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Assessment of data quality of an EMR system, and the effect of CD4 guideline change and patient escort on time to linkage to and retention in ART: a study at Kiambu County Referral Hospital

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Assessment of Data Quality of an EMR System, and the Effect of CD4 Guideline Change and Patient Escort on Time to Linkage to and Retention in ART – A study at Kiambu County Referral Hospital

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DECLARATION

I declare that this work has not been previously submitted and approved for the award of a degree by this or any other University. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made in the thesis itself.

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Signature 

Date 18th May 2018

Approval

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ABSTRACT

Kiambu County Referral Hospital adopted electronic medical records in the HIV clinic for longitudinal follow up of patients enrolled in care. The hospital also implemented CD4 guideline changes on antiretroviral therapy eligibility and a patient escort system to facilitate timely linkage of patients to treatment after HIV diagnosis. This study first evaluated data quality of the electronic medical records database, which was then utilized to assess the effect of CD4 guideline changes and patient escort on time to linkage to and retention in antiretroviral therapy. This study is a cross-sectional study that involved evaluation of medical records of eligible patient populations. For the data quality study, the sample size was based on random sampling on Microsoft Excel using a line list that was extracted from the electronic medical record database. This sample of electronic records was then compared against a similar sample of physical records. For the assessment of effect of CD4 guideline change and patient escort on time to linkage to and retention in antiretroviral therapy, a complete census of the eligible population was done using the electronic medical record database.

There was over 70% completion rate for most clinical indicators evaluated in both electronic and physical records. Both ART start date (96 % vs 77%) and baseline CD4 (73% vs 56%)were significantly more complete in the physical records compared to electronic records. Almost all evaluated indicators had a mismatch rate of less than 10% between physical and electronic records, except for "date started ART" that had the highest mismatch rate of 20%. There was a significant decline in median time to linkage to ART from 51 days in the 350 CD4 cut-off group to 16 days in the "test and treat" group. There was a significantly higher retention in ART, and lower overall attrition and lost to follow up for the "test and treat" group. However, there was no significant difference in retention, overall attrition, lost to follow up and mortality between the pre and post patient escort groups.

The study findings have important implications for the use and interpretation of data derived from EMR databases for ongoing patient follow up and retention in treatment programmes as well as operational research. The "test and treat" strategy showed improvements in both median time to linkage to and retention in ART. More research on patient escort as a behavioral intervention for linkage and retention in ART, as well as impact of "test and treat" strategy on mortality is needed.

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LIST OF ACRONYMS AND ABBREVIATIONS

ADT	ART Dispensing Tool
AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Clinic
ART	Antiretroviral Therapy
CRH	County Referral Hospital
EMR	Electronic Medical Records Systems
HIV	Human Immunodeficiency Virus
HTC	HIV Testing and Counseling
HTS	HIV Testing Services
ICT	Information and Communication Technology
KASF	Kenya AIDS Strategic Framework
LTFu	Lost to Follow Up
NASCOP	National AIDS and STI Control Programme
OI	Opportunistic Infection
PITC	Provider Initiated Testing and Counseling
PLWHIV	Persons Living With HIV
PMTCT	Prevention of Mother to Child Transmission
POC	Point of Care
UNAIDS	Joint United Nations AIDS Programme
WHO	World Health Organization

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DEDICATION

I dedicate this work to my loving parents, my spouse and my son.

OPERATIONAL TERMS AND DEFINITIONS

The following operational terms will be used in the dissertation and are further described in the literature review:

Data Quality:	This refers to "fitness for use" of data to serve the needs of a given user pursuing specific goals
Accuracy:	This refers to closeness of agreement between a data value and the true value using a gold standard
Completeness:	This refers to presence of the necessary data elements
Electronic Medical Record:	This refers to a computerized health information system where healthcare providers record detailed encounter information such as patient demographics, encounter summaries, medical history, allergies, intolerances, and lab test histories
Patient Escort:	This refers to an opt-out model of engaging patients in chronic HIV care whereby HTS counsellors physically escort patients to the HIV clinic for same day registration following a positive HIV test
Enrolment to HIV care and treatment services:	This is defined as registration into chronic HIV care and treatment services with issuance of a standardised unique patient identifier number
Time to linkage to ART:	This is defined as the period from HIV diagnosis to ART initiation for patients who are eligible for ART
CD4 count	Defined as a laboratory indicator of immune function and a predictor of HIV progression
Baseline CD4 count	This is defined as a CD4 count taken three months prior and two weeks after ART start
Retention in ART	Defined as patients who were still active in HIV care at the time of the study
Attrition	Defined as patients who died or were lost to follow up from ART Programmes

WHO staging	Defined as a staging system based on the clinical manifestations of HIV infection from stage 1 to stage 4
"Test and treat" strategy	Refers to immediate initiation of antiretroviral therapy after a positive HIV diagnosis without considering the CD4 count

CHAPTER ONE

1.1 Background of the Study

It is estimated that 35 million people were living with HIV in the world at the end of 2013, out of which 24.7 million were in sub-Saharan Africa (UNAIDS, 2014b). Access to antiretroviral therapy (ART) has improved tremendously in lower-income countries over the past four years as a result of remarkable commitment by the international community, donor agencies and local governments resulting in an estimated 13 million people receiving ART globally at the end of 2013. However, the Joint United Nations Programme on HIV AIDS report (UNAIDS, 2014a) noted that substantial treatment coverage gaps continue to exist within and among regions; on the African continent, for example, treatment coverage in 2013 ranged from 41% in Eastern and Southern Africa to 19% in North Africa . In the same report, the UNAIDS describes an ambitious 90-90-90 treatment target to help end the AIDS epidemic by 2030: by 2020, 90% of all people living with HIV will know their HIV status; 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy; and 90% of all people receiving antiretroviral therapy will have viral suppression. Achievement of these targets by 2020 is expected to have profound health and economic benefits globally.

Furthermore, there is emerging evidence that investments in the health systems in totality in the context of chronic diseases could contribute to strengthening the capacity of health systems to deliver a comprehensive range of services in a sustainable way. Therefore, since effective chronic disease programs are highly dependent on well-functioning national health systems, chronic diseases should be a proof of concept for health-systems strengthening. However, in middle and low-income countries, most chronic diseases have been neglected in discussions around health systems strengthening despite the fact that these diseases will account for about 69% of all global deaths by 2030, with 80% of the deaths occurring in these countries (Samb et al., 2010). Additionally, efforts to scale up interventions for management of common chronic diseases in these countries such as HIV/AIDs often focus on the specific disease and its causes, which results in fragmented and unsustainable vertical programs.

In chronic HIV care, electronic medical records (EMR) have been shown to increase and or ensure availability of patient information; facilitate patient tracking to monitor treatment outcomes ensuring continuity of care; contribution to adherence to treatment guidelines; and have eased the burden of reporting with improved timeliness and accuracy of data. In most developing countries, treatment guidelines require that patients on ART visit healthcare facilities regularly for treatment monitoring. During each visit, substantial detailed clinical information is collected which accumulates to unmanageable levels over time. Consequently, critically important historical data are frequently unavailable to providers during the patient visit; and if available, are usually disorganized or incomplete (Were et al., 2010). While there is a growing interest in automating medical records in both developed and developing countries unfortunately, in some cases, the introduction of an EMR system seems overwhelming and almost impractical to many healthcare providers (WHO, 2006). This is partly due to such challenges as available technology; lack of technical expertise and computer skills of staff; lack of data processing facilities; costs associated with EMR implementation in a competitive funding environment; and resistance from healthcare providers together with their attitude towards EMR systems.

Kenya's response to the evolving HIV epidemic is largely influenced by strong commitment to availing quality data in a timely manner for effective evidence-informed decision making, as well as adherence to change in guidelines as new evidence on HIV management emerges. The National AIDS and STI Control Program (NASCOP) has identified and approved four EMR systems that are specifically designed to support chronic HIV care models in Kenya namely; IQCare, C-PAD, Open MRS and EDPMS. These systems are expected to address key functionalities such as basic demographic and clinical information; clinical decision support; order entry and prescribing; health information and reporting; data security and confidentiality; and exchange of electronic information (Ministry of Health Kenya, 2010). Additionally. Kenya, towards achievement of the ambitious 90-90-90 treatment targets and ensuring universal access to comprehensive HIV prevention, care and treatment services by 2020, developed the Kenya AIDS Strategic Framework 2014/15-2018/2019 (National Aids Control Council, Kenya, 2014). KASF defines the results to be achieved in the next five years and offers

broad strategic guidance to counties on the co-ordination and implementation of the HIV response.

1.2 Problem Statement

Uninterrupted access to lifelong treatment is critical to ending AIDS by 2030. Additionally, political will, system preparedness and timely adoption and implementation of global normative guidance are needed to achieve universal treatment coverage. Longitudinal follow-up of patients on ART to monitor adherence, treatment response and adverse effects is data intensive. As such, EMRs could be a valuable aid to health care providers working in HIV programs in resource-limited settings for clinic management and reporting (Forster et al., 2008). However, the success of EMR systems depends on the quality of the information available to health care professionals in making decisions about patient care (Hayrinen, Saranto, & Nykanen, 2006). Also, the secondary use of EMR data is a promising step towards decreasing research costs, increasing patient-centered research, and speeding the rate of new medical discoveries (Weiskopf & Weng, 2012).

While there is increased uptake of HIV testing services, gaps still exist in treatment coverage, with an estimated ART coverage of 51% for adults aged 15 and above in Kenya (Ministry of Health, Kenya, 2015). ART eligibility has evolved from a CD4 cut-off of 200 in 2003, 350 in 2010, 500 in 2013 to "Test and treat" in 2016 (WHO, 2016). The "Test and treat" guidelines ensure that all people diagnosed with HIV infection are linked to care immediately and commence ART regardless of clinical staging or CD4 cell count. These guideline changes were aligned to the global 90-90-90 treatment targets with emphasis on timely identification and linkage to ART of PLWHIV, and retention in care in order to achieve sustained viral suppression.

Kiambu County has a diverse population due to its proximity to the Kenyan capital, Nairobi, and is among the top 10 counties with the highest burden of HIV in Kenya with an estimated 46,000 PLWHIV by 2014 (National AIDS Control Council, 2014). Kiambu County Referral Hospital is one of the large facilities that serves a significant number of HIV-infected patients in the county. The hospital adopted IQCare (one of the approved EMR systems in Kenya) in the HIV clinic in 2012. IQCare was initially paper based whereby data officers transcribed medical information from paper

records made by clinicians during patient encounter into the EMR system. However, it has since transitioned to a paperless EMR system where clinicians enter real time data as they review patients. In addition to adopting the new CD4 guidelines on ART eligibility, Kiambu CRH also implemented a patient escort system. Patients who tested HIV positive would be physically escorted to the HIV clinic by the HIV Testing Services (HTS) counsellor for same day registration. This system was expected to proactively link patients to care and subsequently to ART in a timely manner. Successful linkage was confirmed by documenting the patient's unique identifier allocated to all patients upon registration in the EMR. Prior to adoption of the patient escort, clients testing HIV positive would be provided with basic HIV information and passively referred for enrolment in the HIV clinic; thus, it was upon the patient to initiate care.

First, this study evaluated the quality of data of the EMR system in the HIV clinic. Once the database was verified as complete and accurate to an acceptable level, it was then utilized for evaluation of the effects of CD4 count guideline change and patient escort on time to ART start and retention in ART in Kiambu CRH. The first step of the study was critical to ensure that the results of this study were reliable. The study findings can be utilized to expand EMR systems and ART coverage and retention in Kenya and other sub-Saharan Africa countries.

1.3 Purpose of the Study

The study aimed to first assess the data quality of electronic medical records against the physical records as the gold standard. The two aspects of data quality that were evaluated included completeness and accuracy. Secondly, using the validated EMR database, the study was to evaluate the effect of CD4 guideline change and patient escort on time to linkage to and retention in ART. The study findings would therefore help in making recommendations on EMR adoption and expansion, as well as accelerate adoption of new guidelines and patient escort for timely linkage to and retention in ART.

1.4 Research Objectives

1.4.1 Main Objective

First to assess completeness and accuracy of electronic medical records. Secondly, to utilize the verified EMR database to assess the effect of CD4 guideline change and

patient escort on time to linkage to and retention in ART in Kiambu County Referral Hospital.

1.4.2 Specific Objectives

I. To assess the completeness of electronic medical records against paper records as the gold standard
II. To assess the accuracy of electronic medical records against paper records as the gold standard
III. To evaluate the effect of CD4 guideline change on time to linkage to and retention in ART using the EMR database
IV. To evaluate the effect of patient escort on linkage to and retention in ART using the EMR database

1.5 Research questions

I. What is the proportion of complete fields for each electronic medical record compared to the paper record?
II. What is the proportion of fields entered correctly for each electronic record compared to the paper record?
III. What is the effect of CD4 guideline change on time to linkage to and retention in ART?
IV. What is the effect of patient escort on time to linkage to and retention in ART?

1.7 Scope of the Study

The study was conducted in Kiambu CRH HIV Clinic, in one of the top 10 counties with the highest burden of HIV in Kenya, Kiambu County. The hospital serves both rural and urban populations and as such the patient population was considered representative of the healthcare service delivery in Kenya. The study aimed to look at the data quality of the EMR database used for patient follow up in the hospital. This database was then utilized to assess the effect of adopting CD4 guideline changes and a patient escort system on time to linkage to and retention in ART.

1.6 Significance of the Study

Reliable data are vital for provision of quality care in long-term follow up of HIV-infected patients. This involves prompt initiation of ART, monitoring treatment response and side effects, and ultimately retention in ART for sustained viral suppression. This study aimed to provide insights first on the level of completeness and accuracy of electronic medical records against paper records as the gold standard in a chronic HIV care model in Kenya. Secondly, after testing data completeness and accuracy, the EMR database was utilized to assess the impact of CD4 guideline change and patient escort on time to linkage to and retention in ART. Linking patients who test HIV positive to ART in a timely manner is a fundamental HIV prevention strategy as ART has been shown to reduce the risk of HIV transmission (Cohen et al., 2011). This information will be used by healthcare managers and policy makers to improve data quality of electronic medical records planned audits. These data can in turn be reliably used for planning purposes and operational research. Additionally, the information will be applied to justify investments in scale up of functional linkage models such as patient escort systems to ensure timely linkage to ART as an HIV prevention strategy. Also, the findings will be used to shed light for further areas of study including impact of the "test and treat" strategy on HIV related morbidity and mortality.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This study was conducted to assess completeness and accuracy of electronic medical records and effect of CD4 guideline change and patient escort on time to linkage to and retention in ART in Kiambu CRH HIV Clinic. The following sub-sections focus on literature reviews on theories, concepts and models pertaining to EMRs and data quality, CD4 guideline change and patient escort systems and time to linkage to and retention in ART.

2.2 Definition of Electronic Medical Records

EMRs have been described as computerized health information systems where healthcare providers record detailed encounter information such as patient demographics, encounter summaries, medical history, allergies, intolerances, and lab test histories. Some of the EMRs may support order entry, results management and decision support, whereas others contain features such as appointment scheduling, billing, and report generation (Ludwick & Doucette, 2009).

The World Health Organization defines an ideal EMR as one that contains all personal health information of an individual patient from the patient's first admission or attendance at the hospital. The medical records should also be entered electronically by healthcare providers at the point of care over the patient's lifetime and that information should be readily available and accessed by all healthcare providers attending to the patient. Likewise, an EMR system should offer support in medical decision making, promote use of guidelines, increase coordination between different healthcare providers and improve the overall quality of care (WHO, 2007).

Hayrinen et al., (2006) described an EMR system as a repository of patient data in digital form, stored and exchanged securely, and accessible by multiple authorized users. It contains retrospective, concurrent, and prospective information and its primary purpose is to support continuing, efficient and quality integrated health care. EMR systems contain both unstructured free text and coded data. Most research has focused on structured data elements including codes, classifications and nomenclatures that are

easy to analyze. Patient summaries have also been identified as the most appropriate way to establish interoperability between different EMR systems.

2.3 Implementation of EMR Systems

Manya et al., (2012) demonstrated that with the improvement of Information and Communication Technology (ICT) infrastructure, deployment of countrywide web-based systems in Africa using a central server and "cloud" based infrastructure is possible. The Kenya DHIS is open source allowing for interoperability between different systems including facility based EMR systems such as IQCare that's currently in use in Kiambu County Referral Hospital.

Martin et al., (2010) sought to establish a sustainable way of successful implementation and scalability of EHRs in multiple sites in resource limited sources, at the same time addressing the human resource and cost constraints of such a venture. They determined that external support through a national technical expertise center supported by global developer and implementer groups can be effective and sustainable.

In their study (Millard, Bru, & Berger, 2012) demonstrated that clinical functionalities vary greatly among the EMR systems that were evaluated, and none of the systems yet meet the minimum requirements for effective implementation in a primary care resource-limited setting. These shortcomings of fully functional EMR systems indicate a need for a greater emphasis by global funding agencies to move beyond disease-specific EMR systems and develop a universal open-source health informatics platform. In the long run, a new Millennium Development Goal should include the creation of a universal open-source health informatics platform that will allow the collection, management and delivery of clinical and population data that will guide decision processes at the local, regional and global levels. Until this goal is achieved, care will continue to consume unnecessary resources because of fragmentation, medical errors and poor data utilization.

Six dimensions of evaluating the success of an information system have been described by DeLone and McLean. These dimensions include information quality, system quality, information use, user satisfaction, individual impact and organizational impact (Hayrinen et al., 2006). System quality refers to the technical level, information quality to the semantic level and service quality to the service provided to the customer.

Information use, user satisfaction, individual impact and organizational impact refer to the effectiveness level. Information quality measures both the output and input of the information system and contains such attributes as completeness, accuracy, legibility, reliability and format. This study focused on evaluation of EMR information quality as part of the continuum for assessing successful implementation of an EMR system.

2.4 Definition and Assessment of EMR Data Quality

Data quality has been defined as "fitness for use" of data to serve the needs of a given user pursuing specific goals. In other literature, data quality assessment has been defined as a process of identifying errors, inconsistencies and other data anomalies and conducting activities aimed at improving the quality of data and eliminating the identified errors (Government of Kenya, 2014). Several studies have described different dimensions of data quality. Figure 2.2 below shows a universal two-layer data quality standard which outlines five dimensions of data quality namely availability, usability, reliability, relevance and presentation quality(Cai & Zhu, 2015). The data quality standard is composed of five dimensions namely availability, usability, reliability, relevance, and presentation quality. The first four quality dimensions are regarded as crucial, inherent features of data quality, and the final dimension involves additional properties that improve customer satisfaction. Availability is defined as the degree of convenience for users to obtain data and related information and contains three elements including accessibility, authorization, and timeliness. Usability refers to whether the data are useful and meet users' needs, including data definition/documentation, reliability, and metadata. Reliability refers to whether the data can be trusted and consists of accuracy, consistency, completeness, adequacy, and auditability elements. Relevance is used to describe the degree of correlation between data content and users' expectations or demands, with adaptability as its quality element. Presentation quality refers to a valid description method for the data, which allows users to fully understand the data. Its dimensions are readability and structure.

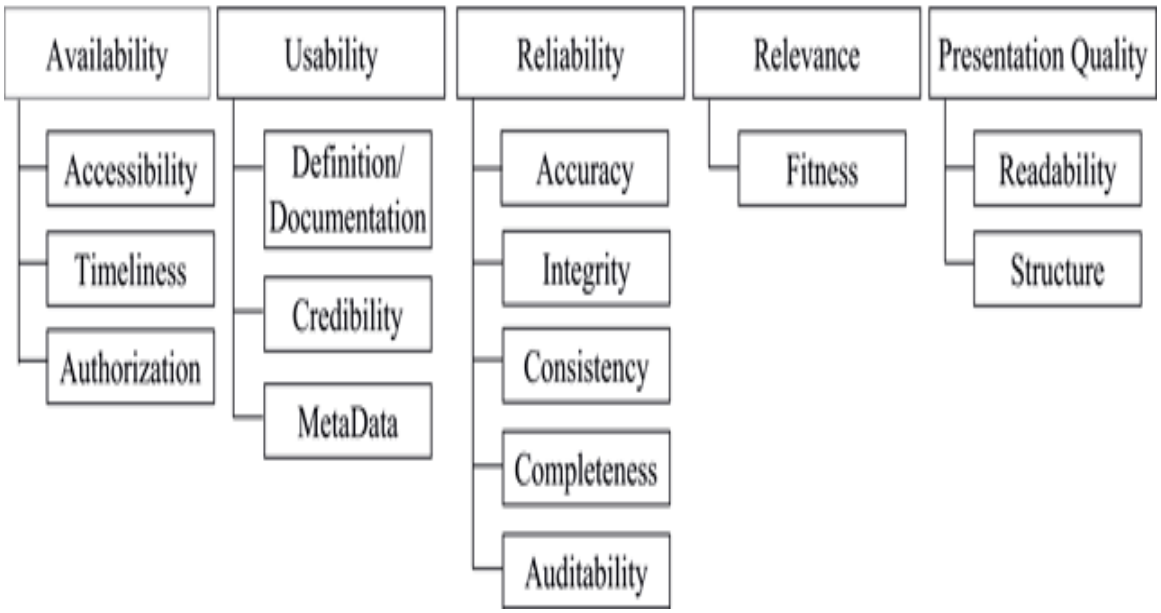

Figure 2. 1 A universal, two-layer data quality standard for assessment (Cai & Zhu, 2015)

In this study, (Hayrinen et al., 2006) it was found that the success of EMR systems depends on the quality of the information available to health care professionals in making decisions about patient care and in the communication between health care professionals during patient care. Good documentation has also been shown to improve the quality of patient care. It is therefore important to assess the quality of information entered in electronic systems by different health care professionals. Furthermore, decision-making tools can be integrated in EMR systems if the record is structured and clearly defined terminologies are used. However, if the data are inaccurate or incomplete, they will not be useful for decision-making, research, statistical or health policy purposes.

With the increased adoption of EMRs, several studies have looked at ways in which these aggregate databases can be reused for clinical research. EMRs contain massive volumes of data compared to many existing registries and data repositories and the reuse of these data may reduce the costs and inefficiencies associated with clinical research. Like other forms of retrospective research, studies that make use of EMR data do not require patient recruitment or data collection, both of which are expensive and time-consuming processes. Additionally, these EMR data provide medical information

of a diverse population that is representative of actual patients. As a result, the secondary use of EMR data is a promising step towards decreasing research costs, increasing patient-centered research, and speeding the rate of new medical discoveries (Weiskopf & Weng, 2012). However, the study also notes that reuse of EMR data has been limited by such factors as concerns about the quality of the data and their suitability for research. The study concluded that there was little consistency or potential generalizability in the methods used to assess EMR data quality. As such, for reuse of EMR data for clinical research to become accepted, researchers should adopt validated, systematic methods of EMR data quality assessment.

Introduction of provider-based EMR had a favorable impact on the quality of data collected with a significant reduction in missing and incorrect information in key variables namely opportunistic infections, reason for ART regimen discontinuation, reason for ART change (e.g. one or more drugs are substituted on that visit without ART interruption), and ART toxicities. The improvement of quality of the routinely collected data has the potential to impact care and lead to more accurate data for research purposes (Castelnuovo et al., 2012)

The study (Kiragga, Castelnuovo, Schaefer, Muwonge, & Easterbrook, 2011)found an overall high level of underreporting for all OIs combined (45.1 and 56.8%), based on a comparison with a nested research cohort that had more intensive and standardized data collection procedures. The underreporting was not explained neither by advanced HIV disease since the patients in both groups had a similar CD4 count of 95 cells/mm^3 at ART initiation nor by temporal differences in OI rates as patients in the research cohort database had started ART over the same time period as the patients in the routine clinic. These findings have important implications for the use and interpretation of data derived from routine HIV observational databases for research and audit, and they highlight the need for ongoing regular validation of key data items in these databases.

2.5 Impact of EMR Systems on Patient Care

Quality healthcare, particularly for chronic conditions, requires medical records that are continuous, comprehensive, captured over multiple patient encounters to multiple settings, describing both concurrent and previous medical conditions. The study

(Braitstein, Einterz, Sidle, Kimaiyo, & Tierney, 2009) described how an EMR system can be used to provide high quality care in management of chronic conditions such as HIV in a large patient population. The AMPATH Medical Record System (AMRS) has a universal identity number for each patient registered in the system. This has enabled follow up of large volumes of patients enrolled in the HIV care program over long periods of time which is critical for adherence to treatment and clinic appointments. This patient information can also be linked to other care sites as well as the national data repository for planning purposes. The system is also designed to serve the information needs of the clinicians through reminders and other types of decision support which facilitate adherence to treatment and testing guidelines and hence increase the quality of care delivered to patients. The AMRS has also strengthened AMPATH's data-focused approach to care, allowing expansion beyond HIV/AIDS. Likewise, the AMRS has allowed AMPATH to provide evidence-based practice grounded in relevant and reliable clinical data.

The study by (Forster et al., 2008) described the electronic medical databases used in antiretroviral therapy (ART) programs in lower-income countries and assessed the measures such programs employ to maintain and improve data quality and reduce the loss of patients to follow up. They found out that EMR systems could play an important role in the scale-up of ART in lower-income countries by providing the necessary data elements for the longitudinal follow up of patients and to ensure that patients are retained in treatment programmes.

Were et al., (2010) demonstrated that even in settings where paperless EMR systems have not been realized, it is possible to provide well-organized, relevant, and up-to-date EMR-based clinical information to assist in patient care. In a resource-poor setting in Uganda, an EMR generating clinical summaries improved the efficiency of care for healthcare providers, allowing them to spend more time directly interacting with and examining the patient. Availability of clinical summaries for providers was also associated with shorter clinic visits for patients. Providers also strongly expressed an association of clinical summaries with improved quality of care and reduction in mistakes while providing healthcare to patients.

Oluoch et al., (2014) found that EMRs can improve quality of HIV care through appropriate placement of ART-eligible patients on treatment in resource-limited settings and not necessarily timely initiation of ART. Other non-EMR factors such as clinician behavior, patient preparation time ART initiation, and patient's readiness to start ART, could have contributed to the relatively unchanged time to treatment initiation and as such need further evaluation. The study noted that rigorous evaluation studies are needed to demonstrate associations between decision support systems implemented in EMRs and important quality of HIV care indicators such as retention on treatment.

Joaquin, Hamish, & Brian, (2010) acknowledge that while it is essential to evaluate the impact of EMRs in resource constrained countries in terms of safety, benefits and cost effectiveness, there is still a huge gap in this process with limited evidence on the actual impact of EMR systems on patient care. Most studies have been small and tend to focus on process indicators rather than patient outcomes; attitudes of users and patients; and are mostly performed by academic groups. Therefore, more rigorous evaluations that include long-term follow-up probably by independent evaluators are needed to accurately document the actual benefits and in turn justify allocation of limited resources for implementation of EMR systems.

2.6 Impact of CD4 count guideline change on time to linkage to and retention in ART

In the study (Siedner et al., 2015), it was found that despite progress in making ART available to millions of HIV-infected persons in sub-Saharan Africa, CD4 counts at presentation to care and at ART initiation had not substantially changed between 2002 and 2013; and that even the most well-designed and well-supported ART programs will have limited capacity to maximize the health benefits of ART and prevent new infections if people continue to present to care during late stages of disease. As such, there is need to identify and link to treatment the remaining 40% of HIV-infected persons who are eligible for but are not receiving ART in order to reduce HIV incidence in sub-Saharan Africa from nearly 1 000 000 new infections annually to zero.

In the study (Cohen et al., 2011) involving 1763 sero-discordant couples in which HIV-1–infected participants had a CD4 count of 350 to 550 cells per cubic millimeter, there was a relative reduction of 96% in the number of linked HIV-1

transmissions resulting from the early initiation of antiretroviral therapy, as compared with delayed therapy. There was a relative reduction of 89% in the total number of HIV-1 transmissions resulting from the early initiation of antiretroviral therapy, regardless of viral linkage with the infected partner.

A mathematical model on universal voluntary HIV testing with immediate antiretroviral therapy as a strategy for elimination of HIV transmission demonstrated that it could reduce HIV incidence and mortality to less than one case per 1000 people per year by 2016, or within 10 years of full implementation of the strategy, and reduce the prevalence of HIV to less than 1% within 50 years (Granich, Gilks, Dye, De Cock, & Williams, 2009).

Delayed linkage to HIV care was associated with older age and African American race. Attending all clinic visits and lower initial CD4 counts led to earlier antiretroviral initiation. Worse retention in the first 2 years was associated with younger age, higher baseline CD4 count, and substance abuse. Therefore, interventions to improve timely HIV diagnosis and linkage to care should focus on older patients and African Americans while efforts to improve retention should address younger patients, those with higher baseline CD4 counts, and substance abuse. Missed clinic visits represent an important obstacle to the timely initiation of antiretroviral therapy (Ulett et al., 2008) .

A study in southwestern Uganda found that individuals starting ARVs at a CD4 cell count ≥250 cells/μL were more likely to experience treatment interruptions in the first three months of therapy and were more likely to have persistent viremia at three months, compared with those starting with a CD4 cell count <250 cells/μL (ADAKUN et al., 2013). Thus, there is need for active and continuous patient education as well as proactive monitoring of adherence for patients who start ART at higher CD4s to minimize treatment interruptions and losses to follow up.

Programmes initiating patients at lower CD4 counts were found to have higher rates of attrition than those initiating patients with higher CD4 counts. This observed attrition could have been due to mortality associated with lower CD4 counts (Fox & Rosen, 2010).

2.7 Impact of patient escort linkage model on time to linkage to and retention in ART

In the study (Craw et al., 2008), it was demonstrated that a brief intervention by a case manager was associated with a significantly higher rate of successful linkage to HIV care when offered to HIV-infected clients soon after their HIV diagnosis. Accessibility of medical services during initial case management or referral activities was found to be an important structural factor that promoted entry into care. Further, accompanying clients to their first HIV medical care encounter might be an effective technique to help clients learn how to navigate the health care system. It was also found to be an affordable and effective strategy to ensure timely linkage to HIV care.

Some of the interventions aimed at increasing patient convenience and accessibility such as point of care (POC) CD4 count testing, inpatient testing, home visits and possibly home-based ART initiation have been found to be effective in increasing ART eligibility screening and initiation rates. Likewise, health system interventions including integration of ART and ANC care appear to increase HIV care and ART enrolment. Additionally, behavioural interventions and peer support such as intensified post-test counselling and peer support have also been found to increase linkage to care. However, most of these interventions have been studied in isolation and more research need to be done to assess their impact on linkage and retention in pre and post ART (Darshini et al., 2014).

2.8 Conceptual Framework

Figure 2.2 below represents the conceptual framework that was utilized for this study. The first step was to assess the data quality of the EMR database, to ensure that the database was reliable for use in the second part of the study. After validation of the electronic medical records, the study then utilized the database to assess for the effect of CD4 guideline change and patient escort on time to linkage to and retention in ART.

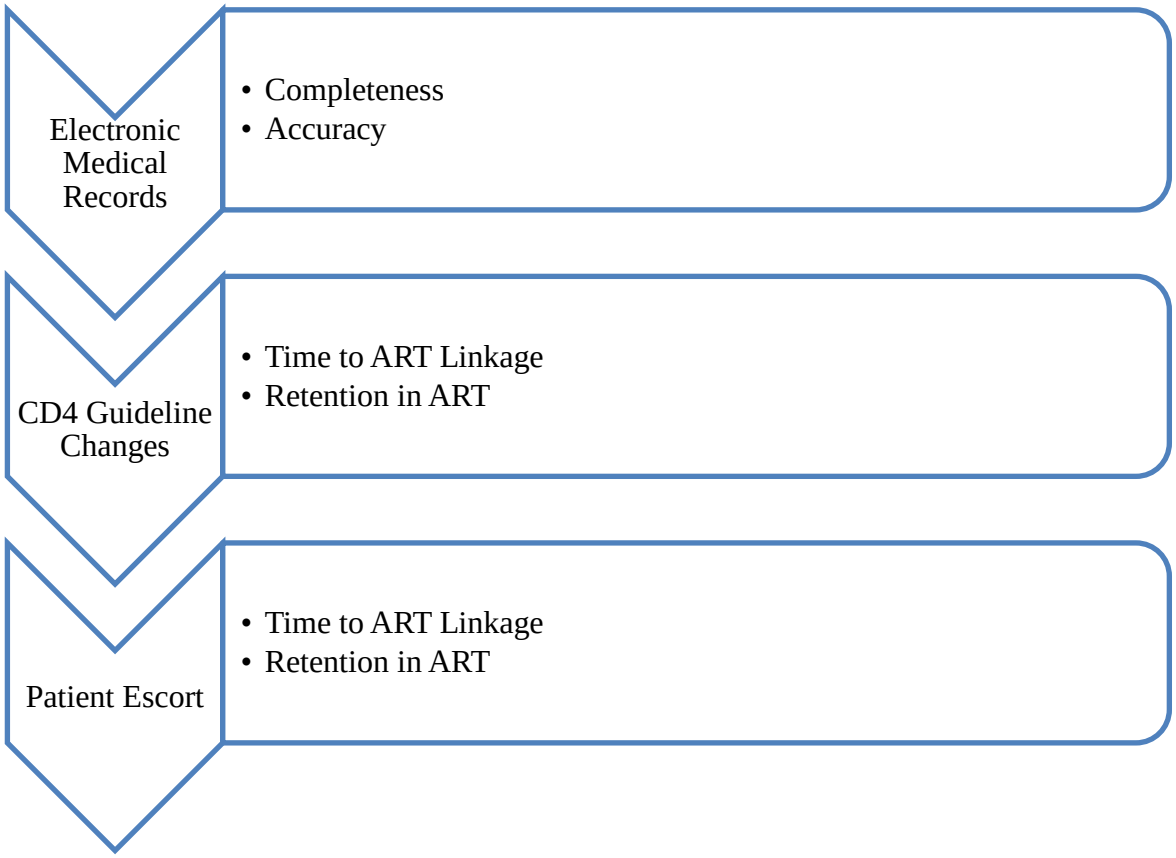

Figure 2. 2 Conceptual Framework

2.9 Conclusion

The literature review points out that management of chronic diseases such as HIV is data-intensive and that EMR systems are essential in collection, storage, analysis and dissemination of this data for evidence-based decision making. Information quality has been described as one of the dimensions of measuring the success of an EMR system. Likewise, data quality assessment is an important component of ensuring provision of high quality healthcare and continuous quality improvement in healthcare. Several dimensions of data quality have been defined including data accuracy and completeness which are the most assessed dimensions of quality and that they been shown to improve with structured electronic data entry. Decision-making tools can be

integrated in EMRs if the record is structured and defined terminologies are used. However, if the data are inaccurate or incomplete, they will not be useful for decision-making, research, statistical or health policy purposes. Initiating patients on ART at higher CD4s has been shown to reduce HIV-related morbidity and mortality, as well as reduction of HIV transmission. Studies on retention rates at higher CD4s had mixed results. The studies on impact of linkage models were few and there was no previous research on patient escort. There is therefore, need for more studies to demonstrate whether higher CD4s at ART initiation as well as facilitated linkage to ART have impact on time to linkage to and retention in ART.

Chapter Three gives the methodology for this project, describing the study design, sample size, population, and research and data management procedures.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Introduction

The purpose of this study was first to assess the completeness and accuracy of electronic medical records. The verified database was then used for assessing the effect of CD4 guideline change and patient escort on time to linkage to and retention in ART in Kiambu CRH HIV Clinic. This chapter will describe the study design, population, sample size, sampling technique and study procedures. The study instrument, data collection method, ethical considerations, quality assurance procedures, data analysis and study limitations will also be described.

3.2 Study Design

A cross-sectional study design was used to describe completeness and accuracy of electronic medical records against paper records as the gold standard; and to establish associations between CD4 guideline change and patient escort and time to linkage to and retention in ART in Kiambu CRH HIV clinic using the EMR database.

3.3 Study Population

The population for this study included medical records of patients enrolled in care between January 2013 and March 2017 within Kiambu CRH HIV clinic. To assess completeness and accuracy of electronic medical records against physical records, the study evaluated medical records of patients enrolled in care between January 2013 and December 2014. Second, the verified EMR database was then used to assess the impact of CD4 guideline change and patient escort on time to linkage to and retention in ART. The study population was categorized into two groups; medical records of patients enrolled in HIV care between January 2013 and December 2014 and those enrolled between January 2015 and March 2017. These categories represented the periods prior to and after adoption of patient escort respectively. These two groups were further disaggregated into four groups namely January 2013 to July 2014; August 2014 to December 2014; January 2015 to July 2016; and August 2016 to March 2017 based on CD4 guideline change and whether patient escort was in place or not.

3.3.1 Inclusion criteria

For assessment of EMR data quality, medical records of all active patients enrolled in care between January 2013 and December 2014 were included in the study. For assessment of effect of CD4 guideline change and patient escort on time to linkage to and retention in ART, all patients enrolled into care and had initiated ART between January 2013 and March 2017 were included in the study.

3.3.2 Exclusion criteria

Medical records of patients who were lost to follow up defined as having no clinical encounter within the last 3 months of the study period, and those who had died or transferred out of the facility between January 2013 and December 2014 were excluded from the EMR data quality assessment study. The exclusion criteria for effect of CD4 guideline change and patient escort on time to linkage to and retention in ART involved patients with missing or wrong date of HIV diagnosis; and those who had not started ART in the two review periods between January 2013 to December 2014 and January 2015 to March 2017 respectively.

3.4 Sample size and Sampling Procedure

Sampling refers to the process of selecting individuals from a given population such that the group selected is representative. The sample size for assessment of EMR data quality was based on random sampling on Microsoft Excel. A line list of the eligible patient records was extracted from IQCare and exported to Microsoft Excel. A column of random numbering was run on excel using the Unique Patient Identifier. This was then ordered by size to give a random sample based on 10% of the patient records (Naing, Winn, & Rusli, 2006). The final sample size was 336 medical records. This sample of electronic records was then compared against a similar sample of the physical records. For the assessment of effect of CD4 guideline change and patient escort on time to linkage to and retention in ART, a complete census of the eligible population was done using the EMR database.

Table 3. 1 Sample Size Selection by CD4 Cut-off and Patient Escort

Category			Sample size (n)
Period	**CD4 Cut-off**	**Patient Escort**	
Jan 2013 to Jul 2014	< 350	No	491
Aug 2014 to Dec 2014	<500	No	65
Jan 2015 to Jul 2016	<500	Yes	297
Aug 2016 to Mar 2017	Test and treat	Yes	65

3.5 Study Instrument

Medical records of patients enrolled in Kiambu CRH HIV Clinic were utilized for the study. A line list of eligible patient records was extracted from EMR database using the Unique Patient Identifier and exported to Microsoft Excel for sampling and assessment of completeness and accuracy against a corresponding set of physical records. The study also utilized a complete census of the EMR database using the registration date for evaluation of the effect of CD4 guideline change and patient escort on time to linkage to and retention in ART.

3.6 Study Procedures

Electronic medical records of eligible patients in the study period were assessed for completeness and accuracy based on predefined clinical indicators against the corresponding physical records using Microsoft Excel. The indicators that were evaluated included date of birth, baseline CD4 count, WHO staging at enrolment, date started ART and ART start regimen. Each matching electronic and physical record was first evaluated for completeness of each of the clinical indicators using a “Yes”, “No” or “N/A” response; following which the electronic record was further evaluated for

mismatch against the paper records as the gold standard to determine the accuracy of the electronic medical records.

After confirming the level of completeness and accuracy of the EMR database, two separate line lists of medical records of patients enrolled in care between January 2013 and December 2014; and January 2015 and March 2017 were extracted from the EMR database using the date of registration. These time periods were based on whether patient escort had been adopted or not. The two groups were further disaggregated into four groups based on changes in CD4 guidelines and patient escort. Key indicators for evaluation included socio-demographic characteristics, date of HIV diagnosis, care entry point, baseline CD4 cell count, WHO staging at enrolment, any opportunistic infection at enrolment, ART start date, time to ART in days, and the last status of the patient defined as active in ART, lost to follow up, or died. The groups were thus evaluated for significant differences in time to linkage to and retention in ART.

3.7 Quality Assurance Procedures

Reliability refers to the degree of consistency and accuracy with which an instrument measures a variable whereas validity refers to the extent to which an instrument measures what its designed to measure. For this study, inbuilt algorithms in IQCare for data validation were utilized to verify that data elements were entered in a valid format and value; historical comparison for the same data element was done so that an alert was prompted if an indicator increased or decreased abruptly; and assessment of data elements for consistency within a specific form or set of indicators. This was done in line with the data validation levels as outlined in the Kenya standards and guidelines for EMR systems (Ministry of Health Kenya, 2010).

3.8 Data Analysis

Data analysis can be defined as the process of evaluating raw data using scientific methods to determine patterns that exist within the data elements. Descriptive statistics and confidence intervals were used to assess the level of completeness and accuracy of electronic records against paper records of the sample population and whether there were significant differences in the findings. Similarly, data from

assessment of the effect of CD4 guideline change and patient escort on time to linkage to and retention in ART were analysed using descriptive statistics. SAS was used to analyse the data.

3.9 Ethical Considerations

Formal approval to conduct the study was sought from Strathmore Business School and Kiambu County Hospital management. The EMR database was de-identified through use of Unique Patient Identifiers instead of actual patient names to maintain patient confidentiality. The data was also accessible only to the authorized research and data personnel.

CHAPTER FOUR: RESULTS AND FINDINGS

4.1 Introduction

This chapter presents the summary of findings, analysis and interpretation of results from the study. The data are presented in tables and graphs with more detailed description of the findings.

4.2 EMR Data Completeness and Accuracy

The first objective of this study was to assess the data quality of electronic medical records against the physical records as the gold standard. The two aspects of data quality that were evaluated included completeness and accuracy.

4.2.1 Data Completeness

Results of the data completeness study, as shown in figure 4.1 below, indicated that both electronic and physical records had over 70% completion rate for most evaluated clinical indicators with over 90% completion in date of birth and ARV start regimen for both physical and electronic records. Date started ART baseline CD4 were significantly more complete in the physical records than the electronic records, whereas WHO staging was significantly more complete in the electronic records (90%) than in the physical records (63%). Baseline CD4 was the least complete in the electronic records (56%) when compared to the physical records (73%).

4.2.2 Data Accuracy (Mismatch)

Data accuracy was evaluated as proportion of mismatch between the electronic and physical records for all records. All indicators had a mismatch rate of less than 10% except for date started ART that had the highest mismatch rate of 20%.

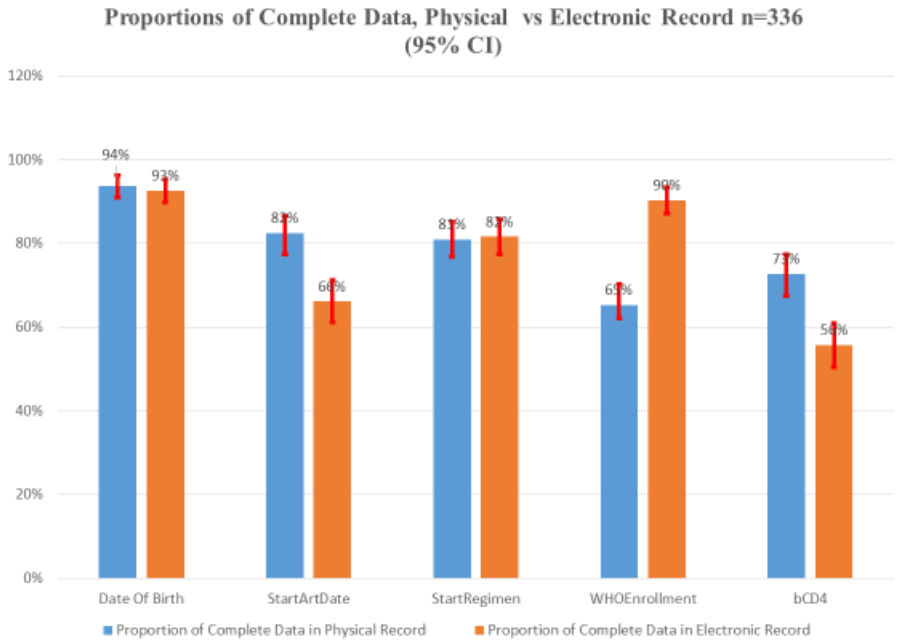

Figure 4. 1 Data Completeness by Source

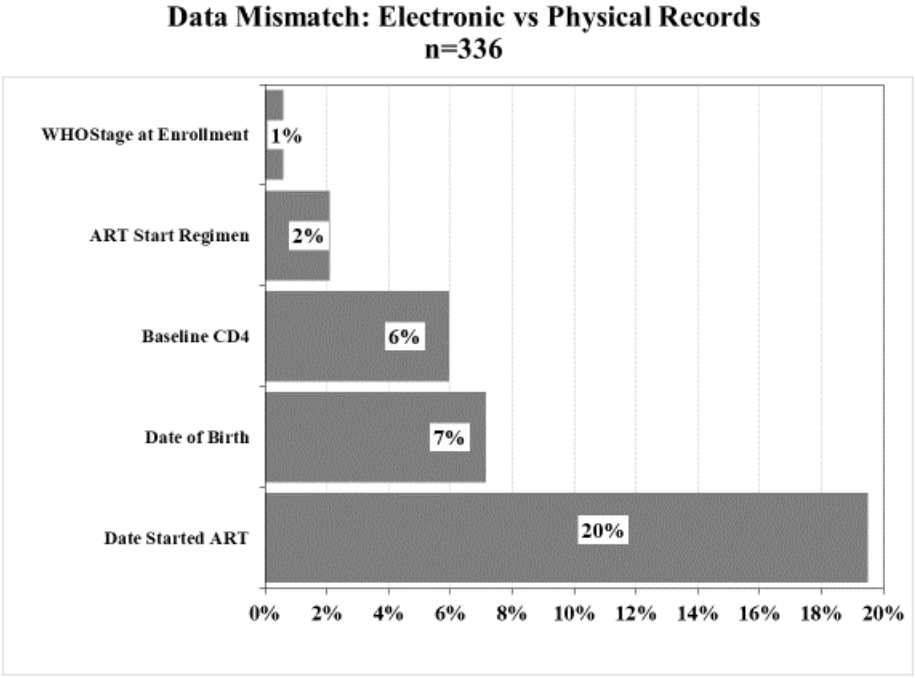

Figure 4. 2 Data Mismatch: Electronic vs Physical Records

4.3 Effect of CD4 Guideline Change and Patient Escort on Time to Linkage to and Retention in ART

The second objective of the study was to establish the effect of CD4 guideline change and patient escort on time to linkage to and retention in ART using the validated EMR database. The first part of this section will give a brief description of the selection criteria of study participants, the socio-demographic and baseline characteristics of the study groups.

4.3.1 Flow Chart of Study Groups

Figure 4.3 below represents the selection criteria that was used to arrive at the two groups under study for the effect of guideline change and patient escort on linkage to and retention in ART. There were 983 patients enrolled into care between January 2013 and December 2014, out of which 10 had a wrong HIV diagnosis date and 253 had a missing HIV diagnosis date and were thus excluded from the study. Another 164 patients had not started ART treatment during the study period and were also excluded from the study leaving 556 patient records for analysis for this group. All the 542 patients enrolled into care between January 2015 and March 2017 had an accurate HIV diagnosis date. However, 180 patients in this group had not started ART at the time of the study and were also excluded from the study leaving 362 patient records for analysis.

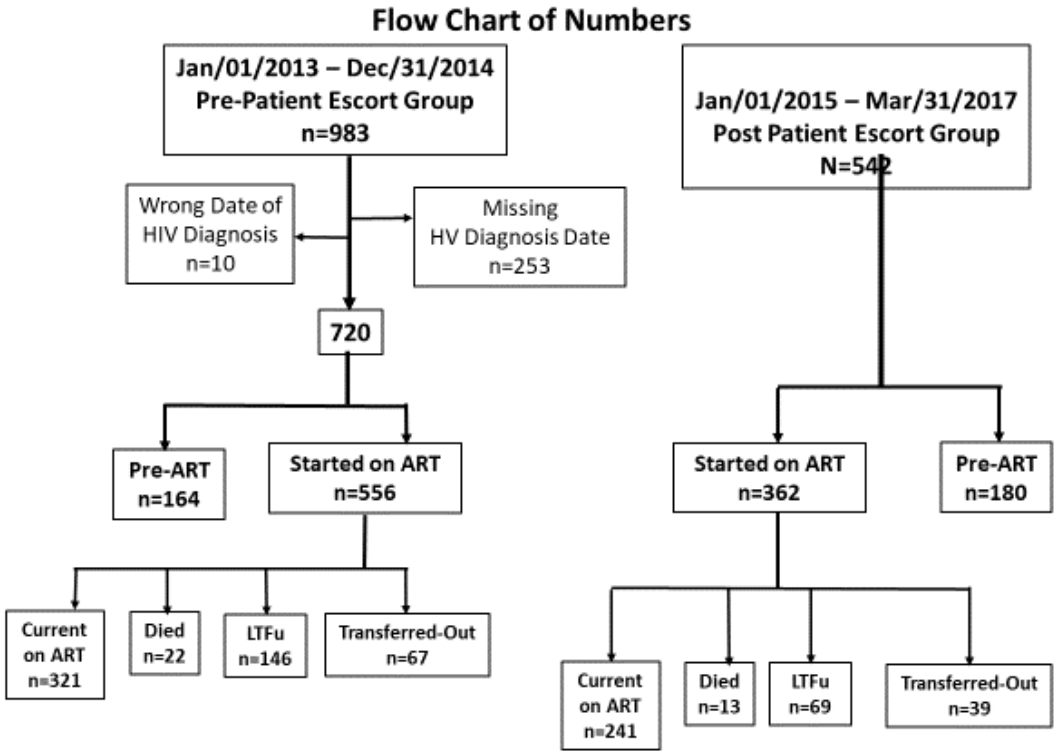

Figure 4. 3 Flow Chart of the Study Groups

4.3.2 Baseline Socio-Demographic Characteristics

The socio-demographic characteristics for the study were based on gender, age and marital status. Most participants were female in both the pre-patient escort group (67.5%) and the post-patient escort group (61.6%). The mean age was 34.3(sd 11.7) for pre-patient escort group and 35.1(sd 10.6) for post-patient escort group with majority of the participants (65.3%) aged between 30-54 years overall. On marital status, 47.5 % of all participants were married and 24.5 % were single.

Table 4. 1 Baseline Socio-Demographic Characteristics

Baseline Socio-Demographic Characteristics by Period of Care Entry			
Baseline Socio-Demographic Characteristic	**Pre-patient escort group**	**Post patient escort group**	**Overall**
	Jan/1/13-Dec/31/14	**Jan/1/15-Mar/31/17**	**Jan/1/13-Mar/31/17**
N	**556**	**362**	**918**
Gender			
%Female	375 (67.5)	223 (61.6)	598 (65.1)
Age *(years)*			
Mean (sd)	34.3 (11.7)	35.1 (10.6)	34.6 (11.3)
Median (IQR)	34.5 (28-42)	35 (29-42)	35 (28-42)
Min-Max	0-80	2-69	0-80
Age Group *n (%)*			
0-14	29 (5.2)	11 (3.0)	40 (4.4)
15-24	56 (10.1)	27 (7.5)	83 (9.0)
25-29	90 (16.2)	67 (18.5)	157 (17.1)
30-54	358 (64.4)	241 (66.6)	599 (65.3)
≥55	23 (4.1)	16 (4.4)	39 (4.2)
Marital Status *n (%)*			
Child	32 (5.8)	12 (3.3)	44 (4.8)
Single	132 (23.7)	93 (25.7)	225 (24.5)
Married	262 (47.1)	170 (47.0)	432 (47.1)
Divorced	77 (13.9)	52 (14.4)	129 (14.1)
Widowed	39 (7.0)	21 (5.8)	60 (6.5)
Not Documented	14 (2.5)	14 (3.9)	28 (3.1)

4.3.3 Baseline Patient Characteristics

The baseline patient characteristics included point of care entry, CD4 cell count, CD4 category, disease stage and whether there was any opportunistic infection at enrolment. Most patients in pre-patient escort group accessed HIV testing services (HTS) voluntarily through HTC (45.7%), whereas those in post patient escort group accessed HTS through Provider Initiated Testing and Counseling (PITC) in the outpatient department (57.5%). The median CD4 cell count for pre-patient escort group was 219 (IQR 103-328) and that of post patient escort group was 245 (IQR 148-419). Overall, most patients with a documented baseline CD4 fell in the 101-250 CD4 category (22.1%). 32.7% and 38.1 % of participants in pre-patient escort and post patient escort groups respectively did not have a documented baseline CD4. In terms of disease stage, while most participants were in WHO stage 1 and 2 overall (68.8%), participants in pre-patient escort group were more likely to have a WHO stage 3 and 4 condition (29.5%) compared to those in post patient escort group (26.5%).

Table 4. 2 Baseline Patient Characteristics

Baseline Patient Characteristic	Pre-patient escort group Jan/1/13-Dec/31/14	Post patient escort group Jan/1/15-Mar/31/17	Overall Jan/1/13-Mar/31/17
N	**556**	**362**	**918**
Care Entry Point *n (%)*			
HTC	254 (45.7)	84 (23.2)	338 (36.8)
PMTCT	82 (14.6)	23 (6.4)	105 (11.4)
In Patient	23 (4.5)	19 (5.3)	42 (4.8)
Out Patient	112 (20.1)	208 (57.5)	320 (34.9)
Other Facility (Transfer-in)	42 (7.6)	19 (5.3)	61 (6.6)
Other source	4 (0.7)	3 (0.8)	7 (0.8)
Not Documented	39 (7.0)	6 (1.7)	45 (4.9)
CD4 Cell Count *(cells/µL)*			
Median (IQR)	219 (103-328)	245 (148-419)	230 (116-355)
Min-Max	1-1761	0-1943	0-1943
CD4 Category *n (%)*			
0-50	55 (9.9)	18 (5.0)	73 (8.0)
51-100	36 (6.5)	19 (5.3)	55 (6.0)
101-250	125 (22.5)	78 (21.6)	203 (22.1)
251-350	78 (14.0)	32 (8.8)	110 (12.0)
351-500	48 (8.6)	46 (12.7)	94 (10.2)
>500	32 (5.8)	31 (8.6)	63 (6.9)
Not Documented	182 (32.7)	138 (38.1)	320 (34.9)
Disease Stage *n (%)*			
WHO Stage 1&2	380 (68.3)	252 (69.6)	632 (68.8)
WHO Stage 3&4	164 (29.5)	96 (26.5)	260 (28.3)
Not Documented	12 (2.2)	14 (3.9)	26 (2.8)
Opportunistic Infection (O)I *n (%)*			
Any OI	144 (25.9)	94 (26.0)	238 (25.9)

4.4 Effect of CD4 Guideline Change and Patient Escort on Time to Linkage to and Retention in ART

To establish the effect of CD4 guideline change and patient escort on time to linkage to and retention in ART.

4.4.1 Effect of CD4 Guideline Change and Patient Escort on Time to Linkage to ART

For evaluation of significant differences in time to linkage to and retention in ART, CD4 guideline change periods were categorized into four groups based on the baseline CD4 cut-off for ART initiation and whether patient escort was in place. Thus, the guideline periods were aligned to the patient escort system as follows: January 2013 to July 2014 at 350 CD4 cut-off pre-patient escort, August 2014 to December 2014 at 500 CD4 cut-off pre-patient escort, January 2015 to July 2016 at 500 CD4 cut-off post patient escort and August 2016 to March 2017 "test and treat" post patient escort.

Table 4.3 and figure 4.4 below show a significant decline in median time to linkage to ART from 51 days for the 350 CD4 cut-off group to16 days for the "test and treat" group when CD4 guideline changes were combined with patient escort. However, there is a notable increase in the median time to linkage between August and December 2014 when the cut-off CD4 was increased to 500 cells with pre-patient escort.

4.4.2 Effect of CD4 Guideline Change and Patient Escort on ART Outcomes

To assess the effect of CD4 guideline change and patient escort on ART outcomes, confidence intervals were utilized to determine statistical significance. From the study results, there was a significantly higher retention in ART, and lower overall attrition and lost to follow up between the "test and treat" group and the CD4 cut-off groups (Table 4.4, Figure 4.5, Figure 4.6 and Figure 4.7). However, there was no significant difference in mortality across the different guideline groups (Figure 4.8).

Table 4. 3 Median Time to Linkage to ART by CD4 guidelines and patient escort

Median (IQR) Time to Linkage to ART

Guidelines			Time to ART (days)	
Period	**CD4 Cutoff**	**Patient Escort**	**n**	**Median (IQR)**
Jan/01/2013 To Jul/31/2014	<350	Pre-patient escort	491	51 (27-224)
Aug/01/2014 To Dec/31/2014	<500	Pre-patient escort	65	63 (43-155)
Jan/01/2015 To Jul/31/2016	<500	Post patient escort	297	44 (24-104)
Aug/01/2016 To Mar/31/2017	Test & Treat	Post patient escort	65	16 (14-22)

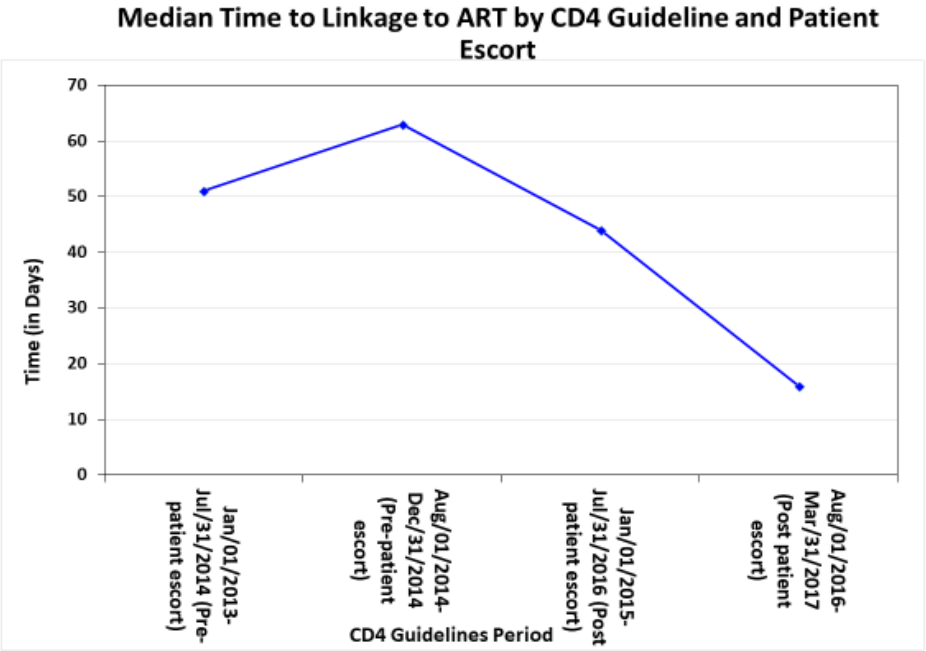

Figure 4. 4 Median Time to Linkage to ART by CD4 guidelines and Patient Escort

Table 4. 4 ART Outcomes by Guidelines Period

ART Outcomes by CD4 Guidelines and Patient Escort				
Period	Jan/01/13-Jul/31/14	Aug/01/14-Dec/31/14	Jan/01/15-Jul/31/16	Aug/01/16-Mar/31/17
CD4 Cut Off	<350	<500	<500	Test & Start
Patient escort	Pre-patient escort	Pre-patient escort	Post patient escort	Post patient escort
N	491	65	297	65
ART Outcome	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
Retention	56.4% (52.0-60.8%)	67.7% (56.3-79.1%)	62.0% (56.4-67.5%)	87.7% (79.7-95.7%)
Mortality	4.1% (2.3-5.8%)	3.1% (0.0-7.3%)	4.0% (1.8-6.3%)	1.5% (0.0-4.5%)
LTFu	27.3% (23.4-31.2%)	18.5% (9.0-27.9%)	22.6% (17.8-27.3%)	3.1% (0.0-7.3%)
Attrition	31.4% (27.3-35.5%)	21.5% (11.5-31.5%)	26.6% (21.6-31.6%)	4.6% (0.0-9.7%)

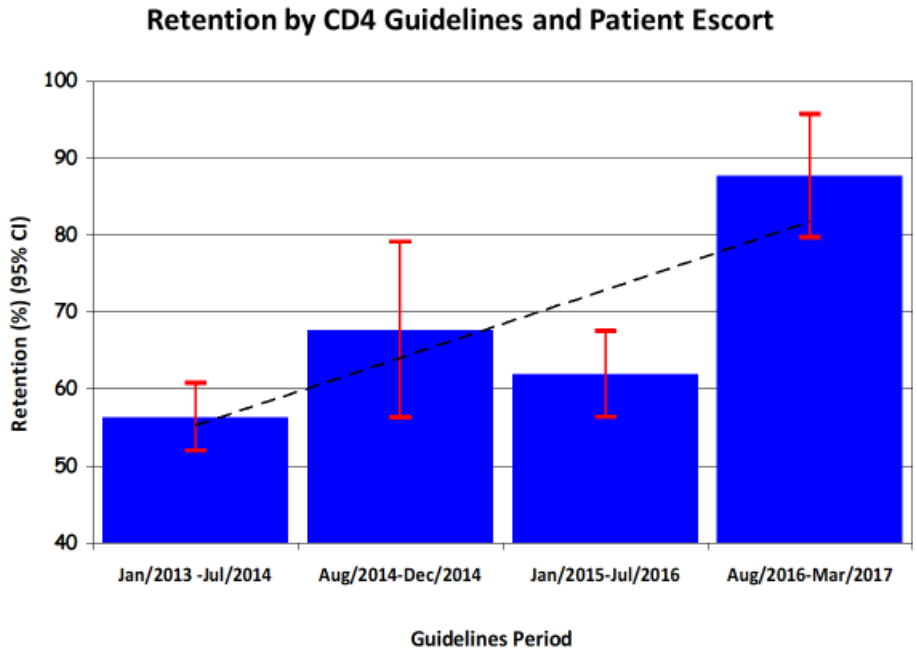

Figure 4. 5 Retention in ART by CD4 Guidelines and Patient Escort

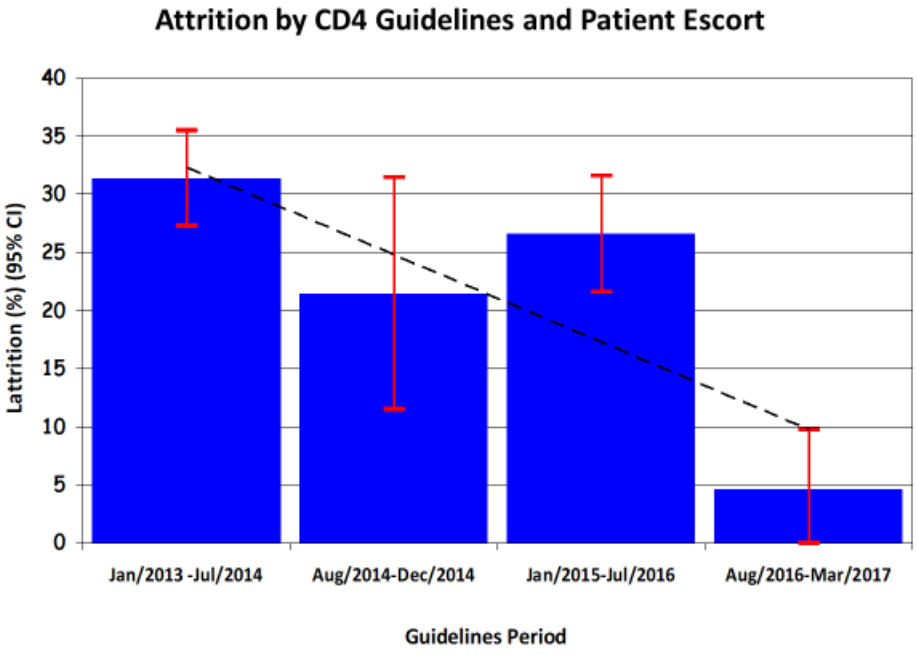

Figure 4. 6 Attrition by CD4 Guidelines and Patient Escort

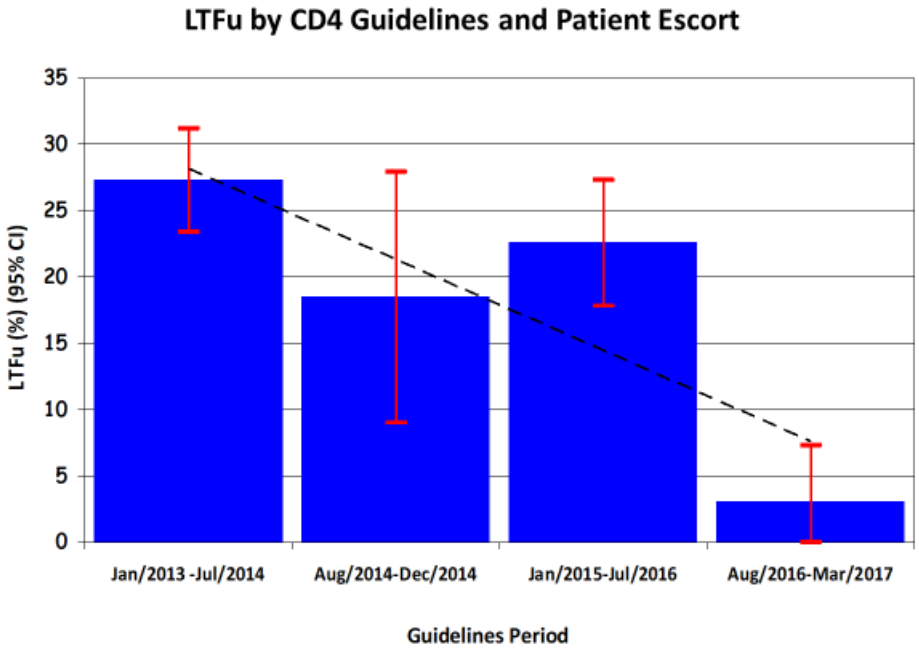

Figure 4. 7 LTFu by CD4 Guidelines and Patient Escort

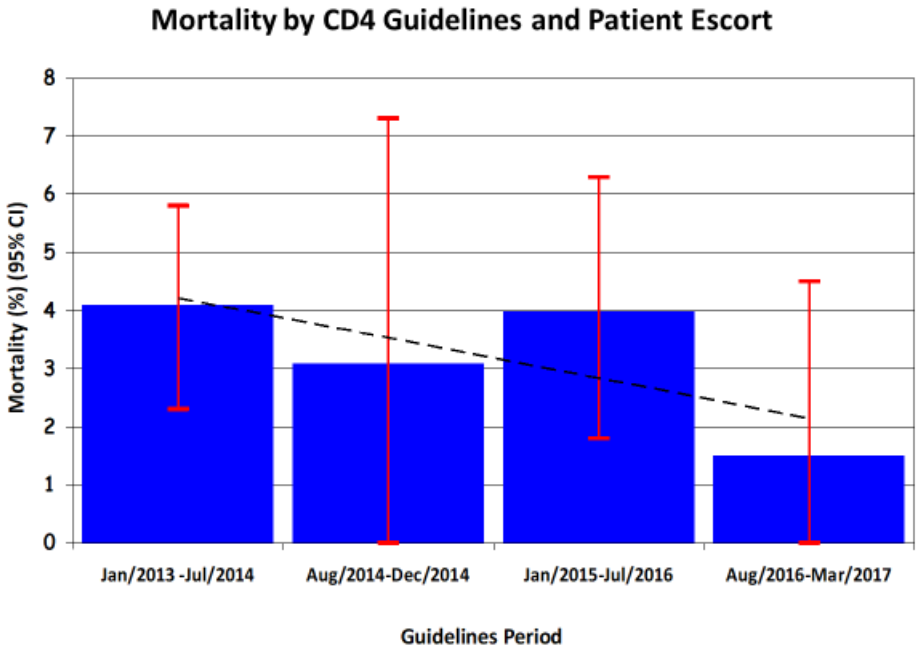

Figure 4. 8 Mortality by CD4 Guidelines and Patient Escort

4.4.3 Effect of Patient Escort on Retention in ART

For assessment of the effect of patient escort alone on retention in ART, there was no significant difference in retention in ART, overall attrition, LTFu and mortality between the pre and post patient groups. However, there was overall improvement in retention from 57.7% to 66.7% in pre and post patient escort groups respectively.

Table 4. 5 ART Outcomes by Patient Escort

ART Outcome by Patient Escort		
ART Outcome	2013-2014 Pre-patient escort % (95% CI)	2015-2017 Post patient escort % (95% CI)
Retention	57.7% (53.6-61.8%)	66.6% (61.7-71.4%)
Attrition	30.2% (26.4-34.0%)	22.7% (18.3-27.0%)
Mortality	4.0% (2.3-5.6%)	3.6% (1.7-5.5%)
LTFu	26.3% (22.6-29.9%)	19.1% (15.0-23.1%)

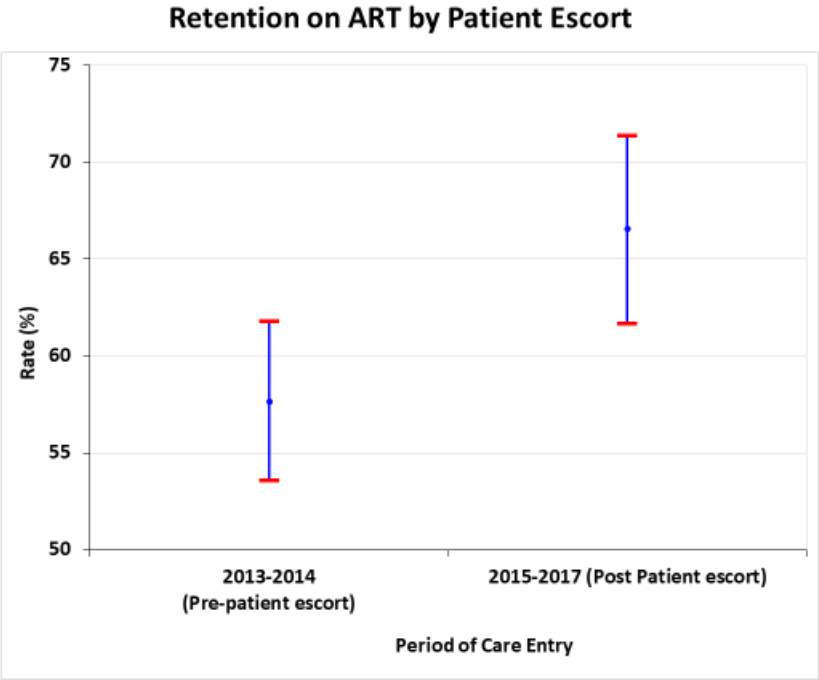

Figure 4. 9 Retention by Patient Escort

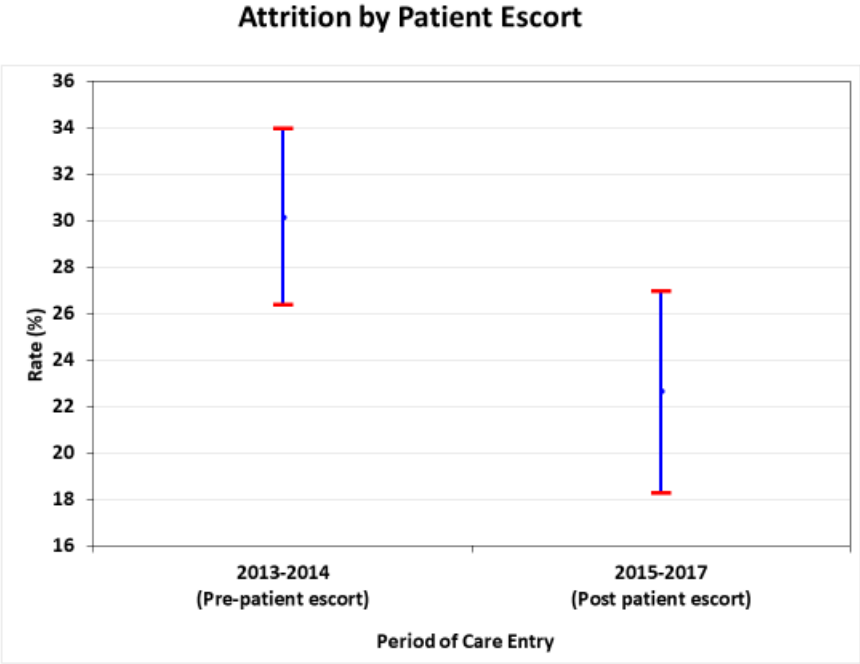

Figure 4. 10 Attrition by Patient Escort

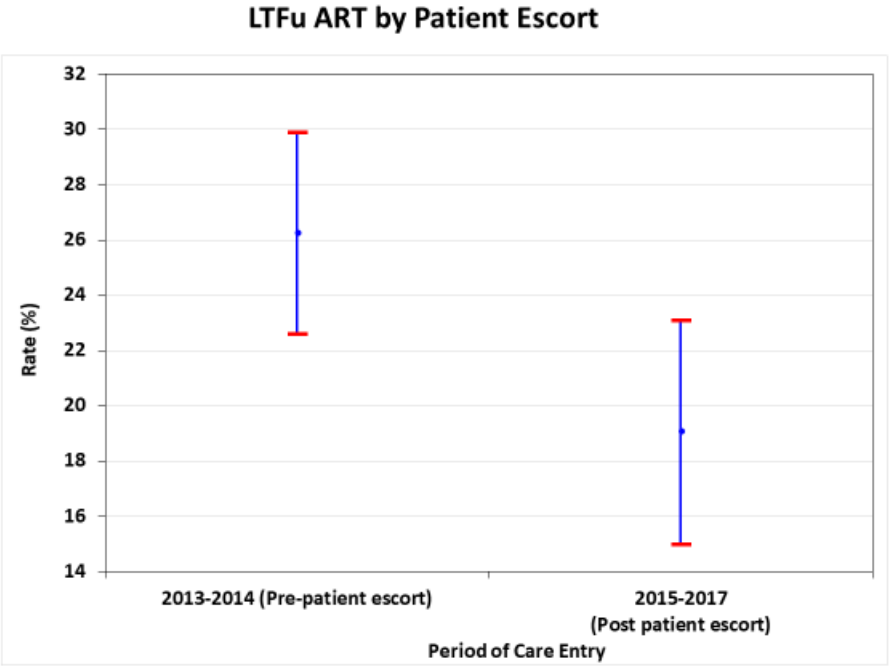

Figure 4. 11 LTFu by Patient Escort

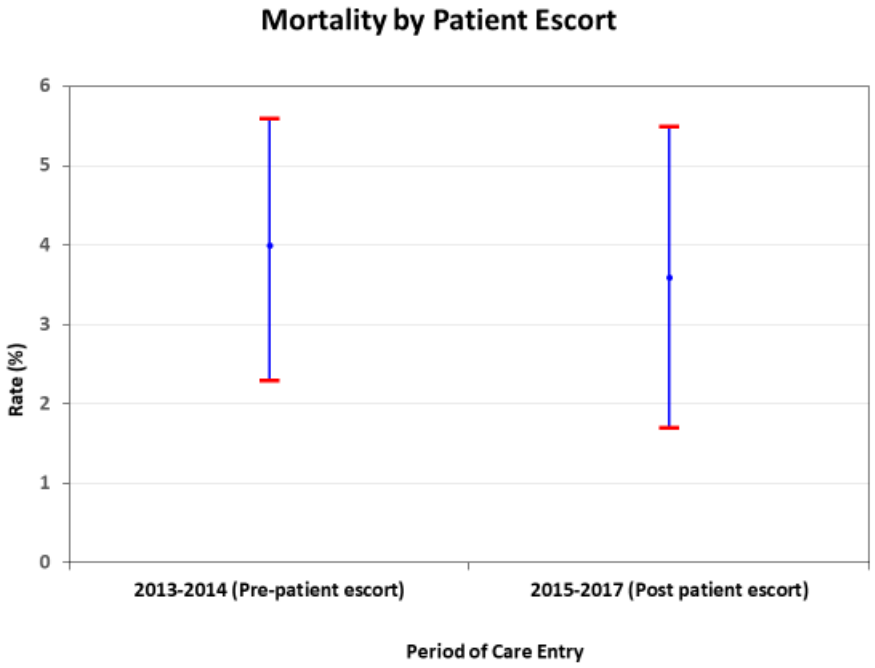

Figure 4. 12 Mortality by Patient Escort

4.2 Conclusion

The study revealed that there was over 70% completion rate for most evaluated clinical indicators in both electronic and physical records except for WHO staging and baseline CD4 in physical and electronic records respectively. Both ART start date and baseline CD4 were significantly more complete in the physical records compared to electronic records, while WHO staging was significantly more complete in the electronic records than the physical records. Almost all evaluated indicators had a mismatch rate of less than 10% except for date started ART that had the highest mismatch rate of 20%. There was a significant decline in median time to linkage to ART from 51 days for the 350 CD4 cell count cut-off to16 days for the "test and treat" group when CD4 guideline changes were combined with patient escort. There was a significant difference in retention in ART, overall attrition and lost to follow up between the "test and treat" group and the CD4 cut-off groups. However, there was no significant difference in retention in ART, overall attrition, LTFu and mortality between pre and post patient escort groups.

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter covers a summary of the major findings of the study, discussion, conclusions and recommendations.

5.2 Summary of Major Findings

This study aimed to first assess the completeness and accuracy of electronic medical records against physical records as the gold standard. There was over 70% completion rate for most evaluated clinical indicators in both electronic and physical records. Almost all evaluated indicators had a mismatch rate of less than 10% except for ART start date that had the highest mismatch rate of 20%. Secondly, the study evaluated the effect of CD4 guideline change and patient escort on time to linkage to and retention in ART using the validated EMR database. There was a significant decline in median time to linkage to ART from 51 days for the 350 CD4 cell count cut-off to16 days for the "test and treat" group. There was a significantly higher retention in ART, and lower overall attrition and lost to follow up between the "test and treat" group and the CD4 cut-off groups. However, there was no significant difference observed in mortality across the groups. Assessing the effect of patient escort showed that there was no significant difference in retention, overall attrition, LTFu and mortality between the pre and post patient escort groups.

5.3.1 EMR Data Completeness and Accuracy

Adoption of provider-based EMR has been shown to improve quality of data collected with a significant reduction in missing and incorrect information (Castelnuovo et al., 2012). However, other studies have found high level of underreporting for key clinical indicators in routine HIV observational databases, based on comparison with a nested research cohort that had more intensive and standardized data collection procedures (Kiragga et al., 2011). In this study, there was over 70% completeness in most of the evaluated indicators in both electronic and physical records. There was a significant difference in data completeness in both baseline CD4 (56%) and ART start

date (66%) when electronic records were compared with physical records. The observed difference in the baseline CD4 was explained by restricting EMR data entry to availability of the appropriate laboratory request form with results in the physical record, whereas the physical record included reviewing of clinical notes for a documented baseline CD4 where the lab request form was missing. For ART start date, the EMR could only pick a date that was later than HIV diagnosis date and utilized the ART Dispensing Tool (ADT) as source of this information too. As such, any ART start date that was earlier than the HIV diagnosis date in the physical file was not considered as correct. Notably, WHO staging at enrolment was significantly lower in the physical record compared to the electronic record. This was due to an inbuilt business rule in the EMR that could not allow the WHO staging field to be left blank; data clerks had to complete this field based on clinical notes at initial evaluation of the patient. On data accuracy, the highest mismatch was observed with the ART start date which could be due to the use of the ADT as another source of verification for this data. From these findings, electronic records were found to be relatively reliable in most indicators when compared to the physical record. Further, EMRs can be improved by use of business rules that ensure mandatory fields are filled before saving a record or moving to the next field. Additionally, clinician's decision support systems act as reminders to prompt clinicians on patient monitoring, correct prescriptions as well as appointment scheduling and missed appointments. Lastly, with adequate data security EMRs act as reliable repositories for big data for patient care as well as operational research.

5.3.2 Effect of CD4 Guideline Change and Patient Escort on Time to Linkage to ART

The median CD4 cell count was greater for post patient escort group at 245 (IQR 148-419) compared to pre-patient escort group at 219 (IQR 103-328). The observed increase in baseline CD4 could be explained by the change of guidelines from the 350 cut-off to 500 and the move towards "test and treat" in 2016. These findings were in contrast with a previous study (Siedner et al., 2015) that showed that CD4 counts at presentation to care and at ART initiation had not appreciably changed between 2002 and 2013 despite guideline changes. Notably, 432.7% and 38.1 % of participants in pre and post patient escort groups respectively did not have a documented baseline CD4,

which corresponded with the findings of data quality in this study. This reiterates the need for regular data quality audits to improve accuracy and completeness of electronic record databases. In terms of disease stage, while most participants were in WHO stage 1 and 2 overall (68.8%), participants in pre-patient escort group were more likely to have a WHO stage 3 and 4 condition (29.5%) compared to those in post patient escort group (26.5%). This was further supported by the CD4 guideline change that resulted in an increase in the baseline CD4 in post patient escort group which correlates with lower disease progression (Nachega et al., 2014).

There was a significant decline in median time to linkage to ART from 51 days for the 350 CD4 cut-off group to16 days for the "test and treat" group when CD4 guideline changes were combined with patient escort. These findings were consistent with the study (Craw et al., 2008), that showed how a brief intervention by a case manager was associated with a significantly higher rate of successful linkage to HIV care when offered to HIV-infected clients soon after their HIV diagnosis. Accessibility of medical services during initial case management or referral activities was found to be an important structural factor that promoted entry into care. Further, accompanying clients to their first HIV medical care encounter might be an effective technique to help clients learn how to navigate the health care system. These findings were similar to those observed with the patient escort system that was adopted in Kiambu CRH.

There was a significantly higher retention in ART, and lower overall attrition and lost to follow up for the "test and treat" group when compared to the CD4 cut-off groups. However, there was no significant difference observed in mortality across the groups. In previous studies, programmes initiating patients at lower CD4 counts were found to have higher rates of attrition than those initiating patients with higher CD4 counts. This observed attrition could have been due to mortality associated with lower CD4 counts (Fox & Rosen, 2010). However, other studies found that individuals starting ARVs at a CD4 cell count ≥250 cells/μL were more likely to experience treatment interruptions in the first three months of therapy and were more likely to have persistent viremia at three months, compared with those starting with a CD4 cell count <250 cells/μL (ADAKUN et al., 2013). Higher CD4s have also been associated with

higher attrition in contrast with our findings (Ulett et al., 2008). There is need for more studies to evaluate the actual impact of the "test and treat" strategy on retention in ART.

Assessing the effect of patient escort showed that there was no difference in retention, overall attrition, LTFu and mortality between the pre and post patient escort groups. However, there was an improvement in retention from 57.7% to 66.7% in pre and post patient groups respectively. These findings contrast those from other studies that showed patients with higher CD4s are more prone to treatment interruptions and losses to follow up since they "feel healthy" (Nachega et al., 2014). More research is needed to understand the effects of patient escort and higher CD4 counts on retention in ART.

5.4 Conclusion

The study findings have important implications for the use and interpretation of data derived from EMR databases for ongoing patient follow up and retention in treatment programmes as well as operational research. Thus, there is need for ongoing data quality audits of EMRs for validation of key data elements. Further, CD4 guideline changes had a positive effect on the median CD4 at ART initiation and disease progression. There was also a significant decline in median time to linkage to ART when the "test and treat" strategy was combined with patient escort after HIV diagnosis. Similarly, there was a significantly higher retention in ART, and lower overall attrition and lost to follow up for the "test and treat" group. However, there was no significant difference in retention, attrition, LTFu, and mortality between the pre and post patient escort groups. More research on patient escort as a behavioral intervention for linkage and retention in ART is needed.

5.5 Recommendations

There is limited literature on the impact of EMRs on patient outcomes in Sub-Saharan Africa despite the increased adoption of EMRs in chronic HIV care settings. Specifically, in Kenya, there are several EMR systems that have been adopted for use in follow up of patients in HIV care. The findings of this study revealed that the EMR database in use in Kiambu CRH was reliable to an acceptable level. Thus, there is

need for ongoing EMR database audits to ensure their validity. Consequently, these data can be utilized for policy making and operational research.

The findings of this study showed that there was no significant difference in mortality with the move towards "test and treat" strategy which is contrary to the findings of a mathematical model on universal voluntary HIV testing with immediate antiretroviral therapy as a strategy for elimination of HIV transmission demonstrated that showed the intervention could reduce HIV incidence and mortality to less than one case per 1000 people per year by 2016, or within 10 years of full implementation of the strategy, and reduce the prevalence of HIV to less than 1% within 50 years (Granich et al., 2009). Further studies on the impact of the "test and treat" strategy as ART uptake increases is needed to document the actual benefit. The findings on impact of patient escort on retention were also inconclusive, and as such more research on patient escort as a behavioral intervention for linkage and retention in ART is needed.

5.6 Limitations

Several limitations existed in this study. Firstly, the study was conducted in only one facility in Central Kenya, Kiambu CRH and only evaluated one EMR system and as such the results may therefore not be generalized across the various EMR systems. To reduce this limitation, the study limited the evaluation to baseline clinical indicators that are expected for all EMR databases. Secondly, the study did not look at other factors associated with poor or variability in data quality such as hours spent by data clerks in data entry and training in data management which have been shown to have effect on data completeness (Forster et al., 2008). Lastly, the HIV clinic in Kiambu CRH is co-located within the facility thus making a patient escort system feasible. Such a system might pose challenges in smaller facilities where co-location is not practical.

5.7 Areas for further studies

Further similar studies should be carried out in other facilities to evaluate the validity of these findings.

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APPENDICES

APPENDIX A: STRATHMORE UNIVERSITY ETHICAL APPROVAL

Strathmore UNIVERSITY

REF: **SU-IRB 0033/16**

22nd March 2016

Dr. Winnie G. Muthee
P.O Box 2582-00202
Nairobi, Kenya.

Email: gckwinnie@gmail.com

MBA-HCM/79135/13

Dear **Dr. Muthee,**

REF: SU-IRB 0033/16 PROPOSAL "AN EVALUATION OF AN EMR SYSTEM FOR COMPLETENESS AND ACCURACY OF MEDICAL DATA: A PARALLEL COMPARISON BETWEEN DUPLICATE ELECTRONIC AND MEDICAL RECORDS IN KIAMBU COUNTY REFERRAL HOSPITAL"

We acknowledge receipt of your application to the Strathmore University Institutional Review Board (SU-IRB) which includes the study proposal version dates 5th February 2016.

The committee has reviewed your application, and your study *"An Evaluation of an EMR System for Completeness and Accuracy of Medical Data: A Parallel Comparison between Duplicate Electronic and Medical Records in Kiambu County Referral Hospital"* has been granted **approval**.

This approval is valid for one year beginning **22nd March 2016** until **21st March 2017**.

In case the study extends beyond one year, you are required to seek an extension of the Ethics approval prior to its expiry. You are required to submit any proposed changes to this proposal to SU-IRB for review and approval prior to implementation of any change.

Thank you

Sincerely,

Amina Salim
Regulatory Affairs Fellow

STRATHMORE UNIVERSITY INSTITUTIONAL REVIEW BOARD APPROVED