developed in 2008, as a tool for researchers to translate their research into practice (Feldstein and Glasgow 2008:228). This model requires the researcher to review the interventions proposed,

the recipients of the intervention, the external environment, the implementation and sustainability infrastructure and aspects related to the adoption, implementation and maintenance of the intervention (Feldstein et al 2008:230). For the sustainability of the implementation of the laboratory-based CCMT Programme Status reporting system, recommendations for organisational and patient perspectives for the intervention are discussed. Additionally the proposed intervention, sustainability infrastructure, implementation and maintenance are also considered. Further details about the proposed PRISM model to translate this research into practice are provided in Annexure L (Page 159).

A national mandate and approvals are required to implement the laboratory based CCMT Programme Status reporting system (NDOH and NHLS) and take it to the next level, co-ordinating the process through the NDOH laboratory co-ordinators quarterly meetings. Laboratory co-ordinators are appointed within the NDOH to manage their relationship with the NHLS at a national, provincial and district level. These co-ordinators are able to discuss the proposed intervention within the NDOH organisational structures and provide input to the national laboratory co-ordinators quarterly meetings. The NDOH would be required to approve the intervention and distribute an official letter to the provincial Heads of Departments (HOD's). Within the NHLS, the Chief Operating Officer (CEO) would issue an internal memorandum to implement the intervention following extensive consultation with regional and business managers. There would be minimal impact on patients (patient perspective) by the intervention as the only change would be the use of a different request form by the health care worker. There is no perceived negative impact anticipated for patients.

The study also revealed that there are many organisational aspects that had to be dealt with during the course of the study. Some of the organisational aspects related to the NHLS laboratory services while others related to the three study sites.

For this study, it was vital that the same LIMS was used throughout the study, as this enabled the collection of the CCMT programme status codes in a consistent format. A change to the LIMS would require retraining data capturers, configuring new test methods and parameters as well as data differently through the Corporate Data Warehouse.

The study also revealed the presence of good laboratory management facilitated the provision of the CCMT programme status on the LIMS. The follow-up visits identified that the Tambo Memorial and Tembisa data capturers were performing better than their counterparts at Far East Rand. During the study period, the Far East Rand laboratory manager was on maternity leave.

The availability of experienced data analysts at the CDW will ensure the long-term success and integrity of the data generated.

The study also revealed that wards that were allocated to use the new CCMT request form at each study site did not materialise. At the Far East Rand study site, CD4 samples were predominantly received from the ART ward. These findings highlights an institutional challenge that could be addressed with training initiatives for health facility managers.

The study also revealed an additional organisational aspect the study had to contend with. This related to the decentralisation of ART services to the primary health care (PHC) facilities surrounding the three study sites using a nursing staff to initiate patients on ART (NIM-ART). The health care workers at the study sites had indicated that nurses in the PHC clinics had been NIM-ART trained and were planning to start initiating patient on ART. As the study commenced the step down of stable patients on ART to PHC clinics had started. According to Colvin, Fairall, Lewin, Georgeu, Zwarenstein, Bachmann, Uebel and Bateman (2010:210) the policy decision by the South African government to expand access to HIV care rapidly and ensure that all health facilities to provide ART is a dramatic and welcome change for the situation when only a few accredited health facilities were offering ART. Due to implementation of NIM-ART it appeared as though patients preferred to attend a closer health facility instead of coming to one of the study sites.

A median CD4 result of 150 cells/ μ l, noted in the group of patients receiving their 'first ever CD4 count', reveals a largely unwell group requiring an urgent treatment intervention. Lamb et al (2012:1) reported data for adults enrolled in HIV care between January 2005 and December 2010 from 190 health facilities in Kenya, Mozambique, Rwanda and Tanzania. This study found that patients initiating ART had a median

CD4 of 144 cells/ μ l, similar to that noted in the current reported study, whilst patients already enrolled into HIV care were noted to have a median level of 259 cells/ μ l. These results are not dissimilar to the “First ever CD4” median of 150 cells/ μ l reported here. However the median CD4 count of the “in ART care” group noted in this study is 90 cells/ μ l higher, at 349 CD4 cells/ μ l, indicating patients are responding more actively to treatment.

The finding of a median CD4 of 150 cells/ μ l for patients with a “First ever CD4” programme status for the study indicates that these patients should, preferably be fast-tracked on ART. Low presentation CD4 counts increases the likelihood of disease progression to AIDS or death and opportunistic infection if patients are not initiated onto ART (WHO 2007:16) According to the WHO immunological classification for established HIV infection (WHO 2007:17), this group has twice the risk of death or virological failure. In this regard, a local randomised controlled trial (RCT) was conducted in Johannesburg and Cape Town, where ART naïve HIV positive patients (n=812) were followed up for a minimum of 96 weeks (Fox, Sanne, Conradie, Zeinecker, Orrell, Ive, Rassool, Dehlinger, van der Hirst, McIntyre and Wood 2010:2042). This study reported that patients with a CD4 count below 200 cells/ μ l had roughly twice the risk of death or virological failure than those patient’s that initiated on ART at CD4 counts above 200 cells/ μ l (Fox et al 2010:2042). For the present study, patients with a “First ever CD4” programme status are presenting with severe HIV-associated immunodeficiency according to the WHO immunological classification for established HIV infection (WHO 2007:17) and may additionally, also be presenting with opportunistic infections and other HIV related conditions (WHO 2007:16) complicating presentation and contributing to the low median CD4 reported.

One of the additional study objectives was to assess the proportion of patients about to start ART with a CD4 count below 50 cells/ μ l. The pre-ART CCMT programme status category was used to identify CD4 testing performed for patients about to start ART. The CD4 results were then categorised into two test ranges, \leq 50 cells/ μ l and $>$ 50 cells/ μ l. Overall 11% of the study samples (ART and pre-ART) had a CD4 count below 50 cells/ μ l. The proportion of pre-ART samples with a CD4 count below 50 cells/ μ l was 22 percent (n=85). This increased to 24% (n=75) for CD4 samples with

“First ever CD4” CCMT programme status, and 14% (n=10) for “CD4 taken previously, not yet in ART care”.

Mechanisms to motivate patients to present for care earlier are required considering the low median CD4 count reported here. One such initiative of the NDOH, is the introduction of the PHC re-engineering strategy that will include the creation of ward-based PHC outreach teams that provide health care service for a defined municipal ward (NDOH 2011f:2). These teams will include a professional nurse, environmental health and health promotion practitioners as well as six community health care workers (CHW) (Pillay and Barron 2011:3). The main function of the ward-based PHC outreach teams is to promote good health and prevent ill-health (Pillay et al 2011:3).

In addition to making it easier for patients to access health care services with the ward-based outreach teams, it is also critical to understand some of the other reasons why patients are presenting late in order to provide a service that will address this problem. In another South African study, patients presenting for voluntary HIV counselling and testing (VCT) were studied at four outpatient clinics in Durban (Drain, Losina, Parker, Giddy, Ross, Katz, Coleman, Bogart, Freedberg, Walensky and Bassett 2013:3). In this study, late presentation was defined as a CD4 count below 100 cells/ μ l (Drain et al 2013:1). Some of the reasons for late presentation included living far from a health facility (incurring unaffordable transport costs), paying for basic necessities and foregoing healthcare, working away from home (migratory), long waiting times at the health facilities and perceptions of barriers to health service delivery (Drain et al 2013:7).

Late presentation of patients can lead to high secondary and tertiary health facility costs related to hospital presentation. Although there is no local costing data published, a Canadian study was conducted in 2004 to compare the costs of medical care in the year following HIV diagnosis for both early and late presenters (late presenters \leq 200 cells/ μ l) (Krentz and Gill 2012:93). This study reported that direct medical costs in the year following HIV diagnosis were more than 200% higher for patients who presented late, and that these costs were incurred by HIV-related hospital care and initiation on ART (Krentz and Gill 2012:93). In a South African context due to high HIV prevalence, population demographics and other factors, it is

clear that late presentation can incur unnecessary costs for the public health care system, as these patients additionally present with HIV related opportunistic such as Tuberculosis and cryptococcosis, prior to commencing ART. Early diagnosis and enrolment onto treatment programmes will improve overall patient immune status and decrease onset/ occurrence of related opportunistic infections. The planned primary health care outreach teams will, it is hoped in future, make it possible to identify these patients before their CD4 counts drop below 100 - 200 cells/ μ l level. Such outreach programmes could potentially reduce the cost on the public health system while improving the outcomes of these patients.

In April 2013, the NDOH released the new ART clinical guidelines including changing the eligibility criteria for ART, based on a CD4 count, from 200 cells/ μ l to 350 cells/ μ l for all HIV adult patients. (NDOH 2013:6). This study reports that patients with a programme status "CD4 taken previously, not yet in ART care" had a median CD4 count of 328 cells/ μ l. This new guideline change would thus enable these patients enrolled onto wellness programmes with a CD4 count between 201 and 350 cells/ μ l to access ART. Of the patients presenting with a "First ever CD4" programme status, 59% (193) would have been eligible for ART with the 2010 ART guidelines whilst 93% (n=243) had a CD4 count below 350 cells/ μ l and would be eligible for ART (20% increase).

Results from this study reveal that there are significant numbers of patients in this group who are currently not eligible for ART but who may be enrolled in the HIV wellness programme at their local health facility. Here, approximately 53% of patients (n=39) had a CD4 count below 350 cells/ μ l will qualify for treatment and 78% (n=58) will qualify if the guideline for treatment is extended to include all patients with a CD4 count below 500 cells/ μ l (WHO 2013b:29). In 2013, the World Health Organisation (WHO) released its consolidated ART guidelines (WHO 2013b:29). These guidelines state that as a priority, ART should be initiated in all patients with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) or a CD4 count below 350 cells/ μ l (WHO 2013b:29). Additionally patients with a CD4 count between 351 and 500 cells/ μ l, currently being referred to the wellness programme in South Africa should be initiated on ART (WHO 2013b:29). The change to the ART guidelines to make ART available at a CD4 count \leq 500 cells/ μ l would increase the percentage of patients presenting

for first ever CD4 testing from 79% (current South African ART guidelines) to 89% (WHO ART guidelines). The universal test and treat strategy would only add an additional 11% of patients with a “First ever CD4” programme status. It would therefore be more cost effective to change the South African ART guidelines in line with WHO recommendations.

Patients in this group may not necessarily be enrolled for wellness evaluation though and may be lost to follow-up. In a local study, of 356 patients enrolled in the wellness programme at the Themba Lethu clinic in Johannesburg, 69% (n=244) of patients enrolled in pre-ART care did not return for their first medical visit within one year of enrolment (Larson et al 2010:45). Furthermore, 21% (n=75) of these patients had a CD4 count below 350 cells/ μ l and were eligible for ART (Larson et al 2010:45).

In another local study HIV-infected adults not yet eligible for ART, with CD4 cell count greater than 200 cells/ μ l were followed up to assess whether they were retained in wellness care (Lessells, Mutevedzi, Cooke, and Newell 2011:79). For the study retention was defined as having a repeat CD4 count within 13 months of the earlier CD4 count (at which the patients were not eligible for ART) (Lessells et al 2011:79). The study reported the retention rates by the initial CD4 test range. For patients with an initial CD4 count between 201 and 350 cells/ μ l, the retention was 51.7% (Lessells et al 2011:79). The retention rate however dropped to 43.2% for CD4 counts between 351 and 500 cells/ μ l (Lessells et al 2011:79). Patients with CD4 counts greater than 500 cells/ μ l had the lowest retention rate at 34.9% (Lessells et al 2011:79). This study confirmed that late presentation affects the retention rate on ART, therefore it is vital that these patients are identified earlier.

In this study, 47% of the patients in the wellness programme (programme status of “CD4 taken previously, not yet in ART care”) had a CD4 count greater than 350 cells/ μ l. Similarly, based on the results of the Larson et al study (2010:45), of the 53% of patients that are eligible for ART, many patients may not return to be initiated on ART.

Urgent interventions are therefore required. In 101 subjects on ART, a median baseline CD4 of 380 cells/ μ l was reported. Recent WHO guidelines suggest that it would be advantageous to increase the CD4 count threshold for ART initiation to 500

cells/ μ l. This study suggests that a test and treat strategy may be worthwhile bearing in mind the overall median count of 348 cells/ μ l, which falls within the current guideline range for ART eligibility. The latter strategy, known as Universal Test and Treat strategy, involves testing the entire population for HIV once a year and then treating immediately all HIV positive patients on ART (Dodds, Garnett and Hallett 2010:729). The hypothesis for the Dodds et al study (2010:729) is that this approach has the potential to eliminate the HIV epidemic and reduce ART costs in the long-term. Their study investigated the impact of test and treat interventions under various assumptions about the HIV epidemic using a deterministic mathematical model (Dodds et al 2010:730). The median CD4 values reported here show that the test and treat intervention could substantially increase numbers of patients on treatment, and hence reduce HIV transmission. The impact of the intervention, however, depends on the epidemiological context. Full coverage is however crucial in order not to increase long-term ART costs (Dodds et al 2010:730). Careful assessment is necessary before implementing such a strategy in a country like South Africa.

This study reported that patients with a programme status of "In ART care" have a median CD4 count of 348 cells/ μ l. Although the period of enrolment is not known for the patients in this study, the median value is not dissimilar to that reported by Bosch, Wang, Vaida, Lederman and Albrecht (2006:433). Patients reported response to treatment has been generally slow in local studies. In HIV-sero-positive patients recruited for the CIPRA "Safeguard the Household" project, (Glencross, Janossy, Coetzee, Lawrie, Scott, Sanne, McIntyre, and Stevens (2008:133), the absolute CD4 count following the first 4 weeks of ART increased from 186 cells/ μ l at baseline to 267 cells/ μ l (Glencross et al 2008:137). Additional two phases in the increase of the CD4 count following ART was noted. Following 4 weeks of ART the CD4 count gained between 50 and 120 cells/ μ l (Glencross et al 2008:138). However, in the second phase an almost imperceptible slow increase of CD4 count was reported (Glencross et al 2008:138). The data collected for the study using the programme status is unable to differentiate the length of time on ART, hence it becomes difficult to directly compare the median CD4 of 348 cells/ μ l obtained for the study to the published South African CIPRA data (Glencross et al 2008:137).

5.3.2 Key components for CCMT Programme Status M&E system

To develop a functional CCMT programme status M&E system within the context of a broader health data systems is a very important consideration. The output of the CCMT programme status M&E system must fit within broader NDOH M&E reporting systems. The UNAIDS describes a programme logic model which can be used to assess the data generated by the study against six key concepts and frameworks that form the foundation of a M&E system for HIV services (UNAIDS 2010:48). The UNAIDS programme logic module has number of requirements for an M&E system:-

- contains a program logic model where the main elements of the intervention including the assumptions made, problem statement, inputs, activities, outputs, outcomes and impacts are described (UNAIDS 2010:48).
- The elements should all work together to reach the program's goal (UNAIDS 2010:49).
- Data should be collected with the intention of being used. This includes defining the inputs and activities that are required to generate the M&E outputs (UNAIDS 2010:49)
- The M&E system should adopt a systems perspective, whereby all the M&E system components need to be present and work to an acceptable standard for the M&E system to function effectively (UNAIDS 2010:53).

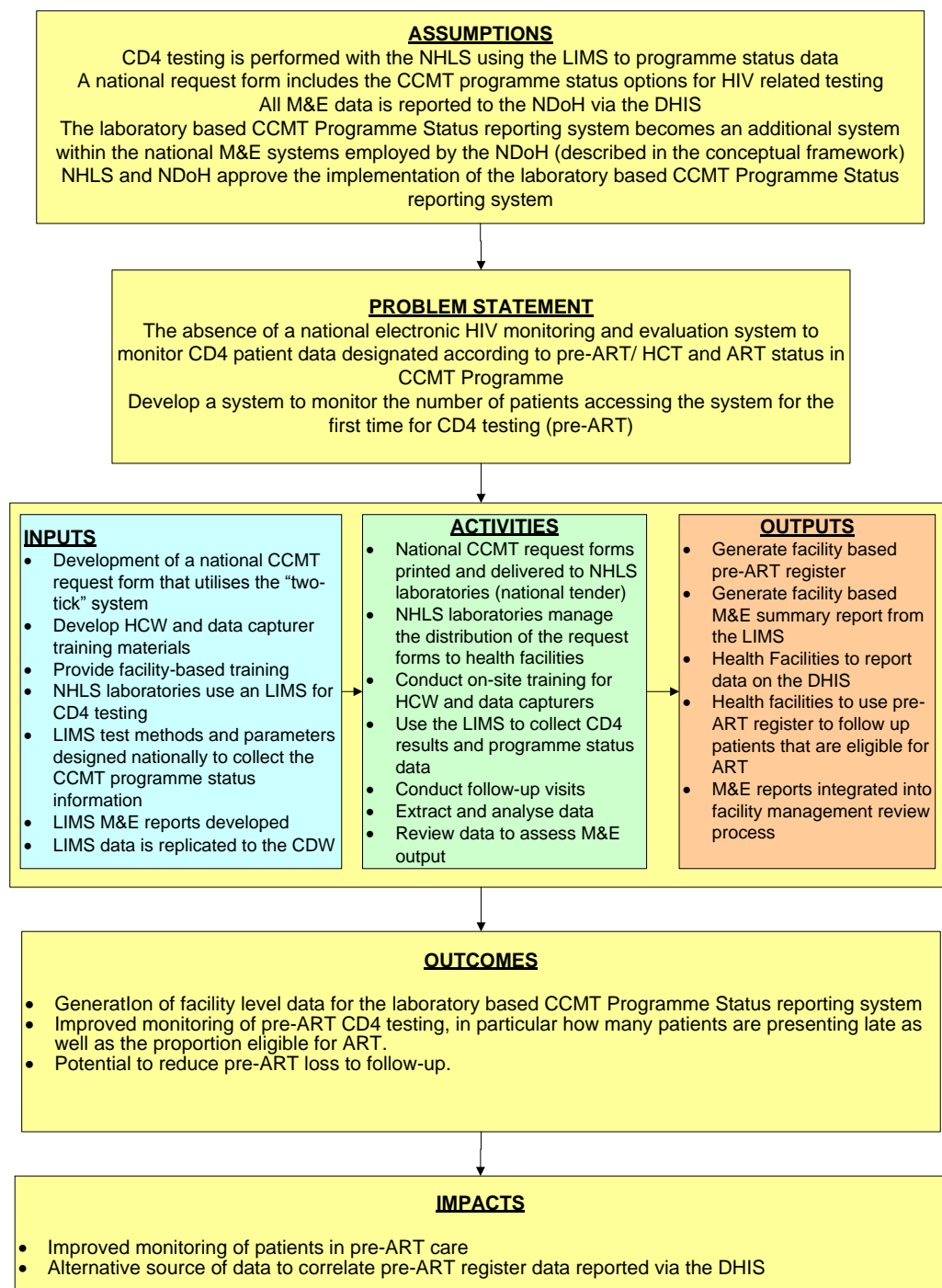


Figure 5.1: Programme Logic Model for the laboratory based CCMT Programme Status reporting system

5.3.3 Limitations of the study

There were a number of limitations identified during the course of the study were as follows:-

- Due to limited funding and resources, the study was limited to the three out of 114 of the busiest public health facilities in the Ekurhuleni health district public health facilities in this health district (Magoro 2012). The study was also conducted at three hospitals and could not include a mix of primary health facilities and hospitals. Should the study have included hospitals, community health centres and primary health care facilities the study would have produced results that could be generalised to the entire health district. Nevertheless it was considered to be a representative sample.

The collection of the CCMT programme status was limited to collecting data for CD4 testing and CCMT programme status data. Due to the size of the team undertaking the research and limited funding available it was not possible to increase number of study sites or the sample size.

5.4 Recommendations

Based on the research findings the following recommendations are suggesting for enhancing the monitoring and evaluation of the CCMT programme and will be classified as either of high, medium and low importance:-

- The development of an NHLS standard for the design of NHLS request forms that will be used for the collection of data for the CCMT programme or other priority programmes. Based on the results from this study, it is proposed that the data collection tools on the priority programme test be linked to the position on the request form where the respective test is being requested, i.e. using a two-tick system. Additionally the data collected for each test should relate only to that test and that the options provided must be mutually exclusive (High priority).
- The establishment of management reports on the TrakCare LIMS system that will enable laboratory managers to extract the laboratory pre-ART register and the summary M&E data, i.e. pre-ART and ART median CD4, proportion of pre-ART and ART CD4 samples, the proportion of CD4 counts ≤ 50 cells/ μ l or other levels with pre-ART CCMT programme status. This recommendation

would allow for decentralising the provision of data to the health facility (Medium priority).

5.5 Concluding Remarks

The data collected for the study using the newly developed CCMT request form and the LIMS was analysed and discussed. The results of the study demonstrate a dramatic improvement in the provision and capture of the CD4 CCMT programme status, data increasing from 28% to 84% using the new CCMT request form (56% improvement in data provision and capture).

This marked improvement in the comprehensiveness and quality of data can be attributed to a few interventions in the study. A key finding of the study was that using the two-tick system on the new CCMT request form (Form 4 page 96) improved the provision of data dramatically from the baseline data analysis. Additionally by using a standardised LIMS across all three sites with specially designed data screens for the capture of the CCMT programme status data meant that it was easier to capture this data in streamlined manner.

The positive study findings could not have been achieved without the on-site training offered to health care workers and laboratory data capturers. The training was supported by follow-up visits to ensure that local practices complied as far as possible to the required standard early in the study. Offering ongoing training to health care workers and data capturers will be crucial to embed the provision and capture of the CD4 CCMT programme status as part of routine health care services.

The future sustainability of the study recommendations are important as the study was largely delivered by researcher efforts. The PRISM model was used to assist in providing guidelines on how to extend the research findings to national implementation of the laboratory based CCMT Programme Status reporting system. A comprehensive monitoring and evaluation control programme needs to be implemented in all 114 health facilities as a means of ensuring value for money. This recommendation is

consistent with similar recommendations made in the past by the WHO for Health Ministries in Sub-Saharan African countries such as South Africa (WHO 2008).

The study also highlighted the many logistical aspects related to the study. These included the proposed change from one LIMS (Disa*Lab) to another (TrakCare) halfway through the study. The level of local supervision of health care workers and laboratory data capturers was also raised by the study.

A similar study should be extended to a larger number of health facilities that include a mix of hospitals, community health centres and primary health care clinics. Additionally the results of this study should be reported to the NHLS/NDOH to make them aware of the findings and recommendations. The findings of the study should also be published in a peer reviewed journal so that it may guide similar approaches in other health districts.

This study has demonstrated that it is possible and feasible to develop a laboratory based CCMT Programme Status reporting system using the new CCMT request form in the Ekurhuleni health district.

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ANNEXURE A: DATA COLLECTION TOOLS

Do you find the flow of the new CCMT request form suitable. If not, Why?

Please add any other information you would like to highlight about the new CCMT request form

Any other notes

Form 2: Week 2 laboratory follow-up visit



NATIONAL HEALTH LABORATORY SERVICE



SITE FOLLOW UP VISIT FORM

Follow up visit conducted by:

Name			
Signature		Date	

Sites visited:

Laboratory Visited		Health Facility Visited	
Lab Prefix		Hospital	
Name		Name	
Signature		Signature	

List of outcomes assessed:

Outcome	Status	Action Proposed
Health Facility		
Percentage of CD4 request forms that were completed with the required CCMT Programme Status information from the health facility on site (prior to courier collection)		
CD4 Request forms completed legibly with the required information provided		
Laboratory		
Percentage of CD4 request where the required CCMT Programme Status information are captured correctly on the LIMS (Random checking on 10 request forms)		
Assess that data capturers are aware of the mechanism to capture request forms with no programme status information provided on the LIMS		
Assess how request forms are stored on site		

Form 4: New CCMT request form



Practice number 5200296

DOH CCMT 2012 v1



CCMT REQUEST FORM (INTERIM)

INT12345
INT12345

MARK IF URGENT

L O C	CHC / CLINIC / HOSP WARD eGK APPROV CODE COPY REPORT TO	S P E C	SPECIMEN ANATOMICAL SITE COLLECTION DATE TIME COLLECTED BY
P A T I E N T	PATIENT ID NO HOSPITAL NUMBER SURNAME FIRST NAME DATE OF BIRTH NHI NUMBER PATIENT ADDRESS PATIENT TEL NO: H: W: C:	C L I N I C	ID TYPE RSA ID No. Passport No. TITLE SEX: M F AGE RACE CLINICAL INFORMATION ICD10 DIAGNOSIS CODES MEDICATION: Warfarin Heparin
H C W	CLINICIAN NAME HPCSA / SANC NO PRACTICE NO CONTACT NO CLINICIAN'S SIGNATURE	A C C O U N T	AUTHORISATION NO FEE CLASS MEDICAL AID PLAN MEDICAL AID NO DEP CODE MEMBER NAME MEMBER ADDRESS MEMBER TEL NO: H: W: C: MEMBER ID NO EMPLOYER MEMBER'S SIGNATURE I consent to tests and take responsibility for payment of this account.

CCMT PROGRAMME:		CCMT ACCOUNT: ZARV003							
P <input type="checkbox"/> CD4 (PLG) If ordering CD4, please tick one category: <input type="checkbox"/> First ever CD4 <input type="checkbox"/> CD4 taken previously, not yet in ART care <input type="checkbox"/> In ART care (please mark drugs)	ARV TESTS <input type="checkbox"/> Creatinine with eGFR (MDRD) Grey* <input type="checkbox"/> ALT <input type="checkbox"/> Cholesterol <input type="checkbox"/> Triglyceride <input type="checkbox"/> Lactate (on ice) Grey <input type="checkbox"/> HIV Serology Provide clinic's HIV Rapid result: <input type="checkbox"/> P <input type="checkbox"/> Y <input type="checkbox"/> PAP smear								
PP <input type="checkbox"/> HIV Viral load If ordering viral load, please tick one category: <input type="checkbox"/> First ever viral load (paediatric) <input type="checkbox"/> Routine monitoring <input type="checkbox"/> Other (e.g., illness, virological failure)	@ <input type="checkbox"/> HIV PCR If ordering HIV PCR, please answer: <input type="checkbox"/> Yes <input type="checkbox"/> Mother received PMTCT <input type="checkbox"/> Yes <input type="checkbox"/> Infant received PMTCT								
ARV DATA COLLECTION - DETAILS MUST BE COMPLETED									
Currently pregnant? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown On TB treatment? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Months since starting ART: <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Baseline / work-up</td> <td style="padding: 2px;">6</td> <td style="padding: 2px;">12</td> <td style="padding: 2px;">24</td> <td style="padding: 2px;">36</td> <td style="padding: 2px;">Other</td> </tr> </table>		Baseline / work-up	6	12	24	36	Other		
Baseline / work-up	6	12	24	36	Other				
Currently off ART due to: <input type="checkbox"/> Adverse event <input type="checkbox"/> Toxicity <input type="checkbox"/> d4T <input type="checkbox"/> 3TC <input type="checkbox"/> EFV <input type="checkbox"/> ABC <input type="checkbox"/> ddl <input type="checkbox"/> KLT <input type="checkbox"/> Other ARVs: <input type="checkbox"/> Non-adherence <input type="checkbox"/> Other <input type="checkbox"/> AZT <input type="checkbox"/> FTC <input type="checkbox"/> NVP <input type="checkbox"/> TDF <input type="checkbox"/> RTV									
TB TESTS		TB DATA COLLECTION - DETAILS MUST BE COMPLETED							
TB SUSPECT <input type="checkbox"/> First-line rapid diagnosis FIRST-LINE TEST NEGATIVE <input type="checkbox"/> TB culture and DST	TB CASE or ON TREATMENT <input type="checkbox"/> TB microscopy <input type="checkbox"/> TB culture TB drug sensitivity testing (DST) <input type="checkbox"/> First line <input type="checkbox"/> Second line Other drugs: _____ Other tests: _____	TB suspect <input type="checkbox"/> Previously treated <input type="checkbox"/> Yes <input type="checkbox"/> No Previous / current DR treatment <input type="checkbox"/> Yes <input type="checkbox"/> No DR contact / suspect <input type="checkbox"/> Yes <input type="checkbox"/> No TB case <input type="checkbox"/> Months on treatment: <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">0</td> <td style="padding: 2px;">2-3</td> <td style="padding: 2px;">5-7</td> <td style="padding: 2px;">Other</td> </tr> </table> Additional data: HIV status <input type="checkbox"/> Neg <input type="checkbox"/> Pos <input type="checkbox"/> Unknown		0	2-3	5-7	Other		
0	2-3	5-7	Other						

Form 5: Pre-ART laboratory register questionnaire



NATIONAL HEALTH LABORATORY SERVICE
PRE-ART LABORATORY REGISTER
QUESTIONNAIRE



Health Facility			
Health Worker Name			
Tel		Cell	
Signature			
Date			

Please tick only one box below for each question: -

Question	Excellent	Very Good	Good	Average	Poor
How would you rate the quality of the pre-ART laboratory register compared to paper-based records at your health facility	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Please rate the format of the PRE-ART laboratory register	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Please rate the service of your local CD4 laboratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please rate questions below by ticking only one box below for each question below:-

Question	Great assistance	Good assistance	Partial assistance	Only limited assistance	No Assistance at all
Has the PRE-ART laboratory register made it easier to track patient to reduce the loss to follow up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has the PRE-ART laboratory register made it easier to ensure that the paper-based records are complete?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has the PRE-ART laboratory register made it easier to report on the DHIS?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has the PRE-ART laboratory register made it easier to report on the DHIS?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has the PRE-ART laboratory register made it easier to manage the flow to patient being staged in your facility?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has the PRE-ART laboratory register made it easier to follow up patients that have not returned to the health facility after a CD4 test?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please add any additional comments about the Laboratory PRE-ART Register below:-

--

ANNEXURE B: ETHICS AND DEPARTMENT OF HEALTH APPROVAL

UNISA ethics certificate:



**UNIVERSITY OF SOUTH AFRICA
Health Studies Higher Degrees Committee
College of Human Sciences
ETHICAL CLEARANCE CERTIFICATE**

HS HDC/59/2012

Date of meeting: 6 June 2012 Student No: 0641-867-8

Project Title: Developing a laboratory based CCMT programme status reporting system in the Ekurhuleni Health District

Researcher: Naseem Cassim

Degree: Masters in Public Health (MPH) Code: DLMIN95

Supervisor: Prof DK Glencross
Qualification: BBCh in medicine
Joint Supervisor: -

DECISION OF COMMITTEE

Approved Conditionally Approved


Prof E Potgieter
CHAIRPERSON: HEALTH STUDIES HIGHER DEGREES COMMITTEE


Dr MM Moleki
ACTING ACADEMIC CHAIRPERSON: DEPARTMENT OF HEALTH STUDIES

Fol

PLEASE QUOTE THE PROJECT NUMBER IN ALL ENQUIRES

Gauteng Department of Health research committee approval:



GAUTENG PROVINCE

HEALTH
REPUBLIC OF SOUTH AFRICA

BANK OF LISBON BUILDING
37 SAUER STREET JHB
PRIVATE BAG X085
MARSHALLTOWN
Tel: (011) 355 3500
Fax: (011) 355 3675

GAUTENG DEPARTMENT OF HEALTH

RESEARCH PROPOSAL EVALUATION FORM

Researcher Name	Mr. Naseem Cassim
Researcher's contact details	Tel: 011 489 8496 Fax: 086 672 7643 Email: naseem.cassim@nhls.ac.za
Institution	Wits medical school
Research Topic	Developing a laboratory based CCMT programme status reporting system in the Ekurhuleni Health District
Date Received by the Directorate PPR	07/06/2012
Date Received Reviewer	25/06/2012
Final Review Date	30/06/2012
Date Submitted to Director of PPR	02/07/2012
Research Site(s)	Public Health facilities in Ekurhuleni
Type of research	Interventional

CRITERIA	YES	NO	COMMENTS
1. Is this research project within the scope of the Department of Health key policy priorities/directives?	X		
2. Content of Research:			
▪ Original work	X		
▪ New facts, ideas	X		
▪ Confirmation of uncertain data	X		
▪ Repetition of known data and consequently of limited importance		X	
▪ Insufficient research information		X	
▪ Confusion of topics/questions		X	
3. Is the title of the research project suitable?	X		
4. Are the objectives of the research project adequate?	X		

CRITERIA	YES	NO	COMMENTS
5. Could the objectives be limited to better focus on the project's main objective?		X	
6. Writing style			
▪ The text of the proposal is clear	X		
▪ The nomenclature used is correct	X		
▪ The references used are relevant, comprehensive and accurate	X		
▪ The spelling and grammar are correct	X		
▪ The language needs improvement		X	
▪ The research proposal needs re-styling and re-writing		X	
7. Are the research methods appropriate to the study?	X		
8. Is data collection method in line with the study design?	X		
9. Does the study have ethical approval? If yes, name the ethics committee.	X		UNISA HSHDC/59/2012
10. Is the definition and measurement of variables consistent with the scope of the proposal?	X		
11. Is the time frame of the proposal adequate to meet the objectives?	X		
12. Is the method of dissemination of the results of the research project stated?		X	It is recommended that the researchers specify how the results will be shared / disseminated
13. Is any possible conflict of interests clarified?	n/a		
14. Are financial implications and financial support transparent?	x		

SUMMARY OF PROPOSAL

Background

It is estimated that of the 33.3 million people living with HIV worldwide in 2009, 67% are from Sub-Saharan Africa (22.5 million) of which 25% (5.3 million or 11% of the SA population) are in South Africa. In 2003 the South African government responded to the HIV epidemic by initiating the Comprehensive Care, Management and Treatment of HIV and AIDS (CCMT) programme. The focus of the CCMT Programme has led to increased access to ART. The rapid scale up of ART provision in South Africa has resulted in over a million HIV infected individuals being placed on ART. Despite the large scale HIV testing campaign initiated in 2010 to accelerate the diagnosis as well as raising the CD4 thresholds to allow for earlier ART eligibility, patients are still presenting very late for ART initiation. Poor pre-ART retention in care or the failure to link patients from HIV testing to HIV care is now recognized as the key factors leading to late presentation. In 2008 the World Health Organisation (WHO) proposed the deployment of a pre-ART register in addition to ART register to improve the linking of patients in HIV care. Paper-based pre-ART and ART registers were introduced in South Africa in 2010 and data is reported at the health district level on the DHIS. Results from the Themba Lethu Clinic reported that only 51.3% of HIV diagnosed patients eligible for ART had completed CD4 testing within 12 weeks of their

initial HIV test. A recent study by Mate et al (2000) in the Kwazulu Natal found that the DHIS data was incomplete in approximately 50% cases and that critical data elements being studied were missing from the clinic registers in 5% to 41% of cases. This research project aims to develop an electronic laboratory-based CCMT Programme Status reporting system, which includes a pre-ART register to improve the identification and follow-up of all pre-ART patients that have not completed CD4 testing.

The purpose of this research is to combine the use of the CCMT request form and the NHLS to capture the CCMT programme status for each CD4 test requested. This information will be used to generate M & E reports to assist programme management at the health facilities. These reports will help the facilities to differentiate between CD4 results for pre-ART screening from ART monitoring. This will assist health facility to follow-up pre-ART patients to ensure that they are placed on ART. Additionally the data will assist the facility manager to plan for ART intake based on the CD4 median data for the pre-ART group.

Primary Objectives

To develop a laboratory based CCMT Programme Status M & E reporting system in the Ekurhuleni Health District.

Secondary objectives

To develop a laboratory based pre-ART register in the Ekurhuleni Health District.

METHODS

Study design and sampling

The study design will be quantitative, consisting of patients attending the selected public health facilities in the Ekurhuleni Health District for HIV care. Eight health facilities in this district have been shortlisted for selection based on the average number of CD4 samples submitted in 2010. Only health facilities that submitted 400 CD4 samples per month on average were shortlisted in order to reach a total of 1500 samples in the study period.

Data collection

The data collection process will be divided into four phases: Phase 1 is the baseline data collection. The baseline data will allow the comparison of data following the interventions to assess the improvement in data provision and capture. Phase 2 is the Pre-Collection Training. Prior to the project start date training on the data tool will be provided to both the health facility staff as well as NHLS data capturers. This will be followed by support visits during the study period to re-emphasize data quality and compliance. Phase 3 is collection of data at source. The CCMT programme status for each CD4 sample collected will be provided by health care workers on the CCMT request form and submitted to their local NHLS laboratories. Phase 4 is the data population. The laboratory data from the individual laboratories will then be populated to the central Disa*Lab repository database via a queuing mechanism and finally extracted to the Corporate Data Warehouse (CDW). Extraction, Transformation and Loading (ETL) rules will be enforced by CDW to ensure only legitimate data values are populated to the target tables.

Data analysis

The CD4 programme status data will be extracted using the Microstrategy business intelligence (BI) tool. The data will be provided excluding patient identifiers. The CDW uses a probabilistic algorithm to match patients and assigns an internal unique patient number, which will be provided in the data extract. The data will be extracted and analyzed using Stata 11 and Microsoft excel.

REVIEWER'S FINAL CONCLUSION

The study will improve how the CCMT programme is managed at a district and facility level. It will assist facility managers to improve the health facility utilization and reduce loss to follow-up. Overall the significance of the study will be to ultimately improve patient care.

Reviewed and Recommended by



Dr Bridget Ikalafeng

Date: 06/07/2012

Approved / ~~not approved~~

13/07/2012
S. le Roux, Director PRB 

Date: _____

ANNEXURE C: DATA COLLECTION INSTRUMENT DEVELOPMENT EMAILS

Data development emails

Message
National Request Form - Message (HTML)

Follow up. Completed on 22 November 2010.

From: Helena Vreede
To: Wessel Kleinhans; Lunga Makamba; Lisa Ungerer; Roy McFarlane; Stan Harvey; Keith Bauer; Gerrit Coetzee; Irene Le Roux; Henry Pieters; Floyd Olsen; Sugaan Marmuthu; Bahule Motonye; Janet Scholtz
Cc: Naseem Cassim
Subject: National Request Form
Sent: Mon 10/10/04 07:09 PM

Dear colleagues

The CEO has asked me, at short notice and with a very short deadline (2 ½ weeks), to propose and design a National Laboratory Request Form, a draft of which is to be presented at the next meeting with the National DOH. I do not want to do it without consultation, but that time frame doesn't leave much room for prior consultation. Note that the first presentation **will only be a draft**, and not final, as consultation with both NHLS and DOH will have to take place.

The only issues specifically mentioned were that the multiplicity of forms in use is a problem, that we need a unified form to reflect our corporate image, and that we must guard against over-servicing. I realize that some of the reasons for the multiple forms are the fact that Provincial DOH's have required different features, and that NHLS programmes have required different input data, and historical reasons. I also think that electronic gate-keeping may introduce requirements for new fields. Finally we must bear in mind that we now have two different LIS systems.

Broadly, I envisage the following:

1. One request form for Primary Health / District Health Clinics. I have requested a discussion with Ray Mabope, to ask whether the Essential Test List for this sector is ready yet.
2. One request form for hospitals. This form to include Clinical Pathology (C / H / I / M / V). This form could also include Histopathology if included on the back of the form. The form currently in use in Gauteng / Limpopo, which is quite similar to the form in use in the Western Cape, may be a reasonable starting point.
3. National Programme Forms (ARV, Cytology, TB) – These forms were not mentioned, neither to include them nor exclude them from this proposal. The use of these forms forces users to use multiple forms. As far as I am aware, only the ARV form serves the purpose of allocating tests to a specific budget, while all 3 forms serve the purpose of data collection. **Can Cytology and TB be included in the hospital form, so that hospitals can have just one combined request form?**
4. Specialist forms (e.g., Genetics / IMD, Allergy, Tissue Immunology, etc.) – To be discussed later.

I would like to request:

- Copies of existing forms in use – I have received a copy of the Gauteng Clinical Pathology form.
- Comments about which features of the forms that you are used to, you feel are most important to keep
- Any comments specifically about the broad outline given above
- Any suggestions whatsoever

Message
RE: Urgent workshop required-DHS lab request form - Message (HTML)

From: Helena Vreede
To: Nicolene Van der Westhuizen
Cc: Wendy Stevens; Naseem Cassim; Gerrit Coetzee; Irene Le Roux; Denise Rodit
Subject: RE: Urgent workshop required-DHS lab request form
Sent: Thu 10/11/25 01:24 PM

Dear Nicolene

All the dates you mention are OK (you mean Monday 29th, not Monday 27th).

I am in favour of the attempt. However, the main issues we have to address are:

1. The DOH's insistence on data collection
2. The DOH's requirement for a separate account number for the CCMT programme.

You must please include the NHLS managers of the Priority Programmes. They know the DOH data requirements for their programme:

- Wendy Stevens (overall)
- Irene Le Roux (Cytology)
- Gerrit Coetzee (TB)
- Naseem Cassim (CCMT) - the CCMT form is due for revision, meeting already scheduled for mid December

In addition, Sagie Pillay has asked that we investigate a separate form for every level of care, i.e., also a form for Secondary Hospitals. To do this requires that we establish:

- if there is one national definition for each level of care;
- if the need exists to have a separate form for each level of care;
- if the need exists, who is best suited to determine what should be on the form, or if it can be the same as the Tertiary Hospital Form.

Can we add that to the agenda?

Regards,
Helena Vreede
Chemical Pathologist: C17 NHLS Pathology Laboratory, Groote Schuur Hospital
National Health Laboratory Service
Office: 021 404 5429
Fax: 021 404 4105
Cell: 082 805 3805

New NHLS request forms - Message (HTML)

Message

Reply Reply to All Forward Delete Move to Folder Create Rule Other Actions Block Sender Not Junk Safe Lists Junk E-mail Categorize Follow Up Mark as Unread Related Select Find Link to Record E-mail Auto-link Send to OneNote Business Contact Manager OneNote

You forwarded this message on 2011/02/16 03:01 PM.

From: Helena Vreede
To: Naseem Cassim; Wendy Stevens; Gerrit Coetzee
Cc: Vivienne Rae; Denise Roditi; Stan Harvey; Patrick Lucwaba
Subject: New NHLS request forms
Sent: Mon 2011/02/14 03:08 AM

Message Standardization and Consolidation Request Forms.doc (40 KB) PHC 1.0 (front).pdf (108 KB) HOS 1.0 (front).pdf (109 KB)
PHC 1.0 (back).pdf (42 KB) HOS 1.0 (back).pdf (47 KB)

Dear Naseem, Gerrit and Wendy

Here are the final proposed NHLS request forms including TB and CCMT tests. I have sent them to Sagie Pillay, together with the proposal for how to handle the CCMT accounts.

I am sending them to you because of your involvement in the process. I will also send the proposed forms to Ray Mabope, Meg Osler and Nicolene Van der Westhuizen, without attaching the proposal document (which I consider an internal NHLS document). I mention that so that you do not need to forward this to them.

Note these new features:

- To incorporate TB and CCMT tests, the form had to be split over 2 sides. Demographics and labels on one side; Tests and programme questions on the other. Note Gerrit asked for an additional question to be added.
- Histology omitted. It will need to be included on the Cytology form, or on its own form.
- On the front there is a box labeled "CCMT Programme" for the clinician to indicate if the patient is on the CCMT programme. This replaces the CCMT form as the indicator for this fact. The ARV account number can be indicated / stamped next to this, except in the W Cape where they want us to drop all ARV accounts.

Regards
Heleen

Dr Helena Vreede
Chemical Pathologist
Groote Schuur Hospital and University of Cape Town
Cell 082 805 3805

NEW LAB REQUEST FORMS - Message (HTML)

Message

Reply Reply to All Forward Delete Move to Folder Create Rule Other Actions Block Sender Not Junk Safe Lists Junk E-mail Categorize Follow Up Mark as Unread Related Select Find Link to Record E-mail Auto-link Send to OneNote Business Contact Manager OneNote

From: Raymond Mabope [raymabope@gmail.com]
To: Helena Vreede
Cc: Sagie Pillay; Naseem Cassim; Gerrit Coetzee; Irene Le Roux
Subject: NEW LAB REQUEST FORMS
Sent: Tue 2010/12/21 12:13 PM

Dear Heleen

I am following up on the latest news regarding the new lab request forms and to find out whether one could see the latest drafts and am interested in the result of the consultation with the CCMT Task Team, the NHLS Exco and the debate regarding TB, HIV and Cytology.

Thanking you in anticipation.

Kind Regards

Ray

Message Re: FW: Copy of latest Lab request form - Message (Plain Text)

Extra line breaks in this message were removed.

From: Raymond Maboep [raymaboep@gmail.com] Sent: Thu 2012/03/22 03:10 PM
 To: Lindiwe Mvusi
 Cc: Naseem Cassim; Chikwe Ihekweazu; Naziri; Wendy Stevens; Linda Erasmus; Mani Naicker; Sicelo Dlamini; Dr Ndjeka; Norbert Ndjeka; David Mametja
 Subject: Re: FW: Copy of latest Lab request form

Message | MOH Submission Annexes.docx (11 KB)

DEAR ALL

I WOULD LIKE TO CONFIRM THAT WE ARE ALL ON THE SAME PAGE.

FIND ATTACHED THE NEW LAB REQUEST FORMS THAT WERE SUBMITTED TO THE DOH BY THE NHLS.

FLOYD OLSEN AND DR HELEEN VREEDE HAVE BEEN COORDINATING THE DEVELOPMENT OF THESE FORMS.

THESE FORMS ARE NOW WITH YOGAN PILLAY FOR APPROVAL.

PLEASE LET ME KNOW IF THE FORMS YOU HAVE ARE THE SAME AS THOSE SUBMITTED BY THE NHLS. IF NOT, WE WILL HAVE TO RAISE THE MATTER WITH THE NHLS CEO, MR SAGIE PILLAY, SOONEST.

REGARDS

RAY

On 22/03/2012, Lindiwe Mvusi <Mvusil@health.gov.za> wrote:
 > I see you are not copied on this. Has this form been discussed with
 > Mbengashe's unit?
 > Regards
 > Lindiwe
 >
 > Dr Lindiwe Mvusi
 > Cluster: TB Control and Management
 > National Department of Health

77% 09:29 PM 2012/05/02

Message Re: NEW LAB REQUEST FORMS - Message (Plain Text)

Extra line breaks in this message were removed.

From: Raymond Maboep [raymaboep@gmail.com] Sent: Wed 2012/03/28 02:10 PM
 To: Lindiwe Mvusi
 Cc: Sicelo Dlamini; David Mametja; Norbert Ndjeka; Floyd Olsen; Naseem Cassim; Wendy Stevens; ChikweI@nicd.ac.za; Linda Erasmus; Naziri; naickerm@wamsys.co.za
 Subject: Re: NEW LAB REQUEST FORMS

Message | NHLS Form 1 - Internal Request Form HIVDR 2012 v3[1].pdf (494 KB) | NHLS Form 2 - DOH CCMT 2012 v7[1].pdf (47 KB)
 NHLS Form 3 - DOH HOS 2012 v4_front[1].pdf (56 KB) | NHLS Form 4 - DOH PHC 2012 v4_front[1].pdf (53 KB)
 NHLS Form 5 - DOH HOS_PHC 2012 v3_back[1].pdf (21 KB) | NHLS Form 6 - DOH CCMT 2012 v3_back[1].pdf (215 KB)

DEAR ALL

FIND ATTACHED THE FINAL LAB REQUEST FORMS TO BE APPROVED BY YOGAN.

I AM SURE THAT THE APPROVAL OF THESE FORMS IS LONG OUTSTANDING.

TO EXPEDITE THE APPROVAL PROCESS I SUGGEST THAT YOU SEND ME YOUR COMMENTS ON THE FORMS BY TOMORROW. LINDI DOES NOT HAVE TO REPEAT HER COMMENTS WHICH EVERYONE SEES ON THIS EMAIL.

IN PARTICULAR, I REQUEST THE TB AND HIV AND AIDS CLUSTERS TO SEND ME THEIR COMMENTS.

I WILL MEET WITH FLOYD TOMORROW AFTERNOON IN JOHANNESBURG TO INCORPORATE YOUR COMMENTS INTO THE NEW LAB REQUEST FORMS.

KIND REGARDS

RAY . .

On 28/03/2012, Lindiwe Mvusi <Mvusil@health.gov.za> wrote:
 > Dear Ray
 > It is a pity these forms were not circulated before submission. I have
 > looked at them and here are my inputs.
 > 1. NHLS assumes that the GeneXpert is only done on CCMT patients,
 > which is not the case. The PHC and Hospital forms do not have the

74% 09:25 PM 2012/05/02

NDoH Meeting: Lab Request Form Expert Meeting - Appointment

Appointment | Insert | Format Text

Save & Close | Invite Attendees | Delete | Forward | Appointment | Scheduling | Show As: Busy | Reminder: 15 minutes | Recurrence | Time Zones | Categorize | High Importance | Low Importance | Spelling | Link to Record | Meeting Notes | OneNote

Adjacent to another appointment on your Calendar.

Subject: NDoH Meeting: Lab Request Form Expert Meeting

Location: Civitas

Start time: Tue 2012/05/08 09:30 AM All day event

End time: Tue 2012/05/08 01:00 PM

>>> Raymond Mabope <raymabope@gmail.com> 04/24/12 12:00 PM >>>
Dear All

Upon the advice from Dr Thobile Mbengashe, the DOH Cluster Manager for HIV & AIDS, I am suggesting a small expert meeting to attend to the following issues:

1. The impact of the GeneXpert on the management of TB and a preliminary evaluation of whether the investment into the technology is justified.
2. The value of laboratory testing (CD4 and Viral Load) in initiating HIV positive patients on ART and what should be done to reduce the waiting times in order not to loose patients due to follow up.
3. The impact of POCT technologists versus laboratory testing in HIV & AIDS and TB management.
4. To finalize the design of the Lab Request Forms, especially with regards to requests for HIV and TB related tests, drug resistance testing, tests to be deducted from the CCMT Grant, and aligning the billing systems of the DOH and NHLs)

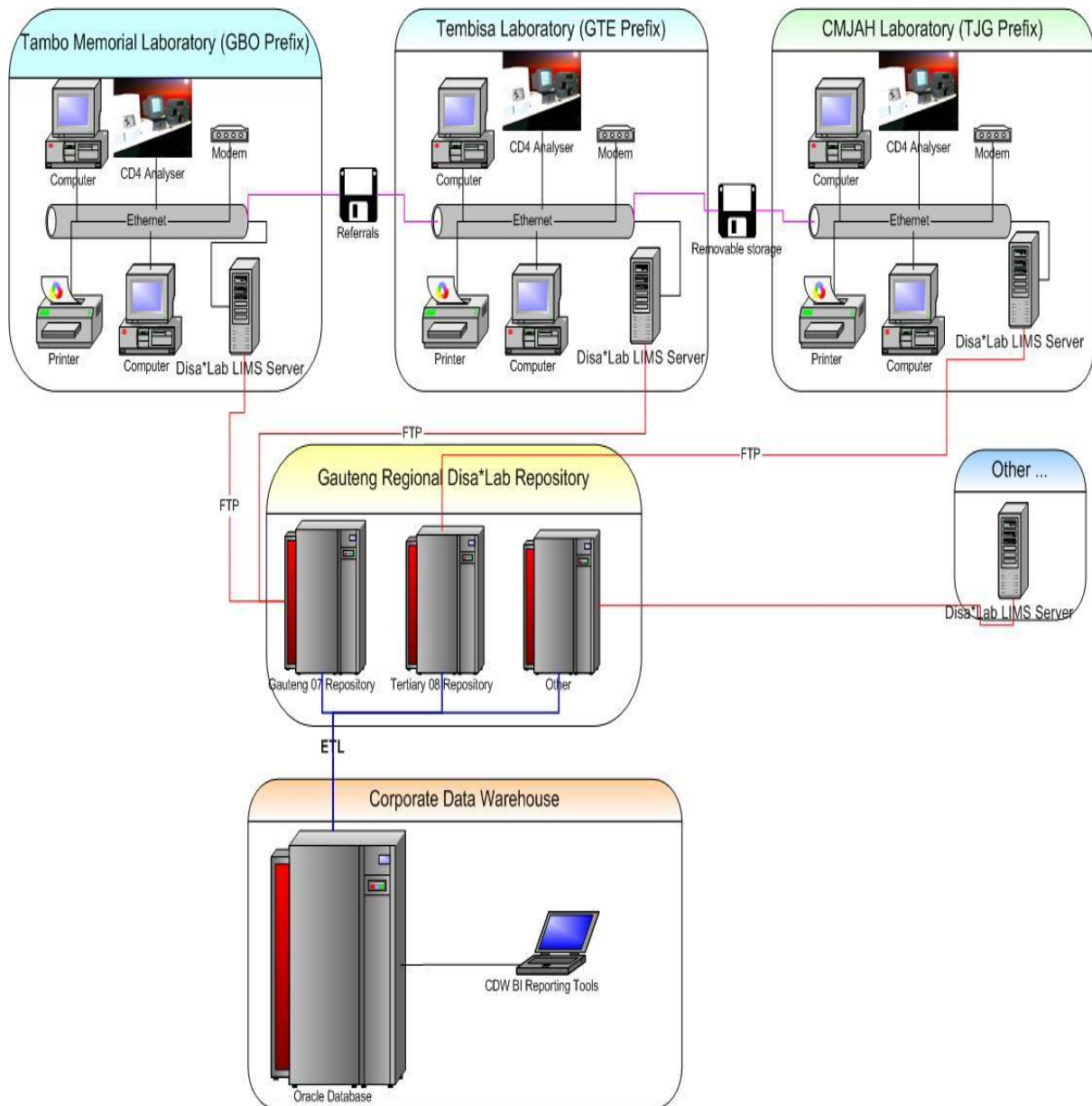
I suggesu that the following persons are part of this expert meeting:

01. Dr Yogan Pillay (DDG)
02. Dr Thobile Mbengashe (Chief Director: HIV & AIDS)
03. Ms Lillian Diseko (CCMT)
04. Mr Dan Monilal (CCMT)
05. Mr David Mamejja (Chief Director: TB)
06. Dr Lindi Mvusi (Director: TB)
07. Dr Nobert Ndjeka (Director: DR-TB)
08. Mr Sagie Pillay (NHLs)
09. Prof. Mphahlele Chabane (MHLG)

75% 09:26 PM 2012/05/02

ANNEXURE D: NHLS DATA FLOW FROM THE DISA*LAB LIMS TO THE CDW

NHLS data flow



ANNEXURE E: STUDY INITIATION DOCUMENTS

Letter from the Gauteng Department of health to health facilities



HAS DIRECTORATE

Enq. Mrs. N. M.Mpela: DD-ART Programme

Tel: (011) 355 3340

Fax: 355-3297

Cell: 079 5058768

Email: sobantu.mpela@gauteng.gov.za

To: Hospitals CEOs

District Chief Director

District Director

District HAST Managers

From: Dr. Z. Pini – Director HAS

Date: 08 August 2012

Subject: DEVELOPING A LABORATORY BASED CCMT PROGRAMME STATUS REPORTING SYSTEM IN THE EKURHULENI DISTRICT

This is to inform you about the visit and briefing that the National Health Laboratory Services (NHLS) and Comprehensive Care Management and Treatment of HIV and AIDS (CCMT) team from the provincial office intend to conduct to your institutions.

NHLS has been granted permission to conduct a research in three health facilities in the Ekurhuleni District namely; Far East Rand, Tambo Memorial, and Tembisa Hospitals. The visits and briefings are proposed as follows:

Date: 22.08.2012

Time: 09:30 - Far East Rand Hospital

Study guide provided at the first meeting with hospital and health district staff

RESEARCH AIM/PURPOSE

The purpose of this research study is to combine the use of the new CCMT request form and the NHLS Laboratory Information Management System (LIMS) to enable the appropriate capture of the CCMT programme status for each CD4 test requested.

RESEARCH OBJECTIVES

The study will address the following objectives:

- Development of a laboratory based CCMT Programme Status reporting system in the Ekurhuleni Health District
- Development of a laboratory based pre-ART register in the Ekurhuleni Health District.
- Reviewing the process to assist trouble shooting and establish guidelines for practical implementation to extend the use of the CCMT Programme Status information in other health districts.

RESEARCH QUESTIONS/HYPOTHESES

The key aspects that will be ascertained from this study include: -

- Median CD4 for pre-ART and ART CCMT programme status at each of the health facilities
- Percentage of CD4 samples in the pre-ART and ART programme status categories as a percentage of total CD4 samples received
- Percentage accuracy of pre-ART electronic register to the paper based pre-ART facility based register.
- Usefulness of the laboratory pre-ART register (assessed with a questionnaire)
- Proportion of patients about to start ART with a CD4 count below 50.

STUDY DESIGN

Target Population: The ART sites at the Tambo Memorial, Far East Rand and Tembisa Hospitals

Sample Selection: All patients requiring a CD4 test until the new request forms have been exhausted

Sample Size: At least 500 CD4 tests on the new request forms per site

How the form should be administered: Health care workers at the selected health care facilities should typically complete the new request form when they order a CD4 count / test on their patients. For this study they will use the newly designed CCMT request form with additional field indicating the patients programme status for the CD4 test. The health care workers will complete the new CCMT request form for all patients requiring a CD4 test.

Confidentiality: The identity of the patients will be protected by removing patient identifiers from the data extract and replacing them with the NHLS Corporate Data

Warehouse (CDW) unique identifier. The pre-ART laboratory register that will be produced will only contain the request form barcode.

KEY ISSUES:

- Provincial and district test request limitations remain in force
- Continue with current operations as is, except for using the new request forms

WHAT WE EXPECT THE HEALTH FACILITY TO DO:

- Use the new request form for all patients on whom a CD4 is requested (with the required information completed)
- Participate in the two week site visit that will be planned
- Provide a letter giving consent for the study to be conducted
- Assess the pre-ART laboratory register generated

WHAT WE WILL DO FOR YOU:

- Provide the request form
- Conduct the two week study visit
- Provide feedback on the study progress
- Present the data collected

Proposed study timeline

Activity	Date
Health facility briefing and planning meeting	22 August 2012
Development of training material	31 August 2012
Procurement of request forms	31 August 2012
Printing of training material	5 September 2012
Laboratory LIMS IT Setup	5 September 2012
Health Facility Training (TBC)	7 September 2012
Laboratory staff Training	10 September 2012
Delivery of laboratory SOPs and scanning sheets	19 September 2012
Delivery of all SOPs and study material	26 September 2012
Follow up Health Facility Training (TBC)	26 September 2012
Project kick off meeting	27 September 2012
Project start date	1 October 2012
Health Facility follow up support visits	17 October 2012
Laboratory follow up support visits	18 October 2012
Project wrap up meeting	TBD
Delivery to laboratory pre-ART registers	TBD
Assessment of pre-ART registers	TBD
Data analysis and reporting	TBD

The study guide also included the ethics certificate from UNISA, Gauteng DoH Research Committee approval and copies all data collection instruments.

Register of the first meeting with hospital and health district staff at the Far East Rand study site

Contact List

Name	Roles	Organisation Site	Tel/Cell	Email
Naseem Cassim	Researcher	NHLS	082-888-0419	naseem.cassim@nhls.ac.za
Nobantu Mpele	CCMT Programme Manager	GDOH	079-505-8768	nobantu.mpele@gauteng.gov.za
Zuki Pini	CCMT Unit	GDOH	082 481 9358	zukiswa.pini@gauteng.gov.za
Francina Nonyane	Laboratory and Blood Services: Ekurhuleni	GDOH	082 558 3483	francina.nonyane@gauteng.gov.za
Bahule Motonye	Business Manager: SEKWE	NHLS	0828072850	bahule.motonye@nhls.ac.za
Floyd Oisen	NPP Unit	NHLS	0828741524	folsen@nhls.ac.za
IVN WAKILEZA	DEPUTY MANAGER NURSING	FERH	011 812 8313	WY. WAKILEZA@gauteng.gov.za
REBONE	PAR EAST RAND HOSPITAL	FERH	011 812 8313	
MATSEISO	ASSISTANT MANAGER NURSING	FERH		
MAKGABE	Senior Consultant, CPD	FERH	(011) 812 8317	
M. BATHO	HOD - OED	FERH	073 229 6836	mashabatho@gmail.com
D.E. Mogashoa	Quality Assurance Manager	FERH	011 812-8408	
Wepwajane	Clinical Manager	FERH	011 812 8372	Medupe.madiso@gauteng.gov.za
L. Madikela	Practitioner -	FERH	011 812 8413	l.madikela085@gmail.com
M. Mole	Senior Ns	FERH	011 812 8441	M.mole@yahoo.com
M.V. RUTAN	Podiatrist	"	011 812 8440	m.v.rutan@gmail.com
Z. Gumede	Assistant Manager HAST	"	011 812 8436	Zandiso.gumede9@gmail.com
M.P. Sankhara	Medical Technology Unit	FERH	0834462770	msankhara@yahoo.com

Letter to the Tembisa Hospital Chief Operating Officer (CEO) requesting permission to conduct the training



MEMO ■

Naseem Cassim (NPP Unit)
1 Modderfontein Rd, Sandringham
Tel: 011 489 8443 Fax: 0866727643
Cell: 0828880419

Date: 11 September 2012

To: The CEO
Tembisa Hospital
Flint Mazibuko Street
Tembisa
Gauteng

From: Naseem Cassim & Bahule Motlonye

RE: Training for research study (ART Site)

Hi,

We met with you and your staff recently to discuss the research study by Naseem Cassim from the National Health Laboratory Service (NHLS). The purpose of this research study is to combine the use of the new CCMT laboratory request form and the NHLS Laboratory Information Management System (LIMS) to enable the appropriate capture of the CCMT programme status for 500 CD4 test requested at the Tembisa Hospital.

We would like to propose conducting training for health care workers at the Tembisa Hospital (ART site only) on the 18th of September at 09:00. The target group for this training would be all health care staff that are actively involved in completing laboratory request forms for CD4 testing.

Please let us know whether this date and time would be convenient.

Many thanks,

Bahule Motlonye (Business Manager:SEKWE): 082 807 2650
Naseem Cassim (NPP Unit): 082 888 0419.

Training register for health care workers at the Far East Rand study site

Register

Date	20/9/2012
Time	10H00
Venue	FEL HOSPITAL OBSERVATION
Activity	HEW TRAINING

Name	Roles	Tel/Cell	Email
Zandile Gumede	Assistant Manager.	0833886504	Hlungane@gmail.com.
Soukheni Makhulu	NYA CAPTURER	0837758407	hlungane@gmail.com
MALI KUBHELA	ENROLLED NURSE	0826304905	N/A
M. KATSONO	DOCTOR	0726343317	epymwana@yehus.co.za
N.S. DANWED	PROF. NURSE	011812819	
M.B. DHEMUS	Prof Nurse	0118128436	N/A
Z.E. SISHINGI	Prof Nurse	011812-8436	Zandile SISHINGI@arwand.com
Mapeisa musisi	acting lab manager	0118132136	mapeisa.musisi@rhl.co.za

Cover page of the training guide for health care workers



**NATIONAL HEALTH
LABORATORY SERVICE**

National Priority Programmes

STANDARD OPERATING PROCEDURE



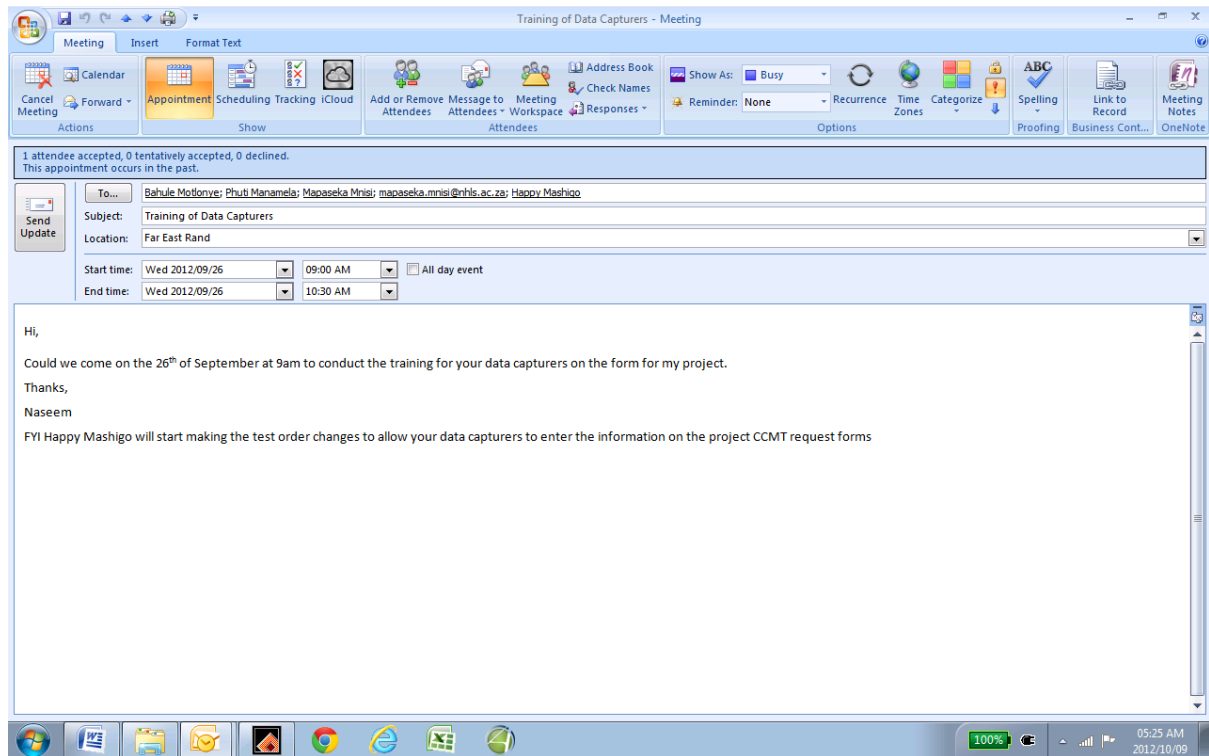
MPH PROJECT REQUEST FORM COMPLETION

MPH001

VERSION: 1

PREPARED BY: NASEEM CASSIM

Email to NHLS business manager and laboratory manager requesting permission to conduct training



Training register for NHLs data capturers at the Tambo Memorial laboratory

Register

Date	01/10/2012
Time	11:00
Venue	TEMBSA LAB
Activity	DATA CAPTURE TRAINING

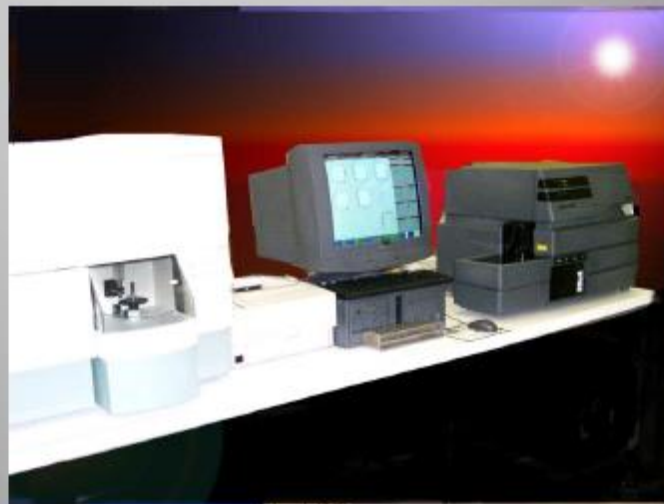
Name	Roles	Tel/Cell	Email
Lesego Dikedi	Phlebotomist student	0725415	lesego.dikedi@gmail.com
Shirley Ramoto	volunteer Clerk	0780733571	
Betty kuumela	phlebotomy	011868803	13etty.kuumela@gmail.com
Confort MORAKE	ADMINISTRATION Clerk	0721057016	Confort.morake@gmail.com
Naica Saka	Volunteer Clerk	0835918550	sacina-naica@yahoo.com
Shanatile Tshe	Admin Clerk	0837112078	ShanatileTshe@gmail.com
Sello Moroto	Lab Manager	07192041196	sello@tambo.nhl.ac.za

Cover page of the training guide used for the training of NHLS data capturers.



**NATIONAL HEALTH
LABORATORY SERVICE**
National Priority Programmes

STANDARD OPERATING PROCEDURE



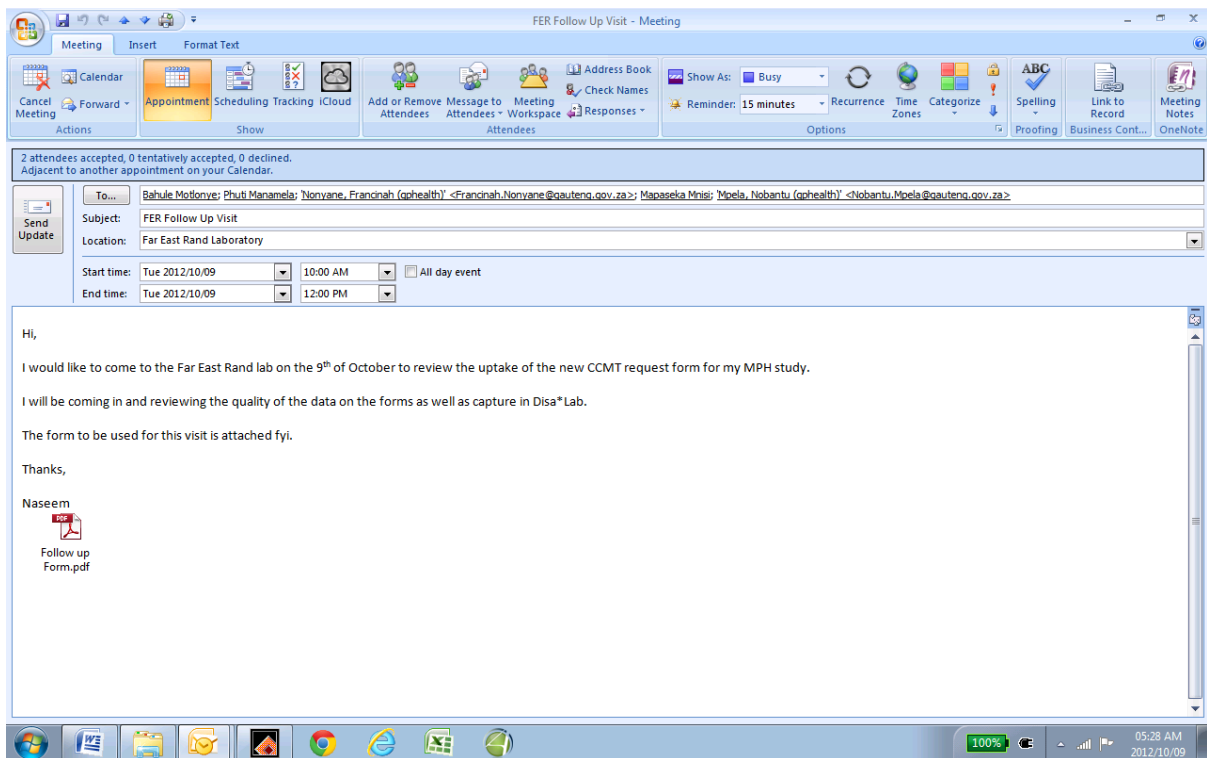
MPH PROJECT REQUEST FORM DATA CAPTURE

MPH002

VERSION: 1

PREPARED BY: NASEEM CASSIM

Email to NHLS business manager and laboratory manager requesting permission to conduct week two laboratory follow up visits.



The health facility manager was informed of the follow-up visit and the results of the visit were discussed and signed off by the facility manager.

Completed week two laboratory follow-up visit form at the Tambo Memorial laboratory



NATIONAL HEALTH LABORATORY SERVICE

SITE FOLLOW UP VISIT FORM



Follow up visit conducted by:

Name	NASEEM CASSIM		
Signature		Date	11/10/2012

Site Details:

Laboratory Visited		Facility Visited	
Lab Prefix	GBD TAMBO MEMORIAL	Hospital	Tambo Memorial Hospital
Name	R. COOKS	Name	Sr Zulu Lovey Mthijane RSN
Date	11/10/12	Date	11/10/2012
Signature		Signature	

List of outcomes assessed:

Outcome	Status	Action Proposed
Health Facility		
Percentage of CD4 request forms that were completed with the required CCMT Programme Status information from the health facility on site (prior to courier collection)	96, 25%	Good compliance, no action required
CD4 Request forms completed legibly with the required information provided	Forms were legible	None
Laboratory		
Percentage of CD4 request where the required CCMT Programme Status information are captured correctly on the LIMS (Random checking on 10 request forms)	n=10 100%	None
Assess that data captureers are aware of the mechanism to capture request forms with no programme status information provided on the LIMS	Yes, they are	None
Assess how request forms are stored on site	Files used to store forms, forms are numbered for monitoring purposes	None

ANNEXURE F: CDW DATA EXTRACT SPECIFICATION FORMS SUBMITTED

Data Extract One: Baseline CCMT programme status data

REC'D CDW:05 10/1/2012

Q-Pulse5/docs/active/FMI0069v3

Page 1 of 5



NATIONAL HEALTH LABORATORY SERVICE HELPDESK
Tel: (011) 386-6125/6/7/9 Fax: (011) 386-6308 email: helpdesk1@nhls.ac.za

APPLICATION FOR DATA FROM NHLS INFORMATION SYSTEMS (Q-Pulse FMI0069)

Each application will be approved or rejected subject to the ability to extract this data and the availability of the data, and subject to the intended usage of the requested data. Applications that are incomplete and/or do not contain supporting documentation, will be rejected.

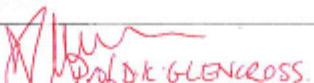
APPLICANT'S DETAILS

Applicant Name	Naseem Cassim	Tel No	011-489-8433	Email	Naseem.cassim@nhls.ac.za
Business Role / Designation		Project Manager			
Laboratory / Department / Branch / Region (Internal applicants)		NPP Unit			
Organisation (External applicants)					
Supervisor Name	Prof. Debbie Glencross	Tel No	011-489-8540	Email	debbie.glencross@nhls.ac.za
Supervisor Designation	Principal Pathologist and CD4 Unit Head				

CONDITIONS

- Data / Information is not to be used in contravention of Sections 14, 15, 16 and 17 of the National Health Act 61 of 2004 and the Promotions of Access to information Act 2 of 2000.
- The applicant undertakes to ensure that the data supplied to it by the NHLS is used ethically and solely for the purposes for which it is provided as detailed in this application, and further acknowledges that it shall remain liable for any breaches of this clause by the end user.
- If the purpose for the data requested in this application is research or if patient identity linked data is required, ethics approval and a one page summary of the protocol shall be attached to this application form. It is the responsibility of the applicant to ensure that their institutions's Human Ethics approval includes explicit authorisation to access the requested NHLS data
- The applicant undertakes to store the NHLS data in a confidential manner by separating patient identifying details from laboratory data and storing the masterlist that links patient identifying details to study patient identifiers in a separate, secure location.
- The information is for the private use of the applicant only, unless further approval is obtained from the NHLS. In the event of this, the applicant shall give due credit, including affiliation, of the participation of the NHLS in any such publications or presentations.
- The applicant undertakes to provide the Executive Manager: Academic Affairs, Research and Quality Assurance at the NHLS with a copy of any report, presentation or publication emanating from the use of this data.

ACCEPTANCE OF CONDITIONS

By signing this document we accept the conditions stated above.			
Applicant Signature		Date	1 / /20
Supervisor Signature		Date	06/08/2012



NATIONAL HEALTH LABORATORY SERVICE HELPDESK
 Tel: (011) 386-6125/6/7/9 Fax: (011) 386-6308 email: helpdesk1@nhls.ac.za

APPLICATION FOR DATA FROM NHLS INFORMATION SYSTEMS (Q-Pulse FMI0069)

All fields in this section must be completed

DATA REQUEST DETAILS

Request Type (Tick)	<input checked="" type="checkbox"/> New <input type="checkbox"/> Modify	Data Format (Tick)	<input type="checkbox"/> Excel <input checked="" type="checkbox"/> CSV	Data Delivery (Tick)	<input type="checkbox"/> CD / DVD <input checked="" type="checkbox"/> Email
Frequency of Extract (Tick)	<input checked="" type="checkbox"/> Once <input type="checkbox"/> Repeat	If Repeat, specify frequency	<input type="checkbox"/> Daily <input type="checkbox"/> Weekly	<input type="checkbox"/> Monthly <input type="checkbox"/> Annually	
DESCRIPTION OF REQUIRED DATA EXTRACT					
Data required	The CD4 and ARV Programme Status information using the current CCMT request form for three ART facilities in the Ekurhuleni Health District. This data extract is the pre-study analysis to assess the current usage of the current CCMT form. Once the study has been conducted a data extract will be requested using the study form. We require the results for all CD4 tests and a CCMT programme status when provided.				
Region (for data extract, e.g. Province or Laboratory)	Please limit the extract to the following location codes: <ul style="list-style-type: none"> • Tambo Memorial Hospital (BOK) • Tembisa Hospital (TEM) • Far East Rand Hospital (FAR) 				
Date range of extract	Please extract the data between 01/06/2012 and 31/07/2012				
Fields required (e.g. Patient name, Date of Birth, etc)	The following fields are required: Laboratory number, testing lab prefix, testing lab name referring lab prefix, referring lab name, location code, location description, ward code, ward description, health sub-district, unique patient id, gender, DOB, race, refnum, hospital number, CD4 absolute count,				
ADDITIONAL INFORMATION					
None					
DESCRIPTION OF INTENDED USE OF DATA EXTRACT (e.g. research, epidemiology study, cost analysis of service, drug effectiveness, disease surveillance)					
Research					
LIST WHO WILL HAVE ACCESS TO THIS DATA					
Debbie Glencross, Lindi Coetzee and Naseem Cassim					
PROJECT NAME AND REGISTRATION NUMBER (if data is required for a registered research project. Please attach the Ethics Approval.)					



NATIONAL HEALTH LABORATORY SERVICE HELPDESK
 Tel: (011) 386-6125/6/7/9 Fax: (011) 386-6308 email: helpdesk1@nhls.ac.za

APPLICATION FOR DATA FROM NHLS INFORMATION SYSTEMS (Q-Pulse FMI0069)

MPH Dissertation Title: Developing a laboratory based CCMT Programme Status reporting system in the Ekurhuleni Health District (Ethics attached)

Addendum One: Ethics Certificate



**UNIVERSITY OF SOUTH AFRICA
 Health Studies Higher Degrees Committee
 College of Human Sciences
 ETHICAL CLEARANCE CERTIFICATE**

HS HDC/59/2012

Date of meeting: 6 June 2012 Student No: 0641-867-6
 Project Title: Developing a laboratory based CCMT programme status reporting system in the Ekurhuleni Health District
 Researcher: Nezem Cossin
 Degree: Masters in Public Health (MPH) Code: DLMING5
 Supervisor: Prof DK Glenness
 Qualification: BBCh in medicine
 Joint Supervisor: -

DECISION OF COMMITTEE

Approved Conditionally Approved

E Potgieter
 Prof E Potgieter
 CHAIRPERSON: HEALTH STUDIES HIGHER DEGREES COMMITTEE

M M Moleki
 Dr MM Moleki
 ACTING ACADEMIC CHAIRPERSON: DEPARTMENT OF HEALTH STUDIES
 PLEASE QUOTE THE PROJECT NUMBER IN ALL ENQUIRES



NATIONAL HEALTH LABORATORY SERVICE HELPDESK
 Tel: (011) 386-6125/6/7/9 Fax: (011) 386-6308 email: helpdesk1@nhls.ac.za

APPLICATION FOR DATA FROM NHLS INFORMATION SYSTEMS (Q-Pulse FMI0069)

Addendum Two: Approval from the Gauteng DOH Research Committee

CONDITIONS OF APPROVAL OF A RESEARCH STUDY PROPOSAL



GAUTENG PROVINCE
 HEALTH
 REPUBLIC OF SOUTH AFRICA

POLICY, PLANNING AND RESEARCH (PPR)
 Enquiries: Dr B Kulafering
 Tel: +2711 355 3590
 Fax: +2711 355 3675 Email: bridget.kulafering@gauteng.gov.za

CONTACT DETAILS OF THE RESEARCHER	
Date	09 July 2012
Contact number	011 489 8496
Email	naseem.cassim@nhls.ac.za
Researcher / Principal Investigator (PI)	Mr Naseem Cassim
Supervisor	Associate Professor Deborah Glencross
Institution	Wits Medical School
Research title	Developing a laboratory based CDMT programme status reporting system in the Ekurhuleni Health District

This approval is granted only for a research proposal submitted to GDH by Mr Naseem Cassim entitled "Developing a laboratory based CDMT programme status reporting system in the Ekurhuleni Health District."



NATIONAL HEALTH LABORATORY SERVICE HELPDESK
 Tel: (011) 386-6125/6/7/9 Fax: (011) 386-6308 email: helpdesk1@nhls.ac.za

APPLICATION FOR DATA FROM NHLS INFORMATION SYSTEMS (Q-Pulse FMI0069)

NHLS RESPONSIBILITIES

<p>The NHLS will:</p> <ul style="list-style-type: none"> • Ascertain if it is possible to extract the required data. • Register the application and issue a registration number. • Only release the requested data to the applicant whose name is specified on this application form.
<p>After this application has been completed and approved, please raise a service request with the NHLS IT Service Desk (Contact Number: (011) 386-6125/6/7/9):</p> <ul style="list-style-type: none"> • Send an email to helpdesk1@nhls.ac.za, and cc the CDW Manager (sue.candy@nhls.ac.za) • Scan this application form and attach it to the email, or fax it to (011) 386-6308.

FOR OFFICE USE				
APPROVAL BY BUSINESS				
(Approval will be obtained by the CDW Manager)				
INFORMATION MANAGEMENT UNIT APPROVAL (required for external requests and patient identifying data)				
Check list for external applicants	<input type="checkbox"/> Signed by Supervisor <input type="checkbox"/> Ethics Approval attached, if applicable			
Executive Manager: Academic Affairs, Research and Quality Assurance		Signature		Date / /20
CEO APPROVAL (required for sensitive data requests)				
Chief Executive Officer		Signature		Date / /20
APPROVAL BY IT				
CDW Manager		Signature		Date / /20
REQUEST TRACKING				
Service Request Number				
Request Commence Date	/ /20			

Data Extract One: Communication with data analyst

The screenshot shows an Outlook window titled "RE: Query - CCMT form extract - Message (HTML)". The interface includes a ribbon with various email actions like Reply, Forward, Delete, and Move to Folder. The message header shows it was sent on Monday, 10/15/2012 at 03:00 PM. The main body of the email contains the following text:

Hi Cindy,

Would you mind pivoting each of the parameters using the max (case ...) function as it will make it easier to read the data.

Thanks,

Naseem

From: Cindy Saunders [mailto:cindys@bitanium.co.za]
Sent: 15 October 2012 09:57 AM
To: Naseem Cassim
Cc: Sue Candy
Subject: Re: Query - CCMT form extract
Importance: High

Hi Naseem,

I have done the primary extract - please review the attached csv file, and advise if you require any additional detail?

Thanks

Regards

Cindy Saunders

Business Analyst

The bottom of the screenshot shows the Windows taskbar with several application icons and a system tray displaying 98% battery and the time 01:10 PM on 2012/11/24.

Data Extract Two: Study data

Q-Pulse5/docs/active/FMI0069v3

Page 1 of 6



NATIONAL HEALTH LABORATORY SERVICE HELPDESK
Tel: (011) 386-6125/6/7/9 Fax: (011) 386-6308 email: helpdesk1@nhls.ac.za

APPLICATION FOR DATA FROM NHLS INFORMATION SYSTEMS (Q-Pulse FMI0069)

Each application will be approved or rejected subject to the ability to extract this data and the availability of the data, and subject to the intended usage of the requested data. Applications that are incomplete and/or do not contain supporting documentation, will be rejected.

APPLICANT'S DETAILS

Applicant Name	Naseem Cassim	Tel No	011-489-8433	Email	Naseem.cassim@nhls.ac.za
Business Role / Designation	Project Manager				
Laboratory / Department / Branch / Region (Internal applicants)	NPP Unit				
Organisation (External applicants)					
Supervisor Name	Prof. Debbie Glencross	Tel No	011-489-8540	Email	debbie.glencross@nhls.ac.za
Supervisor Designation	Principal Pathologist and CD4 Unit Head				

CONDITIONS

- Data / Information is not to be used in contravention of Sections 14, 15, 16 and 17 of the National Health Act 61 of 2004 and the Promotions of Access to information Act 2 of 2000.
- The applicant undertakes to ensure that the data supplied to it by the NHLS is used ethically and solely for the purposes for which it is provided as detailed in this application, and further acknowledges that it shall remain liable for any breaches of this clause by the end user.
- If the purpose for the data requested in this application is research or if patient identity linked data is required, ethics approval and a one page summary of the protocol shall be attached to this application form. It is the responsibility of the applicant to ensure that their institutions' Human Ethics approval includes explicit authorisation to access the requested NHLS data.
- The applicant undertakes to store the NHLS data in a confidential manner by separating patient identifying details from laboratory data and storing the masterlist that links patient identifying details to study patient identifiers in a separate, secure location.
- The information is for the private use of the applicant only, unless further approval is obtained from the NHLS. In the event of this, the applicant shall give due credit, including affiliation, of the participation of the NHLS in any such publications or presentations.
- The applicant undertakes to provide the Executive Manager: Academic Affairs, Research and Quality Assurance at the NHLS with a copy of any report, presentation or publication emanating from the use of this data.

ACCEPTANCE OF CONDITIONS

By signing this document we accept the conditions stated above.	
Applicant Signature	Date 21/10/2012
Supervisor Signature Prof. D.K. Glencross	Date 31/10/20



NATIONAL HEALTH LABORATORY SERVICE HELPDESK
Tel: (011) 386-6125/6/7/9 Fax: (011) 386-6308 email: helpdesk1@nhls.ac.za

APPLICATION FOR DATA FROM NHLS INFORMATION SYSTEMS (Q-Pulse FMI0069)

All fields in this section must be completed

DATA REQUEST DETAILS

Request Type (Tick)	<input checked="" type="checkbox"/> New <input type="checkbox"/> Modify	Data Format (Tick)	<input type="checkbox"/> Excel <input checked="" type="checkbox"/> CSV	Data Delivery (Tick)	<input type="checkbox"/> CD / DVD <input checked="" type="checkbox"/> Email
Frequency of Extract (Tick)	<input type="checkbox"/> Once <input checked="" type="checkbox"/> Repeat	If Repeat, specify frequency	<input type="checkbox"/> Daily <input checked="" type="checkbox"/> Weekly	<input type="checkbox"/> Monthly <input type="checkbox"/> Annually	
DESCRIPTION OF REQUIRED DATA EXTRACT					
Data required	The CD4 and ARV Programme Status information using the project and current CCMT request forms for three ART facilities in the Ekurhuleni Health District. This data extract is the pre-study analysis to assess the current usage of the current CCMT form. Once the study has been conducted a data extract will be requested using the study form. We require the results for all CD4 tests and a CCMT programme status when provided.				
Region (for data extract, e.g. Province or Laboratory)	Please limit the extract to the following location codes: <ul style="list-style-type: none"> • Tambo Memorial Hospital (BOK) • Tembisa Hospital (TEM) • Far East Rand Hospital (FAR) 				
Date range of extract	Please extract the data from 01/10/2012 to date End Date for Extract: 31 December 2012				
Fields required (e.g. Patient name, Date of Birth, etc)	The following fields are required: Laboratory number, testing lab prefix, testing lab name referring lab prefix, referring lab name, location code, location description, ward code, ward description, health sub-district, unique patient id, gender, DOB, race, refnum, hospital number, CD4 absolute count, CCMT programme Status, CD4 Programme Status, Viral Load Programme Status, Months on ART, ARV Drugs (1-3) Please provide the CD4 absolute count to ARV Drugs fields in columns next to each other and not as separate rows of data				
ADDITIONAL INFORMATION					
None					
DESCRIPTION OF INTENDED USE OF DATA EXTRACT (e.g. research, epidemiology study, cost analysis of service, drug effectiveness, disease surveillance)					
Research					
LIST WHO WILL HAVE ACCESS TO THIS DATA					
Debbie Glencross, Lindi Coetzee and Naseem Cassim					



NATIONAL HEALTH LABORATORY SERVICE HELPDESK
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NATIONAL HEALTH
 LABORATORY SERVICE

APPLICATION FOR DATA FROM NHLS INFORMATION SYSTEMS (Q-Pulse FMI0069)

PROJECT NAME AND REGISTRATION NUMBER

(if data is required for a registered research project. Please attach the Ethics Approval.)

MPH Dissertation Title: Developing a laboratory based CCMT Programme Status reporting system in the Ekurhuleni Health District (Ethics attached)

Details for the data extract:-

Data Field	Test Method/s	Parm Code/s
CD4 absolute count	CDARV	CD4#V
CCMT programme Status	ARVID	ARVS
CD4 Programme Status		ARVA
Viral Load Programme Status		ARVB
Months on ART		MOART
ARV Drugs 1		ARVT1
ARV Drugs 2		ARVT2
ARV Drugs 3		ARVT3



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NATIONAL HEALTH
LABORATORY SERVICE

APPLICATION FOR DATA FROM NHLS INFORMATION SYSTEMS (Q-Pulse FMI0069)

Addendum One: Ethics Certificate



UNIVERSITY OF SOUTH AFRICA
Health Studies Higher Degrees Committee
College of Human Sciences
ETHICAL CLEARANCE CERTIFICATE


HS/DC/59/2012

Date of meeting: 6 June 2012 Student No: 0641-967-0
Project Title: Developing a laboratory based COMET programme status reporting system in the Ekurhuleni Health District
Researcher: Naseem Cassim
Degree: Masters in Public Health (MPH) Code: DUMPHS
Supervisor: Prof OK Glenness
Qualification: BSc in medicine
Joint Supervisor: -

DECISION OF COMMITTEE

Approved Conditionally Approved


Prof S Potgieter
CHAIRPERSON: HEALTH STUDIES HIGHER DEGREES COMMITTEE


Dr MM Molelele
ACTING ACADEMIC CHAIRPERSON: DEPARTMENT OF HEALTH STUDIES
fsl
PLEASE QUOTE THE PROJECT NUMBER IN ALL ENTRIES



NATIONAL HEALTH LABORATORY SERVICE HELPDESK
Tel: (011) 386-6125/6/7/9 Fax: (011) 386-6308 email: helpdesk1@nhls.ac.za

APPLICATION FOR DATA FROM NHLS INFORMATION SYSTEMS (Q-Pulse FMI0069)

Addendum Two: Approval from the Gauteng DOH Research Committee

CONDITIONS OF APPROVAL OF A RESEARCH STUDY/PROJECT



GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

POLICY, PLANNING AND RESEARCH (PPR)
Supervisor: Dr S. Fraaijling
Tel: +27(11) 305 8500
Fax: +27(11) 305 8675 Email: drfdp@ppr.gauteng.gov.za

CONTACT DETAILS OF THE RESEARCHER	
Date	09 July 2012
Contact number	011 489 8436
Email	n.cassim@nhls.ac.za
Researcher /Principal Investigator (PI)	Mr Nazeem Cassim
Supervisor	Associate Professor Deborah Gienches
Institution	Wits Medical School
Research title	Developing a laboratory based CD4T programme status reporting system in the Diepsloot Health District

This approval is granted only for a research proposal submitted to CD4T by Mr Nazeem Cassim entitled "Developing a laboratory based CD4T programme status reporting system in the Diepsloot Health District."



NATIONAL HEALTH LABORATORY SERVICE HELPDESK
 Tel: (011) 386-6125/6/7/9 Fax: (011) 386-6308 email: helpdesk1@nhls.ac.za

APPLICATION FOR DATA FROM NHLS INFORMATION SYSTEMS (Q-Pulse FMI0069)

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- Send an email to helpdesk1@nhls.ac.za, and cc the CDW Manager (sue.candy@nhls.ac.za)
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FOR OFFICE USE				
APPROVAL BY BUSINESS				
(Approval will be obtained by the CDW Manager)				
INFORMATION MANAGEMENT UNIT APPROVAL (required for external requests and patient identifying data)				
Check list for external applicants	<input type="checkbox"/> Signed by Supervisor <input type="checkbox"/> Ethics Approval attached, if applicable			
Executive Manager: Academic Affairs, Research and Quality Assurance		Signature		Date / /20
CEO APPROVAL (required for sensitive data requests)				
Chief Executive Officer		Signature		Date / /20
APPROVAL BY IT				
CDW Manager		Signature		Date / /20
REQUEST TRACKING				
Service Request Number				
Request Commence Date	/ /20			

Data Extract Two: Communication with data analyst

RE: Data request for CD4 and ARV Programme Status information using the project and current CCMT request forms - Message (HTML)

This message was sent with High importance.

From: Naseem Cassim
 To: Thomas Papo
 Cc: Michelle Potgieter
 Subject: RE: Data request for CD4 and ARV Programme Status information using the project and current CCMT request forms

Sent: Mon 12/11/12 08:57 AM

Message | FM69v3_External Data Request Study Data.docx (144 KB)

Hi Thomas,

The test codes and parm codes were specified in the data extract document I sent to the IT Helpdesk (attached):-

Details for the data extract:-

Data Field	Test Method/s	Parm Code/s
CD4 absolute count	CDARV	CD4#V
CCMT programme Status	ARVID	ARVS
CD4 Programme Status		ARVA
Viral Load Programme Status		ARVB
Months on ART		MOART
ARV Drugs 1		ARVT1
ARV Drugs 2		ARVT2
ARV Drugs 3		ARVT3

As per my discussion, the parm codes ARVA and ARVB are new parameters on Disa*lab that were added in September 2012.

Hence they are not available in the ARV target tables.

Please let me know if you need any additional details from me.

Regards,

RE: Data request for CD4 and ARV Programme Status information using the project and current CCMT request forms - Message (HTML)

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Months on ART		MOART
ARV Drugs 1		ARVT1
ARV Drugs 2		ARVT2
ARV Drugs 3		ARVT3

As per my discussion, the parm codes ARVA and ARVB are new parameters on Disa*lab that were added in September 2012.

Hence they are not available in the ARV target tables.

Please let me know if you need any additional details from me.

Regards,

Message: CCMT data lack CCMT status info for GFA_FAR.xlsx - Message (HTML)

From: Naseem Cassim
To: Thomas Pappo
Cc: Michelle Polgieter
Subject: CCMT data lack CCMT status info for GFA_FAR.xlsx

Sent: Thu 2012/12/13 01:11 PM

Message: CCMT data lack CCMT status info for GFA_FAR.xlsx (621 KB)

Hi,

I am still getting the same issue with GFA.

Could I rather get two data extracts, one for CD4 results and a separate ARVID extract?

Thanks,
Naseem

Data issue - Message (HTML)

You replied on 2013/01/15 09:17 AM.

From: Sue Candy
To: Naseem Cassim
Cc: Data issue
Subject: Data issue

Sent: Tue 2013/01/15 08:22 AM

Hi Naseem,


I believe Thomas should have resolved your data issue for your pilot study on the East Rand. Please can you check the data Thomas sent through to you and confirm whether or not you are happy with it.

Can you also confirm whether this request needs to be an automated and if so, the frequency with which it should be run and the data sent to you?

I look forward to receiving your prompt response.

Regards,
Sue

Sue Candy
Manager
Corporate Data Warehouse
Tel: (011) 386-6036 / Cell: 083 625 6401
sue.candy@nhls.ac.za | www.nhls.ac.za

 NATIONAL HEALTH LABORATORY SERVICE

Practice Number: 5200296

MPH Data - Message (HTML)

Message

Reply Reply Forward Delete Move to Create Other Block Safe Lists Categorize Follow Mark as Find Related Link to E-mail Record Auto-link Send to OneNote
Respond To All Respond Actions Junk E-mail Options Find Business Contact Manager OneNote

This message was sent with High importance.

From: Naseem Cassim
To: Sue Candy
Cc: Michelle Polgitey; Thomas Pappo
Subject: MPH Data
Sent: Tue 2013/01/15 10:15 AM

Hi Sue,


I have reviewed the MPH extract and I am happy with the data provided.

The issues raised previously have been resolved.

I would need a weekly extract of data until the end of January (to mop up any additional data that still come in : Data from 1 October 2012 to end Jan 2013).

I am happy to run the script created by Michelle and Thomas on Aginity, alternatively the data could be sent to me via email every Monday (until end Jan 2013).

Thanks,



Naseem Cassim
National Priority Programme (NPP) Unit
Wits Medical School, Room 3A14
Tel: (011) 489-8866
Fax: 0866727643
Cell: 082-888-0419
Email: naseem.cassim@nhls.ac.za

PS Data extract now shows ARVID data for FER:-

1	REFNOPREFIX	INT			
2					
3	Count of LAB_NO	Column Labels			
4	Row Labels	FAR EAST RAND HOSPITAL	TAMBO MEMORIAL HOSPITAL	TEMBISA HOSPITAL	Grand Total
5	3TC			4	4
6	ADVERSE EFFECT			4	4

System Administrator
Delivered: MPH Data

10:14 AM
2013/01/15

Untitled - Message (Rich Text)

Message

Reply Reply Forward Delete Move to Create Other Block Safe Lists Categorize Follow Mark as Find Related Link to E-mail Record Auto-link Send to OneNote
Respond To All Respond Actions Junk E-mail Options Find Business Contact Manager OneNote

You forwarded this message on 2012/11/21 11:25 AM.

From: Happy Mashigo
To: Naseem Cassim; Bahule Motonye
Cc:
Subject:
Sent: Wed 2012/11/21 10:55 AM

Dear Naseem and Nimrod

I just spoke to Derek and he will move the Reschedule Far East for early next year. Kindly provide the end date for the Viral load study and the test method that is not available on TRAK.

I will include on the email requesting Far East to be done next year.

Regards

Happy Mashigo

09:15 AM
2012/11/23

**ANNEXURE G: EMAIL FROM NHLS IT CONFIRMING THE CHANGE IN THE
PROJECT PLAN FOR THE ROLLOUT OF THE TRAKCARE LIMS IN THE
EKURHULENI HEALTH DISTRICT**

From: Happy Mashigo
Sent: 21 November 2012 01:30 PM
To: 'Derek Verster'
Cc: Shaun Grimett
Subject: Far East rand

Dear Derek

Kindly reschedule implementation for far East Rand lab from next week to early next year and replace it with Vereeniging lab if possible.

The reason for the request is that **Far EAST Rand, Boksburg and Tembisa** are currently participating in a MPH study the purpose of the study is to combine the use of new CCMT request form and the NHLS laboratory Information Management System(LIMS) to enable the appropriate capture of CCMT programme status for each CD4 test requested.

The study started in October and will end in December. There were new Parameters added on the test method ARVID(for capturing the patient status) the parameters are not yet available on Trak.

Thank you.

Regards

Happy Mashigo

Tel: 011 555 0409 | Cell: 082 8822212
Happy.mashigo@nhls.ac.za | www.nhls.ac.za

ANNEXURE H: EMAIL COMMUNICATION WITH LABORATORY MANAGERS

RE: Week Seven Follow Up Visit - Message (HTML)

Message

Reply Reply Forward Delete Move to Create Other Block Safe Lists Categorize Follow Mark as Find Related Link to E-mail Send to Respond to all Folders Rule Actions Sender Not Junk Junk E-mail Options Unread Select Find Record Auto-link OneNote

You replied on 2012/11/22 09:39 AM. Sent: Thu 2012/11/22 09:37 AM

From: Sello Matsho
To: Naseem Cassim
Cc:
Subject: RE: Week Seven Follow Up Visit


Morning Naseem

I just find out that our ARV Clinic (Masakhane), doesn't have books anymore – is it possible to organize few books for us

Regards

Sello Matsho

Laboratory Manager
National Health Laboratory Services
Tembisa Laboratory
Tel: 011 920 1126 / 2625
Fax: 011 926 2909
Mobile: 072 623 4727
sello.matsho@nhlg.ac.za



Practice Number: S200296

From: Naseem Cassim
Sent: Tuesday, November 20, 2012 10:06 AM
To: Bahule Mofonye; Mpsela, Nobantu (ghealth); Rene Cooks; Sello Matsho; Mapaseka Mlisi
Cc: Debbie Glencross; 'Debbie Glencross' (gglencross@roussos.co.za)
Subject: Week Seven Follow Up Visit
Importance: High

Hi,

Please find attached the results of the week seven follow up visits:-

100% 09:02 AM 2012/11/23

ANNEXURE I: PRINTERS TAX INVOICE

32 years of
Excellence in
Office Products



Forms MEDIA
Independent Africa
Established in 1981

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Riverton
PO Box 30125, Secom 2023
Tel: (011) 229 1300
Fax: (011) 614 467 604 / 1331 5006
Fax: (011) 229 1382 / 604 1219 Sales
Fax: (011) 614 8017 Accounts
Fax: (011) 024 1074 Franchise Office
Tel: (089) 431 0300 - JHB Office

CAPE TOWN
Tel: (021) 386 2423
Fax: (021) 386 2428

DURBAN
Tel: (031) 969 3480
Fax: (031) 969 3450

SECURIDA
Tel: (017) 831 1296
Fax: (017) 831 1295

TZANEEN
Tel: (010) 207 7426
Fax: (010) 207 7267

WITBANK
Tel: (010) 660 1130
Fax: (010) 660 1127

WINDHOLDE
Tel: (010) 660 1130
Fax: (010) 660 1127

POLOMANNE
Tel: (015) 292 8100
Fax: (015) 292 2681

WINDHOLDE
Tel: (010) 660 1130
Fax: (010) 660 1127

WINDHOLDE
Tel: (010) 660 1130
Fax: (010) 660 1127

INVOICE NO.	DU376426
DATE	31/09/2012
PAGE	1

PRINTING

CONSUMABLES

JANITORIAL AND CANTEN SUPPLIES

STATIONERY

OFFICE FURNITURE

PROMOTIONAL PRODUCTS

Goods not returned within 7 days & accepted for credit at their own discretion. All goods will not be returned for credit without prior arrangement with manager. ESOE
TERMS AND CONDITIONS AVAILABLE

NATIONAL HEALTH LABORATORY SER.
P.O. BOX 1038
JOHANNESBURG
2000
VAT Nos: 4900103575

INVOICED BY OUR BRANCH AT
NATIONAL HEALTH LABORATORY SER.
COLLECTING
Phone #1
DELIVER
ATTENTION: MADSEN CASSIM

OUR REF.	CUST. NO.	REP CODE	CUST. ORDER NO.	DATE	DELIVER BY	TERMS
76992	NAT110	M6		18/09/2012 0	COLLECTING	30 DAYS NET

QUANTITY	Supplied	Stock Order	Line no.	ITEM CODE	DESCRIPTION	NO. PRDS	UNIT PRICE	AMOUNT
50	50	0	1	A-XXX-20000001	MELS - INTERIM AAY BOOKS 50 AAY INTERIM BOOKS, SPECIAL PROJECT NO CHANGES PART OF SOCIAL DEVELOPMENT PROGRAMME FOR HEALTH UPLIFTMENT		0.00 EA	0.00
TOTAL								0.00

Goods not returned within 7 days & accepted for credit at their own discretion. All goods will not be returned for credit without prior arrangement with manager. ESOE
TERMS AND CONDITIONS AVAILABLE

Goods put
Packed by: [Signature]
Date: 17/9/12
Checked by: [Signature]
Date: [Signature]
Driver: [Signature]
Date: [Signature]

BANKING DETAILS: Same NEDBANK Branch: BUSINESS CENTRAL, Branch Code: 128805, A/C No: 1294111334
ALL GOODS REMAIN THE PROPERTY OF FMIA (PTY) LTD UNTIL FULLY PAID FOR

TERMS: STRICTLY 30 DAYS NETT

17/09/2012 13:55:16 HERRIETTE

**ANNEXURE J: STUDY DATA PRESENTATION AS WELL AS DELIVERY OF
PRE-ART REGISTER AND QUESTIONNAIRE**

Letters to the study sites to propose dates and time for the study results presentation and delivery of pre-ART register and questionnaire



MEMO ■

Naseem Cassim (NPP Unit)
1 Modderfontein Rd, Sandringham
Tel: 011 489 8866 Fax: 0866727643
Cell: 0828880419

Date: 18 February 2013

To: The CEO
Far East Rand Hospital
Hospital Street
Springs

From: Naseem Cassim, Nobantu Mpela & Bahule Motlonye

RE: Presentation of study results

Dear CEO and clinical staff,

We met with you and your staff in September 2012 to discuss the research study by Naseem Cassim from the National Health Laboratory Service (NHLS). The purpose of this research study was to combine the use of the new CCMT laboratory request form and the NHLS Laboratory Information Management System (LIMS) to enable the appropriate capture of the CCMT programme status at the Far East Rand Hospital.

The collection of data for the study has been completed and we would like to present the results of the study as well as deliver the laboratory Pre-ART register. On receipt of the pre-ART register a feedback questionnaire must be completed and returned to the researcher. The feedback meeting is proposed for the 1st of March 2013 (09:00) at the Far East Rand Hospital. The target group for this meeting would be all health care staff that was actively involved in the study.

Please let us know whether this date and time would be convenient.

Many thanks,

Bahule Motlonye (Business Manager:SEKWE): 082 807 2650
Naseem Cassim (NPP Unit): 082 888 0419.
Nobantu Mpele (GDoH): 079-505-8768

Attendance register at the Far East Rand study site

Register

Date	1 MARCH 2013
Time	09H00
Venue	FER
Activity	Pre-ART Register

Name	Roles	Tel/Cell	Email
T.R. MASHU	CPN	018123481	-
Z.E. SITHINKE	NURSING	083-964-4471	-
M.B. Dlamini	Nursing	0832080430	
N.S. NOMAND	NURSING	0834577451	
L. COETZEE	Subuser	0831595617	
B.N. MOKANYE	BN	011 4899154	

Attendance register at the Tembisa Hospital study site briefing for the senior management team



GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

TEMBISA PROVINCIAL TERTIARY HOSPITAL

ATTENDANCE REGISTER

MEETING: EXECUTIVE/OTHER... NHLS

DATE: MARCH WEEK 1

VENUE: EXECUTIVE BOARD ROOM

NAME (PLEASE PRINT)	POSITION	DEPARTMENT	FAX NO.	TEL/ MOB	E-MAIL	DATE: 06.03.2012 SIGN BELOW:
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<i>T. Nyathi</i>	<i>Registered Nurse</i>	<i>Medicine</i>		<i>X 2161</i>		<i>T. Nyathi</i>
<i>V. Ramokapa</i>	<i>AD</i>	<i>HR</i>		<i>3116</i>		<i>V. Ramokapa</i>
<i>M.M. Mchabe</i>	<i>CPA</i>	<i>Medicine</i>		<i>2007</i>		<i>M.M. Mchabe</i>
<i>N.S. Marake</i>	<i>RN</i>	<i>Medical</i>	<i>0119201195</i>	<i>2008</i>		<i>N.S. Marake</i>
<i>N. Nsoro</i>	<i>CPA</i>	<i>Medical</i>	<i>0119201195</i>	<i>2008</i>		<i>N. Nsoro</i>
<i>M. Sool</i>	<i>CPA</i>	<i>Medical</i>	<i>0119201195</i>	<i>2008</i>		<i>M. Sool</i>
<i>M. Ramolumi</i>	<i>DD HRM</i>	<i>HR</i>	<i>11</i>	<i>20030</i>		<i>M. Ramolumi</i>
<i>M. Ramolumi</i>	<i>Asst Chief NUR</i>	<i>WD 12</i>	<i>011923-2012</i>	<i>2012</i>		<i>M. Ramolumi</i>

Screenshot of the pre-ART Register for the Tambo Memorial study site

Assumptions
 Data collected using the study form with barcode using the "INT" prefix
 CD4 programme status = "first ever CD4"
 CD4 count <= 350
 Data collected between 1 October 2012 and 31 January 2013



LAB_NO	HOSPITAL_ID	DOB	CD4_Count	MPL_PROG_STATUS	REF_NO	LOCATION_CODE	LOCATION_NAME	WARD_NAME	REVIEWED_DATE
GB04599951	1570376	1982-03-13 00:00:00	122	First ever CD4	INT1772	BOK	TAMBO MEMORIAL HOSPITAL	ANTE NATAL CLINIC	2012-11-06 10:14:00
GB04594303	1608165	1969-06-11 00:00:00	278	First ever CD4	INT1781	BOK	TAMBO MEMORIAL HOSPITAL	ANTE NATAL CLINIC	2012-12-05 21:08:00
GB04571385	1621049	1984-11-04 00:00:00	230	First ever CD4	INT1764	BOK	TAMBO MEMORIAL HOSPITAL	ANTE NATAL CLINIC	2012-10-24 07:42:00
GB04590970	1634544	1978-11-30 00:00:00	210	First ever CD4	INT1769	BOK	TAMBO MEMORIAL HOSPITAL	ANTE NATAL CLINIC	2012-11-02 10:03:00
GB04706853	1644389	1983-12-29 00:00:00	305	First ever CD4	INT1799	BOK	TAMBO MEMORIAL HOSPITAL	ANTE NATAL CLINIC	2013-01-16 06:41:00
GB04556138	1648224	1988-10-16 00:00:00	238	First ever CD4	INT1760	BOK	TAMBO MEMORIAL HOSPITAL	ANTE NATAL CLINIC	2012-10-16 21:07:00
GB04539892	1648243	1992-03-30 00:00:00	265	First ever CD4	INT1762	BOK	TAMBO MEMORIAL HOSPITAL	ANTE NATAL CLINIC	2012-10-18 04:22:00
GB04601337	1650503	1970-01-08 00:00:00	128	First ever CD4	INT1774	BOK	TAMBO MEMORIAL HOSPITAL	ANTE NATAL CLINIC	2012-11-08 11:24:00
GB04579843	1650559	1978-09-18 00:00:00	133	First ever CD4	INT1767	BOK	TAMBO MEMORIAL HOSPITAL	ANTE NATAL CLINIC	2012-10-27 20:45:00
GB04674113	1656353	1978-02-10 00:00:00	239	First ever CD4	INT1791	BOK	TAMBO MEMORIAL HOSPITAL	ANTE NATAL CLINIC	2012-12-18 22:35:00
GB04693396	1658469	1983-12-15 00:00:00	189	First ever CD4	INT1793	BOK	TAMBO MEMORIAL HOSPITAL	ANTE NATAL CLINIC	2013-01-08 13:28:00
GB04706872	1659149	1979-10-10 00:00:00	103	First ever CD4	INT1796	BOK	TAMBO MEMORIAL HOSPITAL	ANTE NATAL CLINIC	2013-01-15 06:23:00
GB04597088	197912123	1973-12-23 00:00:00	150	First ever CD4	INT1584	BOK	TAMBO MEMORIAL HOSPITAL	ARV CLINIC	2012-11-07 02:38:00
GB04529638	1556579	1977-06-21 00:00:00	230	First ever CD4	INT1714	BOK	TAMBO MEMORIAL HOSPITAL	ARV CLINIC	2012-10-03 05:41:00
GB04561757	1596888	1971-10-09 00:00:00	47	First ever CD4	INT1714	BOK	TAMBO MEMORIAL HOSPITAL	ARV CLINIC	2012-10-19 11:44:00
GB04531791	1603522	1983-10-02 00:00:00	179	First ever CD4	INT1677	BOK	TAMBO MEMORIAL HOSPITAL	ARV CLINIC	2012-10-04 09:37:00
GB04562755	1625914	1962-12-01 00:00:00	160	First ever CD4	INT1713	BOK	TAMBO MEMORIAL HOSPITAL	ARV CLINIC	2012-10-19 13:40:00
GB04568695	1648335	1977-10-22 00:00:00	34	First ever CD4	INT1610	BOK	TAMBO MEMORIAL HOSPITAL	ARV CLINIC	2012-10-23 09:12:00
GB04568718	1649341	1980-09-17 00:00:00	100	First ever CD4	INT1611	BOK	TAMBO MEMORIAL HOSPITAL	ARV CLINIC	2012-10-23 09:11:00
GB04596961	1649556	1955-11-06 00:00:00	79	First ever CD4	INT1592	BOK	TAMBO MEMORIAL HOSPITAL	ARV CLINIC	2012-11-07 02:37:00
GB04526888	35342012	1972-09-09 00:00:00	188	First ever CD4	INT1952	BOK	TAMBO MEMORIAL HOSPITAL	ARV CLINIC	2012-10-01 23:58:00
GB04599814	197970725	1979-07-25 00:00:00	264	First ever CD4	INT1600	BOK	TAMBO MEMORIAL HOSPITAL	HCT	2012-11-08 05:51:00
GB04597534	1646554	1989-09-17 00:00:00	5	First ever CD4	INT1960	BOK	TAMBO MEMORIAL HOSPITAL	HCT	2012-10-16 20:58:00
GB04555969	6388310	1955-12-01 00:00:00	194	First ever CD4	INT0887	BOK	TAMBO MEMORIAL HOSPITAL	HCT	2012-10-16 20:58:00
GB04542199	754139	1959-09-27 00:00:00	269	First ever CD4	INT0056	BOK	TAMBO MEMORIAL HOSPITAL	HCT	2012-10-09 23:48:00
GB04550094	794824	1979-08-24 00:00:00	180	First ever CD4	INT0078	BOK	TAMBO MEMORIAL HOSPITAL	HCT	2012-10-14 04:44:00
GB04575421	1267517	1971-10-24 00:00:00	34	First ever CD4	INT1633	BOK	TAMBO MEMORIAL HOSPITAL	HCT	2012-10-26 09:11:00
GB04526929	1280333	2000-03-01 00:00:00	180	First ever CD4	INT1951	BOK	TAMBO MEMORIAL HOSPITAL	HCT	2012-10-02 01:48:00
GB04587371	1375410	1966-08-26 00:00:00	98	First ever CD4	INT1564	BOK	TAMBO MEMORIAL HOSPITAL	HCT	2012-11-01 00:48:00
GB04577323	1441629	1985-08-07 00:00:00	172	First ever CD4	INT1643	BOK	TAMBO MEMORIAL HOSPITAL	HCT	2012-10-26 22:56:00
GB04565168	1449929	1957-10-04 00:00:00	64	First ever CD4	INT1609	BOK	TAMBO MEMORIAL HOSPITAL	HCT	2012-10-20 13:33:00



GAUTENG DEPARTMENT OF HEALTH AND
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FAX

TO: RESEARCH PROJECT	FROM: MRS. Z. GUMEDE
ATTENTION: Nasseem.	FAX NO: 011 817 3525
FAX NO: 0866 7276 43	TEL. NO: 011 812 8433
TEL NO: 082 888 0419	E-MAIL ADDRESS:
PAGES TRANSMITTED: (Including cover sheet)	Zanile, Gumede@gpr.health

URGENT REVIEW COMMENT REPLY

MESSAGE: Kindly receive evaluation
of pre art laboratory register

DATE: 26/03/2013 SIGNATURE: Z. Gumede



NATIONAL HEALTH LABORATORY SERVICE
PRE-ART LABORATORY REGISTER
QUESTIONNAIRE



Health Facility	Far East Rand Hospital CCMT clinic		
Health Worker Name	Zandile Gamede		
Tel	011 812 8433	Cell	083 3886504
Signature	Gamede		
Date	26/03/2013		

Please tick only one box below for each question:-

Question	Excellent	Very Good	Good	Average	Poor
How would you rate the quality of the pre-ART laboratory register compared to paper-based records at your health facility?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Please rate the format of the PRE-ART laboratory register	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Please rate the service of your local GDM laboratory	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please rate questions below by ticking only one box below for each question below:-

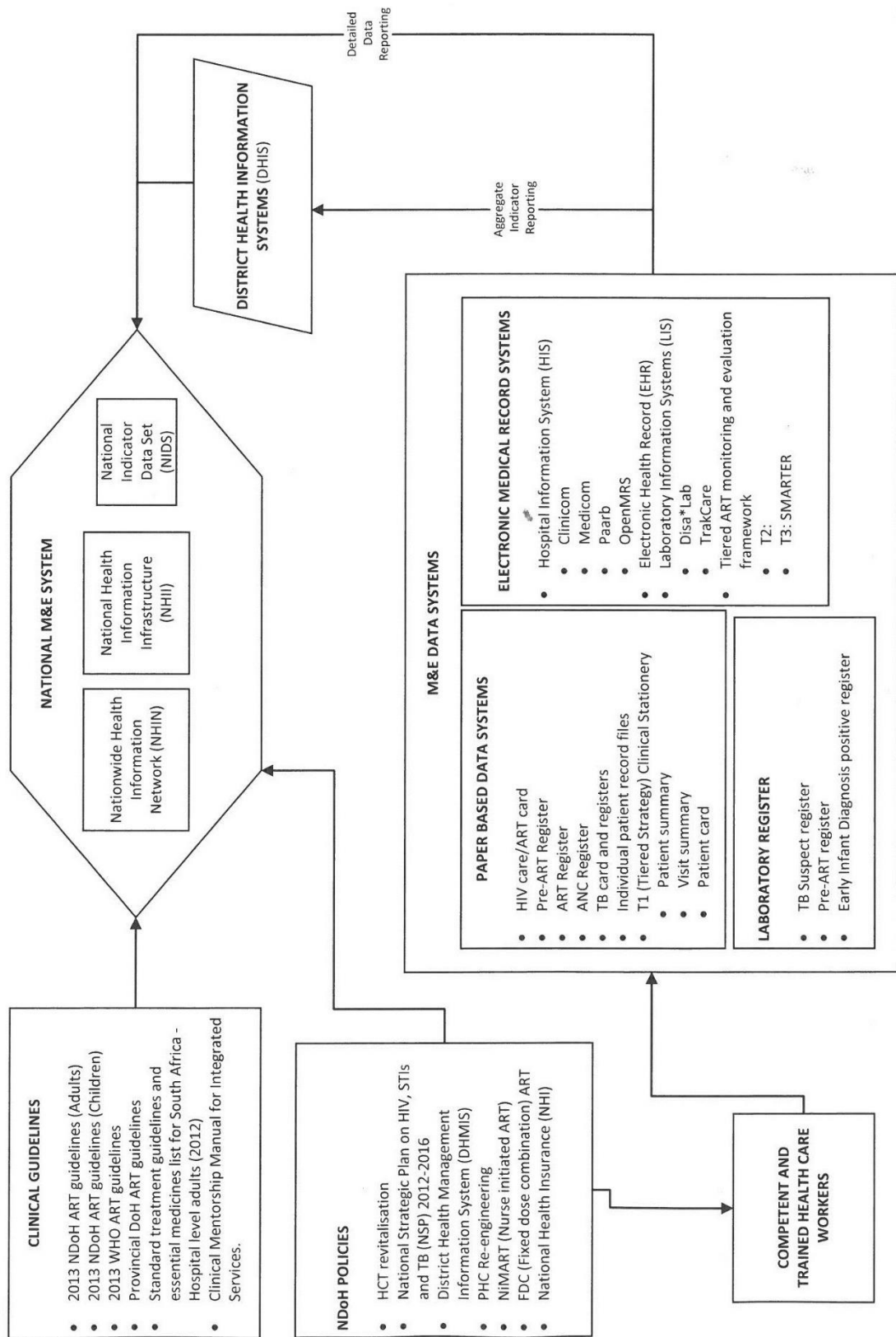
Question	Great assistance	Good assistance	Partial assistance	Only limited assistance	No Assistance at all
Has the PRE-ART laboratory register made it easier to track patient to reduce the loss to follow up?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has the PRE-ART laboratory register made it easier to ensure that the paper-based records are complete?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has the PRE-ART laboratory register made it easier to report on the DHIS?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has the PRE-ART laboratory register made it easier to report on the DHIS?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has the PRE-ART laboratory register made it easier to manage the flow to patient being staged in your facility?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has the PRE-ART laboratory register made it easier to follow up patients that have not returned to the health facility after a CD4 test?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please add any additional comments about the Laboratory PRE-ART Register below:-

Please return the completed questionnaires to NHLS via the routine courier

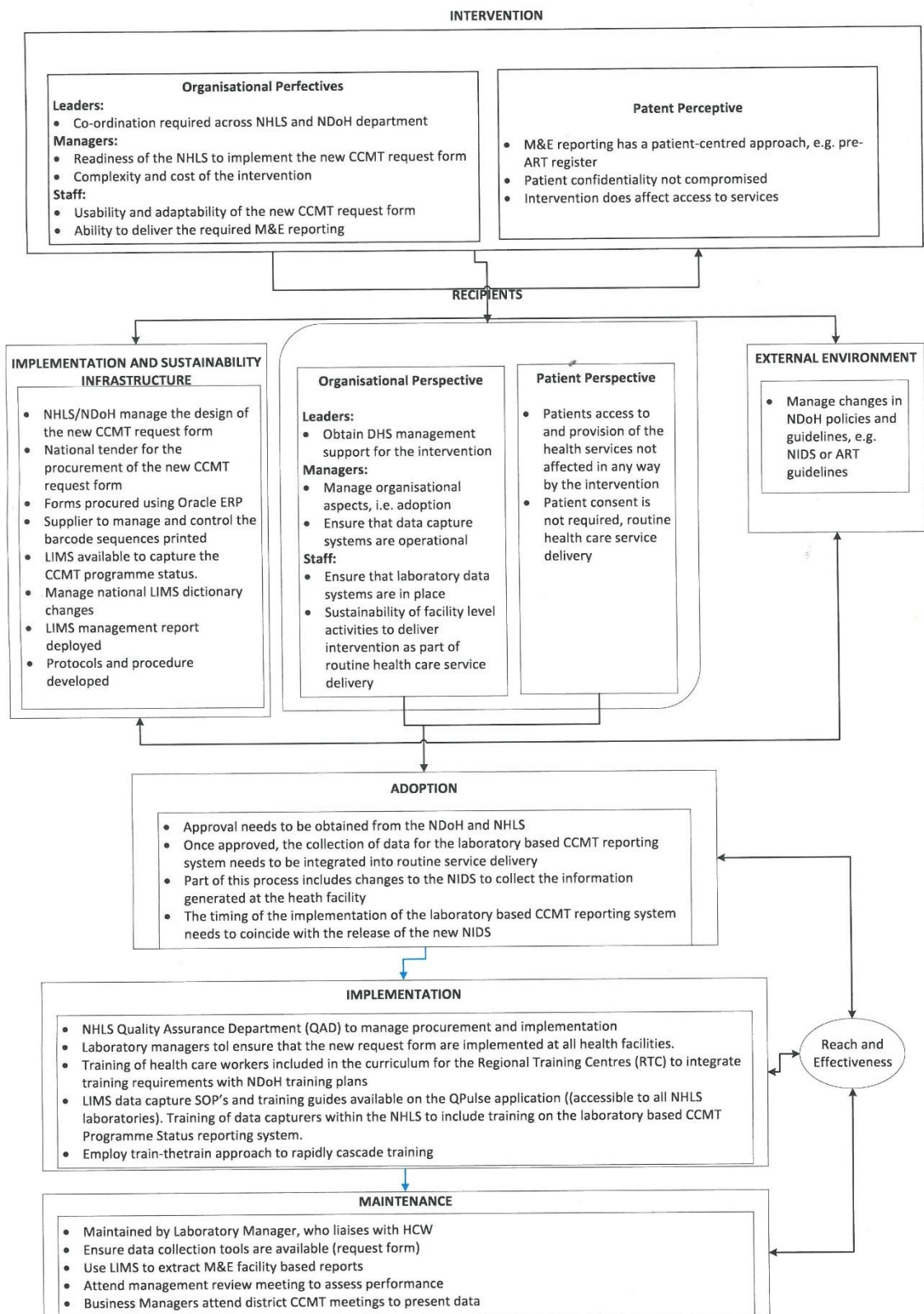
ANNEXURE K: CONCEPTUAL FRAMEWORK

Conceptual Framework



ANNEXURE L: PROPOSED PRISM MODEL FOR IMPLEMENTATION

Proposed PRISM Model for implementation



ANNEXURE M: ETHICAL CONSIDERATIONS RELATED TO DATA COLLECTION

Ethical considerations related to data collection

<p>Relationship to the practice of science (Mouton 2011:239).</p>	<p>Objectivity and integrity: The researcher must at all times maintain integrity and objectivity in the conduct of the study. This included adhering to the highest technical standards during the study, indicating the limitations of the study findings and undertaking to present the results of the study impartially.</p>
	<p>Fabrication of data: The researcher will under no circumstances change the data or observations for the study.</p>
<p>Relationship to society(Mouton 2011:241)</p>	<p>No secret of clandestine research: The researcher has obtained consent to conduct the study from the Gauteng Department of Health. Additionally the approval to conduct the study was obtained from the chief operating officers (CEO's) of the three study sites. Consent to conduct the study was request from the NHLS business manager (BM).</p>
	<p>Obligation to the free and open dissemination of research results: The study results have been shared with the relevant national, provincial, district Department of Health.</p>
	<p>Responsibility to funders and sponsors of research: The study results have been shared within the National Priority Programmes (NPP) CD4 Unit at the NHLS who are the sponsors of this research.</p>
<p>Relationship to the subjects of science (Mouton 2011:243).</p>	<p>Right to privacy: The patient's right to privacy has been ensured both when CD4 samples were being collected as well as the provision of data from the CDW that excluded any patient identifiers.</p>
	<p>Right to anonymity and confidentiality: The NHLS Corporate Data Warehouse (CDW) has extracted the CD4 and CCMT programme status data without any patient identifiers. The study therefore received anonymous laboratory data and did not require informed consent</p>
	<p>The right to full disclosure: All aspects of the study were disclosed to the Gauteng CCMT programme manager, the CEO's at the study sites and finally the study site managers.</p>
	<p>The right not to be harmed in any manner: This study had no experimental or interventional aspects. As the study related to the collection of information during routine healthcare service delivery the patient's were not harmed in any manner</p>
	<p>The rights of vulnerable subjects: The study collected additional information about the patient programme status (pre-ART or ART) offered during routine healthcare delivery; hence the rights of all subjects (including vulnerable subjects) were not compromised.</p>