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Automated Clinical Decision Support in HIV management: a comparative study of Point-of-Care and Retrospective Data Entry outcomes.

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Automated Clinical Decision Support in HIV Management: A Comparative Study of Point-of-Care and Retrospective Data Entry Outcomes

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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 dissertation contains no material previously published or written by another person except where due reference is made in the dissertation itself.

Sammy Wundundi Masibo

Signature: .....

Date: 15 - November - 2021

Approval

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Abstract

Kenyan healthcare facilities are increasingly adopting electronic medical records (EMRs) and electronic health management information systems (HMIS). Many public hospitals have automated HIV/AIDS care services in pursuit of efficiency and better patient outcomes. This has triggered interest in clinical decision support (CDS) systems. The CDS systems are designed to provide patient-specific information that is intelligently filtered to healthcare providers at appropriate times to enhance clinical decision-making. Studies have shown that automating CDS has certain advantages over manual systems. What remains unclear is whether the way the automated CDS is deployed has an impact. Point-of-care deployment refers to the use of CDS systems at the actual time of service delivery (data collection and system delivery are concurrent). Data is entered in real-time. Retrospective data entry (RDE) refers to deployment of systems to be used after the actual service delivery. Data is captured in primary manual tools and later transferred to the electronic database after the fact. This study sought to establish whether deploying a CDS system at point-of-care (POC) is more beneficial than deploying it retrospectively given the incidental capital outlays for POC systems. The study entailed a cross-sectional analysis of data collected through the *KenyaEMR* system; an electronic medical records system developed to manage HIV/AIDS services in Kenya. The study found that deploying CDS systems at point-of-care results in a lower patient missed appointment rate (21.34%, SD 8.24) compared to CDS applied retrospectively (31.58%, SD 15.47). CDS systems deployed at POC also result in better viral load testing rates (42.06%, SD 10.49) compared to retrospective CDS (37.56%, SD 10.03). There was no significant variation in the viral load suppression rates between POC and RDE modes (81.88%, SD 7.47 and 79.67%, SD 7.63 respectively). The study also enumerated challenges faced by system end-users when *KenyaEMR* is deployed retrospectively. These included duplication of work (84%) and lack of quality and timely data (74%). The potential barriers that constrain facility transition from retrospective data entry to point-of-care deployment were also established and included inconsistent power supply (95%) and negative staff attitude (74%).

Key words: *KenyaEMR, HIV/AIDS, point-of-care (POC), retrospective data entry (RDE), clinical decision support (CDS).*

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Abbreviations

AIDS	- Acquired immunodeficiency syndrome
AMPATH	- Academic Model Providing Access to Healthcare
CDS	- Clinical Decision Support
CRSSP	- Central Province Response Integration Strengthening Project
EID	- Early Infant Diagnosis
EMR	- Electronic Medical Records
HIV	- Human Immunodeficiency Virus
HMIS	- Health Management Information System
HRIO	- Health Records and Information Officer
HTC	- HIV Testing and Counselling
I-TECH	- International Training and Education Centre for Health
MCH	- Mother and Child Health
NASCOP	- National AIDS and STIs Control Programme
POC	- Point-of-Care
RDE	- Retrospective Data Entry
TB	- Tuberculosis
UMB	- University of Maryland, Baltimore
VL	- Viral Load

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Chapter 1: Introduction and Background

1.1 Introduction

The introductory chapter outlines the study background and denotes the problem statement. The study objectives as well as the guiding research questions are also defined. Lastly, the scope and significance of the study are outlined to explain the justification for the study.

1.2 Background

Many developing countries have witnessed a clamour for automation in the health sector, especially for HIV/AIDS services (Jawhari et al., 2016). A lot of software installations have been deployed, particularly in the public sector (Muinga et al., 2020). This increased HMIS adoption has been driven by the incidental advantages afforded by clinical decision support (CDS); especially since treatment guidelines have been changing rapidly (Dhiman et al., 2015).

A clinical decision support system analyses patient data to offer diagnostic information to healthcare workers and service providers. CDS tools can for instance, offer reminders for preventive care, give alerts about potentially dangerous drug interactions and alert clinicians on the required laboratory testing their patient should undergo (Sutton et al., 2020). Thus, using a CDS system can theoretically lower costs and increase efficiency (Oluoch, Katana, Kwaro, Santas, Langat, Mwalili, Muthusi, Okeyo, & Ojwang, 2016).

Many systems are configured to be used either retrospectively or at point-of-care (POC). Some systems such as *KenyaEMR* have dual capability. It is often assumed that CDS systems are more useful at POC compared to retrospective data entry (RDE) usage. This is premised on the fact that POC-configured systems afford clinicians with just-in-time, contextual, patient-specific information with relevant clinical reminders (Were et al., 2010). This study sought to understand the value of automation, specifically, assessing whether using a system at POC has advantages over using it retrospectively (RDE).

The *KenyaEMR* system was used as the case study. The *KenyaEMR* system is a tailored distribution of *OpenMRS* designed to manage HIV testing services (HTS), HIV/AIDS

management, tuberculosis, mother and child health (MCH), laboratory and immunization services (Muthee et al., 2018). Specific focus was given to outcomes for patients enrolled into the HIV/AIDS module.

1.3 Problem Statement

With the increased adoption of health management information systems (HMIS) in Kenyan hospitals, focus has shifted to systems that can capture data at point-of-care (POC). A popular example is the clinical decision support (CDS) application (Catalani et al., 2014).

The revised Kenya Standards and Guidelines for mHealth Systems list CDS as one of the minimum mHealth functional requirements for any system deployed in the country (Health, 2017). This requirement further fuelled demand for systems to be used at POC.

Deploying systems at POC has three financial constraints that healthcare managers must grapple with (Boonstra et al., 2014). Firstly, POC deployments call for a complex system design and configuration that ultimately means system developers exact a premium for the final product. Secondly, POC solutions require the inclusion of alternative power solutions as a basic requirement since they are used during actual, active patient visits (no room for power outages). Lastly, POC deployments require that all the primary health providers be trained on the system (Jawhari et al., 2016). This is costlier and more laborious than in an RDE setup, which can run with a handful of trained data clerks.

To date, there is lack of comparative clarity on the value of CDS systems deployed differently. There is little evidence to demonstrate variations in the usefulness of CDS systems, particularly when comparing their use at the point-of-care (as POC CDS systems) and retrospective data entry (as RDE CDS systems).

Since automation of any health service and the implementation of attendant alternative power solutions is costly (Aldredge et al., 2020), it is useful to understand whether there are quality gaps between implementing the systems retrospectively and in real time at point-of-care.

While most authors on the subject have established that automated CDS leads to improved compliance to the intent of treatment guidelines (Gad El-Rab et al., 2017; Hall et al., 2016; Holt et al., 2012), less effort has gone towards comparing the effectiveness of CDS at POC with CDS at RDE; with most literature examined being based exclusively on POC set-ups. This project sought to examine this comparison, contributing to available evidence, and informing hospital managers on whether the mode of CDS deployment matters.

Three treatment outcome variables were selected to test the performance of CDS deployment across the two modes*: missed appointment rate*, *viral load uptake rate* and *viral load suppression rate*.

The *missed appointment rate* relates to the number of honoured appointments based on the number of patients booked in a specified period. Studies have demonstrated the role of EMRs and CDS in reducing the *missed appointment rate* as well as the number of patients who eventually get lost to clinical follow up. One such study was done in Uganda and published in the National Institute of Health Journal (Alamo et al., 2012). It would be important to equally demonstrate whether different CDS deployment modes for the same system would result in varying *missed appointment rate* scores.

The *viral load uptake rate* refers to the number of patients who undertake a scheduled laboratory HIV viral load test from the total number of eligible patients. The role of EMR screening alerts in increasing clinical and laboratory screening has been documented in several studies. One such study in the United States concluded that such CDS alerts significantly increase hepatitis C and HIV screening rates in primary care practices (Tapp et al., 2020). What seems unclear is whether the *viral load uptake rate* depends on the mode of system deployment.

The *viral load suppression rate* is a quality of care indicator that measures the percentage of HIV-infected patients with an undetectable viral load. Previous studies have established a link between CDS and prevention of HIV-related immunological failure (Oluoch et al., 2016). The application of CDS features has also been demonstrated to improve the CD4 count in HIV-infected patients, pointing to better immunity (Robbins

et al., 2012). However, this study could not unearth any research work comparing the *viral load suppression rate* across POC and RDE deployments.

1.4 Study Objectives

To assess the impact of the mode of automated clinical decision support (CDS) deployment on the outcomes of HIV/AIDS care.

Specific objectives:

i. To compare the patient *missed appointment rate* between cases where the CDS system was applied retrospectively and where it was applied at the point-of-care (POC).
ii. To compare the patient *viral load uptake rate* between cases where the CDS system was applied retrospectively and where it was applied at the point-of-care (POC).
iii. To compare the *viral load suppression rate* between cases where the CDS system was applied retrospectively and those where it was applied at the point-of-care (POC).
iv. To determine the strength of the relationship, if any, between the *missed appointment rate* and the *viral load uptake rate*.
v. To explore the end-user challenges of using CDS systems retrospectively as opposed to POC setups.
vi. To explore potential barriers to transitioning hospitals from RDE CDS systems to POC CDS systems.

1.5 Research Questions

This research project sought to determine answers to the following question:

i. Does the *missed appointment rate* depend on the mode of system deployment?
ii. Is there any correlation between the *viral load uptake rate* and *viral load suppression rate* with the mode of system deployment?
iii. What end user challenges inform the general assumption that RDE system deployments are inferior to POC system use?
iv. Are there factors that hinder the transition of hospitals from RDE set-ups to POC use?

1.6 Scope of the Study

This research project was confined to the counties in which *KenyaEMR* was deployed as of July 2019. These included: Baringo, Bungoma, Busia, Elgeiyo Marakwet, Homa Bay, Kakamega, Kiambu, Kirinyaga, Kisii, Kisumu, Migori, Murang'a, Nandi, Nyamira, Nyandarua, Nyeri, Siaya, Trans Nzoia, Turkana, Uasin Gishu, Vihiga and West Pokot.

Where a target facility had more than one system implemented, the research focussed only on *KenyaEMR* for consistency purposes. While *KenyaEMR* is used for managing various medical records electronically, the study focussed on its application in the management of HIV/AIDS only.

Baringo, Uasin Gishu, Nyeri and West Pokot counties were eventually dropped from the study based on the exclusion criteria spelt out in section 3.3 below.

1.7 Significance of the Study

As explained before, this study sought to bridge a critical research gap. Most previous studies have been biased to demonstrating the value of automation over manual medical records. Little focus has been put on exhibiting whether automated CDS at point-of-care is any superior to system deployments used retrospectively.

This is an especially important consideration for low and middle-income countries, which are increasingly pushing for POC system models through policy documents (Aldredge et al., 2020). For instance, Kenya revised its standards and guidelines for mHealth systems to reflect the importance of POC CDS as a minimum functional requirement for any system (Health, 2017).

Deployment of EMR systems at POC implies costlier implementations and the need for alternative power solutions to support the systems. For systems that can be used both retrospectively and at POC, it is important to determine the superiority, if any, of a POC set-up over an RDE set-up. This research will form a strong basis for determining whether POC deployments confer better CDS outcomes than RDE set-ups.

Chapter 2: Literature Review

2.0 Introduction

This chapter is concerned with the review of literature on related study constructs. The chapter outlines the theoretical underpinnings of clinical decision support (CDS) and contrasts point-of-care (POC) system deployments against retrospective data entry (RDE). A discussion on the theoretical and empirical reviews is similarly outlined. The conceptual framework is also discussed to explicate the impact of CDS on *missed appointments rate*, *viral load uptake rate* and *viral load suppression rate*.

2.1 Theoretical Review

There are several theories around electronic medical records and automated clinical decision support systems. These theories are important in providing a broad perspective to the problem under study. The theoretical framework is useful in building an interpretive case of the problem through a wide reflection about reality, thoughts, and ideas (Mwinzi, 2015).

This study examined various theories concerned with adoption of innovation and technology in order to understand the barriers and facilitators of uptake of electronic medical records systems as well as clinical decision support systems.

2.1.1 Innovation Diffusion Theory (IDT)

Also called the *diffusion of innovation theory*, IDT is often applied to explain the adoption of information systems in various disciplines (Oliveira & Fraga Martins, 2011). Developed by E.M. Rogers in 1962, the IDT can help explain the adoption of electronic medical records in the healthcare sector. The theory postulates that the adoption of information systems doesn't happen simultaneously; rather it is a process in which people adopt innovation at different rates. The theory outlines five categories of technology adopters: innovators, early adopters, early majority, late majority, and laggards.

In the context of this study, the *innovation diffusion theory* is useful in answering some of the research questions. For instance, it can be applied to explain the end user challenges

that generally inform the assumption that RDE CDS deployment is inferior to POC system use. The theory is also useful in explaining the factors that hinder the transition of hospitals from RDE set-ups to POC use.

The theory, however, suffers from some established limitations (Rosario Oliveira Martins et al., 2011). For instance, it was not developed to explicitly apply to health behaviour or public health interventions. It also fails to foster a participatory approach to adoption of public health programs. Lastly, it does not work well with cessation of behaviours as it does for adoption of behaviours. In a study like this, which seeks to understand end-user challenges in automation, the theory may fall short.

2.1.2 Technology, Organization and Environmental (TOE) Theory

The TOE framework was first advanced by Tornatzky and Fleischer in their book *The Processes of Technological Innovation* (1990). The theory postulates that three main determinants facilitate the adoption of new technologies in an organization: the technological context, the organizational context, and the environmental context (Rosario Oliveira Martins et al., 2011). These three contexts in concert determine the firm's ability to adopt new technologies and innovation (Williams et al., 2012).

The technological context includes all relevant technologies; those already in use as well as those available in the marketplace but not yet acquired. A firm's existing technologies are important because they determine the scope and pace of technological change a firm can undertake (Collins et al., 1999).

The organizational context includes the characteristics and resources of the firm. Organic and decentralized organizational structures are conducive for the adoption of new technologies. Availability of a communication process also facilitates technological adoption (Tushman & Anderson, 1986).

The environmental context relates to the structure of the industry, the presence or absence of technology service providers and the prevailing regulatory environment (Oliveira & Fraga Martins, 2011). Intense competition and rivalry are associated with faster adoption of innovation. The availability of attendant support infrastructure for technology also impacts on adoption of innovation.

The TOE model has previously been applied to explain the adoption of innovation in healthcare (Jang, 2010). The technology-organisation-environment framework explains how the three elements influence how a firm identifies the need for, searches for, and adopts new technology.

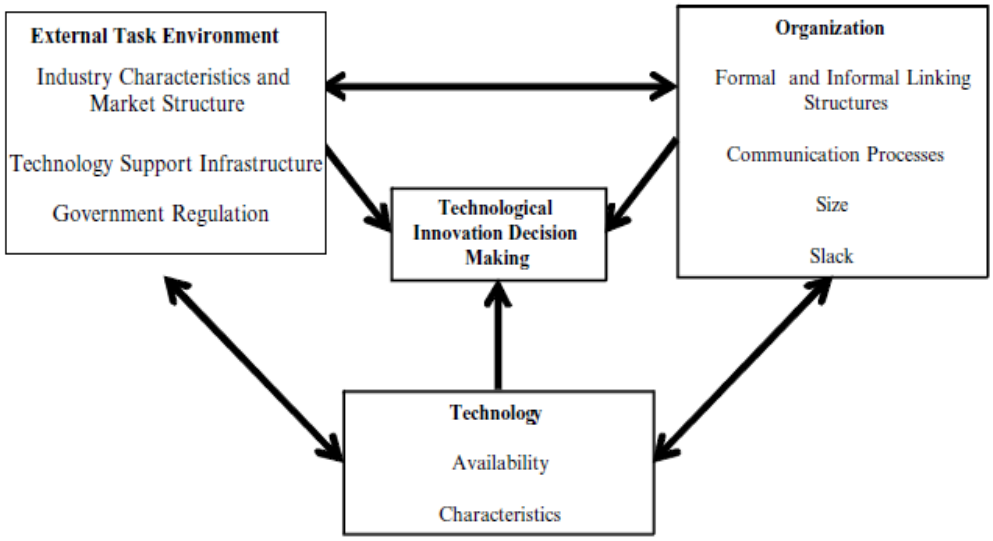


Figure 1: The technology-organisation-environment framework

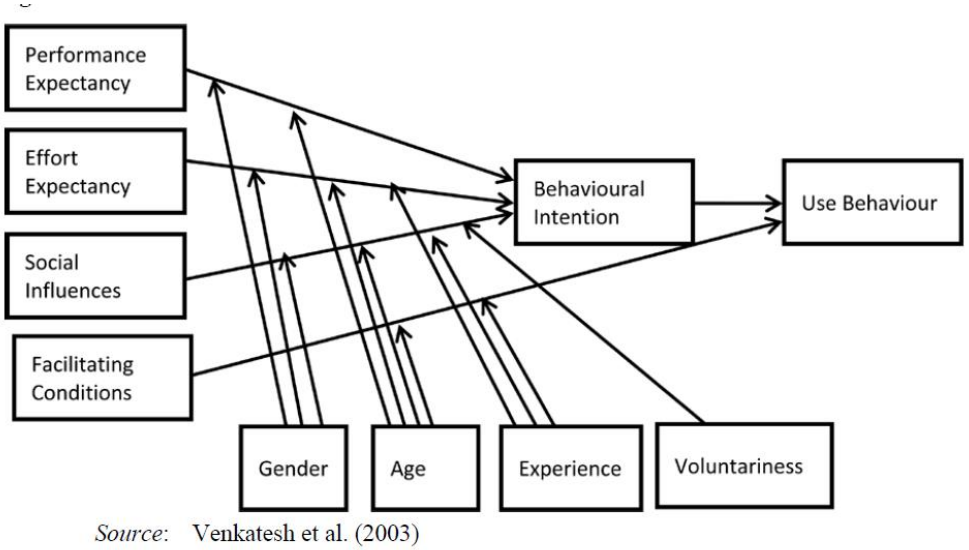
The TOE model however suffers a few setbacks. For instance, it is not useful for research on interorganizational adoption of information systems (Oliveira & Fraga Martins, 2011). The model is only tailored for studies premised on the perspective of a single focal firm. The model additionally requires refinement of the definition of the three elements of a firm's context, as well as the dependent construct.

2.1.3 Unified Theory of Acceptance and Use of Technology (UTAUT)

The UTAUT framework was developed by combining eight other models, including the *Innovation Diffusion Theory*. Thus, the UTAUT model merges theoretical constructs and factors across eight different models (Hennington & Janz, 2007; Venkatesh, 2000).

The UTAUT model has since been expanded to accommodate the consumer context in the adoption of innovative technologies (Venkatesh et al., 2016) The extended version of the original UTAUT is known as UTAUT2 and includes three new constructs: price value,

habit, and hedonic motivation. Compared to UTAUT, UTAUT2 significantly improves the variance explained in technology use and behavioural intention (Chang, 2012).



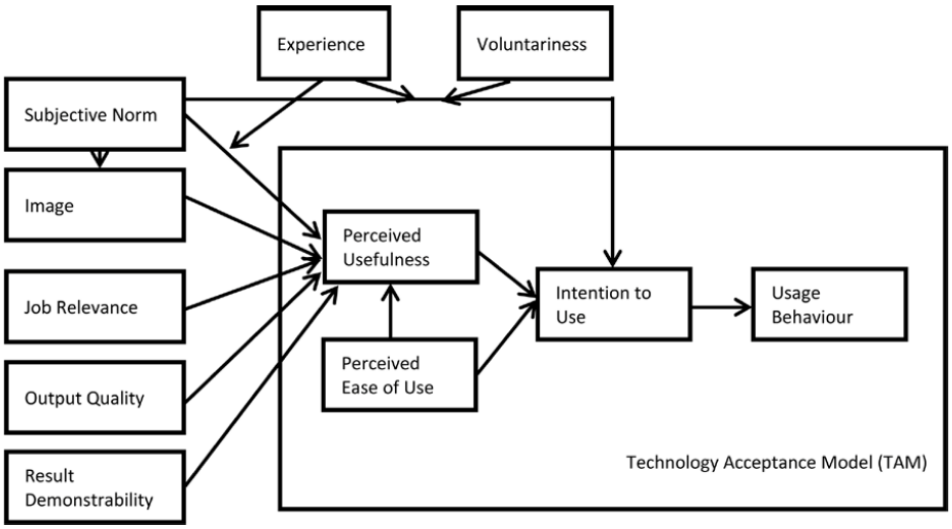
Source: Venkatesh et al. (2003)

Figure 2: Framework for UTAUT model

2.1.4 Technology Acceptance Model (TAM)

The TAM framework was derived from the *Theory of Reasoned Action* (TRA). TAM explains the determinants of computer acceptance, as well as explaining user behaviour across various end-user computer technologies and user populations.

Originally, TAM was developed to understand why end users accept or reject new information systems (Silva & Dias, 2008). The TAM model has since been expanded to include the influence of subjective norms on individual's inclination to accept or reject innovative technologies. The revision of the TAM model to include social influence and cognitive instrumental processes significantly boosted its explanatory power in technology adoption (Gupta et al., 2016).



Source: Venkatesh and Davis (2000)

Figure 3: Framework of Technology Acceptance Model 2 (TAM2)

2.2 Empirical Review

The empirical review presents an overview of the automated clinical decision support (CDS) concept and examines its deployment either retrospectively or at point-of-care. The empirical review is structured as an argumentative review to distinctly bring out the contrasting perspectives.

2.2.1 Clinical Decision Support (CDS)

Typically, clinical practice guidelines are developed based on the best scientific evidence of effectiveness. Without such guidelines, clinical practice would be prone to variation. This would mean sub-optimal care provision by some healthcare providers (Warren et al., n.d.). This is consistent with the systematic review study findings by Jeremy Grimshaw and Ian Russell (Grimshaw & Russell, 1993).

Automating clinical practice guidelines can be useful in guiding the decision making process by healthcare providers (Marcelin et al., 2016). Generally defined, clinical decision support (CDS) is the provision of patient-specific data and information at the appropriate time to enhance decision making and therefore improve patient outcomes. CDS has also been defined as the process of improving health-related actions by combining clinical knowledge and patient-specific information (Middleton et al., 2016)

CDS aids clinicians with decision-making processes, especially patient diagnosis and treatment (Dhiman et al., 2015). It has been innumerably demonstrated that CDS, if carefully selected, generally improves patient outcomes, including quality and safety of care (Alotaibi & Federico, 2017). LeBlanc et al., in a patient-level randomized study compared CDS and usual care. The study concluded that CDS "efficiently improves shared decision making about therapy for osteoporosis between primary care clinicians and at-risk women." (LeBlanc et al., 2015).

When automated, the application of CDS can be expanded to include provision of reference materials, useful patient-specific alerts, medical calculators, clinical diagnoses etc. (Dhiman et al., 2015; Shojania et al., 2009). For example, Rita D. Zielstorff advocates for CDS automation by preferring that CDS is "made accessible through computer-based, patient-specific reminders that are integrated into the clinician's workflow."(Prospects, 1998).

2.2.2 Point-of-Care and Retrospective Data Entry

Automated CDS can be applied retrospectively through retrospective data entry (RDE) or at point-of-care (POC). Some HMIS such as *KenyaEMR* are designed to support both RDE and POC modes. Debate has been raging on, regarding the superiority of CDS when applied at POC as opposed to CDS applied through RDE.

A POC implementation mode typically entails setting up a computer terminal at every patient service point for data entry during an actual patient encounter. A POC set-up therefore allows real-time application of all CDS features (Waters, Rafter, Douglas, & Bwanali, 2010).

An RDE system deployment, on the other hand, entails clinicians using paper records to serve patients. Such records are then captured into the EMR at a single centralized data entry point by the clinicians, designated health facility workers or appointed data clerks. Such data entry occurs after the actual patient encounter and may, theoretically, limit the use of some CDS features such as alerts and warnings (Kang'a, Samuel G., n.d.).

Theoretically, a POC system deployment therefore affords better clinical outcomes, since all the CDS alerts and directives can be applied promptly during an actual clinical

encounter. For a system used retrospectively, such alerts - even when still present - cannot be immediately implemented since data entry occurs after the actual clinic visit.

Most of the published CDS-related studies are based on POC system use. A review of these studies reveals positive outcomes when CDS is applied in a POC environment. In one such publication, CDS at POC significantly increased the HIV testing rates when computer physician order entry (CPOE) systems were modified to include CDS at POC through user prompts (Hall et al., 2016).

In yet another study, CDS was applied at POC to improve appropriate and timely action following immunologic failure in HIV-positive patients in Siaya County, Kenya. The likelihood of clinicians taking appropriate action on treatment failure was considerably increased with CDS at POC than with no CDS at all (Oluoch, Katana, Kwaro, Santas, Langat, Mwalili, Muthusi, Okeyo, & Ojwang, 2016). This was consistent with a similar study examining the effects of POC reminders on processes and outcomes of care (Shojania et al., 2009).

No publications were unearthed on the impact of CDS deployed in a retrospective data entry (RDE) environment. One publication on EMR site readiness assessment prioritized POC CDS over CDS with RDE. In the study, an EMR site readiness tool was applied to determine if health facilities were primed for installation of *KenyaEMR*. Assessed facilities were clustered as either "highly prepared", "moderately prepared" or "not prepared." Highly prepared facilities adopted *KenyaEMR* at POC with multiple terminals while moderately prepared facilities adopted the system for RDE with a single terminal for data entry (Muthee et al., 2018).

An extensive review of literature could not yield any publication comparing CDS outcomes for any system used at POC as opposed to its use within an RDE set-up. There is need to mine evidence on this, to inform the best way to deploy electronic health interventions especially in low-resource settings.

Conclusively, very few publications are available on the value of CDS when applied retrospectively. There are even fewer studies comparing outcomes of CDS applied at POC as opposed to CDS applied retrospectively. This study attempted to fill this

knowledge gap by establishing the variance value of CDS when deployed in the two models.

2.2.3 Missed Appointment, VL Uptake and VL Suppression Rates

The *missed appointment rate* relates to the number of honoured appointments based on the number of patients booked in a specified period. The *viral load uptake rate* relates to the number of patients who undertake a scheduled laboratory viral load test from the total number of eligible patients. Finally, the *viral load suppression rate* is a quality of care indicator that measures the percentage of HIV-infected patients with an undetectable viral load.

The author did not discover studies demonstrating whether different CDS deployment modes for the same system result in varying *missed appointment rate* scores. While the role of automated CDS in increasing laboratory testing seems confirmed, it remains unclear whether the *viral load uptake rate* depends on the mode of system deployment. The author could also not unearth any study comparing the *viral load suppression rate* across POC and RDE deployments.

2.2.4 End User Challenges in RDE deployments

Theoretically, the application of CDS features using RDE system deployments as opposed to POC setups may pose some challenges, including duplication of work, delayed reporting of events, insufficient continuity of patient care, low uptake of and utilisation of services etc.

In Malawi, a pilot POC innovative system for collecting primary care data was superior to the traditional RDE Health Management Information System (HMIS) with regard to end user challenges (Waters, Rafter, Douglas, Bwanali, et al., 2010).

The author did not discover studies demonstrating variations in end user challenges across different CDS deployment modes for the same system. This is an important research gap that needs to be studied.

2.2.5 RDE-to-POC Transition Barriers

The study also sought to understand possible barriers in transitioning from an RDE set-up to a POC set-up. Most EMR systems are designed to be fully tailored for either RDE or POC use. However, systems such as *KenyaEMR* have dual capability, with the POC deployment mode being the gold standard.

Transition from an RDE deployment mode to a POC set-up can be hindered by several factors including lack of alternative power, limited infrastructure, legacy data migration requirements, negative staff attitudes toward POC system usage, etc.

A Kenyan study in two urban primary care clinics running the same open-source EMR system revealed important transition-related barriers (Jawhari et al., 2016). These barriers include infrastructural deficiencies, inconsistent power availability, limited interoperability with other existing systems, as well as resistance from system end users. This study sought to establish if there are similar transition barriers regarding the *KenyaEMR* system.

2.2.6 Summary of Literature Review and Gaps

Table 1: Summary of Literature Review and Research Gaps

Author	Title	Findings	Research Gap
LeBlanc et al., 2015	*Encounter Decision Aid vs. Clinical Decision Support or Usual Care to Support Patient-Centered Treatment Decisions in Osteoporosis: The Osteoporosis Choice Randomized Trial II*	Supporting both patients and clinicians during the clinical encounter a clinical decision aid efficiently improves treatment choices when compared to usual care, with or without clinical decision support.	The study focussed more patients' and clinicians' involvement rather than the CDS system itself. Additionally, the study was conducted exclusively in an RDE set-up while this study is concerned with comparing CDS at RDE with CDS at POC
Hall et al., 2016.	*A feasibility study for a clinical decision support*	Computer Physician Order Entry (CPOE) based CDS applications	The study focussed on laboratory diagnosis of HIV only, while this

Author	Title	Findings	Research Gap
	system prompting HIV testing	for HIV testing are both feasible and acceptable to healthcare workers. Refining the application's risk stratification is likely to make it more effective.	study is concerned with many more indicators beyond diagnostics. The study was also conducted exclusively in a POC set-up while this study is concerned with comparing CDS at RDE with CDS at POC
Alamo et al., 2012	*Electronic Medical Records and Same Day Patient Tracing Improves Clinic Efficiency and Adherence to Appointments in a* *Community Based HIV/AIDS Care Program, in Uganda*	Concurrently using EMR and same day patient tracing can significantly reduce missed appointments and improve clinic efficiency.	The study focussed on tracing clients based on clinic attendance data (cross-sectional) while this study seeks to assess adherence to appointments based purely on the mode of system deployment (longitudinal). Additionally, the study was conducted exclusively in an RDE set-up while this study is concerned with comparing CDS at RDE with CDS at POC
Tapp et al., 2020	*Electronic medical record alert activation increase hepatitis C and HIV screening rates in primary care practices within a large healthcare system*	EMR-based CDS through alerts improves screening for hepatitis C and HIV in primary care practices.	The study focussed on laboratory diagnosis, while this study is concerned with many more indicators beyond diagnostics. The study was also conducted exclusively in a POC set-up while this study is concerned

Author	Title	Findings	Research Gap
			with comparing CDS at RDE with CDS at POC
Oluoch et al., 2016	*Effect of a clinical decision support system on early action on immunological treatment failure in patients with HIV in Kenya: a cluster randomised controlled trial*	Clinicians are more likely to take appropriate action on treatment failure with CDS alerts than with no decision support system.	The study explored variations in patient care between CDS-included EMR systems and non-CDS EMR systems. This study, however, concerns itself with CDS-supported EMR systems deployed differently (RDE or POC deployment)
Waters, Rafter, Douglas, Bwanali, et al., 2010	*Experience Implementing a Point-of-Care Electronic Medical Record System for Primary Care in Malawi*	A point-of-care EMR system improves data quality and strengthens traditional RDE Health Management Information Systems.	The study focussed on data entry models and compared data capture at POC with data capture at RDE, while this study is more concerned with deployment of CDS at RDE as compared to CDS at POC.
Jawhari et al., 2016	*Barriers and facilitators to Electronic Medical Record (EMR) use in an urban slum.*	*Systems-related barriers* (e.g.,power, network, Internet, interoperability), *software-related barriers* (e.g., data integrity, confidentiality, function) and *social factors* (e.g., identity management, training, use incentives) are the most important impediments to EMR use and sustainability	The study was conducted in two urban clinics that were still in the process of adopting the EMR while this study was conducted in healthcare facilities with established EMR exposure. The study was also done in urban slum primary care clinics while this study covers

Author	Title	Findings	Research Gap
			a wider geographic and demographic scope.

2.3 Conceptual Framework

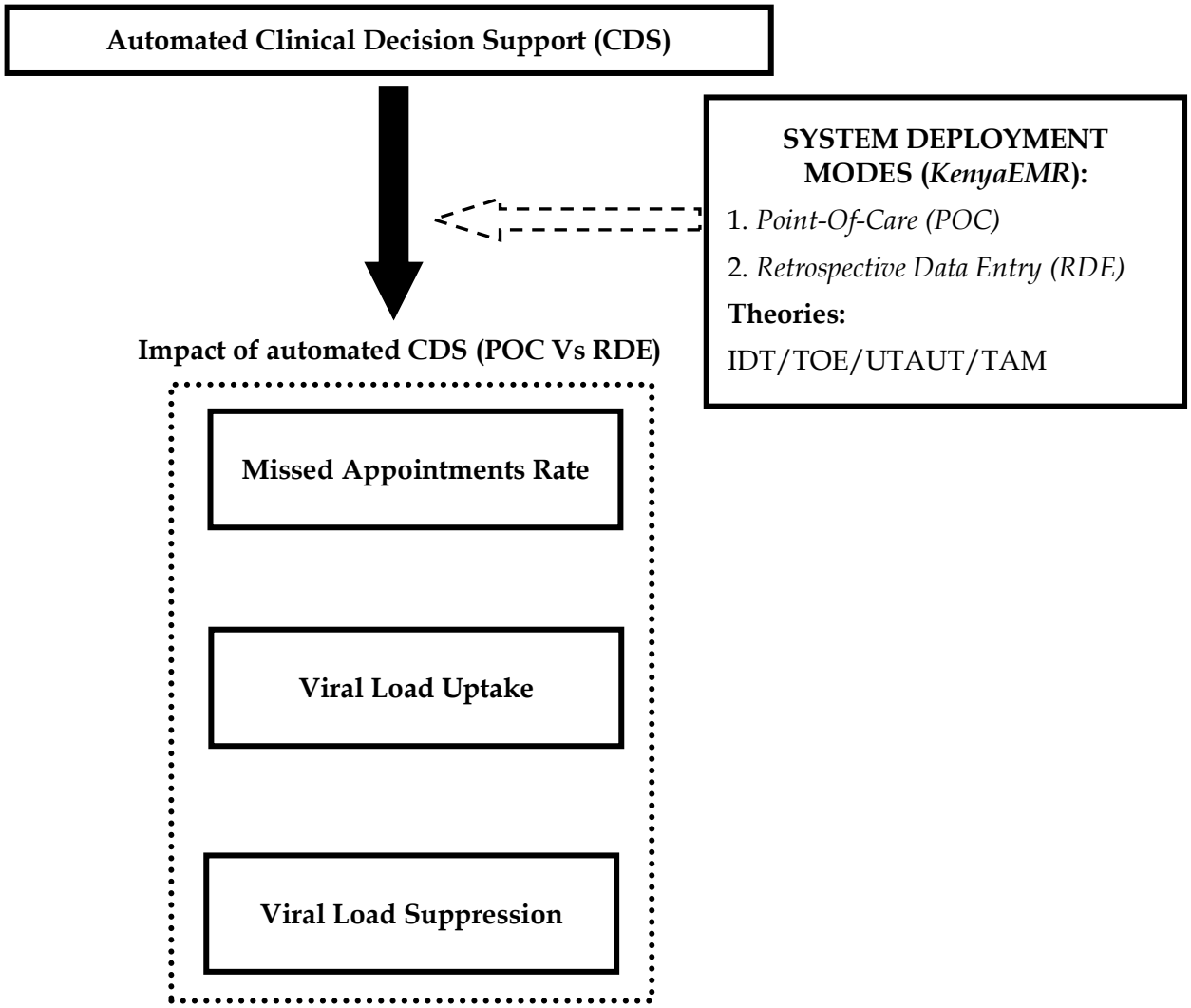


Figure 4: Conceptual Framework

The conceptual framework relates how clinical decision support impacts the three variables of *missed appointments rate*, *viral load uptake rate* and *viral load suppression rate*.

2.3.1 Missed Appointment Rate

The *missed appointment rate* relates to the number of honoured appointments based on the number of patients booked in a specified period. Studies have demonstrated the role of EMRs and CDS in reducing the *missed appointment rate* as well as number of patients who eventually get lost to clinical follow up. One such study done in Uganda and published in the National Institute of Health Journal (Alamo et al., 2012) concluded that electronic medical records and same day patient tracing significantly reduces the *missed appointment rate*. In this study, the CDS system was deployed at POC.

The 'no-show' and predictive modelling study conducted in the United States based on the Resource Management Service (RMS) EMR system demonstrated that appointment scheduling based on no-show probabilities significantly reduces the *missed appointment rate* (Daggy et al., 2010). This study dominantly utilised the RDE model of CDS deployment.

2.3.2 Viral Load Uptake Rate

The *viral load uptake rate* relates to the number of patients who undertake a scheduled laboratory viral load test from the total number of eligible patients. The role of EMR system screening alerts in increasing clinical and laboratory screening is documented in several studies. One such study in the United States concluded that such CDS alerts significantly increase hepatitis C and HIV screening rates in primary care practices (Tapp et al., 2020). This study was conducted on a system deployed at point-of-care.

In another study conducted in the UK, two computer physician order entry systems were modified to prompt health care workers to request an HIV test when other selected tests pointed to a higher probability of HIV infection (Chadwick et al., 2017). In the 3-month study period, there was a 6% increase in the HIV testing rate, pointing to a positive correlation between laboratory testing and EMR system prompts.

2.3.3 Viral Load Suppression Rate

The *viral load suppression rate* is a quality of care indicator that measures the percentage of HIV-infected patients with an undetectable viral load. Previous studies have

established a link between CDS and prevention of HIV-related immunological failure (Oluoch et al., 2016). The application of CDS features has also been demonstrated to improve CD4 counts in HIV-infected patients, pointing to better immunity (Robbins et al., 2012).

These variables are dependent on the mode of EMR system use (point-of-care versus retrospective data entry). The variables are therefore an indirect measure of the effectiveness of POC system use compared to a retrospective system deployment.

A lower comparative *missed appointment rate* means the prevailing system deployment mode is more effective and could thus have more desirable patient outcomes. In contrast, higher comparative *viral load uptake* and *viral load suppression rates* indirectly point to a more effective EMR system deployment mode and better patient outcomes.

2.3.4 Application of Theories

The *infusion diffusion theory* is useful in explaining why some health facilities take longer to transition from RDE setups to POC status (laggards) while some are early adopters. The *technology, organization and environmental theory* on the other hand might help explain the barriers facilities face in transitioning from RDE deployments to POC status, based on the prevailing technological, organizational, and environmental contexts. The *unified theory of acceptance and use of technology* and the *technology acceptance model* are both useful in explaining RDE-to-POC transition barriers as well as challenges used by the end users in RDE setups. Thus, the theories in concert determine the mode of CDS deployment at different facilities, which in turn affects the three variables of *missed appointments rate*, *viral load uptake rate* and *viral load suppression rate*.

2.3.5 Assumptions and Boundaries

The following assumptions and boundary conditions apply to the developed conceptual framework:

i. The same EMR system is deployed in both the RDE and POC set-ups. In the case of this study, the EMR system is *KenyaEMR*.
ii. The EMR system end users in both the RDE and POC set-ups are properly trained

and fully competent in the system's use within their respective contexts.

iii. There are no considerable externalities or significant intervening variables influencing the conceptual framework.

Conclusively, if there is no statistically significant variation on the three key patient outcomes based on the mode of system deployment, managers can forego the high costs associated with POC setups without much consequence. POC set-ups can also be foregone if RDE setups result in better patient outcomes.

2.3.1 Operationalization of Variables

The *missed appointment rate* relates to the number of honoured appointments based on the number of patients booked in a specified period. The *missed appointment rate* was calculated from the number of honoured patient appointments against all appointments made in the period January to March, 2019. The rate was obtained through a query designed to specifically filter out patient records from *KenyaEMR* system databases for the applicable facilities.

The *viral load uptake rate* relates to the number of patients who undertook a scheduled laboratory viral load test from the total number of eligible patients. These data were obtained through abstraction of secondary statistics from the NASCOP EID/VL website (https://eid.nascop.org/) for the period January to March, 2019.

The *viral load suppression rate* is a quality of care indicator that measures the percentage of HIV-infected patients with an undetectable viral load. These data were obtained through abstraction of secondary statistics from the NASCOP EID/VL website (https://eid.nascop.org/) for the period January to March, 2019.

Finally, the facility EMR champion mentors provided detailed qualitative data on various HMIS-related parameters as guided by the electronic questionnaire. These data included challenges encountered when using CDS systems retrospectively, as well as potential barriers to transitioning facilities from RDE to POC.

Table 2: Operationalisation of Variables

Variable	Variable Type	Indicators	Data Collection Tool	Data Analysis
Missed Appointment Rate	Dependent	Percentage of patients who missed their scheduled clinical appointment	Structured questionnaire and a database extraction query	Descriptive and inferential analyses
Viral Load Uptake Rate	Dependent	Percentage of eligible viral load tests undertaken	Structured questionnaire with online secondary data abstraction	Descriptive and inferential analyses
Viral Load Suppression Rate	Dependent	Percentage of HIV-infected patients with an undetectable viral load	Structured questionnaire with online secondary data abstraction	Descriptive and inferential analyses

Chapter 3: Research Methodology

3.1 Introduction

This chapter describes how the research project was conducted, detailing the sampling approach, the observational design, and statistical analysis.

The study was undertaken as mixed methods research, with qualitative data being obtained from the respondents. Additional quantitative data was obtained from facility local *KenyaEMR* databases as well as online on the NASCOP EID/VL website (https://eid.nascop.org/).

The selection of study participants is also discussed, as well as the data collection instruments. The chapter additionally outlines the sampling procedure and statistical techniques for data analysis that were employed.

3.2 Research Design

The research design relates to the structure that holds all the research elements together. It directs the research and depicts how all its various components work in concert to answer the research questions.

This research was conducted as a cross-sectional descriptive project due to time-related constraints. Additionally, a cross-sectional study is simple, affordable and does not suffer respondent loss to follow up (Levin, 2006). The study adopted both quantitative and qualitative approaches based on a structured e-questionnaire.

3.3 Study Area

The study covered 18 of the 22 counties that had active *KenyaEMR* installations as of July 2019. These included: Baringo, Bungoma, Busia, Elgeiyo Marakwet, Homa Bay, Kakamega, Kiambu, Kirinyaga, Kisii, Kisumu, Migori, Murang'a, Nandi, Nyamira, Nyandarua, Nyeri, Siaya, Trans Nzoia, Turkana, Uasin Gishu, Vihiga and West Pokot. The 18 counties were selected based on the applicable exclusion criteria.

Nyeri county was eliminated based on being unresponsive while Baringo, Uasin Gishu and West Pokot counties had both of their target facilities running in the same mode (POC).

Data was collected through a mobile-based application and e-questionnaire, thus making coverage of all the 18 counties possible (see section 3.4).

3.4 Target Population

The research project entailed in-depth telecom interviews with facility *KenyaEMR* champion mentors at the health facilities selected for inclusion into the study. The total number of facilities selected was 36 drawn from 18 counties (2 facilities per county). The researcher selected two facilities from every county based on quota sampling technique. This was informed by the limited time and resources available for the study. For cross-county uniformity, the facility selection was based on patient numbers. Consequently, the busiest POC and RDE facilities by patient volumes in each eligible county were chosen.

Other than the facility EMR champion mentors, no other person was directly engaged in the study.

3.4.1 Inclusion Criteria

Only counties with at least one health facility running *KenyaEMR* in POC mode and at least one health facility running *KenyaEMR* in RDE mode were included in the study. For each such county, the busiest POC and RDE facility (by active patient numbers) respectively was selected for inclusion into the study. Thus, for eligible counties, only two sites were included in the research.

3.4.2 Exclusion Criteria

The system under study was *KenyaEMR*. All facilities without KenyaEMR implementations were therefore not considered for inclusion into the research. Within the same county, if all facilities were running *KenyaEMR* in the same mode (purely POC or purely RDE for all facilities in the county), they were all excluded to allow for consistency in comparison. Unresponsive counties were also excluded from the study.

3.5 Sampling Design

The selection of eligible counties was based on purposive sampling, where all counties with facilities running the *KenyaEMR* system were selected for inclusion. A total of 22 counties were eligible at this stage.

The selected counties were then stratified into three categories: counties in which the system is purely deployed retrospectively in all facilities (0 counties); counties in which the system is purely deployed at point-of-care in all facilities (3 counties); and counties with dual deployment i.e., having at least one facility running the system retrospectively and at least one facility running the system at POC (19 counties).

Based on the exclusion criteria adopted, only counties with dual deployment were included in the study. However, Nyeri county was dropped for being unresponsive, leaving only 18 eligible counties.

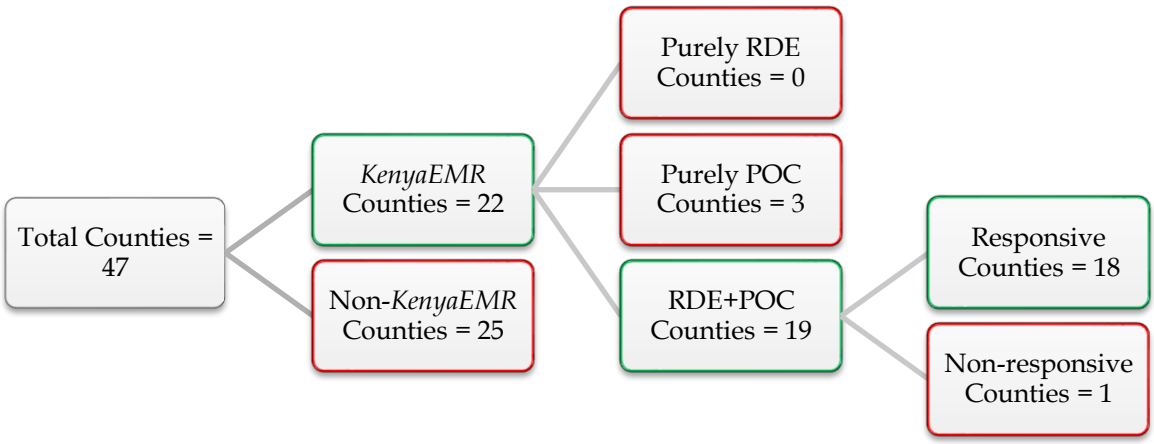


Figure 5: Selection of Target Counties

For the final accepted counties, the selection of target study participants was based on purposive sampling. This was necessary to ensure response uniformity, since all *KenyaEMR* mentors are adequately trained on the system. Thus, the risk of interpretive

respondent errors was significantly reduced since all the target participants had the same general understanding of the system and the questionnaire terminologies.

The facility *KenyaEMR* mentors at the busiest POC and RDE facility in each selected county - by active patient numbers respectively - were selected for inclusion into the study.

Thus, for eligible counties, only two facility EMR mentors were included in the research. A total of 36 facility *KenyaEMR* champions were consequently selected to participate in the study across all the eligible counties.

3.6 Data Collection and Analysis

The study employed a cross-sectional survey design to assess facilities as at a specific point in time. This was important because EMR system deployment status is a dynamic concept, with facilities continuously being transitioned from RDE to POC status.

As of July 2019, *KenyaEMR* was deployed in 22 eligible counties in Kenya, accounting for over 400 implementation instances. The study was done in the busiest facilities by active patient volumes in 18 of the 22 counties, based on the applicable inclusion and exclusion criteria. Nyeri county was eliminated based on being unresponsive while Baringo, Uasin Gishu and West Pokot counties had both of their target facilities running in the same mode (POC).

3.6.1 Data Collection Instrument

Data collection was done electronically via *Hoji*, an integrated mobile data collection tool. *Hoji* is an easy-to-use, professionally supported informatics software solution for surveys and assessments through e-questionnaires (https://www.hoji.co.ke)

The use of questionnaires is widely accepted in economic and business research (Fraenkel & Wallen, 2006). A structured e-questionnaire was developed for this study with a standard set of questions. The questionnaire was informed by the study objectives, research questions and the constructs of the conceptional framework.

A mix of open-ended and close-ended questions were included in the e-questionnaire, with appropriate skip patterns to avoid responded answering unintended or

unapplicable questions. The open-ended questions allowed for the respondents to include non-standard responses to the questions on *RDE end-user challenges* and the *RDE-to-POC transition barriers*. This was necessary to ensure all possible answers beyond those conceptualised by the researcher are accommodated.

3.6.2 Data Collection Procedure

Data collection included in-depth interviews with key informants (facility *KenyaEMR* champion mentors) based on the e-questionnaire. The *Hoji* system supports either direct data entry during an actual physical interview or indirect data entry for interviews done via telecom.

The researcher called all the target respondents and gave a brief background of the study and explained why they had been nominated for the study. At this point willingness to participate was asked of the respondents. Respondents who agreed to participate thereafter had a standard consent form sent to them electronically for signing upon which it was sent back to the researcher.

Upon receipt of signed consent forms, the researcher booked an appointment with the respective respondents and conducted the interview via telecom. All responses were keyed into the *Hoji*® android application and the data visualised on the synchronised *Hoji*® website for analysis and manipulation. Further analysis was done using *Minitab 20* ®.

The facility *KenyaEMR* champion mentors provided detailed information on various HMIS-related parameters as guided by the electronic questionnaire. Additional performance data for the test variables were obtained through abstraction of secondary statistics from electronic sources such as the NASCOP EID/VL website (https://eid.nascop.org/)

The data were analysed and presented using bar graphs, line graphs, word trees and other data presentation tools.

3.7 Data Quality Control

Research data quality control was achieved through reliability and validity tests performed on the e-questionnaire.

3.7.1 Data Reliability

A pilot study was conducted in test mode on ten facility *KenyaEMR* mentors conveniently drawn from non-selected sites within Trans Nzoia County. This enabled the researcher to gain more insights into the clarity of the questions as well as the dependability of the e-questionnaire.

The researcher also administered the e-questionnaire himself to avoid interpretive bias common with the use of research assistants. All the respondents also had to be the respective facility *KenyaEMR* mentors. The facility mentors are highly trained on the *KenyaEMR* system and therefore likely to enhance the data reliability. This is because the risk of interpretive errors is greatly reduced when the respondents adequately understand the *KenyaEMR*-specific jargon and are familiar with all the standard system-related terminologies.

To ensure overall data quality and integrity, the following actions were also undertaken:

i. Designing the electronic questionnaire clearly and including concise instructions where applicable.
ii. Accurate data collection through appropriate skip patterns, data entry checks, automatic data validation and controls for missed responses.

3.7.2 Data Validity

Data validity can be defined as the extent to which the result of a study truly reflects the variable under study. The research study employed content validity checks through expert advice obtained from the primary supervisor as well as the *KenyaEMR* system software developer, leading to refined revisions of the e-questionnaire. The jargon used in the questionnaire was also standardised to match the true meaning and interpretation at the study facility level.

3.8 Ethical Issues

The study was reviewed and approved by the Strathmore University Institutional Research and Ethics Committee (SU-IREC) before commencement. A NACOSTI permit was also sought.

Although the study was conducted in the healthcare context, it was designed so as not to require individual patient consent. All databases accessed were encrypted during transmission with password protected access. The research relied exclusively on de-identified data and did not include documentation of patient names, contact information, identification numbers, physically identifiable characteristics, or other such established identifiers.

Nonetheless, the eligible facility *KenyaEMR* mentors involved in the key informant interviews were asked for prior written consent upon understanding the risks and benefits of voluntary participation.

3.9 Dissemination Plan

The findings of the study were presented in a report form to the Institute of Healthcare Management (IHM), Strathmore University Business School for library reference. All participant counties and the national Ministry of Health may also receive copies of the report upon request.

Chapter 4: Presentation of Research Findings

4.1 Introduction

This chapter is concerned with the description and presentations of the research findings as well as inferential analysis. A descriptive depiction of the relationships between the variables under study is described and presented graphically.

4.2 Response Rate

The study targeted the following 22 eligible counties: Baringo, Bungoma, Busia, Elgeiyo Marakwet, Homa Bay, Kakamega, Kiambu, Kirinyaga, Kisii, Kisumu, Migori, Murang'a, Nandi, Nyamira, Nyandarua, Nyeri, Siaya, Trans Nzoia, Turkana, Uasin Gishu, Vihiga and West Pokot.

In each of these counties, one POC facility and one RDE facility were selected based on patient workloads. Nyeri county was eliminated based on being unresponsive while Baringo, Uasin Gishu and West Pokot counties were excluded because all their target facilities were running *KenyaEMR* in the same mode (POC).

Out of the 22 target counties, only 18 were therefore eventually included in the project, representing 36 health facilities. All the 36 facilities agreed to participate in the study through the respective facility *KenyaEMR* mentors. Thus, the response rate for the study was 100% with respect to eligible respondents.

4.3 Respondents' Demographics

The respondents by gender comprised 22 males (61%) and 14 females (39%). None of the respondents was the overall facility-in-charge at the participating sites.

Most of the EMR Champions (61%) were Health Records and Information Officers (HRIOs) despite the system being used for clinical decision support in all the respective facilities. None of the respondents was a Medical Officer, Pharmacist or Laboratory Technologist. Interestingly, only three (3) facility EMR Champions had a background in ICT.

A majority of the EMR Champions were stationed at the CCC, where the *KenyaEMR* system is located. The figure below depicts the distribution of the respondents by cadre and workstation:

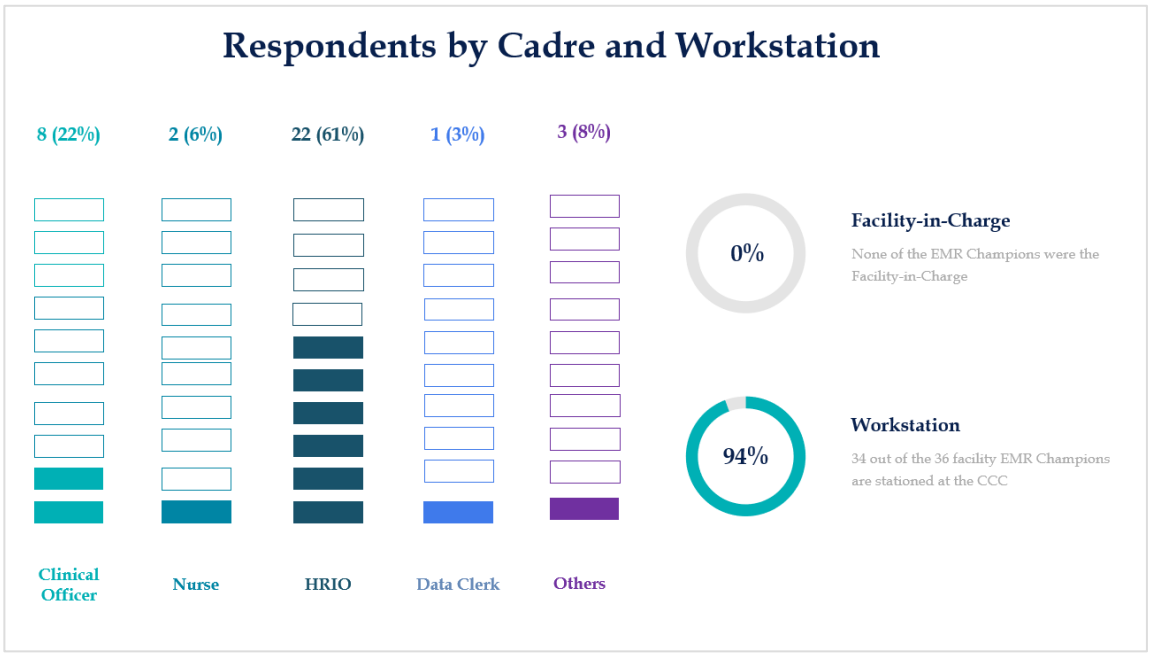


Figure 6: Respondents by Cadre and Workstation

4.4 *KenyaEMR* Landscape

Two facilities running *KenyaEMR* (one POC and one RDE deployment respectively) were selected in each of the eligible 18 counties. AMPATH, CRISSP and UMB were the most dominant implementing partners as well as care and treatment partners across all the *KenyaEMR* sites respectively.

4.4.1 Challenges of Retrospective CDS

84% of system users within the RDE sites reported duplication of work as the greatest challenge of retrospective deployment of the *KenyaEMR* system. Other dominant challenges of RDE system use reported by a majority (more than 50%) of the respondents included the following:

- Lack of quality, up-to-date and reliable data (74%)
- Delayed reporting of events (68%)
- Difficulty in retrieving patient data (68%)

- Insufficient continuity of patient care (63%)
- High cost of manual procedures and records (63%)
- Loss to follow up of patients (58%)
- Insufficient utilization of data and information (58%)

4.4.2 Barriers to Transitioning from RDE to POC deployment

Most of the respondents drawn from RDE *KenyaEMR* sites outlined the following potential barriers to transitioning to POC system use:

- Inconsistent power supply or lack of alternative power (95%)
- Negative staff attitude toward POC system use (74%)
- Limited infrastructure (too few terminals) for POC system use (68%)
- High turnover of trained staff competent at POC system use (58%)
- Concurrent deployment of multiple systems (47%)
- Legacy data migration requirement (42%)

4.5 Missed Appointment Rate

The mean missed appointment rate was lower for POC *KenyaEMR* system deployment (21.34%, SD 8.24) as compared to the RDE system deployment (31.58%, SD 15.47). For POC system use, the highest missed appointment rate recorded was 37.59% as compared to 81.06% for RDE system use. At 11.07%, *KenyaEMR* systems deployed at POC had the lowest missed appointment rate as compared to 11.82% for RDE system deployments.

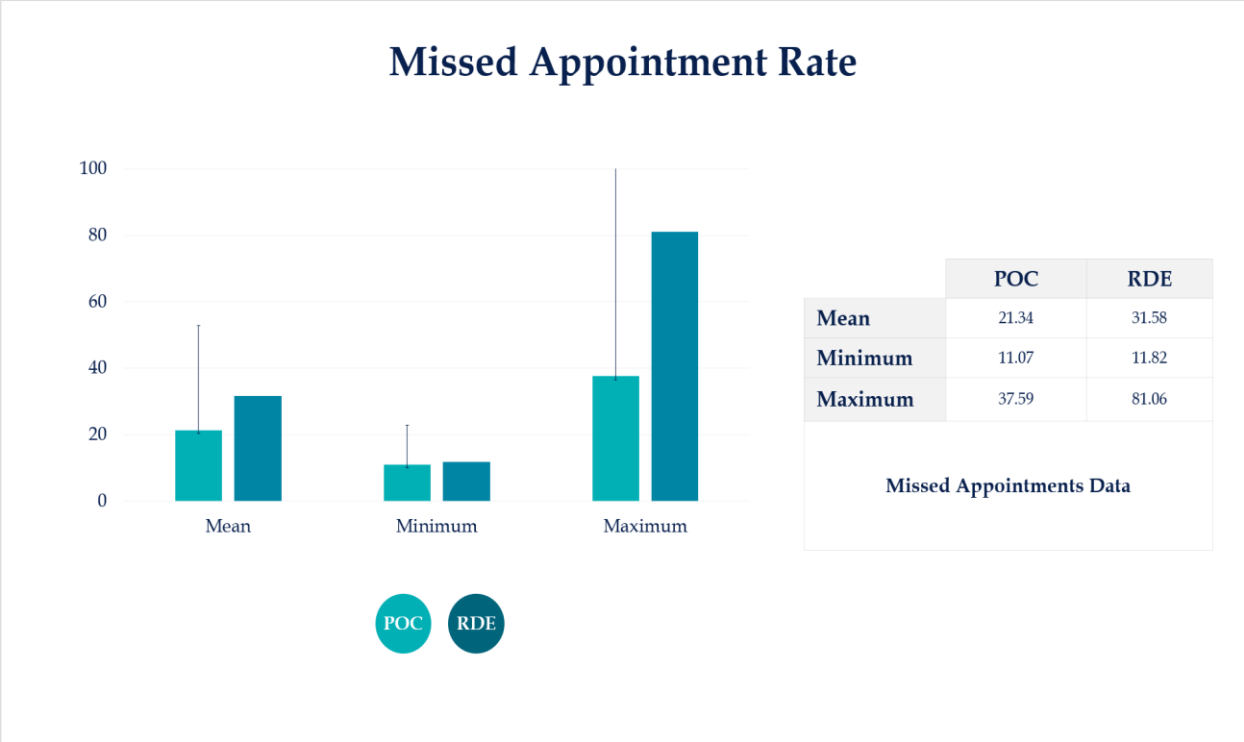


Figure 7: Missed Appointment Rate

4.6 Viral Load Uptake Rate

The mean viral load uptake rate was higher for POC *KenyaEMR* system deployment (42.06%, SD 10.49) as compared to RDE system deployment (37.56%, SD 10.03). For POC system use, the highest viral load uptake rate recorded was 63.0% as compared to 50.0% for RDE system use. At 17.0%, *KenyaEMR* systems deployed at RDE had the lowest viral load uptake rate as compared to 24.0% for POC system use.

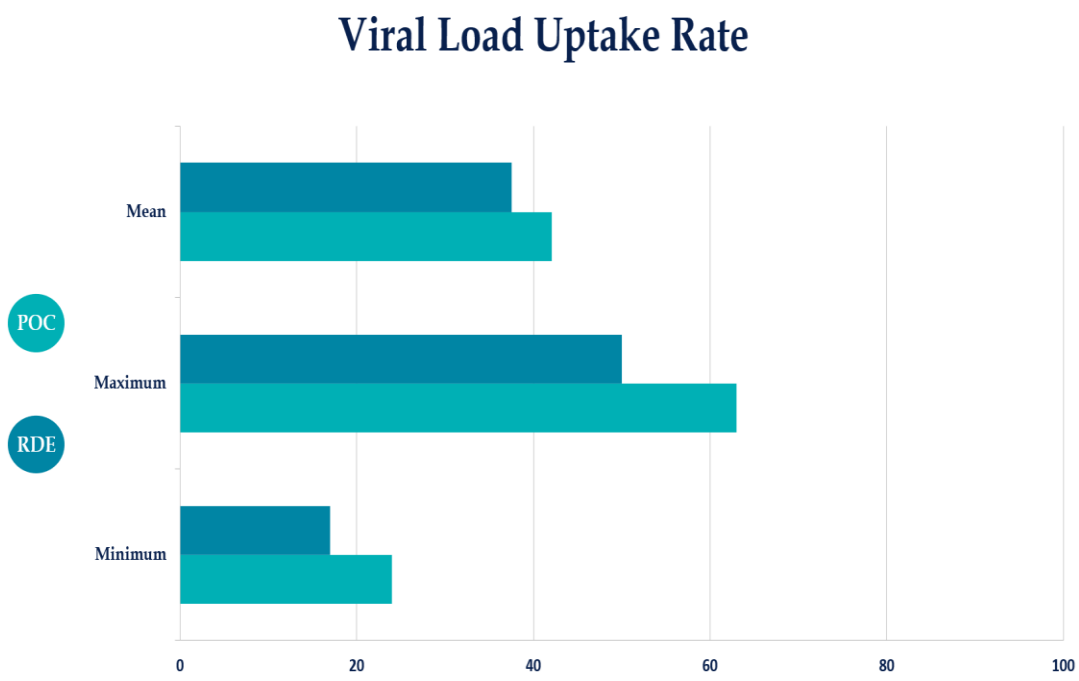


Figure 8: Viral Load Uptake Rate

4.7 Viral Load Suppression Rate

The mean viral load suppression rate for POC *KenyaEMR* system deployment (81.88%, SD 7.47) was comparable to RDE system deployment (79.67%, SD 7.63). For POC system use, the highest viral load suppression rate recorded was 90.70% as compared to 91.70% for RDE system use. At 66.70%, *KenyaEMR* systems deployed retrospectively had the lowest viral load suppression rate as compared to 68.90% for POC system use.

4.8 Graphical Summary - POC

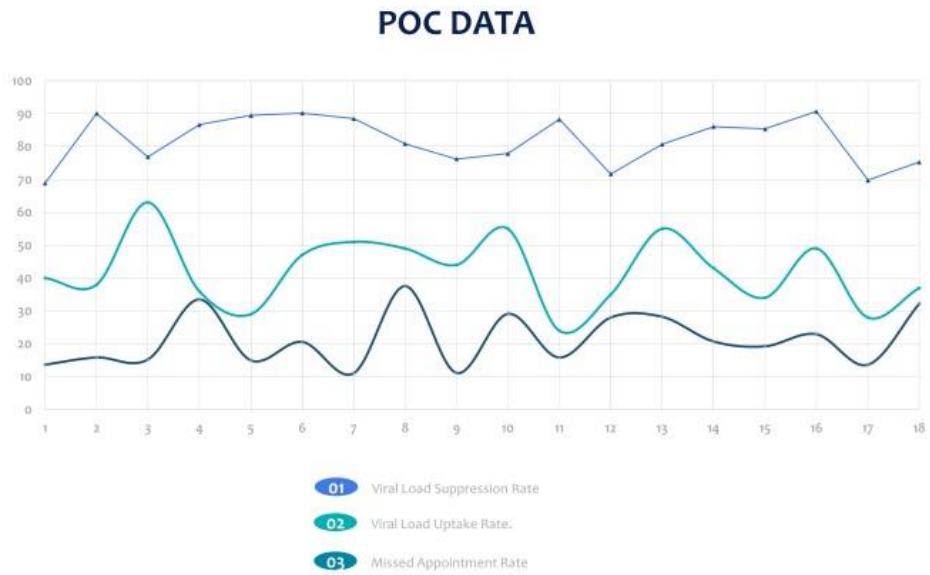


Figure 9: Summary of POC Data

4.9 Graphical Summary – RDE Data

Figure 10: Summary of RDE Data

4.10 Regression Analysis

The study modelled the relationship between the *missed appointment rate* and the *viral load uptake rate* for the various KenyaEMR deployment options. The simple regression models of viral load uptake rate on the missed appointment rate returned the following results:

4.10.1 POC Regression Analysis

Regression Equation

pVLU = 37.63 + 0.207 pMA

Where:

pVLU – *Viral load uptake rate for KenyaEMR systems deployed at POC*

pMA – *Missed appointment rate for KenyaEMR systems deployed at POC*

Coefficients

Term	*Coef*	*SE Coef*	*T-Value*	*P-Value*	*VIF*
Constant	*37.63*	*7.16*	*5.26*	*0.000*	
pMA	*0.207*	*0.314*	*0.66*	*0.519*	*1.00*

Model Summary

S	*R-sq*	*R-sq(adj)*	*R-sq(pred)*
10.6693	*2.65%*	*0.00%*	*0.00%*

4.10.2 RDE Regression Analysis

Regression Equation

rVLU = 34.85 + 0.086 rMA

Where:

rVLU – *Viral load uptake rate for KenyaEMR deployed for retrospective data entry*

rMA – *Missed appointment rate for KenyaEMR systems deployed for RDE*

Coefficients

Term	*Coef*	*SE Coef*	*T-Value*	*P-Value*	*VIF*
Constant	*34.85*	*5.62*	*6.20*	*0.000*	
rMA	*0.086*	*0.161*	*0.53*	*0.602*	*1.00*

Model Summary

S	*R-sq*	*R-sq(adj)*	*R-sq(pred)*
10.2490	*1.74%*	*0.00%*	*0.00%*

Chapter 5: Discussions, Conclusions and Recommendations

5.1 Introduction

This chapter describes the key findings in relation to the study objectives and gives inferential conclusions to the research questions. Possible recommendations are also made based on the study findings.

5.2 Discussions

5.2.1 Missed Appointment Rate

From the results, deploying the *KenyaEMR* system at point-of-care results in fewer patients missing their appointments (21.34%) as compared to when the system is used retrospectively (31.58%). This could be due to real time data entry, during which clinic adherence gaps can be discussed with the patient instantaneously.

The finding is consistent with a Ugandan study that found incorporating same day patient tracing with electronic medical records significantly reduced the *missed appointment rate* (Alamo et al., 2012). With retrospective data entry system deployments, such adherence gaps are often discovered after the fact and are therefore more difficult to remedy.

5.2.2 Viral Load Uptake Rate

Generally, the viral load uptake rate was unsatisfactory, irrespective of the mode of system deployment. The *viral load uptake rate* was statistically determined to be higher when *KenyaEMR* is deployed at point-of-care (42.06%) as compared to retrospective system deployment (37.56%).

This could be due to the increased meaningfulness of viral load testing reminders when the system is used at point-of-care (Tapp et al., 2020). The higher viral load uptake rate with POC *KenyaEMR* system deployment can also be explained by the fact that viral load laboratory requests can only be actualised during an actual patient visit. Viral load testing cannot be done retrospectively.

5.2.3 Missed Appointment Rate & Viral Load Uptake Rate

Based on the P-Values for both POC and retrospective *KenyaEMR* system deployments (0.519 and 0.602 respectively), the relationship between the *missed appointment rate* and the *viral load uptake rate* is statistically insignificant. This implies that there is no consequential statistical correlation or association between the two variables.

This can be explained by several possible reasons. Firstly, HIV viral load testing scheduling is done at specific, often long-term intervals (annually for most patients) while routine clinic appointments are usually scheduled more frequently (quarterly for most clients).

Secondly, due to the associated medical consequences, clinicians tend to emphasize HIV viral load testing appointments as opposed to routine clinic appointments. The incongruence in the two variables could also be explained by weak clinical-laboratory interphases (Alemnji et al., 2017).

The viral load uptake rate is also dependent on several other factors, unlike the missed appointment rate. For instance, lack of laboratory consumables or personnel would mean a lower viral load uptake rate even if the client presents themselves for the screening appointment.

5.2.4 Viral Load Suppression Rate

There was generally no statistically significant variation in the *viral load suppression rate* between the two modes of *KenyaEMR* system deployment under investigation. The mean viral load suppression rate for POC system deployment was 81.88% while the rate was 79.67% for *KenyaEMR* installations running retrospectively.

This finding suggests that variations in *KenyaEMR* system deployment do not significantly alter the adherence of healthcare service providers to national treatment guidelines. All patients are therefore likely to receive standard HIV/AIDS care, irrespective of the mode of *KenyaEMR* system deployment.

Interestingly, both system deployment modes registered high viral load suppression rates. This could mean CDS is useful for any EMR system, irrespective of the mode of

system deployment. This is consistent with similar findings in other studies (Oluoch et al., 2016; Robbins et al., 2012)

5.2.5 RDE End-user Challenges

From the findings of the study, applying CDS retrospectively poses several challenges to the end users. Firstly, there is duplication of work and effort since manual records must be updated before subsequently being transferred to the *KenyaEMR* system. This was a challenge to 84% of the respondents.

Many users (68%) also cited difficulty in retrieving patient data whenever required. This is probably because for facilities using *KenyaEMR* retrospectively, the manual source records are considered the gold standard. Thus, record retrieval is usually based on the manual patient files. Additionally, retrospective data entry may result in data mismatches and losses between the manual and electronic patient medical records, leading to data retrieval challenges.

63% of the respondents using the *KenyaEMR* system retrospectively reported insufficient continuity of patient care as a challenge. This could be because data is often entered into the system after the patient has exited the facility, rendering the clinical decision support system less useful for critical care interventions.

Other significant end-user challenges included high cost of manual procedures (63%), increased lost-to-follow-up patient rates (58%) and insufficient utilization of data and information (58%).

5.2.6 RDE-to-POC Transition Barriers

The *KenyaEMR* CDS system can either be used at point-of-care or retrospectively. The study explored potential barriers limiting the transition of facilities from using the *KenyaEMR* system retrospectively to point-of-care use.

Most of the respondents (95%) cited inconsistent power supply or lack of alternative power as a barrier to point-of-care transition. This is especially because for POC mode, there are no manual patient files and therefore the system must be powered throughout.

Negative attitude by clinical staff towards POC *KenyaEMR* system use was also cited as a potential transition barrier by 74% of the respondents. This could be due to capacity building gaps leading competency deficiencies in the respective healthcare providers. Additionally, with POC use, responsibility over the integrity, accuracy and confidentiality of the data within the system shifts to the actual clinicians and providers. Some providers might find the extra responsibility overwhelming.

In 68% of the RDE *KenyaEMR* facilities, the number of terminals available were inadequate for POC transition, pointing to an infrastructural barrier. POC KenyaEMR requires that all service points have a working terminal, which may require huge capital outlays.

Other potential barriers to *KenyaEMR* point-of-care transition included high turnover of trained, competent staff (58%), concurrent deployment of multiple silo systems (47%) and the condition for legacy data migration before transition (42%).
These potential RDE-to-POC transition barriers are closely related to those established in other related studies. For instance, a Kenyan study in two urban primary care clinics running the same open-source EMR system revealed similar transition-related barriers (Jawhari et al., 2016).

5.3 Conclusion

From the study findings, the missed appointment rate for patients attending HIV/AIDS clinics is lower when the *KenyaEMR* clinical decision support system is deployed at point-of-care as compared to retrospective system deployment.

Secondly, when clinical decision support systems are deployed at point-of-care for HIV/AIDS care, the viral load testing uptake rate is significantly higher than when the systems are used retrospectively.

From the study, there is no significant difference in the viral load suppression rate across facilities running clinical decision support systems in either POC or RDE mode. The

mode of system deployment therefore does not significantly impact a health facility's viral suppression rate.

When clinical decision support systems are applied retrospectively, the end-users experience several challenges including duplication of work, laborious retrieval of patient data, insufficient continuity of patient care, high cost of manual processes, high patient drop-out rates and insufficient utilization of data and information.

Many health facilities that wish to transition from retrospective data entry to point-of-care system deployment often face potential switching barriers. These barriers include inconsistent power supply, negative attitude by the clinical staff, infrastructural inadequacies, high staff turnover, existence of multiple silo health information management systems and legacy data migration conditional requirements.

5.4 Recommendations for Policy and Practice

Based on the findings drawn from the study, the following recommendations are proposed:

i. All facilities running CDS systems retrospectively for HIV/AIDS care should be supported to transition to point-of-care status, for better patient outcomes. The potential barriers to transition should be independently determined for each such facility to ensure a seamless transition.
ii. There is also need for more clinical staff to be trained on the *KenyaEMR* system within the respective facilities, for better patient outcomes and faster transition from retrospective CDS to point-of-care CDS. This will also ensure CDS systems are used for better clinical decisions rather than just for data management.
iii. Where possible, health facility-in-charges should be trained as facility EMR mentors to ensure managerial support for clinical decision support systems within their respective institutions.

5.5 Recommendations for Further Research

The author posits the following areas for further study:

i. A comparative analysis on CDS systems deployed in the hybrid mode (using both POC and RDE).

ii. It is also recommended that an in-depth analysis of the challenges of using CDS systems retrospectively be done to better understand the problem. This study only enumerated the potential challenges as suggested by the respondents but made no attempt to analyse them.

iii. A detailed analysis of the potential barriers to point-of-care CDS transition from retrospective CDS should equally be done. This study only enumerated the potential barriers as suggested by the respondents but made no attempt to analyse them.

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APPENDICES

e-Questionnaire Data Sets

POC/RDE FACILITY DATA COLLECTION		REMARKS
1.	County	County within which the data collection is taking place
2.	Facility Name	Preselected from a list of eligible facilities, based on the County selected in 1 above
3.	Master Facility List (MFL) Code	Auto-selects based on the facility selected in 2 above
4.	Facility EMR Champion Mentor	Full name of the respondent for the facility questionnaire / form
5.	Cadre	Cadre of the respondent (selected from a list that allows for unlisted entries)
6.	Facility-in-Charge?	Clarification on whether the respondent is also the Facility-in-Charge (Y/N)
7.	Work Station	Where the respondent works within the facility (Two options only: CCC or Other - specified)
8.	*KenyaEMR* mode of use	Declaration on mode of system use (POC/RDE) at the facility under analysis (auto-selects based on the facility selected in 2 above)
9.	Implementing partner	Name of implementing partner for the facility (selected from a list that allows for unlisted entries)
10.	Care and treatment partner	Name of C&T partner for the facility (selected from a list that allows for unlisted entries)
11.	Total number of patient appointments between Jan - March 2019 (from system database records)	Data obtained through a query designed specifically to filter out records from system databases for the applicable facilities. *Auto-calculation of the missed appointment rate*
12.	Number of late patient visit counts (missed patient appointments) between Jan - March 2019 (from system database records)	
13.	Proportion of patients who missed appointments	Missed appointments rate (auto-calculated)
14.	Viral load uptake rate (Jan - Mar 2019)	Data abstracted from an online source (https://eid.nascop.org/)
15.	Viral load suppression rate (Jan - Mar 2019)	

16.	Challenges encountered by end-users when using CDS at RDE	Only applicable to RDE sites
17.	Potential barriers to transitioning from RDE to POC mode	Only applicable to RDE sites

Project Timetable

Masibo W. Sammy 111909	**Automated Clinical Decision Support in HIV/AIDS Management: A comparative Study on Point-of-Care and Retrospective Data Entry Outcomes**				
Project Start Date:	8-1-2019 (Thursday)				
Project Lead:	Self				
TASK	**START**	**END**	**DAYS**	**% DONE**	**WORK DAYS**
Research Project					
Research Proposal	Thu 01-08-19	Wed 20-11-19	112	100%	77
Proposal Defense	Tue 10-12-19	N/A	1	100%	1
Data Collection	Mon 10-02-20	Tue 31-03-20	51	0%	36
Writing of Dissertation	Wed 01-04-20	Thu 30-04-20	30	40%	22
Dissertation Defense	TBD	N/A	1	0%	1

Consent Form

Title of the Study	Automated Clinical Decision Support in HIV/AIDS Management: A comparative Study on Point-of-Care and Retrospective Data Entry Outcomes
Study Description	You are invited to participate in a research study conducted by *Sammy Wundundi Masibo*, an MBA student in Healthcare Management at the Strathmore University Business School. The study seeks to collect information on various aspects of your use of the *KenyaEMR* system. Your voluntary participation shall involve being interviewed through a questionnaire either on site or electronically.
Risks	There are no anticipated risks associated with this research
Perceived Benefits	The researcher shall benefit through partial fulfilment for the award of an MBA (Healthcare Management). The findings will also add to the existing body of knowledge and possibly inform how future *KenyaEMR* deployments shall be implemented.
Confidentiality	All information collected shall be treated with utmost confidentiality. The anonymity of the respondents shall be maintained at all times, including after the study. The primary data collected shall be securely stored in an encrypted database and shall only be used for the purpose of this research.
Voluntary Participation	Your participation in this study is entirely voluntary. You may choose not to participate and may withdraw your consent to participate at any time in the course of the interview. You will not be penalized in any way should you decide not to participate or to withdraw from this study.
Contact Information	For any clarifications on the consent please contact me as follows: *Sammy Wundundi Masibo* *0722-540-959* *Institute of Healthcare Management* *Strathmore University Business School*

Consent

I have read and understood this consent, as well as been given the opportunity to ask any incidental questions. I voluntarily give my consent to participate in this study.

Participant's signature: Date:

..../...../2020

Declaration by Principal Investigator

I have clearly explained to the participant the purpose and expected benefits of this study and have answered his/her questions regarding the study on the date of this consent form

Investigator's signature: Date:

..../...../2020

IERC Approval

Strathmore UNIVERSITY

3rd March 2020

Dr Masibo, Sammy
sammy.masibo@strathmore.edu

Dear Dr Masibo,

RE: Automated Clinical Decision Support in HIV and AIDS Management: A Comparative Study on Point-of-Care and Retrospective Data Entry Outcomes

This is to inform you that the SU-IERC has reviewed and **approved** your above research proposal. Your application approval number is **SU-IERC0630/20.** The approval period is **3rd March, 2020 to 2nd March, 2021.**

This approval is subject to compliance with the following requirements:

i. Only approved documents including (informed consents, study instruments, MTA) will be used
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by SU-IERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to SU-IERC within 72 hours of notification
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to SU-IERC within 72 hours
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to SU-IERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

for: Dr Virginia Gichuru,
Secretary; SU-IERC

STRATHMORE UNIVERSITY INSTITUTIONAL ETHICS REVIEW COMMITTEE (SU-IERC)
03 MAR 2020
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This is to Certify that Dr.. sammy wundundi masibo of Strathmore University, has been licensed to conduct research in Baringo, Bungoma, Busia, Elgeyo-Marakwet, Homabay, Kakamega, Kiambu, Kirinyaga, Kisii, Kisumu, Migori, Muranga, Nandi, Nyamira, Nyandarua, Nyeri, Siaya, Transnzoia, Turkana, Vihiga, Westpokot on the topic: Automated Clinical Decision Support in HIV and AIDS Management: A Comparative Study on Point-of-Care and Retrospective Data Entry Outcomes. for the period ending : 30/March/2021.

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