MOI UNIVERSITY

SCHOOL OF MEDICINE

EVALUATION OF PATIENT-SPECIFIC MOBILE PHONE–GENERATED REMINDERS FOR HYPERTENSION CARE IN PRIMARY CARE SETTINGS IN WESTERN KENYA

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A Research Thesis submitted in partial fulfillment of the requirement for the award of the degree of Master of Science in Health Informatics in the School of Medicine of Moi University

Declaration

1. Student's Declaration

This research thesis is my original work and has not been presented for a degree in any other university. No part of this research thesis may be reproduced without prior written permission of the author and/or Moi University.

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SM/PGHI/07/2015

Sign: ……………………………................... **Date**: ……20-April 2022…….

2. Declaration by Academic supervisors

This research thesis has been submitted with our approval as the university academic supervisors.

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Dedication

This work is dedicated to my grandmother Maria, my mother Leah, my wife Emma and my daughter Liana. The gift of strong women whose tireless work and effort span an entire generation. You give forth life from eternity to eternity. Your stories will be told forever.

Abstract

Background: Kenya has a high prevalence of hypertension with rates of 20 – 50% in urban areas. Hypertension care is limited to few highly skilled healthcare facilities with physicians and better diagnostic and clinical care. The Academic Model Providing Access to Healthcare (AMPATH) – Chronic Disease program has instituted task-shifting of hypertension care to dispensaries and health centers with the use of smartphones for electronic data capture and clear hypertension care algorithms and clinical decision support systems (CDSS) rules implemented to ensure best quality of care.

Objective: To evaluate the impact, adherence and clinician barriers to use of patient-specific mobile phone–generated care suggestions for hypertension care in primary care settings in western Kenya.

Methods: This was a prospective comparative study that was conducted in Ministry of Health dispensaries and health centers offering hypertension care in two counties in western Kenya: Uasin Gishu (Turbo sub-county) and Nandi (Chesumei sub-county). Study participants were patients with hypertension. Participants were clustered into the intervention or control group Participants in the intervention group were seen by clinicians who had an mHealth application that generated and availed patient-specific care suggestions during the clinical encounter. In the control arm, care suggestions were triggered in the application but not availed to the providers. A log of the triggered care suggestions in both the control and intervention groups was maintained. The unit of analysis for all analyses was each generated hypertension care suggestion in both the control and intervention groups. Data analysis was done using STATA version 13 SE (College Station, 77845 Texas USA). Comparison of the median for continuous variables was done using two-sample Wilcoxon rank-sum test. Pearson's Chi Square test was used to assess the association between the independent categorical variables and the study arms.

Results: In the study, 378 patients with hypertension had care encounters in which care suggestions were generated (217 in intervention group and 161 in control group). Participants were similar by age, gender and blood pressure ($P>0.05$). Proportion of participants with SBP $\geq$ 140 mm Hg | DBP $\geq$ 90 mm Hg were similar in the two groups (67.4% vs. 61.0%, $p = 0.198$) respectively. A total of 440 of 481 generated care suggestions were fulfilled in the intervention group and 318 of 371 in the control group. There was a higher proportion of adherence to hypertension care suggestions in the intervention group due to the presence of patient specific care suggestions compared to the control group 91.1% vs. 85.7%, however this was not statistically significant with adjusted odds ratio (AOR): 1.78 (95% CI: 0.83, 3.80). Adherence to patient-specific care suggestions had no significant impact on blood pressure control (OR: 2.41, CI: 0.60 – 9.67).

Conclusion: Presence of patient-specific care suggestions led to higher adherence to hypertension care guidelines. However, no impact of care suggestion was observed on blood pressure control.

Recommendation: Use of patient-specific care suggestions should be considered as an additional strategy for improving adherence to hypertension care guidelines. We recommend further mixed methods studies to elucidate the cause of poor control of blood pressure other than adherence to care guidelines.

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I would like to thank all the patients, nurses and clinical officers who participated in this study. I would also like to thank all sub – county health teams that approved this study to take place in the Ministry of Health dispensaries and health centers.

I would like to sincerely thank my wife, Emma and daughter, Liana, parents and siblings for their constant support and encouragement through this labor intensive process. I would also like to thank Simon Savai who helped me with all the programming required for the study. Finally, I would like to thank my research assistant Lawrence Misoi and Steven Rono who helped me collect the data reported in this thesis.

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List of abbreviations

AMPATH	-	Academic Model Providing Access to Healthcare
AMRS	-	AMPATH Medical Records System
CCB	-	Calcium channel blockers
CDM	-	Chronic Disease Management
CDSS	-	Clinical Decision Support Systems
CPOE	-	Computerized provider order entry
CVD	-	Cardiovascular disease
DBP	-	Diastolic blood pressure
DM	-	Diabetes mellitus
DMS	-	Device Management and Security
EDC	-	Electronic data capture
EHR	-	Electronic health records
HCTZ	-	Hydrochlorothiazide
HIV	-	Human Immunodeficiency Virus
IBMI	-	Institute of Biomedical Informatics
IOS	-	Iphone Operating System
IREC	-	Institutional Research and Ethics Committee
IQR	-	Interquartile range
KNH	-	Kenyatta National Hospital
LMIC	-	Low- and Middle-Income Countries
MOH	-	Ministry of Health
MTRH	-	Moi Teaching and Referral Hospital
MUCHS	-	Moi University College of Health Sciences

MUSOM	-	Moi University School of Medicine
NCDs	-	Non-Communicable Diseases
NHIF	-	National Hospital Insurance Fund
OR	-	Odds ratio
SBP	-	Systolic blood pressure
SD	-	Standard deviation
SSA	-	Sub-Saharan Africa
WHO	-	World Health Organization
MNCH	-	Maternal, Newborn and Child Health
USAID	-	United States Agency of International Development
WHO	-	World Health Organization

Definition of terms

Care suggestion/ reminder

Reminders or reminders systems are used to notify healthcare providers of important clinical tasks that need to be done before an event occurs. For example, an outpatient clinic reminder system may generate a list of laboratory investigations that each patient requires on a particular clinic visit.

Task – shifting

The allocation of tasks in health – system delivery to the least costly health worker capable of doing that task reliably. Task-shifting describes a situation where a task normally performed by a physician is transferred to a health professional with a different or lower level of education and training, or to a person specifically trained to perform a limited task only, without having formal health education.

Mobile health (m-Health)

Mobile health is the use of mobile communication technology in the health arena. M-Health is the new edge on healthcare innovation. It proposes to deliver healthcare anytime and anywhere, surpassing geographical, temporal, and even organizational barriers. M-Health systems and its corresponding mobility functionalities have a strong impact on typical healthcare monitoring and alerting systems, clinical and administrative data collection, record maintenance, healthcare delivery programs, medical information awareness, detection and prevention systems, drug-counterfeiting and theft. Typical m-Health services architectures use the Internet and Web services to provide an authentic pervasive interaction among doctors and patients. A physician or a patient can easily access the same medical record anytime and anywhere through his/her personal computer, tablet, or smartphone.

Clinical decision support systems

A clinical decision support system is any electronic system designed to aid directly in clinical decision making, in which characteristics of individual patients are used to generate patient-specific assessments or recommendations that are then presented to clinicians for consideration

CHAPTER ONE: INTRODUCTION

1.1 Background

Non-communicable diseases (NCDs) require a well-integrated healthcare system to meet chronic health care needs. This is a challenge for most countries in Sub-Saharan Africa (SSA), which are faced with limited human, financial, and infrastructure resources (Bloomfield et al., 2014). Globally, NCDs constitute a major challenge to socioeconomic development, environmental sustainability and poverty alleviation. Four categories of NCDs – cardiovascular diseases, cancer, chronic respiratory diseases and diabetes – make the largest contribution to NCD morbidity and mortality ((WHO), 2012).

Hypertension is the leading risk factor for cardiovascular disease and the number one cause of premature death globally. In 2010, 31.1% of the global adult population had hypertension. However, this prevalence varies greatly depending on the social and economic circumstances of a region. A systematic review of population-based studies from 90 countries globally showed wide disparities with prevalence in low and middle income countries being 31.5%, while that in high income countries being 28.5% (Mills et al., 2016). A countrywide survey in Kenya in 2015 showed an age standardized prevalence of hypertension of 24.5% (Mohamed et al., 2018). In view of the high double disease burden of both communicable diseases and NCDs in SSA, and Kenya in particular, innovative models of healthcare delivery that integrate novel use of human and technological resources offer potential solutions for SSA ((WHO), 2002).

The use of mobile communication technology in the health arena (mHealth) has been highlighted as a key strategy to combat NCDs in low- and middle-income countries (LMICs), and this was emphasized during the 2011 United Nations High Level Meeting on Non-Communicable Diseases (NCDs) ((WHO), 2012). In SSA, implementation of mHealth solutions has been increasing, but evidence for a positive effect of these systems on health outcomes is sparse. The efficacy of mHealth interventions in NCD management has been based on two sets of intersecting parameters: health system challenges and spectrum of disease (Bloomfield et al., 2014). The health system challenges to NCD care are prophylaxis and prevention, detection and diagnosis, linkage to care, long-term follow-up, providing high quality care, and coordination of care. The spectrum of disease ranges from those who are healthy to those with complications of disease (Bloomfield et al., 2014). mHealth innovations, offer opportunities which when used appropriately could help strengthen health systems and facilitate the delivery of essential health interventions. Rather than being used as stand-alone solutions, these innovations should be integrated into existing health system functions. As such, they should be used to complement the health system goals, which include: health service provision; well -performing health workforce; functioning health information system; cost-effective use of medical products & technologies and accountability & governance (Labrique, Vasudevan, Kochi, Fabricant, & Mehl, 2013).

The advent of mHealth has redefined the boundaries of the electronic health records. OpenMRS, a popular mHealth-enhanced EHR, allows frontline health workers to access information from a patient's health record using a mobile device and to contribute information into the health record (OpenMRS, 2021). Clinical officers and nurses in dispensaries and health centers at the point-of-care can access and contribute to longitudinal health records, allowing continuity of care that was previously impossible in non-hospital-based settings. This has been demonstrated for management of hypertension in low resource settings (Jindal et al., 2018).

The use of mHealth for electronic data capture at the point-of-care has brought along with it the challenge of ensuring that the quality of care provided to patients is maintained. Ensuring healthcare providers' adherence to protocols is a paramount challenge to implementing complex care guidelines. In particular, shifting tasks, such as screening responsibilities, from physicians to community health workers often entails adapting procedures designed for physicians to cadres with limited formal training. mHealth initiatives that incorporate point-of-care decision support tools with automated algorithm- or rule-based instructions help ensure quality of care in these task-shifting scenarios by prompting clinical officers, nurses and community health workers to follow defined guidelines through clinical decision support tools (Labrique et al., 2013).

A Clinical Decision Support System (CDSS) is "any electronic system designed to aid directly in clinical decision making, in which characteristics of individual patients are used to generate patient-specific assessments or recommendations that are then presented to clinicians for consideration" (Kawamoto, Houlihan, Balas, & Lobach, 2005). CDSS are by and large intended to support healthcare workers in the normal course of their duties, assisting with tasks that rely on the manipulation of data and knowledge. Classic CDSS automatically remind the clinician of a specific action, or provide care summary dashboards that provide performance feedback on quality indicators. The output of classic CDSSs may include alerts, reminders, order sets and drug-dose calculations. These systems have been shown to improve prescribing habits, reduce serious medication errors and enhance delivery of preventive care services.(Kawamoto et al., 2005) The broad process of CDSS has been characterized as improving outcomes by addressing five '***rights***'*:* delivering the '*right*' evidence based information to the '*right*' people (patients and clinicians), in the '*right*' format, through the '*right*' channels at the '*right*' time.(Jenders, 2017) A systematic review by Bright et al in 2012 showed that CDSS had a favorable effect on prescribing treatments (OR, 1.57 [CI, 1.35 to 1.82]), facilitating preventive care services (OR, 1.42 [CI, 1.27 to 1.58]), and ordering clinical studies (OR, 1.72 [CI, 1.47 to 2.00]) across diverse venues and systems (Bright et al., 2012).

CDSSs can be locally developed and integrated into a computerized physician order entry (CPOE) or EHR system, with system-initiated recommendations delivered synchronously at the point of care. The recommendations delivered may or may not require a mandatory clinician response (Bright et al., 2012). The system–initiated recommendations generated automatically may be delivered in real time to enable decision making during the provider–patient encounter through CPOE.

CDSS has been implemented in western Kenya through the AMPATH HIV care program with demonstrable results. A study by Were at al. at AMPATH in 2011 provided compelling evidence that clinical summaries containing mobile phone –generated care suggestions improved clinician adherence with HIV care guidelines in the resource-limited settings of SSA (OR, 1.80 [CI 1.34 to 2.42], p<0.0001) (Were et al., 2011). Another study at AMPATH among pediatric patients, found a fourfold increase in the completion of overdue clinical tasks when care suggestions were availed to providers over the course of the study (68% intervention vs 18% control, p<0.001). Compliance by clinicians to patient-specific care suggestions generated by CDSS has been shown to vary depending on the type of reminder (Were et al., 2013). In a study by Were at al., various reasons have been documented for noncompliance with care suggestions, these included: test previously ordered, patient refused or the clinician disagreed with the care suggestion or considered it not applicable (Were et al., 2013). Similar reasons for non-compliance to clinical care suggestions have been established in other studies (Litzelman & Tierney, 1996). Compliance to the care suggestions was shown to improve when clinicians were offered an opportunity to indicate the reasons for noncompliance with the care suggestions.

1.2 Problem statement

Provision of hypertension care in primary care facilities (dispensaries and health centers) offers a good opportunity for provision of quality care for patients in rural western Kenya. Task shifting is an approach in which nurses and clinical officers are trained to treat hypertension (Mullan & Frehywot, 2007). Such a cadre of professionals can aggressively detect and manage hypertension and its complications as has been demonstrated for HIV and other non-communicable diseases (Kengne, Awah, Fezeu, Sobngwi, & Mbanya, 2009; Scanlon & Vreeman, 2013). Effective and sustainable large-scale task-shifting is only possible when the disease can be managed with simple, straightforward protocols, with early detection and clear referral systems. In the absence of protocols, task-shifting may lead to low quality care. Therefore, there is need for mechanisms to ensure consistent and high quality care. This can be achieved by using innovative mHealth technologies that include use of smartphones for electronic data capture with CDSS through generation of patient-specific care suggestions during the patient – provider encounter. The effectiveness and usefulness of these patient-specific care suggestions has been demonstrated in HIV care (Were et al., 2011). The successful use of CDSS in HIV care programs may be attributed to presence of clear care algorithms and the massive financial support from the government of Kenya and international donor agencies led by the USAID. Similar successes and effectiveness of patient-specific care suggestions for chronic disease care, especially hypertension, is not guaranteed with the minimal patient and health care system support systems compared to that given to HIV care systems. In addition, these models have not been evaluated for hypertension in a resource-limited setting of SSA such as the AMPATH CDM program.

1.3 Study justification

Kenya suffers from a critical shortage of healthcare workers and nurses and clinical officers have been trained to aggressively detect and manage hypertension and its complications (Vedanthan et al., 2020). The AMPATH/CDM program has a unique opportunity to demonstrate that nurses and clinical officers can effectively manage hypertension through its large network of health centers and dispensaries. Currently, the task-shifting approach at AMPATH has been augmented with use of smartphones for electronic data entry by clinicians during patient encounters with generation of patient-specific care suggestions for specific clinical conditions.

The effectiveness of patient-specific care suggestions for chronic disease care especially hypertension has not been evaluated in a resource – limited setting such as the AMPATH CDM program. Therefore, I propose to evaluate the use of patient-specific mobile phone – generated care suggestions for hypertension care in primary care facilities (dispensaries and health centers) in two sub – counties in western Kenya. If demonstrated to be effective, use of patient-specific care suggestions is scalable and can be rolled out in a larger scale so that nurses and clinical officers can be trained to curb the rising epidemic of hypertension in Kenya and SSA in general. This this study, set out to evaluate the impact, adherence and clinician barriers to use of patient-specific mobile phone – generated care suggestions for hypertension care in primary care facilities (dispensaries and health centers) in two sub – counties in western Kenya.

1.4 Research question

What is the adherence to and impact of patient-specific mobile phone–generated care suggestions (reminders) delivered via a smartphone application by clinicians offering hypertension care in primary care facilities in western Kenya?

1.5 Objectives

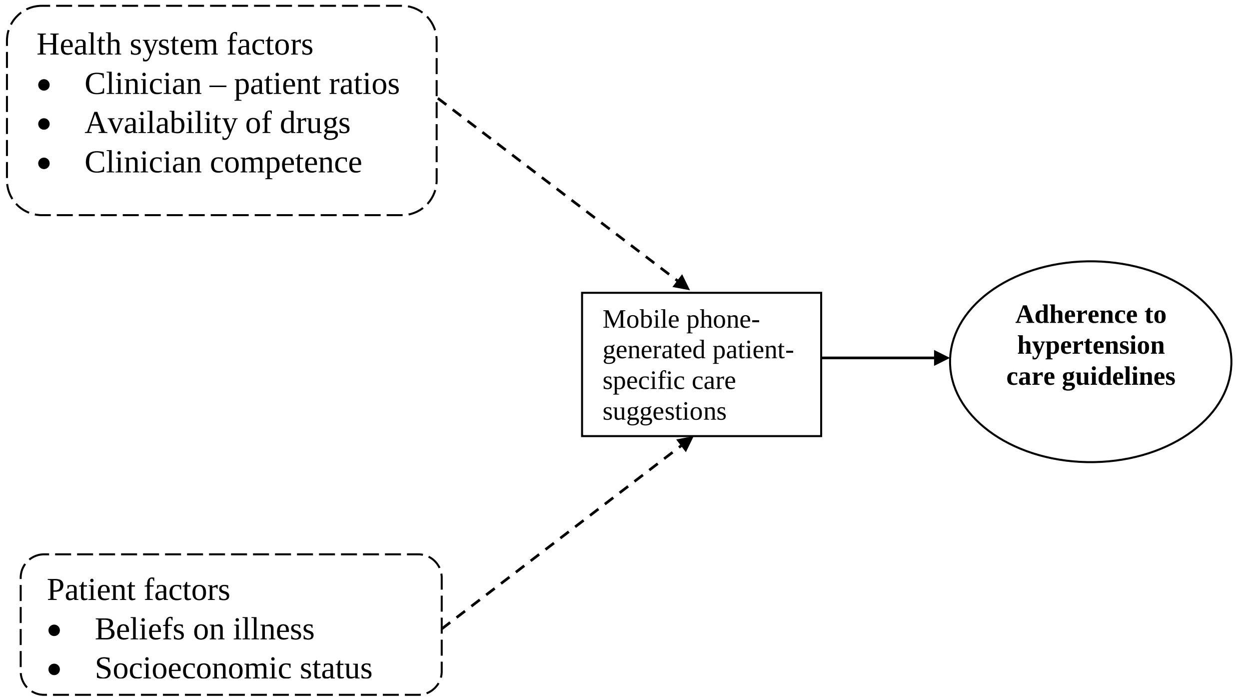
1.5.1 Broad objective

To evaluate the adherence to and impact of patient-specific mobile phone–generated care suggestions (reminders) delivered via a smartphone application by clinicians offering hypertension care in primary care facilities in western Kenya.

1.5.2 Specific objectives

1. To evaluate adherence by clinicians to patient-specific mobile phone–generated care suggestions for hypertension care in primary care facilities in western Kenya based on the patient level clinical decisions by the clinicians.
2. To assess the impact of patient-specific mobile phone–generated care suggestions for hypertension care in primary care facilities in western Kenya based on the patient level clinical decisions by the clinicians.
3. To assess the clinician barriers to adherence to patient-specific mobile phone –generated care suggestions for hypertension care in primary care facilities in western Kenya.

1.6 Conceptual Framework



Adherence to hypertension care guidelines is dependent on health system factors and patient factors. Health system factors include availability of appropriate medications, clinician – patient ratios, and clinician competence and level of training. Patient factors include patient belief system on the role of conventional medication and socioeconomic status that determines the ability of the patients to afford the appropriate medication. This study proposes that the presence of mobile phone-generated patient-specific care reminders during electronic data capture

Figure 1: Conceptual Framework

CHAPTER TWO: LITERATURE REVIEW

2.1 Mobile health technologies in healthcare

Non-communicable diseases require a well-integrated healthcare system to meet chronic healthcare needs. This is a challenge for most countries in SSA, Kenya included, which are faced with limited human, financial, and infrastructure resources (Bloomfield et al., 2014). Globally, NCDs constitute a major challenge to socioeconomic development, environmental sustainability, and poverty alleviation. Four categories of NCDs – cardiovascular diseases, cancer, chronic respiratory diseases and diabetes – make the largest contribution to NCD morbidity and mortality ((WHO), 2012). In view of the above challenges, innovative models of healthcare delivery that integrate novel use of human and technological resources offer potential solutions for SSA ((WHO), 2002).

The use of mobile communication technology in the health arena (mHealth) has been highlighted as a key strategy to combat NCDs in low and middle-income countries (LMICs), and this was emphasized during the 2011 United Nations High Level Meeting on Non-Communicable Diseases (NCDs) ((WHO), 2012). mHealth can alleviate specific health system constraints that hinder effective coverage of health interventions.

In SSA, implementation of mHealth solutions is limited and evidence for a positive effect on health outcomes is sparse. The efficacy of mHealth interventions in NCD management has been based on two sets of intersecting parameters: health system challenges and spectrum of disease (Bloomfield et al., 2014). The health system challenges to NCD care are prophylaxis and prevention, detection and diagnosis, linkage to care, long-term follow-up, providing high quality care, and coordination of care. The spectrum of disease ranges from those who are healthy to those with complications of disease (Bloomfield et al., 2014). mHealth innovations offer opportunities which, when used appropriately, could help strengthen health systems and facilitate the delivery of essential health interventions. These innovations should be integrated into existing health system functions and complement the health system goals of: health service provision; well–performing health workforce; functioning health information system; cost-effective use of medical products & technologies; and accountability & governance, rather than as stand-alone solutions (Labrique et al., 2013).

Several frameworks have been developed to visualize the opportunities for mHealth innovations, which when used appropriately, help strengthen heath systems and the delivery of essential intervention. Two examples include a systematic review by Bloomfield et. al in 2014 of Mobile health for non-communicable diseases in Sub-Saharan Africa (Bloomfield et al., 2014) and Labrique et al. in mHealth innovations as health system strengthening tools: 12 common applications and a visual framework (Labrique et al., 2013).

Bloomfield et al. elaborated mHealth strategies to address health system challenges to NCD care as having two perspectives. Firstly, the chronic disease continuum that includes: a) the normal individual, b) established disease risk factors, c) preclinical disease, d) manifest disease, and e) disease with complications. Secondly, the health system challenges (HSC) in preventing and managing NCDs in LMICs that include: 1) HSC 1: prophylaxis and prevention – client health education, 2) HSC 2: detection and diagnosis of disease, 3) HSC 3: linkage to care of newly diagnosed patients, 4) HSC 4: follow – up/ retention in care, 5) HSC 5: quality of care offered for NCDs and 6) HSC 6: coordination of care (Bloomfield et al., 2014).

Labrique et al. describes the constituent parts of an mHealth strategy and the relationships between common applications of mHealth & ICT and the health systems constraints that they address. These constituent parts include: 1) Client Education and Behavior Change Communication, 2) Sensors and Point-of-Care Diagnostics, 3) Registries and Vital Events Tracking, 4) Data collection and reporting, 5) Electronic health records, 6) Electronic decision support (information, protocols, algorithms, checklists), 7) Provider-to-provider communication (user groups, consultation), 8) Provider work planning and scheduling, 9) Provider training and education, 10) Human resource management, 11) Supply chain management and 12) Financial transactions and incentives (Labrique et al., 2013). However, large-scale implementation or integration of these mHealth innovations into health programs has been limited by a shortage of empirical evidence supporting their value in terms of cost, performance, and health outcomes (Consulting., 2013). A systematic review in 2013 by Free et al. of controlled trials of mobile technology interventions to improve effectiveness of health care delivery processes only showed modest benefits (Free et al., 2013). There is therefore a need to frame mHealth interventions within the broad context of health outcomes or health system goals.

The advent of mHealth has redefined the boundaries of the electronic health records. OpenMRS, a popular mHealth-enhanced EHR, allows frontline health workers to access information from a patient's health record using a mobile device and to contribute information into the health record (OpenMRS, 2021). Rural health workers at the point-of-care (for example, in rural clinics or in the patient's home) can access and contribute to longitudinal health records, allowing continuity of care that was previously impossible in non-hospital-based settings. This has been demonstrated for management of hypertension in low resource settings (Jindal et al., 2018).

The use of mHealth for electronic data capture at the point-of-care has brought along with it the challenge of ensuring quality of care provided to patients. Ensuring providers' adherence to protocols is a paramount challenge to implementing complex care guidelines. In particular, shifting tasks, such as screening responsibilities, from clinicians to frontline health workers often entails adapting procedures designed for clinical workers to cadres with limited formal training. mHealth initiatives that incorporate point-of-care decision support tools with automated algorithm- or rule-based instructions help ensure quality of care in these task-shifting scenarios by prompting frontline health workers to follow defined guidelines through clinical decision support tools (Labrique et al., 2013).

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A traditional CDSS is comprised of software designed to be a direct aid to clinical-decision making, in which the characteristics of an individual patient are matched to a computerized clinical knowledge base and patient-specific assessments or recommendations are then presented to the clinician for a decision. Currently, CDSSs are primarily used at the point of patient – provider interaction, for the clinician to combine their knowledge with or suggestions provided by the CDSS. Studies have shown CDSS can increase adherence to clinical guidelines. This is significant because traditional clinical guidelines and care pathways have been shown to be difficult to implement in practice with low clinician adherence. The assumption that practitioners will read, internalize, and implement new guidelines has not held true (Sutton et al., 2020).

CDSSs can be locally developed and integrated into a computerized physician order entry (CPOE) or electronic health record (EHR) system and system-initiated recommendations delivered synchronously at the point of care. The recommendations delivered may or may not require a mandatory clinician response (Bright et al., 2012). The system–initiated recommendations generated automatically may be delivered in real time to enable decision making during the provider–patient encounter through CPOE.

CDSS has been implemented at AMPATH HIV care with demonstrable results. A study by Were at al. at AMPATH in 2011 provided compelling evidence that clinical summaries containing mobile phone – generated care suggestions improved clinician adherence with HIV care guidelines in the resource-limited settings of SSA (OR, 1.80 [CI 1.34 to 2.42], p<0.0001) (Were et al., 2011). Another study at AMPATH among pediatric patients, found a fourfold increase in the completion of overdue clinical tasks when care suggestions were availed to providers over the course of the study (68% intervention vs 18% control, p<0.001) (Were et al., 2013).

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CDSS can have several pitfalls that include disruption of clinician workflow especially in the case of stand-alone systems, CDSS that are inefficient and not working and thus leading to wastage of resources, alert fatigue to providers and compromising quality of patient care. Extra precautions and conscientious design must be taken when building, implementing, and maintaining to ensure continued usefulness and viability CDSS (Sutton et al., 2020).

2.3 Hypertension and hypertension care models

Hypertension is the leading risk factor for cardiovascular disease and the leading cause of premature death globally. In 2010, 31.1% of the global adult population had hypertension. However, this prevalence varies greatly depending on the social and economic circumstances of a region. A systematic review of population based studies from 90 countries globally showed wide disparities with prevalence in low and middle income countries being 31.5% while that in high income countries being 28.5% (Mills et al., 2016). A country-wide survey in Kenya in 2015 showed an age standardized prevalence of hypertension of 24.5% (Mohamed et al., 2018).

Globally, the prevalence of hypertension is highest in Africa, at about 46% of adults aged 25 years and older, compared to 35 to 40% elsewhere in the world (Anastase Dzudie, 2017). Most patients with hypertension in Africa are unaware of their status, and are rarely treated. Those on treatment are often poorly-controlled. Given the above, hypertension patients in Africa are at a high risk for stroke, heart and renal disease and other cardiovascular diseases (Wilson PW, 1998).

SSA is experiencing an epidemiologic transition from the traditional causes of disability and premature death which were infectious diseases and malnutrition to chronic NCDs that include CVDs (WHO, 2014). CVDs are a leading cause of mortality worldwide with 80% of CVDs deaths occurring in LMICs (WHO, 2013).

The global burden of disease estimates by Mathers et al. show that by 2030, ischemic heart disease will be the leading cause of morbidity and mortality in LMICs, including Kenya (Mathers & Loncar, 2006). As CVDs and cardiovascular risk factors increase, so will the requirement for additional attention and interventions for these diseases and their associated complications.

Various models of hypertension care exist worldwide, with most standard management guidelines based on western experience. This is where multidisciplinary teams offer specialized, resource–intensive care. These are poorly adapted for LMICs, where nurses are the frontline workers attending to patients in the health system at primary health care level (PHC) (Kane, Landes, Carroll, Nolen, & Sodhi, 2017). This is in keeping with the huge disparities that exist in the distribution of the health workforce globally. SSA, with about 11% of the world's population bears over 24% of the global disease burden. Unfortunately, SSA is home to only 3% of the global health workforce, and spends less than 1% of the world's financial resources on health (Anyangwe & Mtonga, 2007). This further compounds the problem of a high disease burden of both infectious diseases and the rising epidemic of chronic non-communicable diseases. Health care provision is a service industry that depends very much on skilled individuals who provide the services to clients. However, over the years in SSA, the health workforce has not been accorded the priority that it deserves. Instead emphasis has been accorded to the provision of commodities, procurement of equipment, and construction of facilities (Omaswa, 2014). In Nigeria, several challenges have been reported within the health workforce, particularly lack of training and funding opportunities and failure of employment, and deployment of the health workforce (Adeloye et al., 2017).

Due to the limited health workforce in SSA, models of care for hypertension based on task-shifting to non–physician clinicians and decentralization to primary care have been successfully demonstrated (Frieden et al., 2020). Similar successful implementations of nurse-based hypertension management have been demonstrated in rural western Kenya (Vedanthan et al., 2015). Evaluation of a nurse–led program in western Kenya showed significant reduction in blood pressure of upto 15 mmHg within the first three months of follow–up (Vedanthan et al., 2020). A qualitative review of the nurse-led programs in western Kenya showed that some of the nurse-related barriers included inadequate training on hypertension care and excessive workload (Vedanthan et al., 2016).

2.4 Theories and models for technology adoption

Technology has presented great potential for the improvement of organizational performance. However outcomes of technology use are dependent on how end users effectively use that particular technology. Use of technology is influenced majorly by system, individual and context factors (Mathieson, 1991).

A number of models have been put forward to explain the factors that affect user acceptance of new information technologies. These include: technology acceptance model, extension of technology acceptance model, theory of planned behavior, theory of reasoned action, motivational model, unified theory of acceptance & use of technology and social cognitive theory (Taherdoost, 2018).

2.4.1 Theory of reasoned action

Behavioral intention which is a function of attitudes and subjective norms is one of the potential reflectors of possible behavioral outcomes (Taherdoost, 2018). Intention is the cognitive representation of a person's readiness to perform a behavior and hence a predictor of actual behavior (Otieno, 2016). Once a positive behavior is developed, a person tends to get involved in performing the actual action. The intention itself is determined by the person's attitude and his subjective norms towards the behavior. Subjective norms refer to the person's perception that most people who are important should or should not perform the behavior in question (Fishbein, 1977).

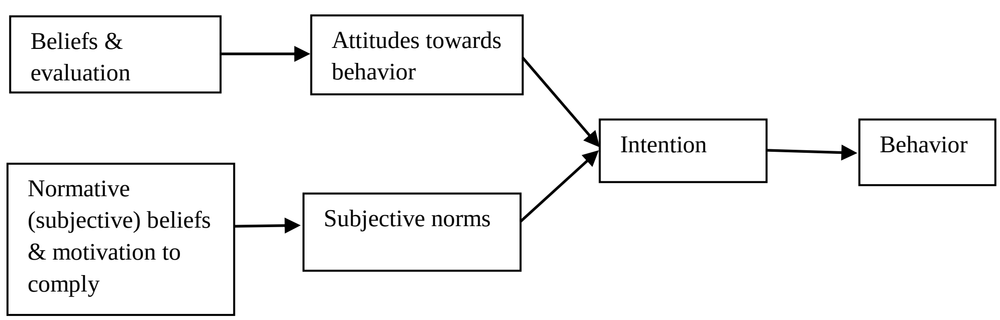

Figure 2: Theory of reasoned action (Otieno, 2016)

2.4.2 Theory of planned behavior

The theory of planned behavior (TPB) builds on the theory of reasoned action by adding perceived behavior control (PBC) as a new variable (Taherdoost, 2018). Theory of planned behavior proposes intention as the best determinant of behavior. Intention is influenced by three factors: attitude, subjective norm and perceived behavior control (Mathieson, 1991). Attitude refers to positive or negative evaluation of behavior. Subjective norms refers to perception of pressure from others to perform the behavior. Perceived behavior control refers to the ease or difficulty of performing the behavior of interest (White et al., 2015).

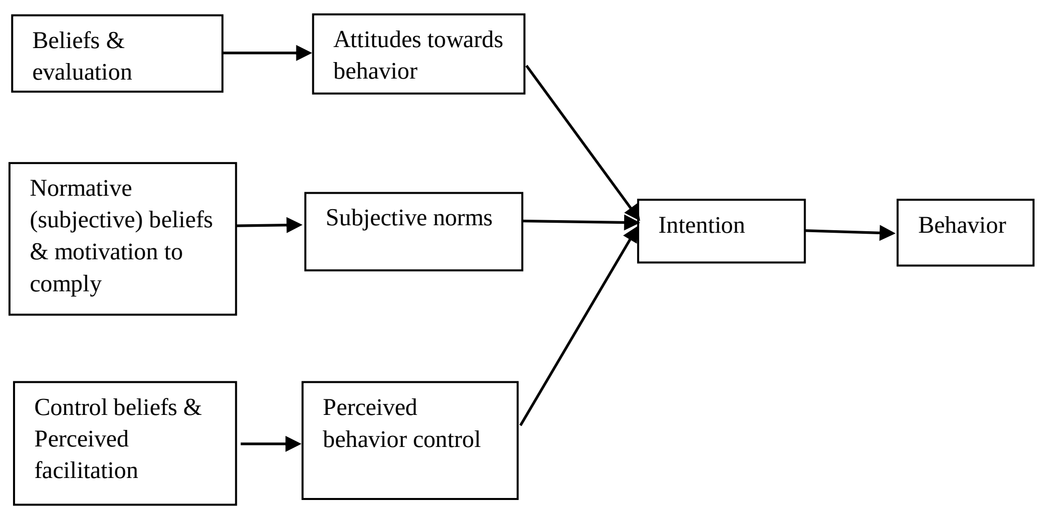

Figure 3: Theory of planned behavior action (Mathieson, 1991)

2.4.3 Technology acceptance model

Technology acceptance model (TAM) was developed in the 1980's as a result of concern that workers were not using information technologies available to them to perform their daily activities (F. D. Davis, Bagozzi, Richard P., Warshaw, Paul R., 1989). TAM was developed with the reasoning that in order to increase use of information technologies, one had to first increase its acceptance through identification of factors that shape an individual's intentions and to manipulate these factors to promote acceptance and eventually the actual use of information technologies (Holden & Karsh, 2010). This model was derived from the theory of reasoned action.

In the TAM, there are three factors that explain, predict and presumably control acceptance. These factors are attitudes, perceived ease of use and perceived usefulness (Mathieson, 1991). Davis et al. in 1989 hypothesized that these were the main factors that determined user acceptance. According to the TAM, the intention to use the system was directly influenced by both the individual's attitude towards the system and their perceived usefulness of the system. The individual's attitudes are in turn affected by the perceived usefulness and perceived ease of use of the system (F. Davis, 1989).

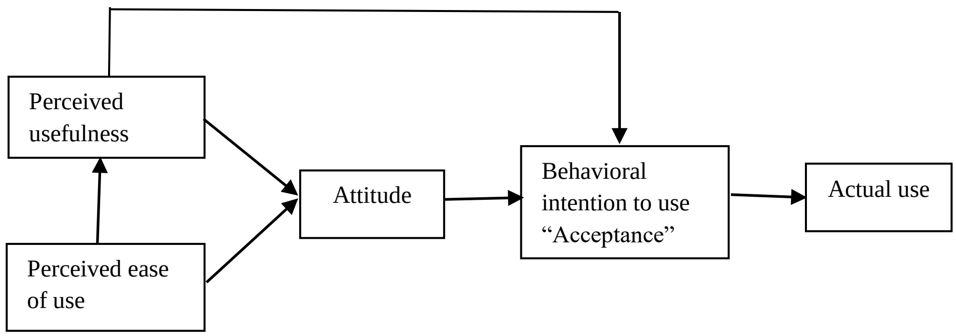

Figure 4: Technology acceptance model (Holden & Karsh, 2010)

2.4.4 Unified theory of acceptance and use of technology

The Unified theory of acceptance and use of technology (UTAT) was developed after comparison of the similarities and differences of eight models: technology acceptance model, theory of reasoned action, technology acceptance model and theory of planned behavior, model of personal computer utilization, diffusion of innovation, motivational model and social cognitive theory (Taherdoost, 2018). UTAT has four main concepts: performance expectancy (PE), effort expectancy (EE), social influence (SI) and facilitating condition (FC) which are independent variables that influence the dependent variables of behavior intention and usage (Venkatesh, 2003). In addition, gender, age, experience and voluntarism of system use have indirectly influenced the dependent variables via the four main concepts. Behavioral intention is seen as a critical predictor of technology use (Venkatesh, 2003). Venkatesh defines performance expectancy as the degree to which an individual believes that using the system will help him or her attain gains in job performance, effort expectancy is the degree of ease associated with the use of the system, social influence is the degree to which an individual perceives that important others believe he or she should use the new system and facilitating condition is the degree to which an individual believes that an organizational and technical infrastructure exists to support use of the system (Venkatesh, 2003).

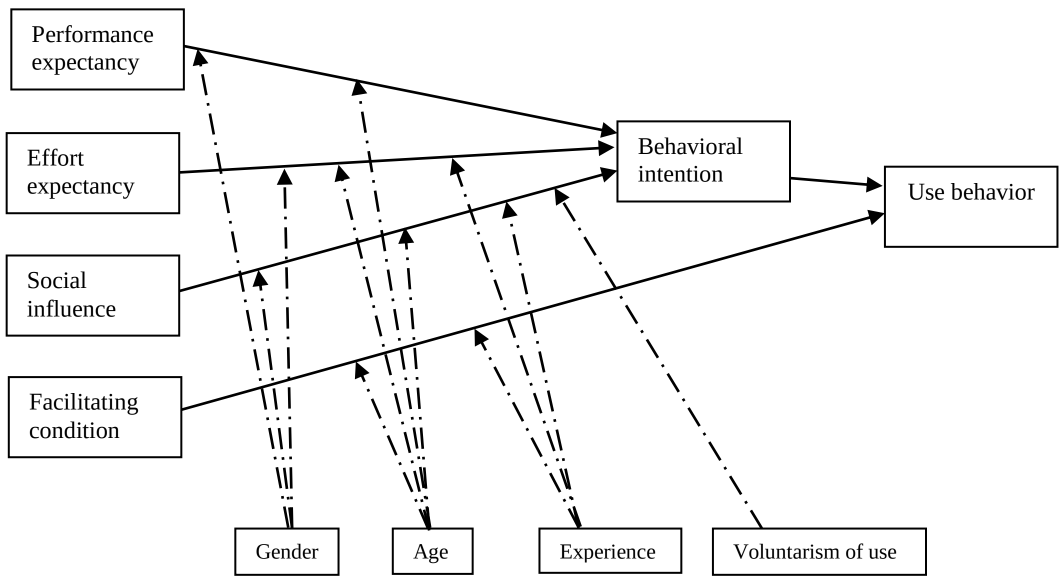

Figure 5: Unified theory of acceptance and use of technology (Venkatesh, 2003)

2.4.5 Relevance of models to this study

Among all the proposed models, the technology acceptance model has captured the most attention in the information systems community (Chuttur, 2009). It is one of the most influential models in the field of information systems and has been validated as a powerful framework to predict the user acceptance of new technology. TAM has been used by researchers to find the behavior or intention of users regarding the use of new information systems in healthcare (Ahlan, 2014).

This study adopted the technology acceptance model components of the perceived ease of use, perceived usefulness and actual use for the evaluation of patient-specific mobile phone generated care suggestions for hypertension care in western Kenya. Swanson in 1982 hypothesized that potential users will select and use information systems after critical analysis of perceived information quality (perceived usefulness) and associated cost of access (perceived ease of use) (Swanson, 1982). In any given situation, behavior would be best predicted by both self – efficacy (perceived ease of use) and outcome judgments (perceived usefulness) (Bandura, 1982). Davis et al. 1989 came up with the conclusion that people tend to use or not use a system based on the level of belief that it will help them perform their job better (perceived usefulness) and also the belief that the level of efforts required to use the system can directly affect the system usage behavior (perceived ease of use) (F. D. Davis, Bagozzi, Richard P., Warshaw, Paul R., 1989).

2.5 Summary of literature review

From the literature above mobile health technologies offer innovative models for provision of hypertension care and other NCDs. This is particularly useful in the face of task shifting of clinical care to nurses and clinical officers due to the low number of physicians in western Kenya and Kenya in general. CDSS are by and large intended to support healthcare workers in the normal course of their duties, assisting with tasks that rely on the manipulation of data and knowledge.

Traditional CDSS is comprised of software that is designed to be a direct aid to clinical-decision making, in which the characteristics of an individual patient are matched to a computerized clinical knowledge base and patient-specific assessments are then presented to the healthcare provider for a decision. CDSS can increase adherence to clinical care guidelines. This is important because traditional clinical guidelines and care pathways have been shown to be difficult to implement in practice with low adherence to care guidelines by healthcare providers.

CDSS can have several pitfalls that include disruption of clinician workflow, especially in the case of stand-alone systems, CDSS that are inefficient and not working and wasting resources, alert fatigue to healthcare providers and compromising quality of patient care.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Study design

This was a prospective comparative study. Health care providers offering hypertension care in these primary healthcare facilities were clustered into two groups: an intervention and a control group. Patients seen by health care providers in the intervention group had patient-specific mobile phone–generated care suggestions triggered and displayed to the provider on their mobile device when certain clinical criteria (Table 1) were met during the provider–patient encounter. Patients seen by health care providers in the control group had patient-specific mobile phone–generated care suggestions triggered but were not displayed to the provider on their mobile device during the provider–patient encounter. We clustered by healthcare provider to avoid sensitizing of the healthcare providers to reminders if they were in the control group.

3.2 Study setting

This study was conducted in Ministry of Health primary care facilities (dispensaries & health centers) in two sub-counties in western Kenya where provision of hypertension care was ongoing in collaboration with AMPATH / CDM program. These sub – counties were Turbo sub-county in Uasin Gishu county and Chesumei sub-county in Nandi County. The study took place in 10 primary care facilities (Appendix 3) in these two sub–counties. The dispensaries and health centers were sampled using convenient sampling method. These were health facilities where hypertension care was being offered and the nurses and clinical officers offering care were using smartphones for electronic data capture at the point of care. All nurses and clinical officers offering care in these ten facilities were participants in the study.

3.1.2 AMPATH

AMPATH is a collaboration between Moi University College of Health Sciences (MUCHS), Moi Teaching and Referral Hospital (MTRH) and a consortium of North American academic medical centers led by Indiana University. In 2001, AMPATH joined with the Ministry of Health (MOH) to develop a robust HIV care system in MOH facilities across Western Kenya. Over time, AMPATH has become one of SSA's most successful HIV treatment and control programs (Einterz et al., 2007).

In 2010, AMPATH in partnership with the Ministry of Health, initiated its Chronic Disease Management (CDM) program on a pilot basis with the aim of creating a comprehensive and scalable model of care for NCD. This program has leveraged on gains made in the HIV program. The major components of the CDM program include: early case finding of patients with hypertension, linkage to an organized healthcare system, initiation of treatment, and retention of patients in care with ongoing training, capacity building, monitoring and evaluation (Bloomfield et al., 2011). Since its inception 50,000 people above 18 years old have been screened for hypertension. Despite less than ideal linkage to care, about 12,450 of these are in care for hypertension (Manji et al., 2016). The AMPATH–CDM program has instituted task-shifting to lower level facilities coupled with clear care algorithms, and a medical record and referral system to approximately 10% of the catchment population (Vedanthan et al., 2020). CDM activities are currently running in 47 public health facilities within the AMPATH catchment area where hypertension care is offered by nurses and clinical officers. The main risk of task-shifting is maintenance of quality of care. This is partly being addressed by the elaborate mentorship strategy, and use of smartphones with clinical decision support systems.

3.1.3 Use of smartphones and integrated health records system within AMPATH

AMPATH has invested and implemented a very successful electronic medical record system since 2004 (Tierney et al., 2010). The AMPATH Medical Record System (AMRS) is used to store comprehensive longitudinal, electronic patient records for all enrolled patients (Buttorff et al., 2012). AMRS was the first implementation of OpenMRS, an open-source EHRs deployed widely in the developing world (OpenMRS, 2021). This system was initially developed for the HIV care program but the CDM program has already converted hypertension primary care level data collection tools into the AMRS. All patients seen within the AMPATH catchment area receive a unique universal identifier which is fed into the system and is used for their management across all levels of care. As a result, a patient's clinical information can be accessed from any facility within the catchment area ensuring continuity of care. Data entry into AMRS is done either by data clerks from filled clinical forms or directly by clinicians using smartphones. The use of smartphones has been preferred in the primary care facilities as it is more efficient given the expected large number of visits, and it gives a platform for real time clinical decision support with clinicians receiving patient-specific mobile phone – generated care suggestions.

One of the mHealth applications used with OpenMRS is mUzima (application, 2021) which is a smartphone-based Android application that allows for data collection, decision support, tele-consultation, and enhanced counseling using pre-recorded media. mUzima is customized to interoperate with the OpenMRS electronic record system, where clinical data for the same patients are stored (OpenMRS, 2021). Unique identifiers for patients are shared between the community and health facilities, and the same sets of terminology are used to define data elements to be collected. Taking into account the reality of poor connectivity, mUzima is customized to work efficiently in both offline and online modes. Data security within the application is achieved through encryption of data within the mobile devices and in the electronic record system, with user-based authentication and automatic time-outs after a period of inactivity. An additional layer of security is offered through a Device Management and Security application that can remotely lock the mobile device, detect SIM card changes, and remotely wipe data from the device (Were, Kamano, & Vedanthan, 2016).

3.2 Study Population

The study population were patients with hypertension receiving care in 10 primary healthcare facilities in Turbo and Chesumei sub-counties from 1st November 2018 to 28th February 2020.

3.3 Eligibility Criteria

3.3.2 Inclusion criteria

1. Patients with hypertension receiving care at primary healthcare facilities (dispensaries and health centers) within the AMPATH / CDM catchment area of Turbo and Chesumei sub-counties.

2. Patients seen at the primary healthcare facilities by clinicians using a smartphone for electronic data capture during the study period.
3. Patients 18 years and older
4. Health care providers who have been trained on use of smartphones for electronic data capture in the primary healthcare facilities.

3.3.3 Exclusion criteria

1. Patients seen at the dispensaries by clinicians who have not been trained to use smartphones for electronic data capture during the study period.

3.4 Study design

3.5 Sample size determination

In this study, the unit of analysis was each unique care reminder that triggered during the patient-provider visit. In order to be 95% sure that the true difference between the proportion of hypertension care suggestions requiring further clinical actions among those who received patient–specific phone-generated care suggestions (intervention group) and the proportion of hypertension care suggestions requiring further clinical actions among those who did not receive phone-generated care suggestions (control group) was at least 15% with a probability of 90%, a sample size to compare the two proportions was computed using the formula below:(Hulley, 2007)

$$n = \frac{Z_{1-\alpha/2}\sqrt{(P_1+P_2)\times(1-P_1+1-P_2)/2} + Z_{1-\beta}\sqrt{P_1(1-P_1)+P_2(1-P_2)}}{P_1-P_2}$$

$$= \frac{1.96\sqrt{(0.4+0.55)\times(1-0.4+1-0.55)/2} + 1.28\sqrt{0.4(1-0.4)+0.55(1-0.55)}}{0.4-0.55}$$

$$= 231$$

Where p_1 is the proportion of clinical conditions that would trigger hypertension care suggestions that were presented as patient–specific care suggestions requiring further clinical actions in the intervention arm and p_2 is the proportion of clinical conditions that would meet the criteria for hypertension care suggestions requiring further clinical actions in the control arm.

$z_{1-\alpha/2}$ is the $100(1-\alpha/2)$ percentile of the standard normal distribution under type I error while $z_{1-\beta}$ is the $100(1-\beta)$ percentile of the standard normal distribution under type II error.

$p_1 - p_2$ gives the effect size called the true difference herein.

In an earlier study by Were et al., the proportion of patients referred for further clinical actions among those who received phone-generated care suggestions was found to be 63% (assigned p_1 in this study), and among those who did not receive phone-generated care suggestions the proportion was found to be 38% (assigned p_2 in this study) (Were et al., 2011). Thus, to avoid over-optimism in our current study and instead enhance the precision and reliability of the findings, I chose to use a slightly narrower difference by using 55% among those who received mobile phone-generated care suggestions and 40% among those who did not receive phone-generated care suggestions. As such, the study set out to find a true difference of at least 15% between the two groups of patients.

The probability of wrongfully rejecting the null hypothesis when there is no difference between the proportions of patient–specific care suggestions requiring further clinical actions was set to be 5%. The study was powered with 90% chance of being able to detect the existence of the true difference between the two groups.

The study assumed the effect size to be the difference between the two proportions. This effect size was taken as the smallest effect that would be important to detect in the sense that any effect smaller that this would not be of clinical or of substantive significance. It was assumed that this effect is reasonable in the sense that an effect of this magnitude could be anticipated in this field of research (Were et al., 2013; Were et al., 2011). The test was two-tailed, meaning that an effect in either direction would be interpreted.

With these conditions the study required a sample size of 231 trigger care suggestions per study arm, giving a total of 462 to allow for detection of the true difference between the two groups of patients.

3.6 Allocation of the cluster

I evaluated the impact and adherence to patient-specific care guidelines for hypertension care in 10 primary care facilities (dispensaries and health centers) in western Kenya. The 10 primary care facilities were grouped using a table of random numbers by the study biostatistician into either the control group or the intervention group. This allowed for allocation of the healthcare providers in each clinic to either a control or intervention arm, thus avoiding contamination. Patients seen by health care providers in the primary care facilities randomized into the intervention group had patient-specific mobile phone–generated care suggestions triggered and displayed when certain clinical conditions were met during the provider–patient encounter. Patients seen by health care providers in the primary care facilities randomized into the control group had patient specific reminders triggered, but these were not displayed to the provider during the provider–patient encounter. The principal investigator and the research assistant travelled to each participating health facility to explain the study and get verbal consent of the health care providers to participate in the evaluation. Verbal consent was obtained because this study only observed the action of the healthcare providers with no additional intervention on patient care and management. The healthcare providers were not blinded as they were already aware of the presence of the phone–generated care suggestions.

3.7 Data variables

Patient level data variables

The patient-level data variables used for this study included demographic data and clinical data routinely collected during the patient-provider encounter by electronic data capture. The demographic and clinical data included:

1. Age
2. Gender
3. Level of education
4. Occupation
5. Residence
6. Hypertension status: new diagnosis or known hypertensive

7. Diabetes status: having diabetes or not
8. History of cigarette smoking
9. History of alcohol use
10. Prospective data collected during routine clinic visits included:
    a. Current chief complaint
    b. Anthropometric measurements: height (centimeters), weight (kilograms), Body mass index, waist circumference
    c. Consecutive blood pressure readings
    d. Laboratory tests ordered
    e. Laboratory results
    f. Care plan for visit: Lifestyle modification, Salt reduction, Exercise, Reduce alcohol, Smoking cessation, Weight reduction, Diet education
    g. Mediation prescribed during visit.
    h. Referrals made

Clinician level data variables

The following clinician-level data were collected using self-administered questionnaires:

1. Age
2. Gender
3. Profession
4. Number of years in service
5. Training on hypertension care algorithms.

6. Challenges and barriers in adherence to patient-specific care suggestions in the provision of hypertension care using smartphones for EDC and clinical decision support.
7. Challenges and barriers in use of smartphones for EDC and provision of hypertension care in dispensaries.

Facility-level data variables

Use of smartphones for electronic data capture is a new technique for data acquisition and its use may be limited by health system challenges that will be important to identify. Therefore, the following facility-level data variables were collected from the facility in-charge in each study facility:

1. Number of clinicians in facility.
2. Number of clinicians trained to offer hypertension care in the facility.
3. Facility challenges and barriers in use of smartphones for EDC and provision of hypertension care in dispensaries.
4. Challenges and barriers in adherence to patient-specific care suggestions in the provision of hypertension care using smartphones for EDC and clinical decision support.

3.8 Mobile phone–generated patient-specific care suggestions

This study evaluated seven mobile phone–generated patient-specific care suggestions that were divided broadly into three categories, namely:

a. Care suggestions that prompted the clinician to initiate specific hypertension medication.

b. Care suggestions that prompted the clinician to titrate hypertension medication due to uncontrolled blood pressure.

c. Care suggestions that prompted the clinician to monitor for potential medication side effects (ACE-I or CCB medication adverse effects).

The patient-specific care suggestions had been developed earlier within the AMPATH Chronic Disease Management program by a team of cardiologists, physicians, clinical officers and nurses from the Department of Non-communicable diseases, Ministry of Health, Moi University College of Health Sciences, Moi Teaching and Referral Hospital and the county health management teams in Uasin Gishu and Nandi counties.

Table 1 below shows specific mobile phone–generated patient-specific care suggestions that were evaluated.

Table 1: Clinical Criteria that triggered hypertension care suggestions

	Reminder	**Indication for care suggestion**	**Care suggestion generated**
1.	Start hypertension treatment	If visit type first after screening or walk-in first visit and SBP ≥150 and <180 or DBP ≥90 and <110 and Age ≥ 35 and ‘Urine Pregnancy’ is ‘Negative’ or ‘Indeterminate’ with no oedema dyspnea or reduced urine output.	- Start HCTZ 25mg OD and give instructions on salt reduction and review after a month
2.	Start hypertension treatment	If visit type is ‘Second dispensary visit after screening or walk-in second visit’ and ‘SBP’ >=140 and <= 180 and ‘DBP’ >= 90 and < 110 and ‘Urine Pregnancy is negative or intermediate’ and age >= 35 yrs with no edema of legs or DOE or reduced urine output	- Confirmed hypertension - Start HCTZ 25mg OD - Advise on Salt reduction, weight reduction if BMI >30, exercise, smoking cessation and alcohol reduction (if applicable);’ to be seen in 3 months
3.	Titrate hypertension Medication	If visit type is ‘Return Visit’ and ‘SBP’ >=140 and <= 180 and DBP’ >= 90 and < 110] and ‘Urine Pregnancy is negative or intermediate’ and age >= 35 years with no edema of legs or DOE or reduced urine output and on HCTZ 25mg a day	- Continue HCTZ 25mg a day add amlodipine 5mg OD or felodipine 5mg OD or nifedipine 20mg BD, and’ - Advise on salt reduction, weight reduction if BMI >30, exercise, smoking cessation and alcohol reduction (if applicable);’ to be seen in a month. - Refer to CO if this is third dispensary visit on this drug regimen’
4.	Titrate hypertension Medication	If visit type is ‘Return Visit’ and ‘Systolic Blood Pressure >=140 and <= 180’ and ‘Diastolic Blood Pressure’ >= 90 and < 110’ and is adherent to current drugs and Urine Pregnancy is negative or intermediate and age >= 35 yrs with no edema of legs or	- Continue HCTZ 25mg a day and increase amlodipine or felodipine to 5mg OD - Patient to be seen in a MONTH and advise on salt reduction, weight reduction if BMI >30, exercise, smoking

		DOE or reduced urine output and on HCTZ 25mg a day and Amlodipine or Felodipine 2.5mg OD	cessation and alcohol reduction (if applicable); - To be seen in a month. Refer to CO if this is third dispensary visit on this drug regimen
5.	Refer patient with uncontrolled hypertension	If visit type is 'Return Visit' and 'Systolic Blood Pressure >=140 and <= 180' and 'Diastolic Blood Pressure >= 90 and < 110' and Urine Pregnancy is negative or indeterminate and age >= 35 yrs with no edema of legs or reduced urine output and on HCTZ 25mg a day and Amlodipine 5mg or felodipine 5mg OD	- Uncontrolled hypertension - Refer to CO - Advise on salt reduction, weight reduction if BMI >30, exercise, smoking cessation and alcohol reduction (if applicable)
6.	Side effects of calcium channel blockers (CCB)	If patient on nifedipine, felodipine or Amlodipine and with complaints of headaches, leg swelling, palpitations , or flashing, or has heart rate >100beats /min,	- Possible side effects of CCBs reduce dose or change prescription.
7.	Side effects of ACEI /ARBs	If patient on enalapril, lisinopril, losartan or zestoretic, and has mouth swelling or neck swelling	- Possible angioedema from ACE-I/ARB. - Stop these class of drugs immediately and consult

Patient–specific care suggestions

Within the mUzima mHealth application, the data collection form are programmed using HyperText Markup Language (HTML), Cascading Style Sheets (CSS) and Javascript as programming languages. HTML is used for defining the structure of the forms, and the elements such as input fields, labels and reminder messages. CSS is used for styling the forms so as to specify the appearance of the form elements. Javascript is used for defining logic that control the display of form elements so as to hide or display them based on user input. For this study, clinical care suggestions were programmed using Javascript, which was used to: (a) evaluate logic to trigger the care suggestion, (b) display the care suggestion for the intervention group, (c) generate logs reflecting the care suggestion triggered, whether it was displayed, and the result of the action taken based on the care guideline. The triggered care suggestions are shown in the screenshots of mUzima application in Figure 3 below.

Below is an example of a programmed care suggestion '*Start hypertension treatment'* (Reminder 1 above):

a. Pseudocode

1. Start
2. Get VisitType, BP reading and ProviderID
3. If VisitType == 'Return Visit' Go to 4, Else go to 5
4. If BP >= 140 and BP<= 180, Go to 6, Else Go to 5
5. Generate Criteria not fulfilled log. Go to 9
6. Generate Criteria fulfilled log
7. If ProviderID is in ArmA [Intervention Arm] study participants, Go to 8, Else Go to 9
8. Display Reminder. Go to 10
9. Hide Reminder
10. End

b. Flow chart of the logic

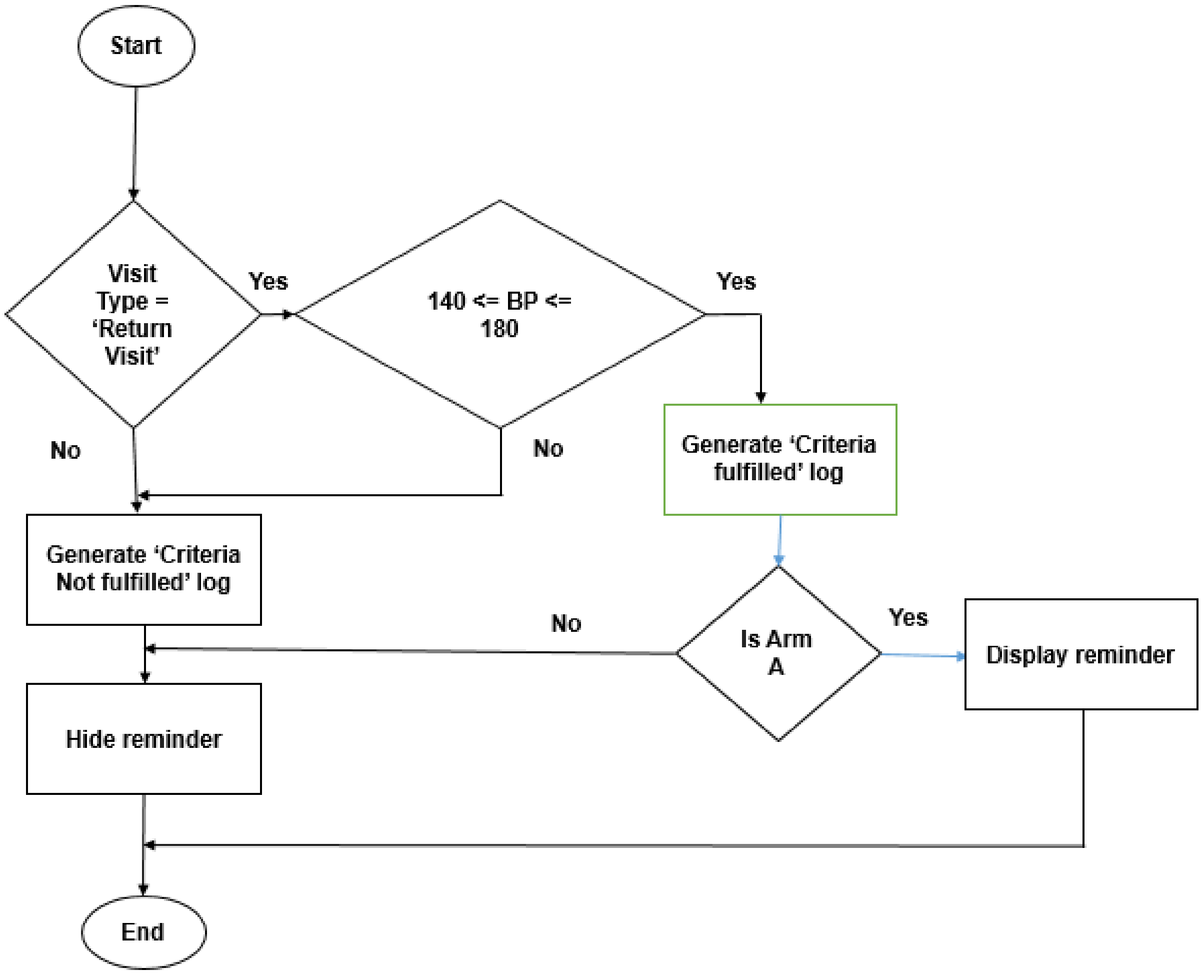

Figure 6: Programming logic flow

c. HTML and javascript

HTN Column C - Reminder 1

HTML script

```
<label class="alert alert-info" id="htnColumnC">
       <b>Pt under 35 with elevated BP</b>
        <ul>
            <li>Refer to CO/Health Center</li>
            <li>Start HCTZ 25 mg</li>
        </ul>
        <div class="form-group">
            <label for="reminder1.response">
                Action on Reminder: <span class="required">*</span>
            </label>
            <select id="reminder1.response" name="reminder1.response" required="required"
                    class="form-control">
```

```
            <option value="">...</option>
            <option value="Accepted">Accepted</option>
            <option value="Not applicable">Not applicable</option>
            <option value="Previously ordered">Previously ordered</option>
            <option value="Patient Allergic">Patient Allergic</option>
            <option value="Patient declined">Patient declined</option>
            <option value="I do not agree with reminder">I do not agree with
reminder</option>
        </select>
      </div>
   </label>
```

Javascript

```
var hTNReminderColumnC = function () {
      var $htnColumnC = $('#htnColumnC');
      var selectedVisitType = $currentVisitType.val();
      var systolicBloodValue = parseFloat($systolicBloodPressure.val());
      var diastolicBloodValue = parseFloat($diastolicBloodPressure.val());
      if ((systolicBloodValue >= 140 && systolicBloodValue < 180 && diastolicBloodValue
<110
        || diastolicBloodValue >= 90 && diastolicBloodValue <110 && systolicBloodValue <
180)
        && !isAtLeast35YearsOld()) {
        triggerAndLogReminderStatus($htnColumnC, 1, REMINDER_LOGIC_FULFILLED);
      } else {
        triggerAndLogReminderStatus($htnColumnC, 1,
REMINDER_LOGIC_NOT_FULFILLED);
      }
   } ;
hTNReminderColumnC();
```

The logic of the patient–specific care suggestions programmed in html and javascript and can be accessed from the a Github code repository on github.(mUzima-form, 2018)

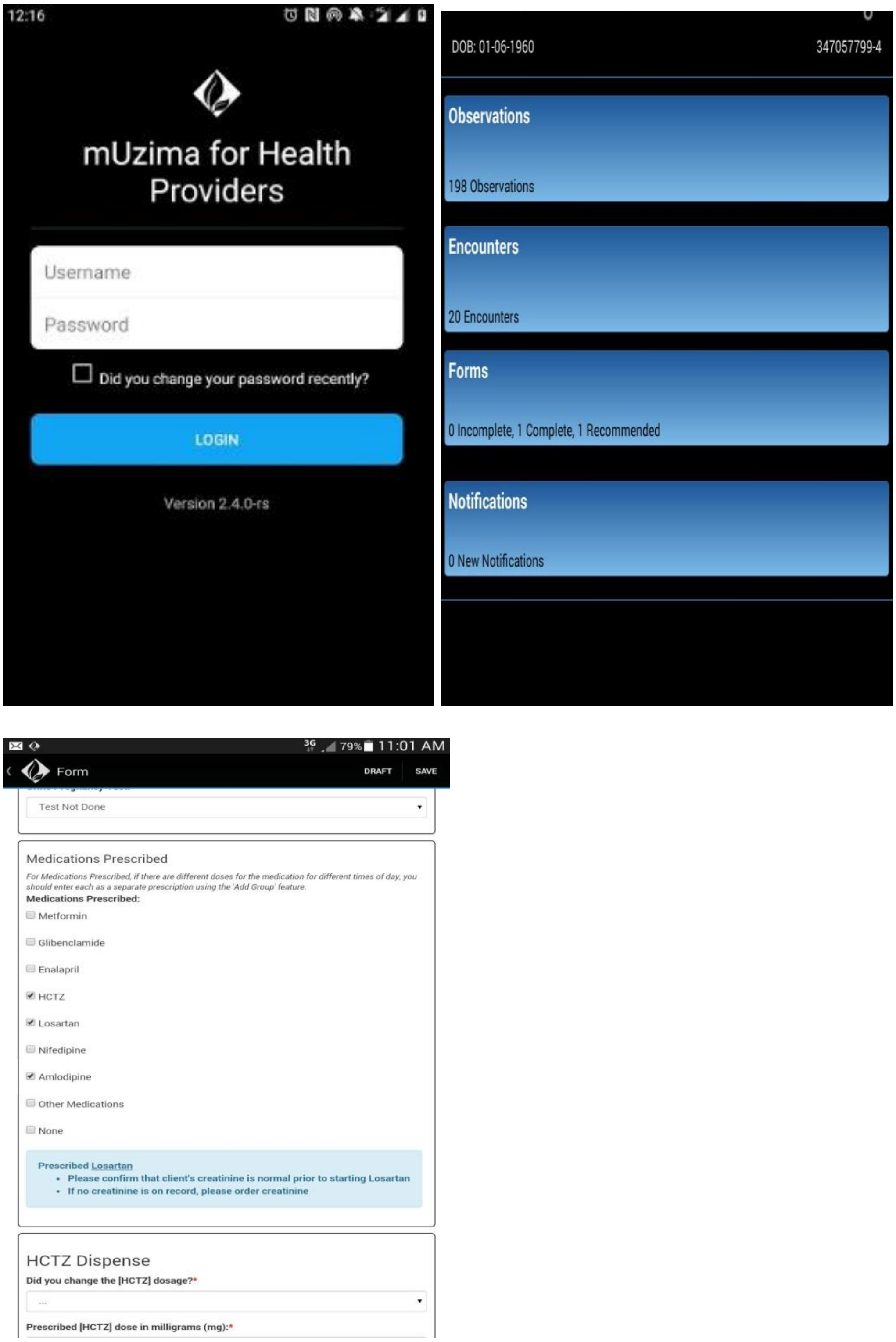

Figure 7: mUzima application - screenshots

3.9 Outcome variables

The primary outcome of interest was the differences in compliance with hypertension care guidelines between the intervention and the control groups based on the criteria specified within the reminders. Primary focus was on:

a. Number of patients requiring initiation of BP medication who were actually initiated.
b. Number of patients requiring titration of BP medication whose medication was actually titrated.
c. Number of patients with potential ACE-I or CCB medication adverse effects for whom a change in or stoppage of medications was made.

Though not powered for this, the secondary outcome evaluated was the number of patients with reduction in blood pressure in both arms and percentage decrease in blood pressure.

3.10 Study procedure

Health care providers in the participating health facilities were approached to participate in the study by the Principal Investigator and the research assistant. The study was explained and verbal consent was obtained from the providers. All providers who gave consent were then trained on the mUzima mobile application and equipped with the mobile phones. Each provider was given a unique user name and password. The password was immediately changed by the provider to ensure that the provider was the only one with access to the relevant clinical data. mUzima application was programmed so that all patients seen by health care providers in the dispensaries in the intervention group had patient-specific mobile phone–generated care suggestions triggered and displayed when necessary during the provider–patient encounter. Patients seen by health care providers in the dispensaries in the control group had patient-specific mobile phone-generated care suggestions triggered during the provider–patient encounter, but this reminders were not displayed.

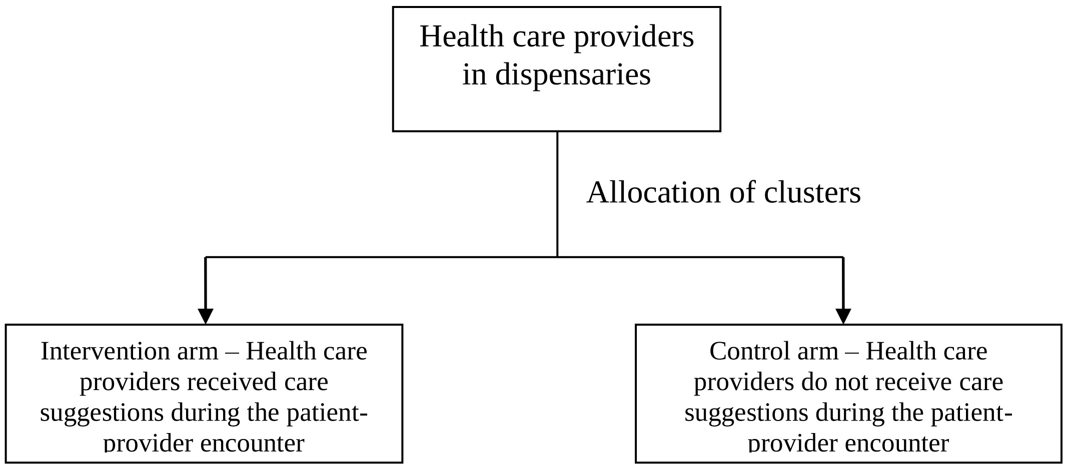

Figure 8: Study procedure

3.11 Data collection

In the sites where the study was conducted, mUzima was used routinely for electronic data capture. A module was programmed within mUzima to enable login of clinicians' actions when patients' data was input during the patient–provider encounter. This application had built in clinical decision support with patient-specific care suggestions being displayed during the clinician–patient encounter for intervention providers. In this study, logs for the various clinical decision support and action taken by the clinicians were recorded within the mobile application. The logs were transmitted with other patient-level data collected to to a server. Figure 5 below shows the dash board for access of the patient logs. The logs were stored in a separate cloud server, while the patient data was transmitted into the

AMRS. For analysis, the transmitted logs were downloaded in form of excel spreadsheet at the end of every week. The study data was enhanced with clinical-level data abstracted into a pro-forma (Appendix A) from the AMRS. The data were merged and stored in password-protected computers that were only accessible by the Investigator and the Co-Investigators.

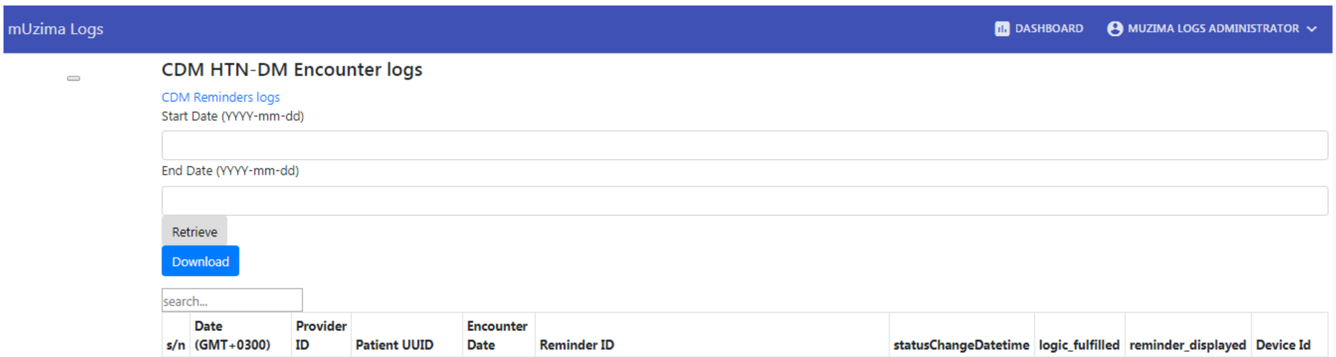

Figure 9: mUzima logs

3.11 Data management & Data Analysis

The unit of analysis for all analyses was each unique patient–specific reminder triggered. Descriptive statistics, including frequencies and the corresponding percentages, as well as the median and the corresponding inter-quartile range (IQR) were used to summarize categorical variables, and continuous and discrete variables respectively. Continuous variables were assessed for Gaussian assumptions using histograms. Whenever the Gaussian assumptions were violated, the continuous variable was summarized using the median and the corresponding interquartile range.

Comparison of the median for continuous variables between the treatment groups was done using two-sample Wilcoxon rank-sum test. Pearson's Chi Square test was used to assess the association between the independent categorical variables and the treatment groups. Fisher's Exact test was used whenever the Chi Square assumptions were violated.

Random effects logistic regression model was used to determine the effect of the treatment group on adherence to care suggestions. For this model, the effect of the healthcare providers was included in the model as a random effect. The effect of adherence on blood pressure control was determined using random effects logistic regression model adjusting for the visit month and baseline hypertension status. The interaction of adherence and the treatment group was included in this model. The visits among the participants was highly staggered with some having the next visit occurring more than six months from the first visit. Due to this, the analysis was restricted to visits that occurred at most 6 months from the baseline to avoid severe impact of long duration of lack of contact between the clinician and the patient on the outcome (blood pressure control). Participants who had only one visit were dropped from the analysis of effect of adherence on blood pressure control since they did not have an outcome. Age (continuous variable) at enrollment and gender were not independently associated with the outcome, thus they were not included in the adjusted model. Further, the variability within the participants was included in the model as a random effect. Robust standard errors were calculated in both models to adjust for clustering by healthcare providers and multiple measurements/observations of the participants respectively. Likelihood ratio test was used to aid model selection between a fixed effects model (considered a simple model) and random effects model (preferred model). The proportions and the odds ratios (OR) and the corresponding 95% confidence intervals (95% CI) were reported. Using the estimates from the second model, the effect (odds ratio) of adherence and the corresponding 95% confidence intervals (95% CI) between treatment groups were calculated.

Data analyses were done using STATA version 13 SE (College Station, 77845 Texas USA).

3.12 Ethical considerations

Ethics review and approval was sought and received from the Moi Teaching and Referral Hospital/Moi University School of Medicine Institutional Research and Ethics Committee. Permission was sought and received from the management of MTRH and AMPATH. Waiver of informed consent from patients and care providers was requested and received because patient–specific care suggestions have been considered routine components of care at AMPATH.(Were et al., 2013) In addition, only routine clinical data and the logs of the clinician decisions were collected. All patient information was kept confidential. There was no conflict of interest in this study. The investigators in this study did not take part in provision of clinical care to the patients during the period of the study. However, if the investigators had to review the patients, the patient data was excluded from the analysis.

CHAPTER 4: RESULTS

4.1 Facility characteristics

The study was conducted in 10 primary healthcare facilities (nine dispensaries and one health centre) in two counties in western Kenya: Uasin Gishu (Turbo sub-county) and Nandi (Chesumei sub-county). The median number of nurses per facility was two, with one facility having only one nurse and two facilities having three nurses. Only four facilities had one clinical officer each, with most of them having administrative positions and not providing clinical care except in two facilities.

4.2 Healthcare provider characteristics

Sixteen healthcare providers (12 nurses and 4 clinical officers) participated in the study with most (90%) being female, with a median (IQR) age of 36 (31.5 – 38.8) years. All the HCPs had attained their medical training from the Kenya Medical Training colleges. They had been working for a median (IQR) of 9.0 (5.0 – 10.75) years since completing their medical training and having worked in the current facility for a median (IQR) of 3.9 (3.2 – 5.8) years.

4.3 Participant social, demographic and clinical characteristics

There were 378 participants/patients seen during the study period who had clinical conditions that fulfilled the criteria for the hypertension care suggestions. These included 217 in the intervention arm and 161 in the control arm.

Table 2: Demographic characteristics

		Group		
Characteristic	**N**	**Control (n = 161)**	**Intervention (n = 217)**	**P-value**
Age (Years), Median(IQR)	354	60.0 (24.5, 73.5)	60.0 (38.0, 70.0)	0.987[w]
Range (Min. – Max.)		21.0 – 102.0	20.0 – 105.0	
18 – 29		49 (32.2%)	47 (23.3%)	0.030[c]
30 – 49		7 (4.6%)	20 (9.9%)	
50 – 59		17 (11.2%)	32 (15.8%)	
60 – 69		28 (18.4%)	51 (25.3%)	
≥ 70		51 (33.6%)	52 (25.7%)	
Gender, n (%)	378			
Female		118 (73.3%)	159 (73.3%)	0.997[c]
Male		43 (26.7%)	58 (26.7%)	
Have NHIF, n (%)				
No		121 (81.2%)	195 (91.6%)	0.004[c]
Yes	362	28 (18.8%)	18 (8.5%)	

N – Represents the number of participants who responded or who had data for the characteristic, [c] Pearson's Chi-Square test for comparison of proportions, [w] Two-sample Wilcoxon rank-sum test for comparison of median estimates

The participants in the control and intervention arms were similar by age (continuous) and gender with a median age of 60 years and 73% being female in both arms (P>0.05). Those in the control group (19%) were more likely to have National Health Insurance Fund coverage compared to the intervention group (9%). This was statistically significant P=0.004 (Table 2).

The results show that the participants in the intervention arm and those in the control arm had high blood pressure; median SBP 142 (IQR: 127.0 – 151.0) mm Hg in the control arm and 143 (IQR: 129.0 – 156.0) mm Hg in the intervention arm. There was no statistically significant difference in the systolic and diastolic blood pressures between the two study groups. The data further indicate that the proportion of participants with SBP ≥ 140 mm Hg | DBP ≥ 90 mm Hg were similar in the two groups; 67.4% vs. 61.0%, $p = 0.198$ (Table 3).

Table 3: Clinical characteristics

		Group		
Characteristic	**N**	**Control (n = 161)**	**Intervention (n = 217)**	**P-value**
SBP (mmHg), Median (IQR)	374	142.0 (127.0 – 151.0)	143.0 (129.0 – 156.0)	0.129[w]
Range (Min. – Max.)		104.0 – 198.0	102.0 – 208.0	
< 120		16 (10.1%)	23 (10.7%)	
120 – 139		57 (35.9%)	57 (26.5%)	
140 – 159		67 (42.1%)	97 (45.1%)	0.219[f]
160 – 179		18 (11.3%)	32 (14.9%)	
≥ 180		(0.6%)	6 (2.8%)	
DBP (mmHg), Median (IQR)	374	81.0 (72.0 – 919.0)	80.0 (74.0 – 92.0)	0.577[w]
Range (Min. – Max.)		58.0 – 117.0	59.0 – 114.0	
< 80		73 (45.9%)	102 (47.4%)	
80 – 89		46 (28.9%)	42 (19.5%)	
90 – 99		29 (18.2%)	62 (28.8%)	0.041[f]
100 – 109		10 (6.3%)	8 (3.7%)	
≥ 110		1 (0.6%)	1 (0.5%)	
SBP ≥ 140 | DBP ≥ 90, n (%)	374			
No		62 (39.0%)	70 (32.6%)	0.198[c]
Yes		97 (61.0%)	145 (67.4%)	
SBP ≥ 180 | DBP ≥ 110, n (%)	374			
No		157 (98.7%)	208 (96.7%)	0.312[f]
Yes		2 (1.3%)	7 (3.2%)	

SBP – Systolic blood pressure, DBP – Diastolic blood pressure, N – Represents the number of participants who responded or who had data for the characteristic, [c] Pearson's Chi-Square test for comparison of proportions, [f] Fisher's Exact text for comparison of proportions when Chi Square assumptions are violated, [w] Two-sample Wilcoxon rank-sum test for comparison of median estimates

4.4 Objective 1: Adherence to hypertension care suggestions

The crude estimates demonstrated evidence of higher proportion of adherence to hypertension care suggestions by healthcare providers in the intervention arm compared to the control arm, 91.1% (95% CI: 88.6, 93.6) vs. 85.7% (95% CI: 82.2, 89.3, p = 0.014, unadjusted odds ratio (UOR): 1.71 (95% CI: 1.11, 2.61). However, upon adjusting for the effect of the different healthcare providers (clinical officers and nurses) through random effects model with robust standard errors, the effect of hypertension care suggestions did not change but became statistically not significant, adjusted odds ratio AOR: 1.78 (95% CI: 0.83, 3.80) The random effects model show that the variability among the healthcare providers was significantly high (Different from zero), variance: 0.44 (95% CI: 0.12, 1.62) (Table 4).

Table 4: Adherence to hypertension care suggestions

			Crude Estimates		**Random Effects model with robust standard errors**	
Study group	**N**	**Number Adherent**	**ᵀProportion (95% CI)**	**Odds Ratio (95% CI)**	**Odds Ratio (95% CI)**	**Random Effect (95% CI)**
Control	371	318	85.7% (82.2 – 89.3)	Reference	Reference	-
Intervention	481	440	91.1% (88.6 – 93.6)	1.71 (1.11 – 2.61)	1.78 (0.83 – 3.80)	-
Healthcare provider	16		-	-		0.44 (0.12 – 1.62)

95% CI: 95% Confidence Interval, ᵀWald test for the equality of the percentage adherent in the two groups p-value = 0.014. Robust standard errors are standard errors adjusted for clustering by healthcare providers

4.5 Objective 2: Clinician barriers to adherence to patient – specific care suggestions

There were 276 triggered and displayed patient – specific care suggestions in the intervention arm during the study period. Of these, 236 (85.5%) had a provider response provided. Table 6 below provides the clinician responses to these patient–specific care suggestions. Half of the patient – specific care suggestions were accepted by the health providers while the other half of the care suggestions were not accepted due to the following reasons: 14% did not agree with the care suggestions, 6% were not applicable, 1% were declined by the patients while 30% of the care suggestions had been suggested in an earlier patient – provider interaction and were not applicable in the present patient – provider encounter. The healthcare providers did not agree with 14% of the care suggestions due to various reasons shown in Table 6 below. The most common feature of all rejected care suggestions was a discordance between the care suggestion and the actual clinical condition of the patient. The most probable reason could be due to the fact that the CDSS that resulted in the care suggestions only relied on data entered during the current patient – provider encounter without reference to the historical electronic health data.

Table 5: Provider response for the participants who had the reminder displayed

Provider response	**n (%)**
Accepted	117 (49.6%)
Do not agree with reminder	33 (14.0%)
Not applicable	14 (5.9%)
Patient declined	2 (0.9%)
Previously ordered	70 (29.7%)
Total	**236 (100.0%)**

Table 6: Reasons for the rejection of the care suggestions

Reasons for rejection of the reminder	**n (%)**
Patient still has high BP	15 (51.7%)
Patient is non-adherent to treatment	5 (17.2%)
Patient has already been started on the drugs	4 (13.8%)
Patient has been referred for UECs	3 (10.3%)
Patient is aged above 35 years	1 (3.5%)
Patient has symptoms of heart failure	1 (3.5%)
***Total**	**29 (100.0%)**

* Up to 75% (119) of the providers who did not agree with the reminder did not provide the reason for rejection

Table 7 below shows some of the perceptions of the healthcare providers to use of smartphones for EDC during the patient encounter and use of patient-specific care suggestions. Seventy five percent of the HCPs were of the perception that the use of smartphones did not improve the quality of care provided to the patients.

Table 7: Clinician perceptions to use of smartphones and patient – specific care suggestions in both control and intervention groups

Variable	**N**	**n (%) or Median (IQR)**
Use of smartphones has improved quality of care, n (%)		
• Yes	16	4 (25%)
• No		12 (75%)
Benefits of smartphone use, n (%)		
• Use less time to see patients	15	2 (13.3%)
• Able to follow – up patients better		6 (40%)
• Has improved patient care		7 (46.7%)
Challenges of smartphone use, n (%)		
• Takes more time to see patients	11	4 (36.4%)
• Has provided additional work		4 (36.4%)
• There are no challenges		3 (27.3%)
Recommendations to improve care		
• Improve internet speed	18	6 (33.3%)
• Use offline system		4 (22.2%)
• Train more staff on NCDs and use o smartphones		2 (11.1%)
• Provide sufficient data bundles		3 (16.7%)
• Shorten the form		1 (5.6%)
• Provide tablets for bigger screen		1 (5.6%)
• Avoid repetition of same content in the form		1 (5.6%)
Benefits of use of care suggestions, n (%)		
• It has led to better blood pressure control	12	3 (25%)
• Clinicians are more aware of the care protocols		9 (75%)
Challenges of use of care suggestions, n (%)		
• Care suggestions are not clear	12	1 (8.3%)
• Most care suggestions are not applicable		1 (8.3%)
• Use of care suggestions has provided additional work		1 (8.3%)
• There are no challenges		9 (75%)

4.6 Objective 3: Impact of adherence to patient –specific care suggestions on blood pressure control

Adherence to patient – specific care suggestions had no significant effect on blood pressure control (SBP < 140 mm Hg & DBP < 90 mm Hg) in the intervention arm vs the control arm OR: 2.41 (95% CI: 0.60 – 9.67) as shown in Table 8. However there was a high number of participants excluded from this model because of the need for follow-up of the participants with most not coming for the subsequent visits.

Table 8: Impact of adherence to patient –specific care suggestions on blood pressure control

Group	**[a]OR (95% CI)**
Adherent in the Intervention arm vs. Adherent in the control arm	2.41 (0.60 – 9.67)
Adherent in the Intervention arm vs. non-adherent in the control arm	0.57 (0.07 – 4.56)
Adherent in the Intervention arm vs. non-adherent in the intervention arm	1.43 (0.18 – 11.32)
Number of triggered care suggestions	298
Number of participants/patients	161

OR – Odds Ratio, 95% CI – 95% Confidence Interval, [a]Model adjusted for baseline blood pressure and visit time. 172 participants who had only the baseline encounter were not included in this model. 99 visits that occurred more than 180 days from the enrollment date were excluded from this model also. Therefore 217 participants were excluded from this model.

CHAPTER FIVE: DISCUSSION

5.1 Adherence to patient – specific care suggestions

This study demonstrated a high level of adherence to patient –specific care suggestions in both the intervention and control groups. This shows a high potential for the use of care suggestions in hypertension care programs. Several factors could explain this overall high level of adherence. Firstly, this study was conducted after rollout of the use of hypertension care suggestions and multiple trainings of the healthcare providers had been conducted over time. Therefore the providers were already familiar with the care guidelines that were used in the care suggestions. Secondly, the algorithms in the primary healthcare facilities are straight forward and basic, and most providers could easily remember them without need for care suggestions. This is primarily because at the lower level primary health care facilities for this study, treatment and medications options available to the healthcare providers and patients are limited. Care suggestions work well when there are big gaps in care guidelines and clinical practice with a wide range of laboratory & radiological investigations and management options. They are very useful in complex clinical scenarios and decision making.

Despite the overall high adherence rate, the adherence rates to care guidelines were still significantly higher in the intervention group compared to the control group: 91.1% vs 85.7%, AOR 1.78 (95% CI: 0.83 -3.80). The small difference in the two groups could be due to the fact that the healthcare providers in both arms were already familiar with the care guidelines through previous multiple trainings and were well trained. Although there could be various reasons to the small difference in the two groups, the presence of the patient – specific care suggestions in primary health care facilities provides confidence to the health leadership that the health care providers in the primary health care facilities have regular prompts on hypertension care guidelines and therefore an opportunity to standardize hypertension care in these facilities. Use of patient – specific care suggestions for other NCDs offers an opportunity to scale – up NCD care for other conditions including diabetes mellitus and common mental health conditions in primary care facilities. However for any additional task shifting of other NCDs to be successful, there will be need to address the gaps in HRH including posting higher cadre of staff to the primary care facilities.

5.2 Impact of patient – specific care suggestions on blood pressure control

There was no significant effect of the patient – specific care suggestions on blood pressure in this study. Bright et al. in a systematic review of 148 randomized controlled trials on the effectiveness of CDSS showed that CDSS are effective at improving health care process measures across diverse settings but evidence for measurable clinical, economic and efficiency outcomes were scarce (Bright et al., 2012). Secondly, CDSS and clinical care suggestions do not always improve clinical practice and patient outcomes (Kawamoto et al., 2005). Little sound scientific evidence is available to explain why some CDSS succeed and why others fail and do not lead to measurable clinical outcomes (Kaplan, 2001). In addition there are many other factors beyond adherence of hypertension care guidelines that influence blood pressure control that include: use of counterfeit essential drugs, poor adherence to medication by patients due to side effects, and therapy with only one blood pressure pill when therapy with more than one blood pressure pill is necessary (Chow et al., 2013).

5.3 Clinician barriers to adherence to patient – specific care suggestions

One of the dominant benefits in use of smartphones and patient –specific care suggestions in this study is that the health care providers were more aware of the hypertension care guidelines. Other studies have demonstrated that CDSS improve awareness of recommended care guidelines and standards. In addition, they also improve prescribing habits, reduce serious medication errors, and enhance delivery of preventive care services (Kawamoto et al., 2005). CDSS with resultant patient – specific care suggestions are most effective when based on real-time sensor data and historical electronic health data (El-Sappagh, Ali, Hendawi, Jang, & Kwak, 2019). However in our study, the patient – specific care suggestions did not use historical electronic health data. Therefore most of the patient – specific care suggestions that were rejected by the healthcare providers may have been implemented in previous patient – provider encounters and could have been unnecessary in the present patient provider encounters. From this observation, one of the proposals from this study is the incorporation of historical electronic health data in the generation of patient – specific hypertension care suggestions. In addition, there should be an emphasis on the entry of good quality data to ensure accuracy and safety of the patient – specific care suggestions that result from the CDSS.

Another barrier to use of smartphones and patient – specific care suggestions include healthcare provider attitude and alert fatigue. This is because 75% of the respondents in both the control and intervention groups did not think that the mHealth intervention in their respective primary care facilities had any impact on patient care. In addition, this response could also be because of lack of training and stakeholder participation at the stage of concept design, development and implementation of the mHealth interventions. Patient specific care suggestions are present continuously during the patient – provider encounter and alert fatigue has been blamed for the high override rates in contemporary CDSS (Ancker et al., 2017). Two mechanisms of alert fatigue are cognitive overload and desensitization. Cognitive overload is associated with increased amount of work, increased complexity of work and increased effort differentiating informative from uninformative alerts. Desensitization is from repeated exposure of the same alert over time. An alert is most effective when it is first noticed and steadily becomes less effective as an individual becomes acclimatized over time. Both of these mechanisms could apply to the primary health facilities where this study was conducted. An element of desensitization which may be more applicable is repeats. This is where a specific care suggestion (reminder) is delivered to one clinician multiple times in a year for the same patient. These were extremely common in other studies and represented one quarter of the best practice advisories and one third of drug alerts (Ancker et al., 2017). Alert fatigue might be reduced by prioritizing and selecting alerts that are critically important, that will have the greatest impact, and by tailoring alerts to specific specialties and severities (personalization) (Scheepers-Hoeks, Grouls, Neef, & Korsten, 2009). Another barrier in this study is the few number of health care providers (nurses and clinical officers) in the primary care facilities. This has a high impact on the quality of patient care and provider morale. Sustainable implementation of primary health services requires a competent and motivated human resources for health (Ministry of Health, 2014b).

5.4 Facility and health care provider characteristics

Primary healthcare facilities (dispensaries and health centers) provide basic essential healthcare services to the communities they serve (Ministry of Health, 2014a). Until a few years ago, dispensaries and health centers provided curative services for common infectious diseases and maternal & neonatal healthcare services. However, due to the rapid increase in chronic NCDs, there has been a need to scale – up services for common NCDs e.g hypertension & DM to the primary healthcare facilities. This is guided by the strategy to provide care for hypertension and other chronic NCDs in primary care facilities in line with the Kenya Health Sector Strategic and Investment Plan (KHSSP) July 2014 – June 2018 whose aim is to accelerate attainment of health goals (Ministry of Health, 2014a). This study demonstrates that hypertension care has been scaled up successfully in Turbo sub-county in Uasin Gishu County and Chesumei sub-county in Nandi County. This successful scale–up has also been demonstrated in other counties in western Kenya (Vedanthan et al., 2015).

Sustainable implementation of primary health services requires a competent and motivated human-resources for health. The Human Resources For Health Norms and Standards Guidelines for the Health Sector contained in the Kenya Health Strategic and Investment Plan, 2014 - 2018 specifies norms for all the range of cadres required for delivery of the Kenya Essential Package of Health for the health system (Ministry of Health, 2014b).

According to the Norms and Standards guidelines, each dispensary should have two to four community health nurses and two clinical officers. Health centers should have 8 – 12 community nurses in and six clinical officers (Ministry of Health, 2014b). In the primary health facilities where the study was conducted, there was inadequate provision of HRH, with one facility having only one nurse, with the median number of nurses in these facilities being two nurses. In 60% of the facilities, the only cadre of HCPs available were nurses who provided all the clinical services and covered administrative duties. Vedanthan et al. in a study in western Kenya on the workforce estimation model showed that for a primary care facility to efficiently offer hypertension care for two days in a month would require 4.4 – 5.3 full-time equivalent (FTE) time for clinical officers and 4.8 – 5.8 FTE time for community nurses (Vedanthan et al., 2019). These are targets that have not been achieved and the inadequate staffing in these facilities has a big impact on the quality of service provision and motivation of the personnel. The staff are unable to get time off work for on job training and the necessary leave days.

5.5 mHealth in primary healthcare facilities

Use of mobile communication technology in the health arena (mHealth) has been highlighted as a key strategy to combat NCDs in LMICs ((WHO), 2012). This is demonstrated in this study where use of smartphones has been implemented for electronic data capture at the patient – provider encounter using the mUzima application (application, 2021). This application then uploads all patient data to the AMRS. Use of mHealth technologies in these two sub-counties enables the collection of important clinical data that can be used for policy making and improvement of the quality of healthcare provision for

NCDs. In addition to the above technologies, implementation of patient specific care suggestions as part of the clinical decision support systems has been demonstrated in this study. CDSS implemented in these primary health care facilities enable standardization of care through use of hypertension care guidelines.

5.6 Patient demographic and clinical characteristics

Hypertension is one of the leading risk factors for cardiovascular disease and the leading cause of mortality globally (Mills et al., 2016). Hypertension is more prevalent in the elderly population. Results from a national survey in Kenya showed that respondents above the age of 50 years were significantly five times more likely to be hypertensive compared to those aged 18 – 24 years (Mohamed et al., 2018). This is demonstrated in our study with the study participants having a median age of 60 years in both the control and intervention groups, with one third of the participants being above the age of 70 years. However, in this study though there is approximately one third of the participants being below the age of 50 years. This is a young population that is the most economically productive, but yet susceptible to cardiovascular disease and its associated morbidity and mortality.

Patients with hypertension on care should be well-controlled with target blood pressures being less than 140/90 mmHg. The rate of blood pressure control among patients on treatment should ideally be 100%. However optimal blood pressure control in clinical settings has always been a challenge (Mohamed et al., 2018). In this study, 60% of the study participants had uncontrolled blood pressures of above 140/90mmHg with about 1 – 3% having blood pressures of above 180/110 mmHg. This is much higher than the national survey that showed that among those on treatment, a little over 50% of the study participants had achieved good blood pressure control (Mohamed et al., 2018). Though this study did not look at the reasons for poorly controlled hypertension, reasons that lead to poor blood pressure control could include counterfeit essential drugs, poor adherence to medication due to side effects, and therapy with only one blood pressure pill when therapy with more than one blood pressure pill is necessary (Chow et al., 2013).

5.7 Limitations of the study

The following were limitations of the study:

1. The patient – specific care suggestions in the smartphones did not utilize any historical electronic health data. Therefore some care suggestions were triggered by input of data whose action had already been effected in a previous visit.
2. There has been a low uptake of the use of smartphones in the primary care facilities and therefore resulted in a prolonged duration to achieve the desired sample size.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

Adherence to hypertension care guidelines in this study was high but higher in the intervention arm due to the presence of patient – specific phone generated care suggestions. However, there was no impact of adherence to the patient – specific care suggestions on blood pressure control.

6.2 RECOMMENDATIONS

1. Use of patient specific –care suggestions in primary care facilities should be considered as an additional strategy for improving adherence to hypertension care guidelines.
2. Further mixed methods studies to elucidate the cause of poor control of blood pressure other than adherence to care guidelines.
3. Upgrading of the patient – specific care suggestions to utilize historical electronic health data and therefore reduce the number of patient –specific care suggestions triggered in each patient – provider encounter.

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8. APPENDICES

Appendix I: Pro-forma for patient details abstracted

EVALUATION OF PATIENT-SPECIFIC MOBILE PHONE – GENERATED REMINDERS FOR HYPERTENSION CARE IN PRIMARY CARE SETTINGS IN WESTERN KENYA

Instructions

1. Data to be abstracted from Logins in the muZima mobile application during data entry by the clinician

Study Number __ __/__ __ __

Date (MUST FILL): dd/mm/year __ __/__ __/__ __ __ __

BIODATA

1. Date of birth: __ __/__ __/__ __ __ __ **(dd/mm/year)**
2. Gender (**Tick appropriate response**)
   ☐ Male ☐ Female
3. Primary language ________________
4. What is the patient's highest level of education?
   - ☐ No formal education
   - ☐ Primary school
   - ☐ Secondary school
   - ☐ College/ Technical Institute
   - ☐ University
5. What is the patient's occupation?
   - ☐ Casual laborer
   - ☐ Small scale business person
   - ☐ Farmer
   - ☐ Employed e.g teacher, police officer
6. Location ________________________
7. Sub-location ________________________
8. Name of dispensary ___________________
9. Hypertension status:
   - ☐ New hypertension patient
   - ☐ Known hypertension patient – Year of diagnosis ____/____ (**month/year**)

10. Diabetes status:

- ☐ Patient with diabetes mellitus – Year of diagnosis ____/____ (**month/year**)
- ☐ No history of diabetes mellitus

11. Do you smoke cigarettes

- ☐ Yes
- ☐ No
- ☐ Stopped

12. Do you sometimes take alcohol

- ☐ Yes
- ☐ No
- ☐ Stopped

<u>ANTHROPOMETRIC MEASUREMENTS</u>

1. Height (cm) _______________
2. Weight (Kg) _______________
3. BMI _______________
4. Waist circumference _______________
5. Blood pressure (mmHg) ________________

Observation	**First visit during study**	**Second visit during study**	**Third visit during study**
Chief complaint			
Blood pressure			
Blood sugar if DM			

Current medication	**Status**		**Dose**	**Status**		**Dose**	**Status**		**Dose**
	Yes	No		Yes	No		Yes	No	
1. Enalapril									
2. Lisinopril									
3. Lisinopril/HCTZ									
4. Losartan									
5. Nifedipine									
6. Felodipine									

Laboratory tests	Status		Status		Status	
	Yes	No	Yes	No	Yes	No

ordered							
	1.Urinalysis						
	2.HbA1C						
	3.Microalbumin						
	4.Creatinine						
	5.Potassium						
	6.ECG						
	7.Lipid profile						
	8.Other						

Care plan for visit		Status		Status		Status	
		Yes	No	Yes	No	Yes	No
	1.Lifestyle modification						
	2.Salt reduction						
	3.Exercise						
	4.Reduce alcohol						
	5.Smoking cessation						
	6.Weight reduction						
	7.Diet education						

Medication prescribed in this visit		**Status**		**Dose**	**Status**		**Dose**	**Status**		**Dose**
		Yes	No		Yes	Yes		Yes	No	
	1. Enalapril									
	2. Lisinopril									
	3. Lisinopril/hctz									
	4. Losartan									
	5. Nifedipine									
	6. Felodipine									

Referrals made		**Status**		**Status**		**Status**	
		Yes	No	Yes	No	Yes	No
	1.Health center						
	2.MTRH						
	3.Kitale District H.						
	4.Webuye D H.						
	5.Teso D H.						

Appendix II: Clinician questionnaire

EVALUATION OF PATIENT-SPECIFIC MOBILE PHONE – GENERATED REMINDERS FOR HYPERTENSION CARE IN PRIMARY CARE SETTINGS IN WESTERN KENYA

<u>Instructions</u>

2. To be filled by research assistant once the clinician consents to the study.
3. Please fill all sections.
4. If the response is a date and the participant does not remember the exact put the approximate year if still cannot remember the year write **00/0000**
5. Please write legibly and clearly.
6. Follow the instructions in each of the sections.

Clinician study Number __ __/__ __ __

Date (MUST FILL): dd/mm/year __ __/__ __/__ __ __ __

Mobile phone # ___________________________________

<u>BIODATA</u>

13. Date of birth: **__ __/__ __/__ __ __ __ (dd/mm/year)**
14. If date of birth unknown, age at last birthday: __ __ __ years
15. Gender (**Tick appropriate response**)
    ☐ Male ☐ Female
16. Religion (**Tick appropriate response**)
    ☐ Christian ☐ Muslim ☐ Hinduism ☐ Other
17. Primary language _________________

<u>WORK EXPERIENCE</u>

1. What is your medical training? (**Tick appropriate response**)
   ☐ Community Nursing
   ☐ Clinical officer
   ☐ Medical officer

2. Name of institution where you are working?
   a. ____
   b. ____
   c. ____
   d. ____
   e. ____

f. ____

3. For how many months/ years have you been working? (**months**)
   __ ____ __ __ __ (**months & year**)

4. For how many months/ years have you been working in this facility? (**months & year**) __ ____ __ __ __ (**months & year**)

USE OF MOBILE TECHNOLOGY FOR HEALTH

5. Have you been trained to use of smartphones for data entry during the patient-provider encounter?
   ☐ Yes ☐ No

6. Use of smartphones for data entry during the patient-provider has improved quality of patient care?
   ☐ Strongly agree
   ☐ Agree
   ☐ Disagree
   ☐ Disagree
   ☐ Strongly disagree

7. What are the benefits of the use of mobile device for data entry?

   ☐ Use less time to see patients
   ☐ Able to follow – up patients better
   ☐ Use of reminders has improved patient care
   ☐ There are no benefits

8. What are the challenges of the use of mobile device for data entry?

   ☐ Takes more time to see patients
   ☐ Small print makes difficulty to use
   ☐ It has provided additional work
   ☐ There are no challenges

9. What recommendations do you have to improve use of smartphones in the provision of patient care?
   i. ____
   ii. ____
   iii. ____
   iv. ____

v. ____

USE OF PATIENT REMINDERS DURING PATIENT CARE

10. Use of reminders during the patient-provider has improved quality of patient care?
    - ☐ Strongly agree
    - ☐ Agree
    - ☐ Disagree
    - ☐ Disagree
    - ☐ Strongly disagree

11. What are the benefits of use of reminders during the patient-provider?
    - ☐ It has led to better blood pressure control
    - ☐ It has shortened the time needed to see patients
    - ☐ The clinicians are more aware of the care protocols
    - ☐ There are no benefits

12. What are the challenges of the use of reminders during the patient-provider encounter?
    - ☐ The reminders are not clear
    - ☐ Most reminders are not applicable
    - ☐ It has provided additional work
    - ☐ There are no challenges

13. What recommendations do you have to improve the use of reminders during the patient-provider encounter?
    a) ____
    b) ____
    c) ____
    d) ____
    e) ____

Appendix III: Facility Data Collection Questionnaire

EVALUATION OF PATIENT-SPECIFIC MOBILE PHONE – GENERATED REMINDERS FOR HYPERTENSION CARE IN PRIMARY CARE SETTINGS IN WESTERN KENYA

Instructions

a. To be filled by research assistant once the facility in-charge clinician consents to the study.
b. Please fill all sections.
c. If the response is a date and the participant does not remember the exact put the approximate year if still cannot remember the year write **00/0000**
d. Please write legibly and clearly.
e. Follow the instructions in each of the sections.

Facility study Number __ __/__ __ __

Date (MUST FILL): dd/mm/year __ __/__ __/__ __ __ __

Participant name ________________________________

Mobile phone # __________________________________

FACILITY PROFILE

1. What level of care does this facility offer? (**Tick appropriate response**)
   - ☐ Dispensary
   - ☐ Health center
   - ☐ Sub – county hospital
   - ☐ County hospital

2. Name of health facility?

   ____

3. How many clinicians offer care in this facility? (**months**)
   i. Nurses' ____ __ __ __
   ii. Clinical officers' ____ __ __ __
   iii. Medical officers' ____ __ __ __

4. How many clinicians are trained to offer care chronic disease care (hypertension and diabetes mellitus) in this facility? (**months**)

i. Nurses' ____ __ __ __
ii. Clinical officers' ____ __ __ __
iii. Medical officers' ____ __ __ __

USE OF MOBILE TECHNOLOGY FOR HEALTH

5. Have any of the health care providers in this facility been trained on the use of smartphones for data entry during the patient-provider encounter?

☐ Yes ☐ No

6. How many health care providers in this facility been trained on the use of smartphones for data entry during the patient-provider encounter? (**months**)

iv. Nurses' ____ __ __ __
v. Clinical officers' ____ __ __ __
vi. Medical officers' ____ __ __ __

7. Has use of smartphones for data entry during the patient-provider has improved quality of patient care in this facility?

☐ Strongly agree
☐ Agree
☐ Disagree
☐ Disagree
☐ Strongly disagree

8. What are the benefits of the use of mobile device for data entry?

☐ Use less time to see patients
☐ Able to follow – up patients better
☐ Use of reminders has improved patient care
☐ There are no benefits

9. What are the challenges of the use of mobile device for data entry?

☐ Takes more time to see patients
☐ Small print makes difficulty to use
☐ It has provided additional work
☐ There are no challenges

10. What recommendations do you have to improve use of smartphones in the provision of patient care?
    vi. ______________________________
    vii. ______________________________
    viii. ______________________________
    ix. ______________________________
    x. ______________________________

USE OF PATIENT REMINDERS DURING PATIENT CARE

11. Has use of reminders during the patient-provider improved quality of patient care?
    - ☐ Strongly agree
    - ☐ Agree
    - ☐ Disagree
    - ☐ Disagree
    - ☐ Strongly disagree

12. What are the benefits of use of reminders during the patient-provider?
    - ☐ It has led to better blood pressure control
    - ☐ It has shortened the time needed to see patients
    - ☐ The clinicians are more aware of the care protocols
    - ☐ There are no benefits

13. What are the challenges of the use of reminders during the patient-provider encounter?

    - ☐ The reminders are not clear
    - ☐ Most reminders are not applicable
    - ☐ It has provided additional work
    - ☐ There are no challenges

14. What recommendations do you have to improve the use of reminders during the patient-provider encounter?
    f) ______________________________
    g) ______________________________
    h) ______________________________
    i) ______________________________
    j) ______________________________

Appendix IV: MOH facilities offering hypertension care where study was conducted

1	Birbiriet
2	Sambut
3	Chepsaita
4	Cheramei
5	Osorongai
6	Kokwet
7	Ngenyilel
8	Mogoget
9	Sugoi A
10	Sugoi B

Appendix V: MU – MTRH IREC Approval