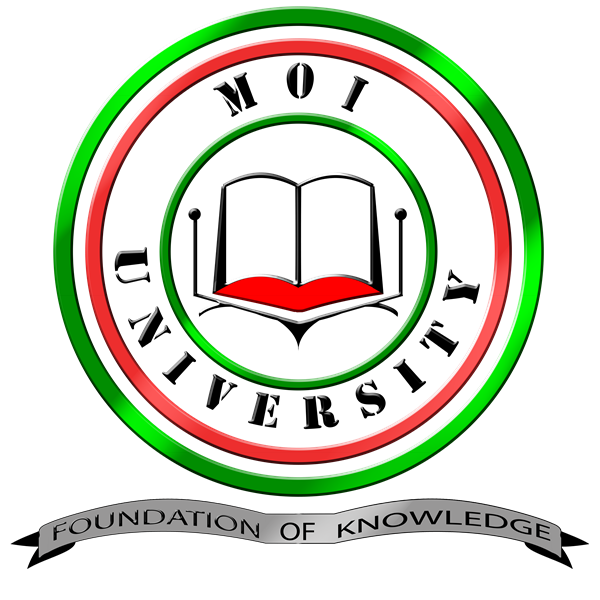
****

**MOI UNIVERSITY KENYA**

**COLLEGE OF HEALTH SCIENCES**

**INSTITUTE OF BIOMEDICAL INFORMATICS**

**Usability evaluation of a mobile application for monitoring home**

**blood glucose at AMPATH, Eldoret, Kenya.**

**BY: MAKUBA IGNATIUS**

**A Proposal Submitted to Moi University as a Partial Fulfillment of the**

**Requirement for the Award of a Master’s Degree in Health Informatics.**

**DECLARATION**

I IGNATIUS MAKUBA hereby affirm that I have personally developed this proposal on usability and feasibility of personal health record (PHR) for diabetes management. The contents of this proposal are original and not a duplication of similar published work of any scholar for academic purpose as a partial requirement of any university or higher institution of learning. I therefore declare that all material cited in this proposal which are not mine have been duly acknowledged.

Signed:

Date:

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APPROVAL

This proposal has been under our supervision as the University Academic Supervisors and has our approval for submission to the Institutional Research and Ethics Committee (IREC) for review.

|  |  |
| --- | --- |
| Signed: | Signed: |
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# Abstract

Background**:** Diabetes is a chronic disease where the body’s ability to produce or respond to the hormone insulin is impaired and can lead to multiple complications. There is strong evidence that patients with chronic diseases have better outcomes if they are empowered to self-manage their conditions. We intend to implement a mHealth application to support patient self-management of diabetes in a clinic in Western Kenya.

**Objectives:** Evaluate usability of self-monitoring feature of the mHealth application.

**Study design:** Cross-sectional study.

**Setting:** Academic Model Providing Access to Healthcare (AMPATH), Eldoret, Kenya.

**Subjects:** Diabetic patients with uncontrolled blood glucose, who own a smart-phone and aged between 18-65 years.

Methods:Twenty patients with smartphones will be recruited during diabetes clinic visits to participate in the study. The mHealth application designed for patients to enter their blood glucose values will be installed on their mobile devices and they will be trained to use it. Mixed methods approach will be used to evaluate usability, usage patterns, and effectiveness of the mHealth application in provider-patient communication.

**Data management and analysis:** Patient responses on the three usability metrics namely efficiency, effectiveness and satisfaction of the mobile application will be measured using ISO/IEC 25022:2016 standard. Descriptive statistics will be employed for usage patterns.

**Expected outcome:** A better understanding of the usability and feasibility of a mobile health application to support self-management by diabetic patients in an LMIC setting.

Conclusion: Engaging patients as copilots in health care hypothetically improves health care quality.

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# ABBREVIATIONS & ACRONYMS

AMPATH: Academic Model Providing Access to HealthCare.

AHIMA: American Health Information Management Association.

IBMI: Institute of Biomedical Informatics.

IREC: Institutional Research and Ethics Committee.

LMICs: Low and Middle Income Countries.

mPHR: Mobile Personal Health Record.

MTRH: Moi Training and Teaching Hospital.

OpenMRS: Open Medical Records System.

PHR: Personal Health Record.

WHO: World Health Organization.

# Chapter one: Introduction

Chronic diseases are a leading cause of mortality worldwide, and disproportionately affect LMICs which now account for 80% of deaths from cardiovascular disease and diabetes. There are big gaps (between patients in the same country) in the quality of care received by patients with chronic diseases in LMICs, and innovative strategies are needed to improve health outcomes.[1] There is strong evidence that these patients have better outcomes if they are empowered to self-manage their conditions. [2], [3]

Having patients as copilots in care can significantly enhance the quality of health care by upholding Institute Of Medicine’s (IOM) design rules [4]. However contemporary Electronic Health Record systems (EHRs) are provider oriented and insufficiently engage patients [4]. The need to facilitate patient engagement has proliferated inventions in patient-facing applications like Personal Health Records (PHRs).This study focuses on a mobile tethered PHR that will be developed for Home Glucose Monitoring (HGM) program. This is a project at Academic Model Providing Access to Healthcare (AMPATH) in Eldoret, Kenya. HGM program enrolls patients with uncontrolled blood glucose from AMPATH diabetes clinic.

## Problem statement

The HGM program issues strips, glucometers and manual booklets to patients for recording their blood glucose readings remotely from their homes. Providers call the patients on their mobile phones once a fortnight to obtain the recordings. If a provider notices out of range glucose values for a sustained period during the mobile conversation, the patient is advised accordingly; this could be a recommendation to change a diet or dosage, increase in exercise or any other change as deemed appropriate. The solicited details are then entered in a Microsoft Access database used to generate aggregate reports.

Both patients and providers in the current care setting have no access to meaningful information like charts to highlight individual’s disease trend and in case the manual booklet is misplaced the patient is left without any reference. There is a limitation to the reports providers can generate from the Microsoft Access system, for instance during the HGM clinic episode, providers want to see a comprehensive history of the patient from the Open Medical Record System (OpenMRS) used in AMPATH. This is not possible because the Microsoft Access information system operates as a data silo, it does not exchange data with OpenMRS. Another limitation to the HGM program is that, glucose values can only be retrieved from patients after providers contact them. This is exhausting to providers and inefficient in triaging treatment, since they must contact all patients instead of only those who need medical attention.

## Justification of the study.

The increasing demographics of the elderly population rises the odds of chronic diseases morbidity, which has implications of health costs escalation [5]. To contain the sky rocketing health care costs more effective and efficient methods are necessitated [5]. Remote Patient Monitoring (RPM) is a novel practice with potential to improve health care quality at reduced costs [5]. RPM facilitates proactive longitudinal clinical care which is an improvement compared to the conventional reactive outpatient visit-based model [6].

## Significance of the study

The significance of this study is to unravel usability constraints of a mobile application developed for patient self-data entry.

## Research question

What are the usability challenges that needs to be addressed to achieve an adaptable mobile application for self-data entry?

## Objectives of the study

### Broad objective

Evaluate usability of a mobile application developed for patient self-data entry.

### Specific Objectives

* Evaluate the efficiency of the mHealth application to support patient care.
* Evaluate effectiveness at facilitating patient-provider communication and collaborative diabetes management
* Evaluate user satisfaction and usage-patterns of the application

# Chapter two: Literature Review

## PHR definition

“An electronic application through which individuals can access, manage and share their health information, and that of others for whom they are authorized, in a private, secure, and confidential environment”[7].

## PHR architectures

PHR can be classified in three categories based on communication with external systems[8].

* Standalone PHR; exist independently from other systems and only managed by the consumer.
* Integrated PHR; exchanges information with other systems but lacks standards to manipulate the imported information. This model is tethered to providers EHR and patients can have access to a subset of the EHR data.
* Interconnected PHR; integrates with external systems and has established standards to interpret and use the exchanged information.

## PHR data types

PHRs have two main sources of data; health facilities and individuals[8]. The list below shows the various data elements that can be collected on a PHR[8].

* Problem list is “significant illnesses and operations the patient has experienced”[9].
* Procedures
* Major illnesses
* Provider list
* Allergy data
* Home monitored data
* Family history
* Social history and lifestyle
* Immunizations
* Medications
* Laboratory tests

## PHR adoption facilitators

Health Insurance Privacy and Portability Act (HIPAA) mandates patients to access their medical records[10]. The uptake of this legislation has promoted growth of Patient-Facing Information Systems (PFIS) which promotes patient engagement in health care. PFIS are technologies offering functionalities that allow patients to actively participate in their health care [11]. The rising morbidity of chronic diseases has also made many patients and their families open to health interventions like PHRs[7].

## PHR barriers to adoption

The following factors are seen as encumbrances to the uptake of PHRs[12][13][14][15][16];

* Data security and privacy concerns
* How to handle authentication for minors
* Provider’s reservations over perceived loss of control in health proceedings
* The type of information to be shared by patient (e.g. problem lists, medication, clinical notes)
* Lack of ubiquitous EHR adoption by health facilities
* Legal implications of using PHRs (e.g. negligence charges on practitioners)
* Low accuracy of patient entered data
* Lack of financial incentives and reimbursement mechanism for providers
* Lack of evidence to endorse their effectiveness in improving health outcomes
* Limited consumer physical and cognitive abilities

## PHR perceived benefits

PHRs have been demonstrated to improve patient adherence to medications, reduce medical errors, improve patient-provider communication, improve chronic disease management, and promote behavior change[8], [17], [18]. PHRs integrated with EHRs show even greater benefits when compared to standalone PHRs[8], [19]. These benefits are especially relevant to patients with chronic diseases who need to manage their conditions over time[20]. Electronic personal health records have the potential to empower patients through greater access to personal data, health information, and communications tools, which may aid self-care, shared decision making, and clinical outcomes[13][21]. A PHR can consolidate longitudinal individual health information improving quality and simultaneously reducing health care expenses[5].

## Remote Patient Monitoring (RPM) feature of a PHR

### Application of remote patient monitoring

RPM is defined as “the monitoring of vital signs in a setting other than a hospital, using information and communication technologies to transfer data over geographical distances” [22]. Physiological variables that can be monitored remotely are; blood pressure, heart rate, ECG, SpO2, temperature, respiration, blood glucose and weight [5].

### Benefits of remote patient monitoring for diabetes

RPM can enable providers detect patterns of glycemic control early and recommend therapy in time before it becomes a chronic problem[23]. Practitioners can monitor glucose level fluctuations and testing frequency and advise treatment frequently than it is contemporarily possible[23]. The immediate feedback obtained from RPM on glycemic control might enhance patient’s satisfaction with treatment[24].

### Usability of remote patient monitoring feature

“Usability is usually defined as the extent to which people can quickly learn to reliably and safely operate a device” [25]. Disability and discomfort resulting from chronic diseases may compound the difficulty of using technologies like RPM, especially for the elderly patients [25]. RPM is yet to be fully integrated into the mainstream health care system, one of the challenges being technical incompatibility emanating from poor usability[22]. The usability limitations of RPM necessitates thorough evaluation of usability metrics to enhance its adoption in mainstream health care.

# Chapter three: Methodology

## Scope of the study

Study area

Study site will be at AMPATH center in Eldoret. AMPATH is an acronym for Academic Model Providing Access to Healthcare. It’s a research organization focusing on providing care for chronic disease patients like HIV AIDS, diabetes, hypertension, cancer and tuberculosis.

### Study population

Diabetic patients enrolled in HGM program.

### Eligibility criteria

#### Inclusion criteria

* Must be Patients enrolled in home glucose monitoring program.
* Must have a smartphone or tablet.
* Must be English or Swahili speaker.

#### Exclusion criteria

* Patients below 18 years of age.
* Patients above 75 years.
* Non-android operating systems.

## Study design

A cross-sectional study design will be used. A cross-sectional study is a type of observational study in which the investigator measures the outcomes and the exposures in the participants at the same time. Cross-sectional study is the apt design for this study because of the limited research time.

## Sample size determination

Twenty patients will be sampled during diabetes clinic visits to participate in the study, 10 male and 10 female. Faulkner’s recommendation for 10-20 users uncovers about 90 to 95% of usability issues[26].

### Sampling procedure

Purposive sampling will be used to recruit 20 participants. Purposive sampling is a non-probability sampling method and it occurs when elements selected for the sample are chosen by the judgment of the researcher with the goal of obtaining a representative sample.

## Data collection

The research will be divided into three phases: 1) PHR application installation on patient’s mobile devices and training; 2) Patients will use the application for a two months period to enter and submit blood glucose values to OpenMRS; 3) Usability evaluation will be conducted by a research assistant (RA) on their subsequent next visit date after the two months. In phase 1, patients will be trained how to login in the application, record blood glucose values and transmit it via the internet to an OpenMRS server used by HGM providers. During the training patients will be asked to perform the above processes on their own before ending the session. In phase 2, patients will be asked to use the PHR app for two months to record the actual blood glucose values remotely once they obtain them from the glucometers. Phase 3 will be performed on the next visit date after the two months period. A think aloud usability evaluation will be performed on each participant’s interaction with the PHR app to identify usage patterns. Semi-structured questionnaires will be used to decode participant responses. Observations and interviews will be audio recorded and transcribed verbatim.

## Data management

Participant responses will be coded and labeled then stored on password protected computers. This will ensure access by only authorized personnel. The data will be backed up on secure cloud servers.

## Data analysis

Mixed methods employing both quantitative and qualitative techniques.

## Quantitative analysis

ISO/IEC 25022:2016 standard will be used to measure user satisfaction, efficiency and effectiveness in using the application for provider-patient communication.

The ISO/IEC 25022:2016 standard defines quality in use measures for the characteristics defined in ISO/IEC 25010, and is intended to be used together with ISO/IEC 25010. It can be used in conjunction with the ISO/IEC 2503n and the ISO/IEC 2504n standards or to more generally meet user needs with regard to product or system quality[27]. The three usability constructs can be defined as follows according to ISO/IEC 9126-4 [28];

* **Effectiveness:** The accuracy and completeness with which users achieve specified goals
* **Efficiency:** The resources expended in relation to the accuracy and completeness with which users achieve goals.
* **Satisfaction:** The comfort and acceptability of use.

User satisfaction, efficiency & effectiveness of the application will be evaluated using the tools in appendix I, II and III respectively. Various descriptive statistics including mean, median, mode and standard deviation will be computed to describe the consumer responses. Tables and graphs will be drawn for visual representation of the data.

## Qualitative analysis

Qualitative methodology will be leveraged to measure usage patterns of the glucose self-monitoring application through a think aloud exercise. The observation guide tool in appendix IV will be utilized. This observation guide was developed from previous studies that categorizes four usability issues namely, (1) navigation problems (e.g. difficulty advancing a page), (2) content comprehension and completeness (e.g., health terminology not well understood, or desired information missing), (3) socio-cultural appropriateness (e.g., misfit of message or technology with the user’s socio-cultural background) and (4) proxy user problems, defined as user difficulty understanding content or performing tasks due to being a proxy, not a target user of the intervention [29]. Responses will be coded to identify existing and emerging themes that will be quoted for analysis.

## Dissemination plan

Dissertation will be presented to IREC and IBMI, I also plan to write a paper for dissemination of this knowledge.

## Study limitations

Most elderly diabetic patients might not be in ownership of smartphones and so this might introduce a selection biased during study recruitment. I will develop a native android application and so participants with smartphones running ios, windows, blackberry and others will not be eligible.

## Ethical considerations

Written Informed consent will be provided to participants in both English and Swahili before enrollment.

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## APPENDECIES

## APPENDIX I: POST-TEST QUESTIONNAIRE ON SATISFACTION

|  |  |  |
| --- | --- | --- |
| **Study number:** | |  |
| **SECTION 1: DEMOGRAPHICS** | | |
| **Question** | | **Responses (circle one)** |
| 1.1 | Gender | 1. Male 2. Female |
| 1.2 | Age | 1. 18-27 2. 28-37 3. 38-47 4. 48-57 5. 58-67 6. 68-Above |
| **SECTION 2: LEVEL OF SATISFACTION**  **Instructions:** For each of the following statements, mark one box that best describes your response. | | |

***strongly agree strongly disagree***

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | 1 |  | 2 | 3 | 4 | 5 | 6 | 7 |
| 1. | Overall, I am satisfied with how easy it is to use this system. |  |  |  |  |  |  |  |  |
| 2. | It was simple to use this system. |  |  |  |  |  |  |  |  |
| 3. | I can effectively complete my work using this system. |  |  |  |  |  |  |  |  |
| 4. | I am able to complete my work quickly using this system. |  |  |  |  |  |  |  |  |
| 5. | I am able to efficiently complete my work using this system. |  |  |  |  |  |  |  |  |
| 6. | I feel comfortable using this system. |  |  |  |  |  |  |  |  |
| 7. | It was easy to learn to use this system. |  |  |  |  |  |  |  |  |
| 8. | I believe I became productive quickly using this system. |  |  |  |  |  |  |  |  |
| 9. | The system gives error messages that clearly tell me how to fix problems. |  |  |  |  |  |  |  |  |
| 10. | Whenever I make a mistake using the system, I recover easily and quickly. |  |  |  |  |  |  |  |  |
| 11. | The information (such as online help, on-screen messages, and other documentation) provided with this system is clear. |  |  |  |  |  |  |  |  |
| 12. | It is easy to find the information I needed. |  |  |  |  |  |  |  |  |
| 13. | The information provided for the system is easy to understand. |  |  |  |  |  |  |  |  |
| 14. | The information is effective in helping me complete the tasks and scenarios. |  |  |  |  |  |  |  |  |
| 15. | The organization of the information on the systems screens is clear. |  |  |  |  |  |  |  |  |
| 16. | The interface of the system is pleasant. |  |  |  |  |  |  |  |  |
| 17. | I like using the interface of this system. |  |  |  |  |  |  |  |  |
| 18. | This system has all the functions and capabilities I expect it to have. |  |  |  |  |  |  |  |  |
| 19. | Overall, I am satisfied with this system. |  |  |  |  |  |  |  |  |

**APPENDIX II: POST-TEST QUESTIONNAIRE ON EFFECTIVENESS**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Day | User can login | User can record glucose values | User can send data to provider | Provider received data | User can view historical data | User can interpret data |
| Day 1 |  |  |  |  |  |  |
| Day 2 |  |  |  |  |  |  |
| Day 3 |  |  |  |  |  |  |
| Day 4 |  |  |  |  |  |  |
| Day 5 |  |  |  |  |  |  |
| Day 6 |  |  |  |  |  |  |
| Day 7 |  |  |  |  |  |  |
| Day 8 |  |  |  |  |  |  |
| Day 9 |  |  |  |  |  |  |
| Day 10 |  |  |  |  |  |  |

**Instructions**: Fill 0 or 1 in the boxes above appropriately.

0: goal is not achieved

1: goal is achieved

**APPENDIX III:** **POST-TEST QUESTIONNAIRE ON EFFICIENCY.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Day | Using the Application | Without using the application | Time entered by patient | Time received by provider | Duration  Between patient glucose reading and provider obtaining results (Seconds) |
| Day 1 |  |  |  |  |  |
| Day 2 |  |  |  |  |  |
| Day 3 |  |  |  |  |  |
| Day 4 |  |  |  |  |  |
| Day 5 |  |  |  |  |  |
| Day 6 |  |  |  |  |  |
| Day 7 |  |  |  |  |  |
| Day 8 |  |  |  |  |  |
| Day 9 |  |  |  |  |  |
| Day 10 |  |  |  |  |  |

**APPENDIX IV: OBSERVATION GUIDE FOR USAGE PATTERNS.**

1. Participant had difficulty navigating the application?

Yes……No….. If yes explain………………………………………..

………………………………………………………………………………………………………………………………………………………………………………………………………………………………

1. Participant had difficulty with content comprehension? Yes………No……If yes explain ……..……………………………....

……………………………………………………………………………..…………………………………………………………………...……………..…………………………………………………………...……………………………………………………………………………

1. Participant raised concerns with social-cultural appropriateness? Yes…..No…..If yes explain………………………………………….

……………………………………………………………………………..………………………………………………………………………………..…………………………………………………………………………………………………………………………………….

1. Proxy user problems?

Yes…..No…..If yes explain………………………………………….

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1. Other………………………………………………………………………..………………………………………………………………………………...………………………………………………………………………………...…………………………………………………………………………………...