Mobile Viewing and Self-Management of Patient's Electronic Health Records (EHRs) with MyHealthCloud

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complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Abstract

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Muhammad Nsr Khan

Mobile computing has become one of the most dominant computer use paradigms and an essential part of the modern healthcare environment. As these applications become more sophisticated, a trend will inevitably develop towards providing comprehensive support for healthcare practitioners.

According to industry estimates, by 2018, 50 percent of more than 3.4 billion smart phone and tablet users will have downloaded mobile healthcare apps. These users include healthcare professionals, consumers and patients. In the United States, the Food and Drug Administration (FDA) is encouraging the development of mobile medical applications that improve healthcare and provide consumers and healthcare professionals with valuable health information.

In this thesis, we propose a novel mobile healthcare platform for the visualization and management of patients' medical reports, named MyHealthCloud. The research offers a new approach to store, retrieve and share the medical reports for patients and doctors. This new platform maximizes the benefits of mobile health technology by providing the best possible way for healthcare professionals to share information with their patients efficiently and effectively.

This thesis empirically validates the usability of the proposed approach and clearly demonstrates its usefulness, providing details of the empirical study conducted with end-users in a real environment at various hospitals.

Dedication

I am grateful to the Almighty for his guidance and protection throughout my life.

First and foremost, I would like to express my thanks and gratitude to my thesis advisors Dr. Olga Ormandjieva and Dr. Kristina Pitula for their confidence in me, guidance, moral support and constant encouragement during this journey of research.

I would like to express my deepest thanks and gratitude to my parents for giving and bringing so much happiness into my life and for their special encouragement, prayers and support.

A special feeling of gratitude to my elder brother, Mr. Muhammad Omar Khan for being a role model in academic interest and for his emotional and financial support, patience and understanding throughout this long process.

A warm appreciation to my friend, Mr. Osama Ali for his support and motivation through every step of my thesis work.

Love for my family specially my nephews and nieces and also my friends who added great pleasure to my life during the challenging times of this work.

I dedicate this work to my wonderful parents, Mr. Mushtaq Ahmed Khan and Mrs. Tasneem Khan, who disciplined my childhood with their love and measureless support.

Lastly, I would like to thank everyone who has contributed to the success of this research. I pray that the Almighty reward you all abundantly.

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Chapter 1. Introduction

An **electronic health record** (EHR) is a digital version of a patient's paper based record. EHRs are real-time, patient-centric medical records that make information available instantly and securely to authorized users. It is a more reliable and flexible technique to store and consume patients' data (see Fig 1.1). Since the introduction of this technology to the market, hundreds of health related mobile applications have been developed so far, out of which the majority are just *"a little more than glorified diaries or pamphlets"* [1]. A growing number, though, are tapping into this technology and packing some sophisticated features in their apps.

"The truth is, we're all cyborgs with cell phones and online identities." (Geoff Johns)

There is no doubt in considering that cell phones have become our identity and stay with us all the time. So why do we not use it as a platform to communicate with healthcare professionals? As people travel around the world, they often require support and guidance from their doctors. So, there should be a mechanism in place whereby we can discuss and share our problems with healthcare professionals anytime and anywhere. There should be a mechanism whereby we could share our medical history in the form of EHRs, and get an opinion from professional medical practitioners.

"The mobile phone... is a tool for those whose professions require a fast response, such as doctors or plumbers." (Umberto Eco)

Mobile applications have a potential to help people manage their own health and wellness and promote healthy living. According to industry estimates, by 2018, 50 percent of the more than 3.4 billion smart phone and tablet users will be using mobile health applications [2]. These users include healthcare professionals, consumers, and patients.

"EHRs will improve caregivers' decisions and patients' outcomes. Once patients experience the benefits of this technology, they will demand nothing less from their providers. Hundreds of thousands of physicians have already seen these benefits in their clinical practice" [3]. The FDA also supports the use of EHRs and patient-driven health systems for clinical investigations [4].

The FDA encourages the development of mobile medical apps that improve health and provide patients, consumers and healthcare professionals with valuable health information. The FDA also has a public health responsibility to oversee the safety and effectiveness of medical devices - including mobile medical applications. The FDA has issued the "Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff" [5] that explains the FDA's categorization of mobile medical applications as Class III (high-risk) to Class I (low-risk). Applications that analyze a patient's data or create a medical report pose a greater risk to a patient's health. The FDA focuses only on those applications that pose a greater risk to patients' health to make sure that they work properly without any malfunctioning.

Health Canada Infoway, Health Canada and the Canadian Institute for Health Information have produced a report in 2013, "Better Information for Improved Health: A Vision for Health System Use of Data in Canada" about the rapid emergence of electronic health records. It explains that technological advances and innovations will support health system decision-making in the future by providing privacy and security options [6]. The report states, *"The vision's foundation rests on key enablers that support the appropriate and responsible collection and use of electronic health data. The enablers include the governance mechanisms that establish leadership and accountability, the legislation and policies that identify how data should be used and protected, as well as the technology that allows us to collect, exchange, integrate and analyze health data and turn it into actionable information".*

Top Benefits of Electronic Medical Records

	Disagree	Neutral	Agree
Greater accessibility of charts	19.15%	4.26%	76.6%
Greater legibility of notes	14.9%	12.77%	72.34%
More accurate and up-to-date patient information	25.53%	8.51%	65.96%
Improves coordination of treatment by more than one provider	23.41%	10.64%	65.96%

Figure 1.1 Survey showing top benefits of Electronic Health Records (EHRs) [7]

1.1 Motivation

In a recent study of the top 300 iPhone and Android medical/health apps, the leading categories in order of popularity were exercise, reference, and weight loss [8].

A Smartphone's Global Positioning System (GPS) can communicate with medical mobile applications to guide users about their running, fitness and other exercises. Numerous Smartphones have sensors and accelerometers that measure increasing speed during running. There are also some applications that guide the users with general medical information and fitness tips [8].

1.1.1 Advantages of Mobile Apps use in Public Health Arena

The main advantage of cell phone use in a public health arena may be the accessibility and dissemination of information. Today, 88% of Americans own a cell phone, half of which are smartphones, and only 20% of US adults do not access the Internet at all either through traditional home computing or devices such as smartphones [9], giving us a total of 140.316 Million users only from the USA.

Given adequate network availability, patients now have access to new tools for changing health behaviors, managing medications, and perhaps being notified about test results by their healthcare providers.

Healthcare providers in more remote locations can use smart phones as a form of telemedicine. Around the world, initiatives are underway to use smart phone-based systems in rural healthcare settings, or as public health tools in various research or hospital-based outcome studies.

Doctors' and caregivers' ability to make educated treatment choices improve rapidly and securely by using a patient's complete medical information [10].

A majority of adopters reported having accessed a patient's chart remotely (74%) and of being alerted to critical lab values (52%) by using their EHR system within the past 30 days [11]. A majority also reported that using the EHR system had resulted in enhanced overall patient care (74%), as shown in Fig 1.2 [11].

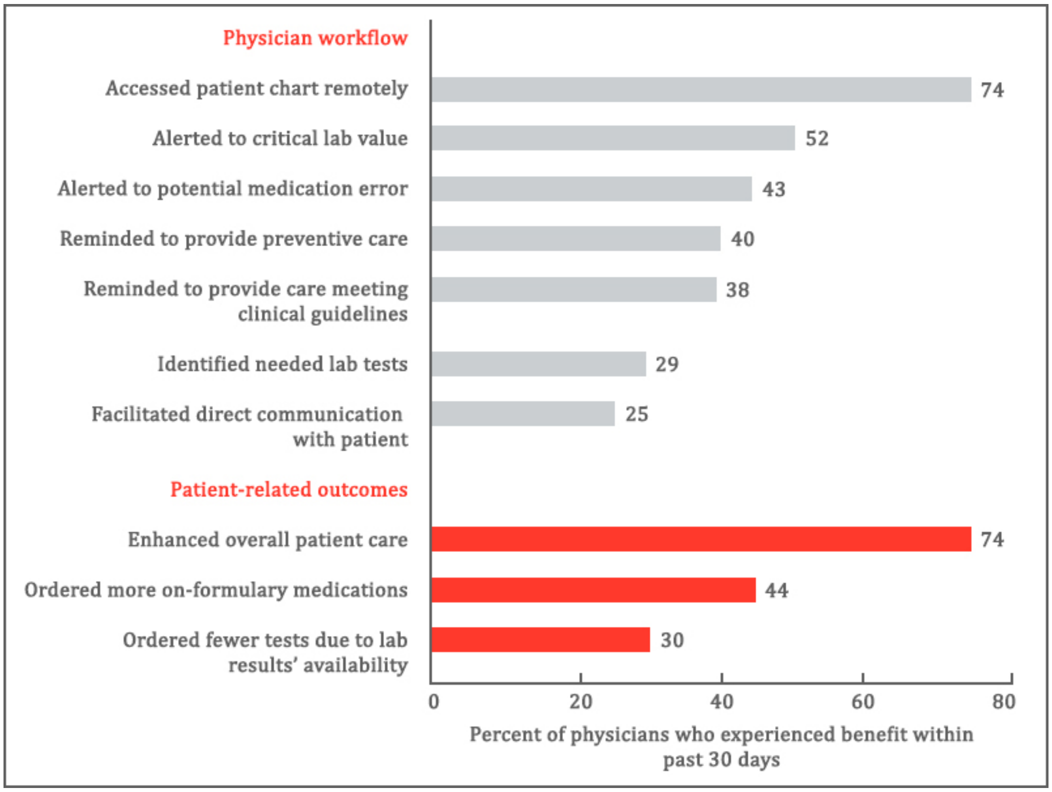


Figure 1.2 Percentage of physicians who's EHRs provided selected benefits: United States, 2011

eClinicalWorks is a privately held, leader in ambulatory clinical solutions. Its technology extends the use of electronic health records beyond practice walls and creates community-wide records [12]. According to eClinicalWorks, here are few statistics about e-Health [13]:

- 89% of Physicians would recommend a mobile health app to a patient.
- 93% believes that a mobile health app can improve a patient health outcome (find value in having a mobile health app connected to EHRs).

- Six out of ten Physicians said a top benefit would be the ability to provide patients with automatic appointment alerts and reminders.

1.1.2 Potential Impact of EHR Self-Management with Mobile Apps

The top health issues where a mobile health application linked to an EHR could make an impact are [13]:

- Preventative care – 52%
- Diabetes – 54%
- Medication Adherence – 65%

"We are all now connected by the Internet, like neurons in a giant brain." (Stephen Hawking)

In this research we target EHR self-management that has the potential to impact top issues in heath intervention.

1.1.3 Top EHR Self-Management Strategies for Mobile Apps

In this research, four key health intervention strategies were identified for mobile phone applications:

Key#1: Tracking health information (self-monitoring).

Keeping track of all paper-based medical test results can be a challenge. With a mobile medical application, users can view and manage all that information in one easily accessible location.

Key#2: Involving the healthcare team (remote coaching and remote symptom monitoring).

Lack of patient-doctor communication creates situations where medical errors can occur. These errors have the potential to cause severe injury or unexpected patient death. So it is better to have a remote coaching app to receive help when needed.

Key#3: Leveraging social influence (support from peers or family).

Mobile medical applications can be used for facilitating peer-to-peer support, influence and/or modeling, with the integration of social media functions.

Key#4: Increasing the accessibility of health information.

Seventy percent of Canadians go online to search for medical or health-related information [14], and it has been reported that the Internet, rather than physicians, is the first source of information for many people [15].

The above four key strategies greatly motivated the problem statement of this thesis.

1.1.4 Need for Mobile Devices at the Point of Care

One major motivation driving the widespread adoption of mobile devices by Health Care Professionals (HCPs) has been the need for better communication and information resources at the point of care [16, 17]. As the **National Center for Biotechnology Information (NCBI)** described, ideally, HCPs require access to many types of resources in a clinical setting, including:

- Communication capabilities - voice calling, video conferencing, text, and e-mail.
- Hospital information systems (HISs) - electronic health records (EHRs), electronic medical records (EMRs), clinical decision support systems (CDSSs), picture archiving and communication systems (PACSs), and laboratory information systems (LISs).
- Informational resources - textbooks, guidelines, medical literature, drug references.
- Clinical software applications - disease diagnosis aids, medical calculators.

"The Internet: transforming society and shaping the future through chat." (Dave Barry)

Based on a survey of 182 colorectal surgeons aged 21-50 across the UK and Europe, 83.5% owned a Smartphone or tablet and many responded that they were likely to use them for accessing medical information [18].

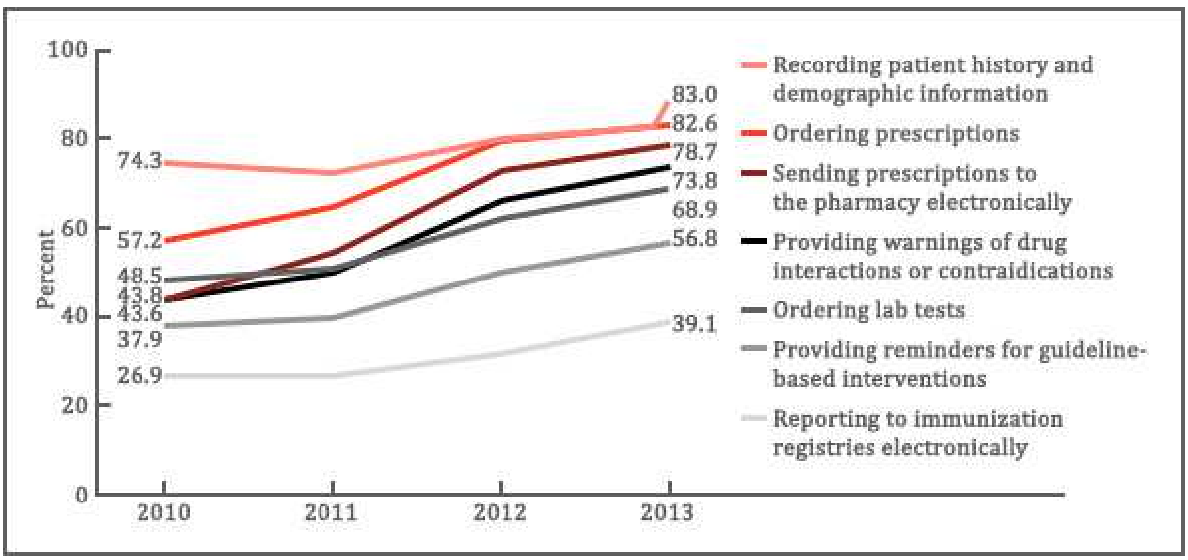


Figure 1.3 Percentage of Physicians with computerized capabilities to meet selected Stage 2 Core Objectives: United States, 2010 – 2013 [19]

Fig 1.3 shows the increased adoption that occurred for seven of the capabilities for which trend data from 2010 is available. Adoption increased by 12% for the objective of recording patient demographics and increased by 80% for the objective of sending prescriptions calculated electronically [19]. In 2013, the adoption of computerized capabilities supporting seven Stage 2 Core objectives for meaningful use ranged from 39% (submitting electronic data to immunization registries or information systems) to 83% (recording patient demographics).

This along with the points previously listed in Section 1.1 inspired this research on EHRs and motivated the research problem and objectives of this work.

1.2 Problem Statement

According to the discussion above, the problem tackled by this research is:

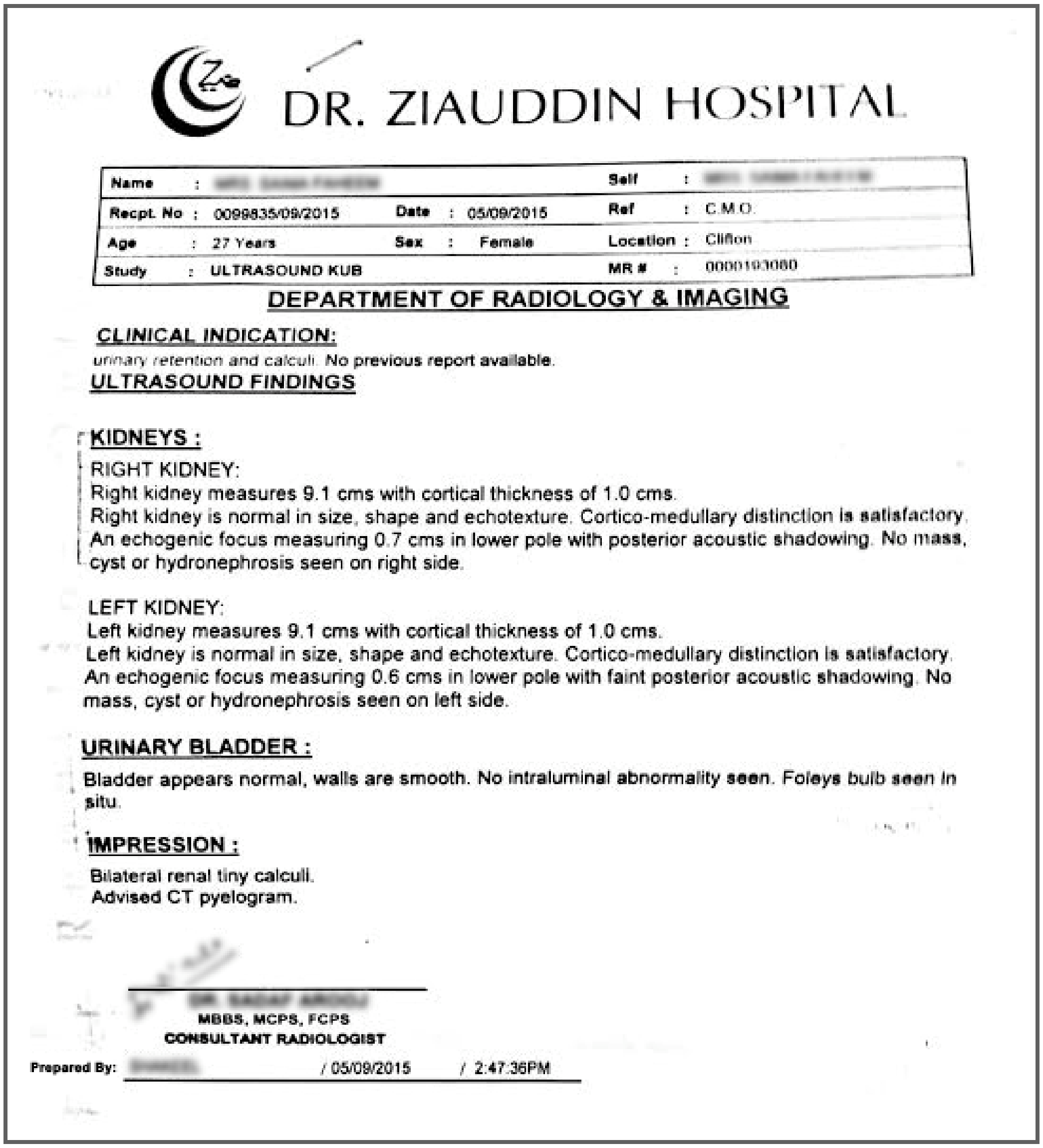
EHRs have already eased the life of medical practitioners in terms of saving, searching and retrieving data digitally instead of writing patient information on paper and keeping it in a folder. EHR technology consumes less time and effort than a hand-written method. But even after adopting EHR, many hospitals and clinics keep their patients' records to themselves. They do not intend to share them with other hospitals or even with the respective patient.

Healthcare is currently facing the challenge of a large amount of data that is unstructured, diverse and growing at an exponential rate. Data is constantly streamed through sensors, monitors and instruments in real time, faster than medical personnel can keep up with it. For instance, there are about 16,000 hospitals worldwide that collect patient data and 80% of this data is unstructured. With the advanced techniques and high capacities of cloud computing, processing of a large amount of data can be performed more efficiently and support big data analytics.

Currently, hospitals and clinics may only share some of their data with insurance companies. But what if a patient wants to access his medical records, as he/she might need to discuss and share them with another doctor? Fig 1.4 shows a typical version of a printed medical report that is being provided by doctors, hospitals or clinics upon a patient's request.

"We're still in the first minutes of the first day of the Internet revolution." (Scott Cook)

Unfortunately, even after so many advances in technology, we still lack a platform where we can instantly contact any medical professional for assistance at the time of an emergency for free. Dialing 911 does not work in all countries, but the Internet does.



DR. ZIAUDDIN HOSPITAL

Name	: [illegible]			Self	: [illegible]
Recpt. No	: 0099835/09/2015	Date	: 05/09/2015	Ref	: C.M.O.
Age	: 27 Years	Sex	: Female	Location	: Clifton
Study	: ULTRASOUND KUB			MR #	: 0000193080

DEPARTMENT OF RADIOLOGY & IMAGING

CLINICAL INDICATION:

urinary retention and calculi. No previous report available.

ULTRASOUND FINDINGS

KIDNEYS :

RIGHT KIDNEY:
Right kidney measures 9.1 cms with cortical thickness of 1.0 cms.
Right kidney is normal in size, shape and echotexture. Cortico-medullary distinction is satisfactory.
An echogenic focus measuring 0.7 cms in lower pole with posterior acoustic shadowing. No mass, cyst or hydronephrosis seen on right side.

LEFT KIDNEY:
Left kidney measures 9.1 cms with cortical thickness of 1.0 cms.
Left kidney is normal in size, shape and echotexture. Cortico-medullary distinction is satisfactory.
An echogenic focus measuring 0.6 cms in lower pole with faint posterior acoustic shadowing. No mass, cyst or hydronephrosis seen on left side.

URINARY BLADDER :

Bladder appears normal, walls are smooth. No intraluminal abnormality seen. Foleys bulb seen in situ.

IMPRESSION :

Bilateral renal tiny calculi.
Advised CT pyelogram.

[illegible]
MBBS, MCPS, FCPS
CONSULTANT RADIOLOGIST

Prepared By: [illegible] / 05/09/2015 / 2:47:36PM

Figure 1.4 Example of a typical patient's paper based medical report

1.3 Research Objectives

The objective of this research is to bridge the gap between IT and the Health Care sector by creating an efficient and secured (FDA approved) mobile platform for the viewing and self-management of EHRs, as well as patient-doctor or patient-caregiver EHR sharing. Additionally, an SOS Message Service is also introduced that will help patients send their current location and ask for help from caregivers by tapping a single button at the time of an emergency. This feature should go viral such that caregivers could provide assistance to patients at the time of an emergency and save as many lives as possible.

The user interface should be so simple that any customer, regardless of age or IT familiarity could use it with ease.

1.4 Research Questions and Hypotheses

The research problem discussed in the previous section leads us to the following research questions:

1. Will patients', doctors' and caregivers' satisfaction be increased by viewing and self-managing medical health reports on a mobile device via a secured platform?

2. Will patient-doctor and patient-caregiver communications be enhanced via mobile devices by providing a medical reports sharing option?

We hypothesize that our proposed approach called MyHealthCloud, offers a far more effective way to view and self-manage medical health reports on a mobile phone. It also offers a secure mobile-based patient-doctor and patient-caregiver means of communications.

Based on the research questions above, the following hypotheses are to be specifically tested in this study:

Hypothesis H1: Patients, doctors and caregivers prefer to use MyHealthCloud to view their medical reports.

Hypothesis H2: Patients, doctors and caregivers prefer medical reports self-management with MyHealthCloud.

Hypothesis H3: MyHealthCloud improves communication and connectivity between patients, doctors and caregivers (including receiving and sending of patient medical health reports and a novel emergency contact to a doctor or friend).

A usability study will be designed and conducted to support or refute the hypotheses H1, H2 & H3 and to answer the research questions.

1.5 Contributions

We propose a novel platform for viewing and self-managing a patient's medical reports (EHRs) on a mobile device using MyHealthCloud, as opposed to other possible medical reports management methods such as paper based record keeping. The MyHealthCloud will not only allow a patient to receive his medical reports, but he/she can also share them with doctors and other caregivers. In this way, we can, not only save the doctor's time but also the patient's time, money and energy.

Using a patient-driven approach, we are "flipping the paradigm" by involving the patients in the decision making of managing their EHRs by giving access of EHRs to the patients and letting them share those medical reports with a doctor when needed.

As a proof of concept, we built a prototype of MyHealthCloud for visualizing, sending, receiving and sharing a patient's medical reports (EHRs). The prototype was used in an empirical study aimed at exploring the opinions of paramedical practitioners and the general public about online access to EHRs and patient health information.

Results of the structured evaluation of MyHealthCloud show that the system is accurate in terms of performing tasks very quickly and in an acceptable amount of time, efficient and effective in terms of the limited number of wrongly chosen options and wrongly selected icons, and is easy to use, even with no training whatsoever (see Section 7.1). The implementation of an iterative, user-centered approach not only resulted in major improvements to the UI design of the current system, but also allowed better understanding of the users, their work, and their needs and preferences, and fine-tuning of MyHealthCloud accordingly.

1.6 Thesis Organization

This thesis is organized as follows: Chapter 1 is the introduction of the thesis. Chapter 2 explains the background of mobile technology integration in Health care and surveys the published work related to Health Cloud Technology. Chapter 3 explains the FDA regulations for MyHealthCloud. Chapter 4 surveys the information security aspect of the mobile medical application. Chapter 5 describes the prototype created and used as a proof of concept for this thesis. Chapter 6 explains the empirical studies conducted for the thesis. The results obtained from the empirical study with the doctors and general public are presented in Chapter 7. Chapter 8 concludes with a summary of this thesis and outlines possible future work directions.

Chapter 2. Background & Related Work

In this chapter, we provide a brief synopsis of Cloud Computing, Electronic Health Records (EHRs) and Health Cloud Technology on which we based our approach and developed the prototype as a proof of concept for the main thesis and the empirical investigation of the research hypotheses. The amount of related work pertaining to the emerging field of visualization for EHRs is not very high. This chapter provides an introduction to the field of EHR visualization and contains a critical review of the related work concerning the use of Health Cloud Technology. We first outline the related work done in the field of Health Cloud Technology, and then discuss its possible integration with mobile medical applications, more specifically to EHRs.

2.1 Cloud Computing

In the most straightforward terms, cloud computing implies putting away and getting to information and projects over the Internet rather than a PC's hard drive. The cloud is only an allegory for the Internet. It goes back to the times of flowcharts and presentations that would present the colossal server-farm framework of the Internet as only a puffy, white cumulus cloud, tolerating associations and doling out data as it floats.

The origin of the term cloud computing is ambiguous. "Cloud" is normally used in science to depict an extensive cluster of data that outwardly shows up from a distance as a cloud and portrays any arrangement of things whose individual elements are not further assessed in a given context [20]. Another possible explanation is that the old projects that drew system schematics encompassed the symbols for servers with a circle, and a group of servers in a system diagram had a few covering circles, which looked like a cloud [21].

MyHealthCloud works on Cloud Computing technology, which is typically defined as a type of computing that relies on remote computing networks rather than having local servers or personal devices to handle applications. Users access cloud computing using networked client devices, such as desktop computers, laptops, tablets and Smart Phones.

Cloud computing has turned into a highly requested service because of the benefits of high computing power, low service expense, high speed, adaptability, openness and in addition accessibility. Cloud providers are encountering growth rates of 50% per year [22], yet still being in an early stage, cloud computing has drawbacks that should be addressed to make such services more dependable and easy to use [23, 24].

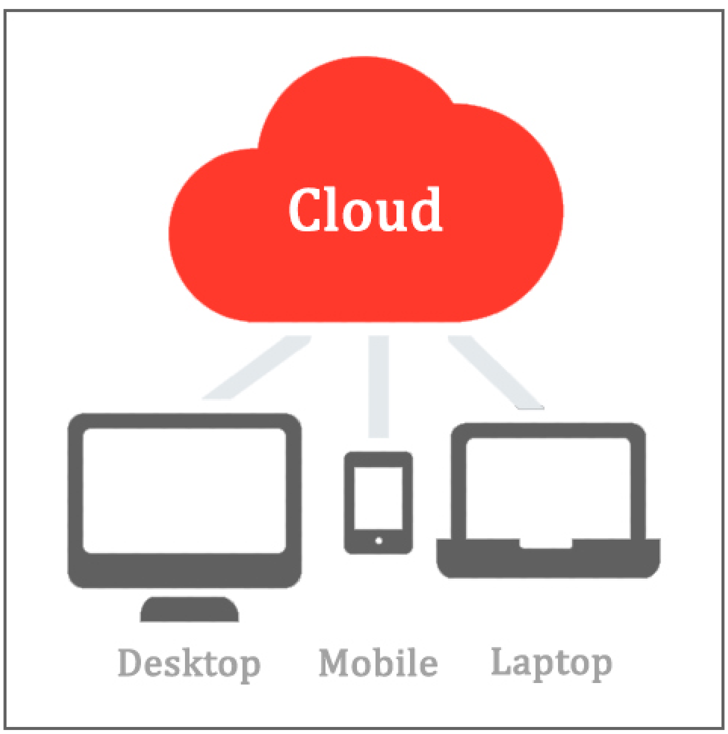


Figure 2.1 Example of typical Cloud Computing Technology

Distributed/Cloud computing is the consequence of the development and acceptance of existing innovations, technologies and prototypes. The objective of cloud computing is to permit clients to take advantage of these advances, without requiring deep knowledge or aptitude with every one of them. The cloud plans to cut expenses, and to help clients concentrate on their core business without being obstructed by IT hurdles [25].

The proposed platform that will be developed will be enhanced in this work by using cloud computing and mobile technology that, in turn, will introduce new challenges to EHR data visualization.

2.2 Electronic Health Records

The term Electronic Health Record (EHR) alludes to the organized agglomeration of a patient's digitally stored medical information [26]. These medical records can be shared crosswise over various health care frameworks. Records are shared through system-associated, enterprise-wide data frameworks or other data systems and networks. EHRs may incorporate a scope of information, including demographics, medical history, drug and hypersensitivities, inoculation status, research facility test results, radiology pictures, vital signs, a patient's discharge information or individual measurements like body mass index [27].

An EHR system is built to store and retrieve information precisely and to capture a patient’s condition over time. An EHR provides information without the need to find a patient's past paper medical records and it helps to ensure that the information is precise and neat. It reduces the risk of information repetition, as there is only one modifiable document, meaning that the record is more likely to be current and it also reduces the risk of losing printed medical reports. EHRs may contain a wide range of information, including demographics, prescriptions and sensitivities, inoculation status, restorative history, research facility test outcomes, radiology pictures, key vital signs, individual insights like age and weight, and hospital admittance information [28]. Electronic record information is searchable and can be considered as a single document.

2.2.1 Comparison with paper-based records

USA Federal and state governments, insurance agencies and other medical organizations are vigorously promoting the use of electronic medical records. The US Congress incorporated a formula of both incentives (up to $44,000 per doctor under Medicare, or up to $65,000 more than six years under Medicaid) and punishments (i.e. diminished Medicare and Medicaid repayments to specialists who neglect to use EMRs by 2015, for secured patients) for EMR/EHR use versus use of paper records as a major aspect of the Health Information Technology for Economic and Clinical Health (HITECH) Act, instituted as a feature of the American Recovery and Reinvestment Act of 2009 [29].

A U.S. Department of Veterans Affairs (VA) study evaluates that its electronic medical record system may enhance general proficiency by 6% every year, and the month to month expense of an EMR may (contingent upon the expense of the EMR) be balanced by the expense of just a couple of "pointless" tests or admissions [30, 31]. Jerome Groopman debated these outcomes, freely soliciting *"how such sensational cases from* *cost-sparing and quality change could be true"* [32]. However, a 2014 review of the American College of Physicians member test found that family practice doctors spent 48 minutes more every day when using EMRs. 90% reported that at least 1 data management function was slower after EMRs were adopted, and 64% reported that note composing took longer. A third (34%) reported that it took more time to discover and survey restorative record information, and 32% reported that it was slower to go over other clinicians' notes [33].

The expanded convenience and availability of electronic medical records may likewise increase the simplicity with which they can be accessed and stolen by unapproved persons or deceitful clients versus paper medical records, as recognized by the expanded security requirements for electronic restorative records incorporated into the Health Information and Accessibility Act and by vast scale ruptures in private records reported by EMR users [34, 35]. Concerns about security add to the apparent resistance to their across the board adoption.

Handwritten paper medical records might be difficult to decipher, which can add to medical errors [36]. Pre-printed forms, standardization of truncations and benchmarks for handwriting were urged to enhance consistent quality of paper medical records. Electronic records may help with the standardization of structures, wording and information. Digitization of structures encourages the accumulation of information for the study of disease transmission and clinical studies [37, 38].

EHRs can be constantly updated (within certain legal limitations). On the off chance that the capacity to trade records between various EHR frameworks were perfected ("interoperability"[39]), this would facilitate the co-ordination of health care delivery in non-affiliated health care facilities. In addition, information from an electronic system can be used namelessly for statistical reporting in matters such as quality improvement, resource management and public health communicable disease surveillance [40].

2.3 What is Visualization?

Visualization is about giving a subjective review of substantial and complex information sets, condensing information, and helping in identifying areas of interest and fitting parameters for more engaged quantitative analysis [41]. EHR visualization is the graphical representation of information in a manner that data can be extracted with ease by the client seeing this representation [42].

2.3.1 EHRs Visualization

Electronic Health Record (EHR) databases contain a great many patient records including, for example, diagnosis, test results, or medication prescriptions. These records are priceless information hotspots for clinical examination and change of clinical quality, as they give improved longitudinal data about patient populaces [43]. The use of EHR databases could be significantly enhanced if simple to-use interfaces permitted clinical scientists and quality change examiners to investigate complex examples keeping in mind the end goal to fabricate and test.

Novel procedures in data representation and visual investigation are required. The enthusiasm for this subject is developing at an exceptionally fast pace and is extremely interdisciplinary by nature, both as a field (in medicine and computer engineering) and in different investigation environments (academic research as well as industry and government agencies).

2.3.2 Advantages of EHR Visualization

The best advantage of EHR visualization is the capacity to distinguish and outwardly distil the most significant and pertinent information content of large data. The subsequent representation can be immediately deciphered when introduced well [44].

- It gives a capacity to skim, and fathom, gigantic amounts of information.
- Allows the view of emerging properties that were not expected.
- Enables issues with the information itself to be promptly visible.
- Facilitates comprehension of both vast and little scale elements of the information.

MyHealthCloud reduces the size of medical data by creating a simple Portable Document Format (PDF) file for the visualization of an EHR on a mobile device.

2.3.3 Types of EHRs

For the sake of our hypotheses, MyHealthCloud shows different types of EHRs like those listed below [45]. An example of typical patient EHR is provided in the figure that follows.

- History & Physical (H&P).
- Consultation (Consult)
- Operative Report (OP)
- Discharge Summary (DS)

- Radiology Report
- Pathology Report
- Laboratory Report

CHUGHTAIS LAHORE LAB

Patient No.: 23101-16-2716558

Case #: 23101-08-02

Patient Name:	[illegible]	**Registration Date:**	08-Feb-2016 6:23 pm
Father/Husband Name:			
Age/Sex:	22 Year(s)/Male	**Registration Location:**	[illegible]
Blood	-	**Destination Location:**	[illegible]
NIC:	-	**Reference:**	[illegible]
Phone:	- , 03452321991	**Consultant**	[illegible]
Address:			

LIVER FUNCTION TESTS:

TEST	NORMAL VALUE	UNIT	RESULT 23101-08-02 08-Feb-2016 18:23
BILIRUBIN TOTAL	0.2 - 1.2	mg/dl	0.5
BILIRUBIN CONJUGATED	Less Than 0.5	mg/dl	0.2
BILIRUBIN UNCONJUGATED	0.1 - 1	mg/dl	0.3
S.G.P.T (A.L.T)	5 - 55	U/L	52
S.G.O.T (A.S.T)	5 - 40	U/L	**47**
ALKALINE PHOSPHATASE	40 - 150	U/L	50
GAMMA G.T.	12 - 64	U/L	55
TOTAL PROTEIN	6 - 8.5	G/dl	7.8
ALBUMIN	3.5 - 5	G/dl	4.5
GLOBULINS	1.8 - 3.4	G/dl	3.3
A/G RATIO	1.2 - 2.2		1.4

RENAL FUNCTION TEST:

TEST	NORMAL VALUE	UNIT	RESULT 23101-08-02 08-Feb-2016 18:23
BUN (Blood Urea Nitrogen)	8 - 22	mg/dl	11
CREATININE (Serum)	0.7 - 1.3	mg/dl	1.1

MALE: 0.7 - 1.3
FEMALE: 0.6 - 1.1

Electronically verified report. No signatures necessary.
Lab reports should be interpreted by a physician in correlation with clinical and radiologic findings

M.B.B.S. (Pb) , M. Phil. Consultant Haematologist

M.B.B.S., F.C.P.S. Consultant Haematologist

PhD, DipBME Consultant Molecular Biologist

M.B.B.S., M.D., F.C.A.P. Diplomate American Board of Anatomic and Clinical Pathology Consultant Pathologist

M.B.B.S., M.D., M.I.A.C., M.Phil. F.C.P.S., F.C.P.P. Consultant Pathologist

Head Office:

Figure 2.2 Example of a typical Patient's Electronic Health Record (EHR)

2.4 Health Cloud Technology

Health Cloud Technology is a cloud computing service used by health care providers for storing, maintaining and backing up personal heath information (PHI) [46].

Health care cloud administrations are equipped for storing fundamentally a larger amount of information than an on-location physical server, especially with regards to the extensive picture records typical in radiology divisions. Moreover, health care cloud storage expenses are small compared to those for on-location servers. In any case, the move requires a full-fledged server virtualization implementation [46].

Numerous doctors and medicinal services associations are hesitant to use health care cloud services because of fear of an information rupture that goes against the Health Insurance Portability and Accountability Act (HIPAA) [47]. Because of security concerns, numerous health care associations are selecting to dodge open cloud benefits and execute a private cloud administration in-house.

The health care industry depends on information. Doctors need information to make the correct diagnosis, and they progressively need to impart information to different providers. One method for making this information accessible to the individuals who need it is to store it in the cloud. Be that as it may, a few information proprietorship issues must be tended to before going into an administration level agreement with a distributed/cloud storage supplier.

The term information possession has more to do with obligation regarding the information. The individuals who are in control of the information are in charge of the safe keeping of that data. In such a manner, the information proprietor can view and take advantage of the information and, additionally, make the information accessible to others.

2.4.1 Data ownership, possession and backup

Data ownership is defined as the demonstration of having legal rights and complete control over a single piece or set of data elements and the responsibility to keep it safe. Even though cloud service providers may not be the legal owners of the data, they possess the data and, therefore, have several responsibilities [48].

The most important responsibility of cloud service providers is access control. Access control refers to the security provided by the data owners to maintain the integrity of data. User authentication and authorization are needed to access the data. Only the cloud service provider decides how much data can be accessed (usually data on a cloud is only accessible to the organization that uploaded it).

Mostly employees of cloud storage providers do not have direct access to the data uploaded by their customers. They are not authorized to view or access that data. However, it is their responsibility to create and maintain the backup of the data and keep it secure to prevent data disclosure.

HIPAA is mostly concerned about a patient's access to his/her own medical test reports. Although the hospitals, clinics, laboratories and other organizations that generate the medical reports keep ownership of the data, HIPAA allows the patient to request his/her own copy of medical test reports. HIPAA also allows the patient to review and request the correction of inaccuracies in medical records (if any).

MyHealthCloud works according to the HIPAA rules and regulations discussed above. It secures the data from disclosure and only shares the medical record with the respective patient. Health care organizations must work with cloud storage providers like MyHealthCloud to ensure that patients are able to receive the required information to promote the use of EHRs.

MyHealthCloud does not have complete ownership of the data but shares some burden of the physical ownership, since it is not creating or generating any data. But it allows a doctor, hospital or clinic to upload a patient's report on its server and it will send a copy of that report to the respective patient's mobile phone, as patients should not be accessing the cloud directly to download their medical records.

HIPAA also allows patients to know who has the access to their medical reports. This is an issue that cloud storage providers need to consider before uploading any data on the cloud. A result is that cloud storage providers must have the explanation of who collected the data, who generated the results, who has ownership, who is the legal owner and other authorization and authentication details that a patient might want to know about.

Since cloud storage is still relatively new, many issues remain to be sorted out. Although the HIPAA Security Rule [49] expresses that "*covered entities that outsource some of their business processes to a third party must ensure that their vendors also have a framework in place to comply with HIPAA requirements*".

2.5 Related Work

This section contains a critical review of the related work concerning the use of mobile technology and cloud computing for EHR viewing and self-managing.

In [50] the authors discuss different types of risk that medical use of mobile technology may contribute to, and scenarios where these may arise, one of them being the poor quality of patient data. The authors also developed a simple yet useful generic framework that app users, developers, and other stakeholders can use to survey the reasonable risks presented by a particular application in a particular context. This ought to help application managers, developers, and users to oversee risks and enhance patient safety [50].

The limitations of paper-based medical records as compared to Electronic Health Records (EHRs) are addressed in [51]. The study shows that EHRs permit a simple path through a patient's entire medical history. Another important positive characteristic is that the record is accessible 24 hours a day, seven days a week and does not require a representative to pull the graph, nor additional space to store it. Selection of electronic health records has spared costs by diminishing full time equivalents (FTEs) and changing over records rooms into more beneficial space, for example, exam rooms. Critically, electronic health records are available to various healthcare professionals at numerous locations. The study suggests that EHRs should improve patient safety in the following ways:

- Improved legibility of clinical notes.
- Improved access anytime and anywhere.
- Reduced duplication.

- Reminders that tests or preventive services are overdue.
- Clinical decision support that reminds clinicians about patient allergies, correct dosage of drugs, etc.
- Electronic problem summary lists provide diagnoses, allergies and surgeries at a glance.

The paper explains that the main reason for using EHRs instead of paper records is *"to have patient information available to anyone who needs it, when they need it and where they need it".* With an EHR, lab results can be retrieved much more rapidly, thus saving time and money. The study also mentions that The National Ambulatory Medical Care Survey (2012) reported that 72% of office-based respondents had an EHR, compared to 48% reported in 2009. The percentage varied by state from a low of 54% to a high of 89% [52]. Fig 2.3 shows HHS Press Office statistics for EHR adoption by physicians as of April 2013 [53].

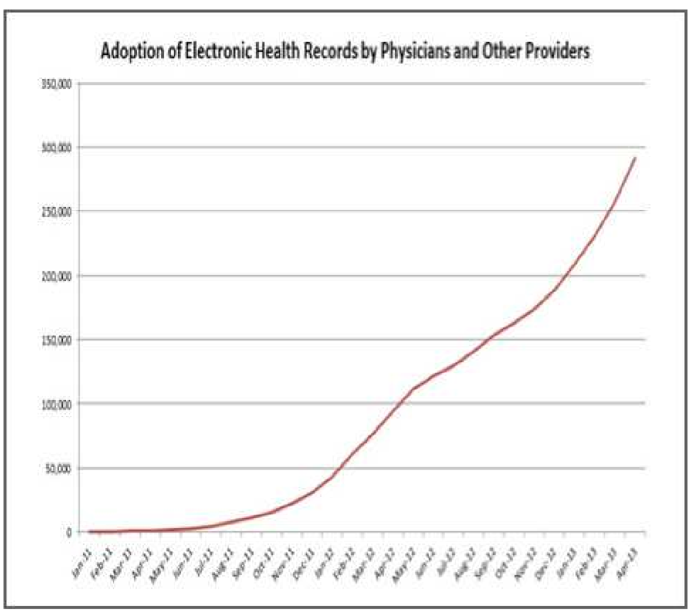


Figure 2.3 EHR Adoption by physicians in the United States (Courtesy HHS Press Office)

In [54], the importance of electronic health records (EHRs), aggregating data and health information technology has been explained with respect to comparative effectiveness research (CER) and healthcare learning. Medical information in digital form can help in cancer care and research. The future depends on medical information access, use and reuse. EHRs are the key component in the development and implementation of evidence-based medicine, but they are not being used to their full potential. Instead of being used as a digital rendering of paper medical charts, they can also be used to extract data that can be used as a mechanism through which EHRs can facilitate comparative effectiveness research (CER) and such mechanism could also be used as a large database to answer comparative questions by healthcare professionals. With the advancement of EHRs, large databases will continuously aggregate data and this data together with the enhancement of real-time analytics could help healthcare professionals.

In [55], the Internet of Things and Cloud Computing were used for developing an Android platform based portable medical application 'ECG Android App'. It furnishes the patient with visualization of their Electro Cardiogram (ECG) waves at run time and useful information logging in the background. The issue that the makers of the ECG Android App had to face was the tremendous amount of information created from the sensors, which was unstructured data. The authors discussed the advantages and disadvantages of the proposed centralized architectural design pattern for this application [55]. The advantages included the following:

- The data are easily placed in the server.
- All the related data are kept together.
- Data redundancies are avoided.

The disadvantages can be summarized as follows:

- The data may be too distant from the user for adequate service.
- There is an overhead to maintain user authentication for the different users.

In [56], a graphic-based, image-based and symptom location-based EMR visualization system was proposed. The system is integrated with a minimal amount of textual data and simple navigation. It divides the diseases into five categories of physiological systems, such as skeletal, muscular, cardiovascular, digestive, and nervous systems. The framework gives a novel approach to show the history record by incorporating course of events and symbols. Users can easily and efficiently recover valuable records with the assistance of significant symbols and an effective filtration capacity. For usability testing of the system, the author invited six doctors and four medical students to participate in a simple informal survey. For future work, multiple 2-D views (e.g., front body, back body) can be used to provide more accurate symptom location information.

In [57], different types of patient-driven EHR systems are explained. Patients still do not have any easy way to get copies of their electronic health records (EHRs). In 1998, the "Indivo" system was developed for automatically and continuously updating patient-controlled data storage. It downloads the updates and enriches them with patient annotations. Later on, a few similar applications, "GoogleHealth" and "Microsoft HealthVault" were introduced, but they allow patients to first upload their EHRs to the application and then manage or share them. A system called "The Blue Button" was developed that allows veterans to easily download their EHR data, but this app never matured. Salesforce also introduced their EHR system called the "Salesforce Health Cloud" that helps medical professionals to manage and share patients' EHRs and communicate within the app. Sensing an opportunity, in 2015, Apple released HealthKit, which provides interfaces for medical devices like heart-rate monitors and pulse oximeters. There are also many third party applications online that provide some basic functionalities to manage medical data. The approach proposed in this thesis differs considerably from the related work: MyHealthCloud will not only allow users to receive and manage their EHRs on their mobile devices wherever they go, but it also will let them share those reports with physicians as needed.

In [58], the author explains the *"causal relationships between intention to use and resistance to the health cloud in Taiwan"*. The novelty of this study is that it gives an all-encompassing perspective of the critical factors (e.g., enablers and inhibitors) that impact technological intention to use and resistance to use a health cloud. The discoveries support the underlying expectations that patients' intent to use the health cloud is anticipated by both enabling (e.g., performance expectancy, effort expectancy, social influence and facilitating conditions) and inhibiting (e.g., sunk costs, inertia, perceived value, transition costs and uncertainty) perceptions, although a few inhibitors might be less notable to foreseeing resistance to use. The study was conducted using SPSS 10.0 and AMOS 20 as analysis tools. The data analysis method involved descriptive statistics, exploratory factor analysis (EFA), confirmatory factor analysis (CFA), and the structural equation model (SEM). The target participants were patients in Taiwan.

The planning and development of a backend Android based software for an Electronic Health Record (EHR) Management System was presented in [59]. The proposed system offered easy and secure connection to a centralized database offered by the hospital or clinic and retrieval of a patient's EHR. This allows complete digitization of all the common procedures performed by the health providers, thus enabling completeness in a patient's treatment and hospitalization in a health unit. The main objective of the study was to achieve the connection between the Android Client and the Server.

The proposed system was intended to meet several standards for health records:

- ANSI X12 (EDI)
- CEN 's TC/251
- Continuity of Care Record – ASTM DICOM
- HL7
- ISO 18308
- ISO TC 215
- Google health

The study shows that the proposed client-server model also offers the following:

- Secure connection
- Wireless connection
- Speed
- Easy to use

In [60], the authors aimed to explain the challenges and interoperability issues from a Cloud computing adoption perspective. The paper also describes the two related paradigms, Service-Oriented computing (SOC) and Grid computing, and their relationship to Cloud computing. The Cloud community has extensively used the following service models to categorize cloud services:

- Software as a Service (SaaS)
- Platform as a Service (PaaS)
- Infrastructure as a Service (IaaS)
- Data storage as a Service (DaaS)

"The encapsulation, componentization, decentralization, and integration capability provided by SOC are substantial: they provide both architectural principles and software specifications to connect computers and devices using standardized protocols across the Internet" [61]. Advances in SOC can benefit Cloud computing in several ways:

- Service Description for cloud services.
- Service Discovery for cloud services.
- Service Composition for cloud services.
- Service Management for cloud services.

Grid computing [62] is *"a hardware and software infrastructure motivated by real problems appearing in advanced scientific research".* Grid computing aims to achieve resource virtualization like Cloud computing.

The study shows that the major challenges that prevent Cloud Computing from being adopted are:

- Security
- Costing model
- Charging model
- Service level Agreement
- What to migrate

The paper also explained that poor interoperability, for example, restrictive APIs and excessively unpredictable or uncertain information structures use by a Human Recourse (HR) cloud SaaS will significantly expand the integration troubles, putting the IT division into a difficult situation.

In [63], the paper explained the cloud computing concept and its current place in health care, and uses 4 aspects (management, technology, security, and legal) to evaluate the opportunities and challenges of this computing model.

Opportunities:

- Management:
  - Lower cost of new IT infrastructure
  - Computing resources available on demand
  - Payment of use on a short-term basis as needed
- Technology:
  - Reduction of IT maintenance burdens
  - Scalability and flexibility of infrastructure
  - Advantage for green computing
- Security:
  - More resources available for data protection
  - Replication of data in multiple locations increasing data security
  - Dynamically scaled defensive resources strengthening resilience
- Legal:
  - Provider's commitments to protect customers' data and privacy
  - Development of guidelines and technologies to enable the construction of trusted platforms by non-profit organizations

  - Fostering of regulations by government for data and privacy protection

Challenges:

- Management:
  - Lack of trust by health care professionals
  - Organizational inertia
  - Loss of governance
- Technology:
  - Resource exhaustion issues
  - Unpredictable performance
  - Data lock-in
- Security:
  - Separation failure
  - Public management interface issues
  - Poor encryption key management
- Legal:
  - Data jurisdiction issues
  - Privacy issues

In [64], the authors discussed the concept of integrating cloud computing and mobile health records systems. The benefits (scalability and flexibility, increased efficiency, economic savings, ease of use and high availability), constraints (confidence in the cloud provider, development of a legal framework, data security, and mobile-platforms standardization), and issues (cloud computing as an evolution of MHRs, connecting different health care centers, and improving communication with patients) and requisites (bandwidth internet connection, standardized MHRs, and management

MHRs web-application development) of a Mobile Health Record System implemented on the Cloud were also analyzed. The study concludes that Cloud companies must win the trust of their users by providing them security and legal guarantees in privacy terms.

In [65], the paper explains the empirical usability evaluation processes described in a total of 22 selected studies related with mHealth (Mobile Health) applications by means of a Systematic Literature Review. The study shows how adopting a usability model can affect the application. By asking about which individual characteristics of usability are dealt with most often, the importance of quality attributes like Understandability, Learnability, Attractiveness, Operability, Efficiency, Satisfaction, and Effectiveness for a mHealth application were explained. Usability is one of the main barriers to the adoption of mHealth systems, principally in the case of users with special needs, like older adults or children. Researchers and developers often evaluate the usability of their mHealth proposals by working with empirical methods that involve real users.

In [66], the authors discussed the integration problems between electronic health records (EHRs) and health information systems (HIS) and the growing need of patient-driven EHR systems in Taiwan. They developed a patient-driven mobile application called the Mobile Medical Information System (MMIS). They also collected both quantitative and qualitative responses from clinician, nurses, doctors, hospital administrative and patients. In their research, they compared their work with a picture archiving and communication system (PACS). *"The MMIS has a highly graphical illustration timeline mode on continuous data, such as vital signs (temperature, pulse rate, systolic and diastolic blood pressure, respiratory rate), and laboratory data, such as* *a complete blood count (CBC): red blood cell count (RBC), white blood cell count (WBC), platelets count, hemoglobin level (HGB), blood glucose level, and C- reactive protein (CRP), or liver and kidney functions, such as glutamate oxaloacetate transaminase (GOT) and glutamic pyruvic transaminase (GPT). Blood urea nitrogen (BUN) and serum creatinine (Cr) are measured after admission or surgery."* They came up with satisfactory results but planned to expand their research in Taiwan.

2.6 Summary

There are several challenges and issues that need to be resolved in order to integrate Cloud computing and mHealth with Electronic Health Records (EHRs). Some of them are Security, Management, Privacy, Technology, Sharing, and Usability Testing of mHealth apps.

We have a clear vision of HIPAA's policies and related work done for the adoption of mHealth apps, we should now move to the rules and regulations provided by the FDA for developing mobile medical applications. If **MyHealthCloud** follows all the rules and fulfills basic necessities like security, ease of use, efficiency and effectiveness, then we could assess our hypotheses.

Chapter 3. FDA Regulations Applicable to MyHealthCloud

Many mobile apps are not medical devices (meaning that such mobile apps do not meet the definition of a device under section 201(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act)), and the FDA does not regulate such devices [5]. In this chapter, the guiding principles for developing a mobile medical application have been explained with highlights from the guidance document "Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff" issued on February 9, 2015, by Food and Drug Administration Staff (FDA).

Our proposed approach follows the FDA guidelines because these guidelines are recognized when deploying internationally.

3.1 MyHealthCloud

MyHealthCloud (myHC) was created as a new report-keeping mobile medical application that could substitute for all the capricious paper records or different electronic reporting systems that grasp the bits and pieces of an individual's medical history record.

The objective is to use the latest stable development tools to build the most advanced, secure and technologically innovative mobile medical application, rich in functionality and most importantly free to use all over the world.

MyHealthCloud is supposed to allow the user to visualize his medical test reports on his/her mobile and let him/her share those medical test reports with the doctor. Each patient has an identification number in MyHealthCloud that opens what is known as the 'patient file', which contains that patient's medical history and his/her medical reports sharing history with doctors. It also contains the patient's demographic information and administrative information specific to that patient.

The purpose of this thesis is to investigate if a mobile medical application like MyHealthCloud could be used by a patient to view and self-manage his/her Electronic Health Records (EHRs) on a mobile device and share them with a doctor. By structured evaluation of the application, and by accessing user needs and involving users at every stage of the design process, we aim to develop a simple-to-use, user-centered health information mobile medical application.

3.2 Confounds

Electronic health records (EHRs) contain comprehensive clinical information. A major challenge to using comprehensive information involves the possibility of mixing critical values and of handling a large amount of data that results in compromising the integrity of medical test results. Considering all the integrity risks, we propose a novel data-driven method to view and self-manage a patient's medical reports on a mobile device.

Mobile devices are typically used for general communication. With MyHealthCloud we attempt to create a secured platform for patients, doctors and caregivers to share Electronic health records (EHRs).

FDA terms and conditions for medical mobile applications have also been taken into consideration in designing MyHealthCloud. All the FDA rules and regulation have been followed.

For the study, the collection of an actual patient's records and meeting with doctors and an information security firm took time. But it was necessary in order to make sure that our proposed app maintains the integrity of a patient's data.

MyHealthCloud is a tool that has been designed to be so simple that even a non-technical person can use it with ease. The following top 5 trends in app design [67] were followed in its development:

- Larger Screens (Showing bigger medical images)
- Depth and Weight (Balanced and Light Colored Design)
- Hidden Menus (Icons instead of details to use extra space)
- Playfulness and Personality (Simple design so that older people can use it easily)
- Increased Connectivity (Less loading time, 24/7 connection with the cloud)

Finally, for the empirical studies, recruiting doctors and caregivers has been a challenge.

3.3 MyHealthCloud App Features

These are the featured points that have been finalized as the core of the product:

- Increase the use of Electronic Health Records (EHRs).
- Allow people to view their medical test results on a mobile device.
- Allow people to self-manage their medical test results time-efficient way.
- Improve patient-doctor and patient-caregiver communications.

After asking the appropriate questions and discussing the details about these features, the following points were concluded:

- A mobile platform would be a good solution for these particular needs.
- The age limit for targeted users would be from 18 to 50 year. Because eighteen is the adult age [68] and older adults (50-65 years old) showed a lower performance and comfort than younger adults (20-35 years old) when handling the interface of a mobile phone [69].
- Security consultation is provided by a Dubai based information security consulting firm called **Rewterz** [70].
- Prototype usability testing must be conducted with a group of people of all ages.

The final product to be developed, based on the research findings and the supporting prototype, should be a secured and FDA approved mobile medical application with all the features for signing up, visualizing and sharing test reports with doctors and family and for communicating with friends and family via SMS (Short message service) at the time of an emergency.

3.4 MyHealthCloud Mobile Usable Application

MyHealthCloud is a usable medical mobile application as it does not suffer with usability issues like information overload, screen clutter, lack of task support or limited interaction mechanisms [71]. The app was originally implemented on an iPhone 5™ using Xcode 7 and Adobe Photoshop CS6. It also uses a special framework for emergency message delivery with the patient’s current location added. After Apple introduced the iPhone 6S™ in September 2015, we shifted the design of MyHealthCloud from the iPhone 5™ to the iPhone 6S™, using the updated version of iOS, Xcode, and the location framework.

3.5 Guidance For Industry and Food and Drug Administration Staff

In order to design a mobile medical application, we had to study the guidelines from the Food and Drug Administration (FDA). For this, we studied the latest guidance document issued on February 9, 2015, named **"Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff"**.

The document describes the Food and Drug Administration's (FDA) views with regards to the growing usage of current and potential functions of mobile medical applications, the growing innovations in mobile medical applications and the potential advantages and issues to a patient's health caused by these apps. The FDA issued this guidance document to let developers, designers, distributors, and other entities know about how the FDA plans to apply its regulatory management and authorities to select medical applications intended for use on mobile phones. Given the extensive growth and broad applicability of mobile applications, the FDA issued this guidance document to identify the subset of mobile applications to which the FDA plans to apply its control.

3.5.1 Regulatory Approach For Mobile Medical Applications

Consistent with the FDA's existing oversight approach that considers functionality rather than platform, the FDA intends to apply its regulatory oversight to only those mobile apps that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended. This subset of mobile apps the FDA refers to as mobile medical apps. Some of these new mobile apps are specifically targeted to assisting individuals in their own health and wellness management while other mobile apps are targeted to healthcare providers as tools to improve and facilitate the delivery of patient care.

The FDA published a regulation down-classifying certain mobile, computer or software-based devices intended to be used for the electronic transfer, storage, display, and/or format conversion of medical device data, called **Medical Device Data Systems (MDDSs)** from Class 3 (high risk) to Class 1 (low risk).

There are certain mobile applications that may pose risks that are unique to the features of the technology on which the mobile medical application is built. For example, the explanation of x-rays or any other radiological images on a mobile device could be adversely affected by the smaller screen size or/and uncontrolled contrast ratio.

If a mobile application is built to be used for performing a medical device function (i.e. for diagnosis of any disease or other medical problem, or the treatment, mitigation, prevention, or cure of any disease) it would be treated as a medical device, regardless of the technology on which it is built. For example, certain mobile applications intended to run on smartphones to analyze and interpret Electrocardiograph (ECG) waveforms to detect heart function irregularities. But such applications are considered similar to the software running on a desktop computer in a hospital or a clinic under the supervision of medical practitioners, which is regulated under **21 CFR 870.2340 ("Electrocardiograph")** [72].

3.5.2 FDA Enforcement Discretion

The FDA intends to exercise enforcement discretion for mobile apps that:

- Help patients (i.e., users) self-manage their disease or conditions without providing specific treatment or treatment suggestions.
- Provide patients with simple tools to organize and track their health information.
- Provide easy access to information related to patients' health conditions or treatments.
- Help patients document, show, or communicate potential medical conditions to health care providers
- Automate simple tasks for health care providers.
- Enable patients or providers to interact with Personal Health Record (PHR) or Electronic Health Record (EHR) systems.
- Are intended to transfer, store, convert format, and display medical device data in its original format from a medical device (as defined by MDDS regulation 880.6310 OUG).

3.5.3 MyHealthCloud Under FDA's Current Regulations

MyHealthCloud lies under the mobile medical applications for which FDA intends to exercise enforcement discretion (see section 3.5.4). The following are a few points that prove that MyHealthCloud is a type of mobile medical application that poses lower risk to the public:

- "Mobile apps that enable, during an encounter, a health care provider to access their patient's personal health record (health information) that is hosted on a web-based or other platform".
- "Mobile apps that allow a user to, collect, log, track and trend data, such as blood glucose, blood pressure, heart rate, weight or other data from a device to eventually share with a heath care provider, or upload it to an online (cloud) database, personal or electronic health record".
- "Mobile apps that are not intended for diagnostic image review such as image display for multidisciplinary patient management meetings (e.g., rounds) or patient consultation (and include a persistent on-screen notice, such as "for informational purposes only and not intended for diagnostic use")".
- "Mobile apps that transfer, store, convert formats, and display medical device data without modifying the data and do not control or alter the functions or parameters of any connected medical device (i.e., mobile apps that meet the definition of MDDS under 21 CFR 880.6310)".
- "Mobile apps that allow a user to collect (electronically or manually entered) blood pressure data and share this data through e-mail, track and trend it, or upload it to a personal or electronic health record".

- “Mobile apps that provide patients a portal into their own health information, such as access to information captured during a previous clinical visit or historical trending and comparison of vital signs (e.g., body temperature, heart rate, blood pressure, or respiratory rate)”.
- “Mobile apps that are intended to allow a user to initiate a pre-specified nurse call or emergency call using broadband or cellular phone technology”.

3.5.4 Classification Of Medical Applications Like MyHealthCloud

MyHealthCloud lies under the submission type “510(k) exempt”. According to this submission, the developers, or the creators of the application are not obliged to submit a premarket prototype of the medical application before the launch. The features of MyHealthCloud were matched with the functionalities of 510(k) exempt medical applications provided by the document. The details follow:

Regulation Number: 862.2100

Regulation Description: Calculator/data processing module for clinical use.

Example Device(s) within the Regulation (and current product code): Digital Image, Storage And Communications, Non-Diagnostic, Laboratory Information System (NVV)

Device Class: 1

Submission Type: 510(k) exempt

3.6 Summary

MyHealthCloud is a mobile medical application that poses a low risk to public health. The FDA has set some guiding rules as described in Section 3.5.3 to let developers and manufactures know how they should design mobile medical applications so that those applications fall under the category of FDA's 510(k) exemption. MyHealthCloud is clearly one of those applications.

Chapter 4. Mobile Application Security Requirements and Constraints

It is safe to say that medical applications are becoming one of the cornerstones of the health care industry. According to the FDA, the number of users of different types of medical applications is expected to grow by 1.7 billion users by 2018 [2]. There are several different types of applications being introduced on the market, each offering various benefits including (but not limited to):

- Knowledge to patients
- Ease of data accessibility for patients
- Ease of data distribution
- Ease of use for professionals/medical practitioners

But wherever data is involved, here are always the associated security risks. With medical applications the major risk is leakage of PHI (personal health information).

There are millions of mobile and web based attacks reported each year. Keeping that in mind, it becomes absolutely necessary to ensure all levels of security of the application and data that resides within and processed by it including:

- Project management
- Application layer
- Host layer
- Network layer
- Parameter

Considering the protection of data in the cloud, there are three areas of use that security and privacy professionals need to consider: data in transit, data at rest, and data in use. While the first two areas are generally well understood, the third is consistently overlooked [73]. Fig 4.1 explains our goal of data protection:

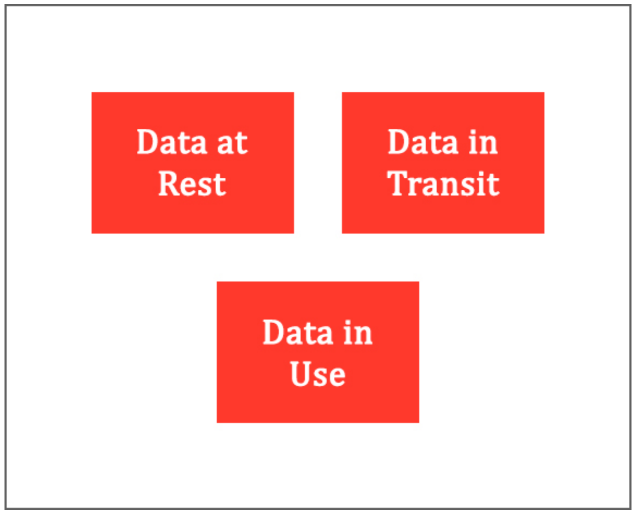


Figure 4.1 Mobile Application Data types that need protection

As discussed, the FDA's approach (see section 3.5.2) of examining a mobile medical application is based on its features rather than the technology. But it is also obligatory for the manufacturers to provide the necessary security to these medical applications to maintain the integrity of patient data. To address this concern, we contacted a group of information security professionals [70] to look for an appropriate security solution for our proposed mobile application. Together we discussed the core security leaks of mobile data and ways to protect it. We gathered the security requirements for a mobile medical application by the analysis of the FDA and HIPAA rules. The consultants proposed solutions for all possible security risks.

The security of our proposed approach is outside the scope of this research, but it is necessary to cover the basics to comply with the security requirements provided by the FDA and HIPAA.

4.1 Security at Application Layer

For the sake of this project, it was recommended to follow the Open Web Application Security Project (OWASP) secure development guidelines [74]. In order to comply with the OWASP mobile security checklist, developers need to make sure that the following vulnerabilities do not exist in the app:

- **Application is Vulnerable to Reverse Engineering Attack**
    - MyHealthCloud will use obfuscation (deliberately creating the code difficult for humans to understand) to protect its code and part of it will be written in Objective-C and added as a compiled library. Furthermore all data stored will be obfuscated to prevent reverse engineering.
- **Account Lockout not Implemented**
    - MyHealthCloud will lockout the user account after three invalid attempts. After that, the user has to send a request for re-activation through SMS, or reset the password through the email address used during registration.
- **Application is Vulnerable to XSS**
    - Cross-Site scripting (XSS) attacks occur when an attacker uses a web application to send malicious code. However, since MyHealthCloud will not be a web app, it will not use HTML5. Instead, it will be built on native iOS and Android code. So the threat of XSS becomes minimal.
- **Authentication bypassed**
    - MyHealthCloud will use virtual two-factor authentication. The user's device ID would be one factor and the user's password would be another. An attacker will need to have both to bypass authentication.

- **Hard coded sensitive information in Application Code**
    - MyHealthCloud will not store any sensitive information in the code. Any data that would be stored in the mobile phone's memory would be encrypted/obfuscated.
- **Malicious File Upload**
    - MyHealthCloud will not allow any random file to be uploaded. There will be a secured mechanism provided only to the hospitals to upload the data.
- **Session Fixation**
    - Session Fixation is an attack in which the hacker is permitted to hijack a valid user session. MyHealthCloud will destroy the sessions every time the application is closed. Sessions are not fixed.
- **Privilege Escalation**
    - Privilege Escalation is an act of exploiting a bug or design flaw in a system to get access to protected resources. MyHealthCloud will not be prone to privilege escalation as there will be a flat user hierarchy.
- **SQL Injection**
    - SQL Injection is a code injecting technique, used to attack data-driven applications. MyHealthCloud itself will not be prone to SQL injection because it will not perform any database queries itself. All the SQL transactions will happen on the server side where a web application firewall will be setup to protect against such attacks.

- **Attacker can bypass Second Level Authentication**
    - Attackers usually bypass two-factor authentication by tricking the system with a user's phone number, security service, etc. MyHealthCloud will not provide any second level privileges.
- **Application is vulnerable to LDAP Injection**
    - Lightweight Directory Access Protocol (LDAP) Injection is used for manipulating directory services. MyHealthCloud will not use directory-based authentication. It will be done through SQL database.
- **Application is vulnerable to OS Command Injection**
    - OS Command Injection is used to execute OS commands on a web server. Checks will be added on all MyHealthCloud input variables to accept certain specific types of inputs. If the data does not match the type, the input will be rejected.
- **iOS snapshot/back grounding Vulnerability iOS**
    - When the user presses the iPhone's home button, and the application performs back grounding, iOS takes a snapshot of the current page and stores it insecurely on the device. It may contain personal info like a medical report. MyHealthCloud will block caching of application snapshots using internal code. The code will override the applicationDidEnterBackground method and all sensitive information in the user interface will be removed before it returns.

- **Debug is set to TRUE**
    - Besides hurting an application's performance in production, a TRUE value of Debug turns the software lifecycle into a vicious circle. Debugging will always be disabled in live version of MyHealthCloud.
- **Application makes use of Weak Cryptography**
    - Using Weak Cryptography often leads to data disclosure and illegal user authentications. MyHealthCloud will not use weak cryptographic algorithms (e.g. SHA1 and MD5). Instead, it will make use of approved public algorithms such as AES and SHA-256.
- **Clear text information under SSL Tunnel**
    - A weak SSL protocol hurts not only confidentiality, but also authentication. MyHealthCloud will not send clear text information over a weak SSL. All the information will first be encrypted and then sent to the server through JSON APIs over SSL.
- **Client Side Validation can be bypassed**
    - It is possible to enter a starting value into the input field in the browser, intercept the validated submission with your proxy, and modify the data to some desired value. Since MyHealthCloud will be built on native languages (will not use HTML), it will be not prone to this attack.
- **Invalid SSL Certificate**
    - Attackers exploit the invalidity of SSL (Secure Socket Layer) certifications by revoking the certificate signature. The server side APIs will be hosted on a server with a valid and registered SSL Certificate.

- **CAPTCHA is not implemented on Public Pages/Login Pages**
    - CAPTCHA is a system to distinguish between human and machine inputs to avoid spam. CAPTCHA will be implemented on registration.
- **Improper or NO implementation of Change Password Page**
    - Improper implementation of the change password page allows attackers to enter the system by entering fake passwords. A proper "forgot password" feature will be presented.
- **Application does not have Logout Functionality**
    - Attackers often look for any logged in account so that they can enter the system. There will be a button/link available to log-out in MyHealthCloud and users will also get logged-out automatically when the app is force closed.
- **Sensitive information in Application Log Files**
    - MyHealthCloud will not store any sensitive information in log files.
- **Sensitive information sent as a query string parameter**
    - MyHealthCloud will encrypt all data before sending the query string to the server.
- **Sensitive information in Memory Dump**
    - MyHealthCloud will not store any sensitive information in memory, especially nothing unencrypted.
- **Weak Password Policy**
    - MyHealthCloud will require passwords to be 12 characters long, containing at-least one uppercase letter, one lowercase letter, one special character and one number.

- **Auto complete is not set to OFF**
    - Auto complete will be disabled
- **Application is accessible on Rooted or Jail Broken Device**
    - The application will not be functional on jail broken device as the code itself will be obfuscated and partially written in Objective C. Plus every user will be authenticated by the server with a specific device ID.
- **Back-and-Refresh attack**
    - MyHealthCloud will not be prone to this attack, as it will require a web browser to work. MyHealthCloud will be written on native code.
- **Usage of Persistent Cookies**
    - MyHealthCloud will not use persistent cookies. All sessions will be destroyed every time the app is closed.
- **Improper exception Handling: In code**
    - All exceptions in the code will be properly handled.
- **Application build contains Obsolete Files**
    - All the code will be reviewed for obsolete files and pieces of code before uploading the application to the app stores.
- **Last Login information is not displayed**
    - Every time a user will log-out, a summary of user activity with time and date will be displayed. And there will be a section in the user profile that will provide information about last login attempts.
- **Cached Cookies or information not cleaned after application removal/Clos**
    - Everything will be removed once the application is uninstalled.

- **ASLR Not Used**
    - MyHealthCloud will use ASLR (Address Space Layout Randomization).
- **Clipboard is not disabled**
    - Copy/paste mechanism will be disabled/not used.
- **Cache smashing protection is not enabled**
    - Cache smashing protection will always be enabled in MyHealthCloud's iOS version.

4.2 Server and Network Security

To avoid devastating consequences down the line, it's imperative to think about security and privacy at the time of setting up the infrastructure.

Listed below are some of the basic security measures that will be implemented on the server and network side [75]:

- SSH Keys
- Firewalls
- Vulnerability Assessment and Server Hardening
- Modular Deployment

4.2.1 SSH Keys

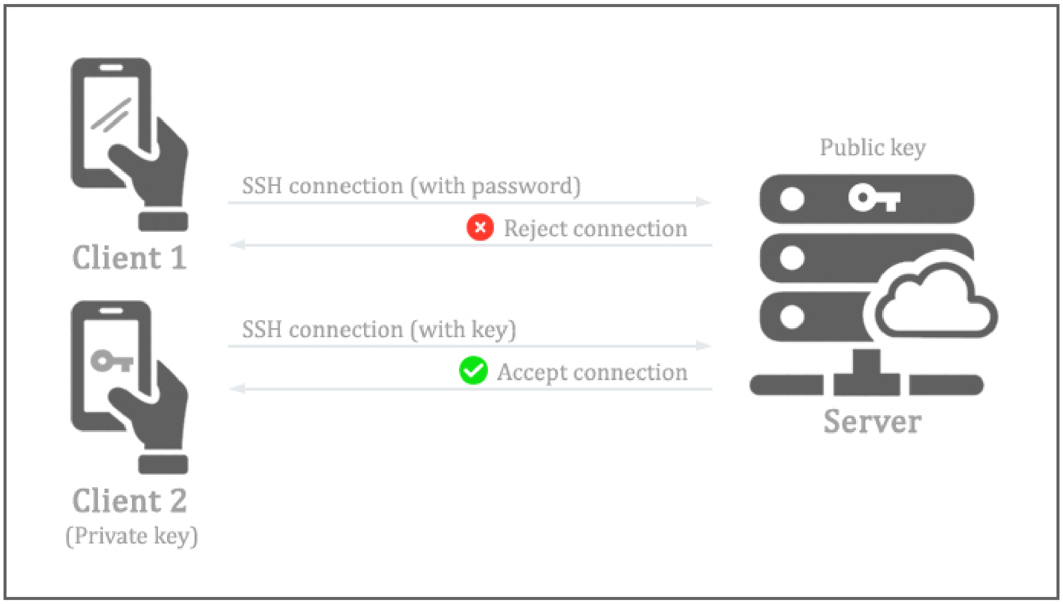


Figure 4.2 SSH Key Authentication

Passwords are the most common type of authentication mechanism. But these are also easy to attack. When password-based logins are allowed, attackers can run a brute-force attack, which simply consists of sending repeated, automated requests to access the server. In this attack, the attacker sends combination after combination of passwords until the right password is found.

"SSH keys are a pair of cryptographic keys that can be used to authenticate to an SSH server as an alternative to password-based logins. Private and public key pair are created prior to authentication. The private key is kept secret and secure by the user, while the public key can be shared with anyone" [75]. With SSH, any kind of authentication, including password authentication, is completely encrypted.

The majority of SSH key algorithms are considered to be uncrackable because they involve more data, hence require much more time to run through all possible matches.

Our server will have valid SSL certificates and all communication will happen on that channel. Furthermore, as mentioned in sec 4.1, all the data will be encrypted before it is sent to the server. So even inside the SSL tunnel, the data will not be readable.

4.2.2 Firewalls

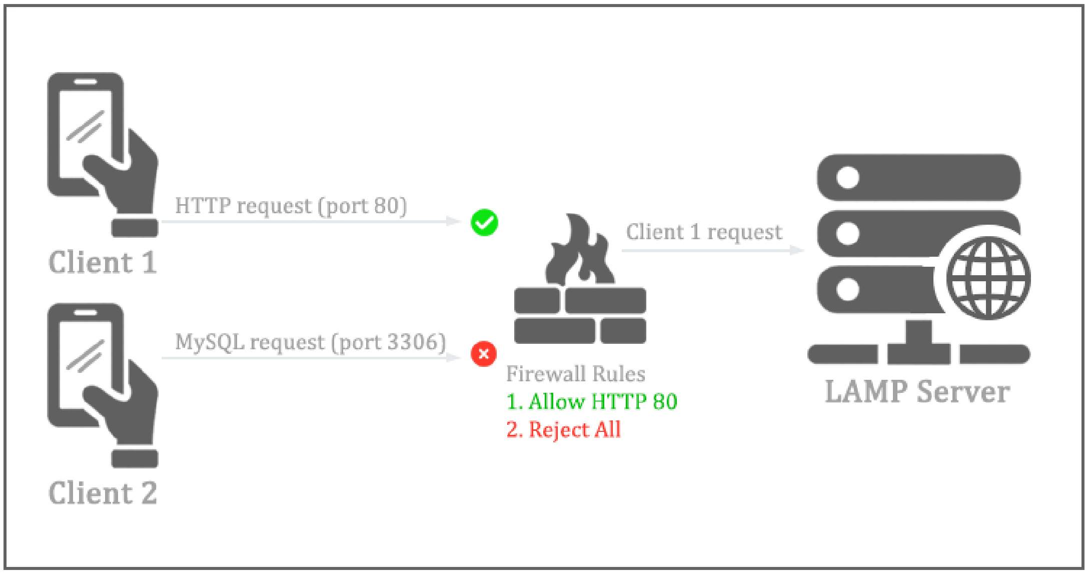


Figure 4.3 Firewall

Firewalls act as the first line of defense. These are now considered to be an essential part of any server configuration. The key to using a Firewall is to disable everything and then allow only those services that are required to be accessed. This way the firewall restricts access to everything except the specific services needed to remain open. Exposing only a few pieces of software reduces the attack surface and limits the services that are vulnerable to exploitation.

Our server will exist behind a firewall, protecting against all attacks on the web server. Port 80 and 443 will be allowed for HTTP and HTTPS traffic.

We will also use a Web Application Firewall (WAF) to filter out all web application related attacks (e.g. SQL injection, XSS, Session fixation etc.).

4.2.3 Vulnerability Assessment and Server Hardening

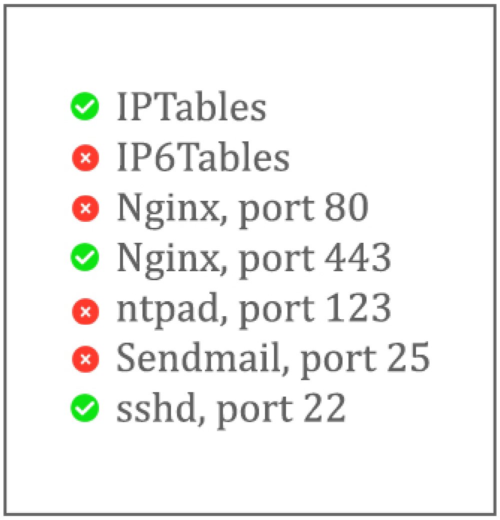


Figure 4.4 Service Checklist

Just like all technology implementations and configurations are important, testing your systems, understanding the available attack surfaces, and locking down the components (as best as you can), is equally important [75].

Fig 4.4 shows the service checklist used during vulnerability assessment. It is the process of discovering which services are running on the server, which ports are being used and which protocols are accepted. Once that step is done, we then check which services are running outdated versions, which services are vulnerable and are running for no reason.

This is important because often, the default operating system is configured to run certain services at boot. Installing additional software can sometimes pull in dependencies that are also auto-started.

Servers start many processes for internal purposes and to handle external clients. Each of these represents an expanded attack surface for malicious users.

MyHealthCloud servers will be checked for vulnerabilities on a periodic basis. The specialists [70] will conduct penetration testing to confirm if vulnerabilities exists on our server, and suggest a fix.

4.2.4 Modular Deployment

Modular deployment means each individual component runs within its own dedicated space.

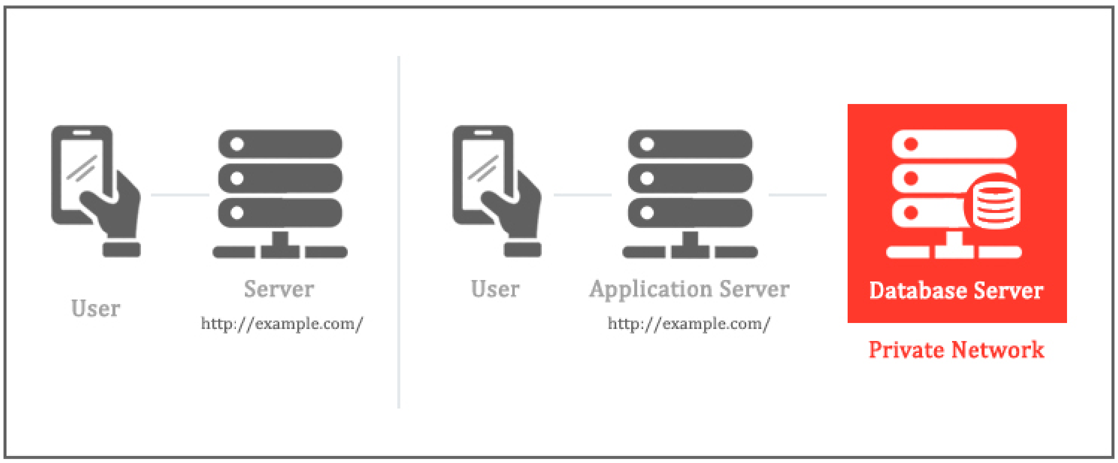


Figure 4.5 Single Server vs Isolated App and Database Servers

This means deploying application components within their own servers or virtual servers. By running components in an isolated environment, we achieve the following three main benefits:

- Enhanced speed
- Scalability
- Ability to isolate any security problems that may arise

4.3 Security By Policy

Following are some of the policies that can be used as security parameters if the proposed approach is launched in future:

- We will require users to set strong passwords (see section 4.1).
- We will never store unencrypted sensitive information on the mobile app.
- We will never send unencrypted data over the Internet.
- We will plan to educate our users about security issues, using friendly in-app messages.
- The app administration will conduct periodic assessments and penetration tests to identify loopholes on the server and application. All servers will be hardened according to the recommendations of penetration test reports and best practices.
- Encryption
  - All sensitive data on servers and backup drives will be encrypted using Advanced Encryption Standard (AES).
  - All developers and other entities accessing the database, code or server, will use whole disk encryption on their devices.
  - All sensitive data within the database will be encrypted.
  - Application code will be encrypted and obfuscated to avoid reverse engineering.
  - We will never use FTP (File Transfer Protocol) to access the server or data from the server. An SSH connection will be used all the time.
  - All communication between the application and server will be encrypted and over an SSL connection.

4.4 Summary

By implementing a well-structured, regulated security policy, we can ensure the productivity of physicians without sacrificing the security of sensitive patient information. As stated earlier, we will follow OWASP methodologies to avoid potential risks to the app. And we will have the support of a dedicated information security team of professionals [70], to guide us and direct us along the way.

Chapter 5. Prototype of MyHealthCloud

This chapter focuses on core processing and design of MyHealthCloud and its integration with Electronic Health Records (EHRs). We will start by reviewing the context, use-case and workflow diagrams that explain the difference between the current procedure and the projected approach. We will describe each screen of the prototype with all its functions in detail. We will conclude this with an explanation of the connections between the screens of the prototype created and used for testing our hypotheses. The usability testing procedure and results will be covered in Chapter 6 and Chapter 7.

5.1 Current and Projected Workflow

Currently a very small amount of healthcare practitioners make use of EHRs not only in Quebec, but across Canada. The reasons for this are varied: concerns about privacy, implementation costs, and data security [40]. Fig 5.1 shows the current/general workflow and activities performed by patients to receive their medical reports from doctors across the globe.

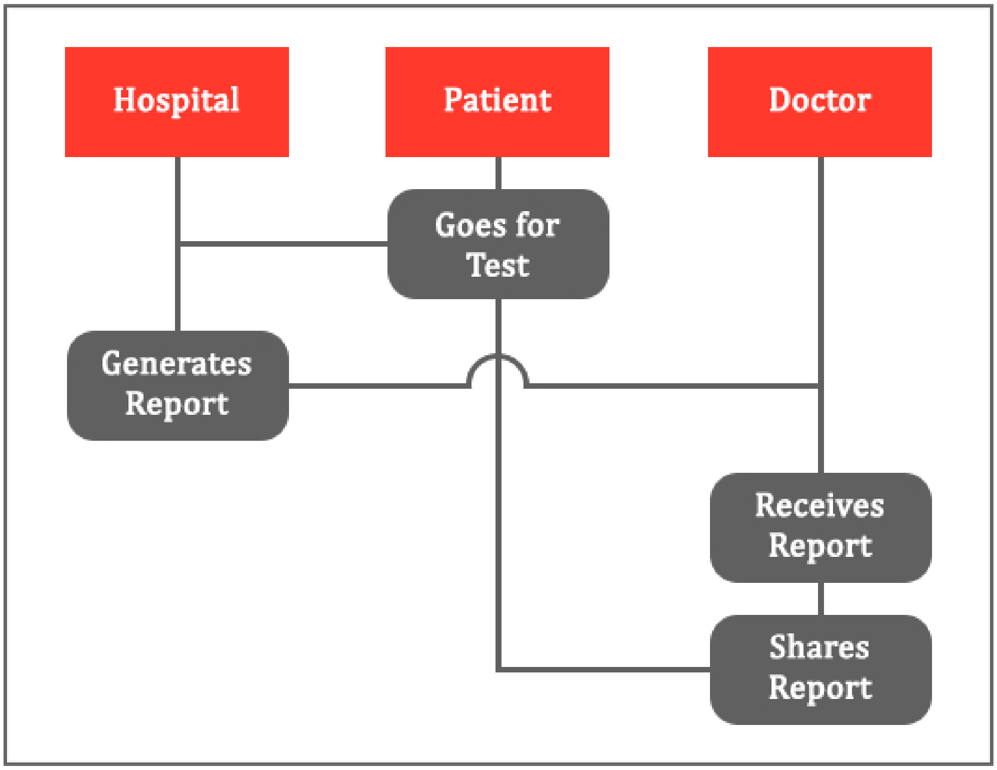


Figure 5.1 General Procedure of receiving a medical report

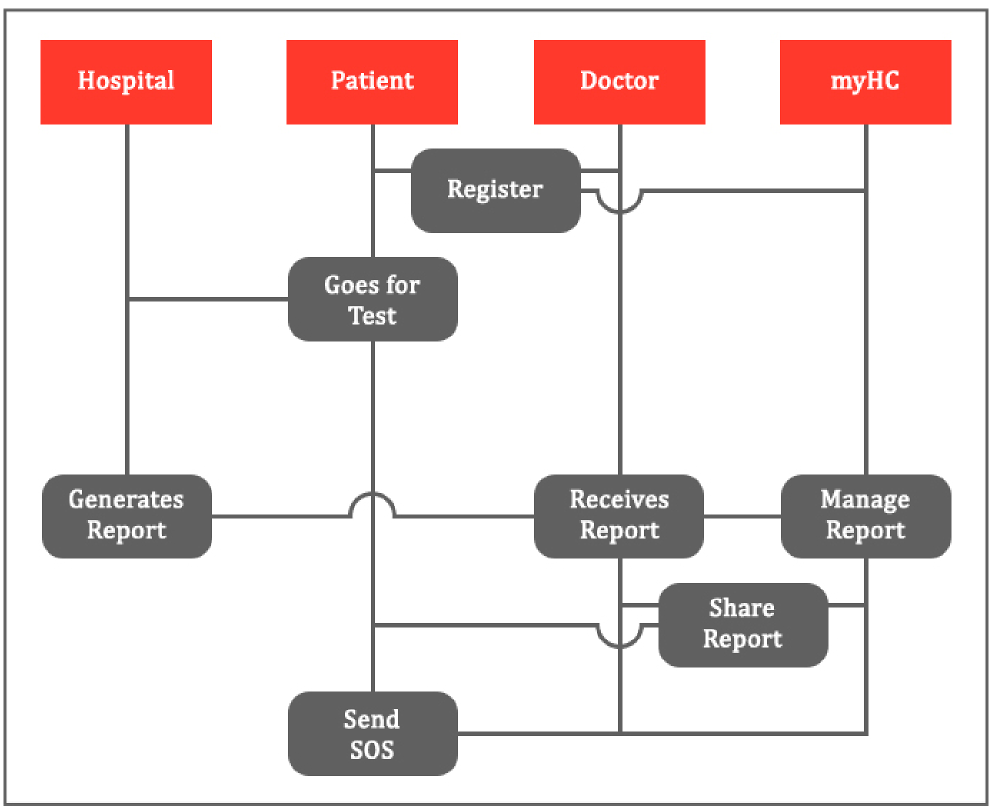


Figure 5.2 MyHealthCloud Workflow Diagram

MyHealthCloud will be a secured and free-of-cost platform for the patients to receive and manage their medical reports in the form of Electronic Health Records (EHRs). The workflow of the proposed approach is slightly different from the typical process [76] as shown above. MyHealthCloud saves the time and energy of the patient that he would otherwise spend to collect his report.

Assuming that both the doctor and patient are registered on MyHealthCloud, the patient goes to a hospital for a medical test on the advice of his/her doctor. After the test, the patient goes back home and waits for the report. The hospital generates the report and sends it to the doctor. The doctor sends it to the patient using his MyHealthCloud ID directly on the patient's mobile phone instead of waiting for the next appointment. This way MyHealthCloud is not only saving the patient's time but also the doctor's.

5.2 Back-end Procedure

We have discussed the basic workflow of the prototype above. Next, we will discuss the context of the prototype, meaning where the data (EHRs) comes from and what information patients or doctors can access.

For the sake of this study, only a mobile version of the prototype was created for now. Our future work includes the development of a desktop version.

Users would only have access to their respective reports. There would be only one way to get access to someone else's report and that is if that user shares his/her report.

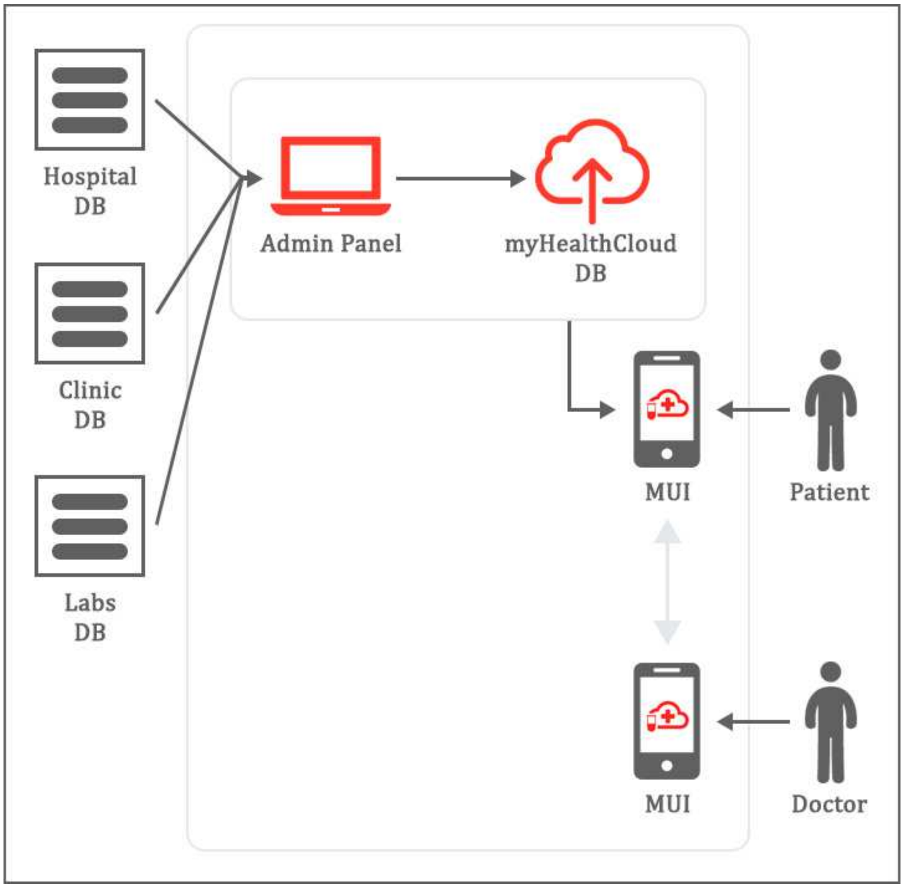


Figure 5.3 MyHealthCloud Context Diagram

Fig 5.3 shows how data coming from different sources like Hospitals, Clinics or Laboratories is uploaded to the MyHealthCloud Database in the form of Electronic Health Records (EHRs). Patients and doctors can access their respective reports using the proposed Mobile User Interface (MUI). No user can access the data directly from the admin panel.

As mentioned in Chapter 3, MyHealthCloud does not create or alter the information in the medical report. It sends it to the concerned patient's mobile device using a secured path.

The user interface of the prototype is the same for a patient and a doctor.

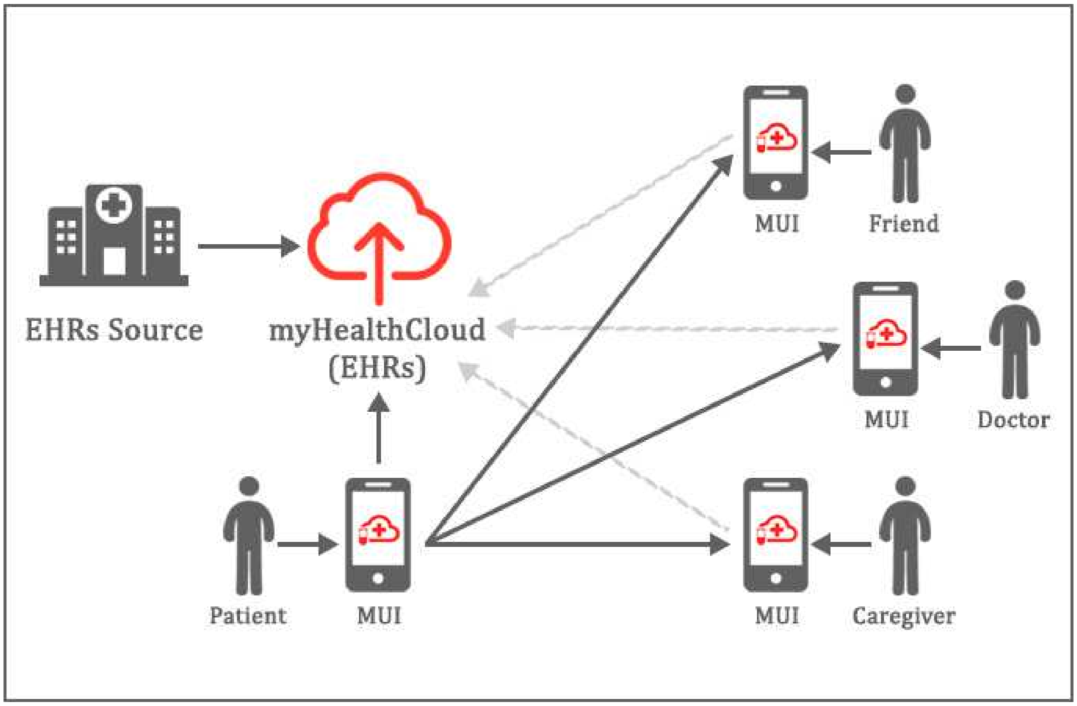


Figure 5.4 Context with Access Control

Fig 5.4 shows the EHRs entering the system and a patient getting access to those EHRs. The uploading of these reports on the MyHealthCloud Server and its security is outside our research scope. But it is clear that once the data is uploaded on the server, a patient can access it from a mobile phone and can share it with a friend, doctor or caregiver as needed. All the users within the application will use it as a patient. Some of the users will be doctors so they can consult the EHRs of any patient or provide access to other doctors as well.

5.3 Use-Case Model

There are three primary actors in MyHealthCloud: Admin, Patient and Doctor. Admin generates the reports received from the hospital, clinic or the laboratory and sends it to the registered doctor and patient. If the patient is not registered on MyHealthCloud, the doctor would ask the patient to get registered in order to receive his/her medical report (EHR) on his/her mobile. The admin also gets to manage the doctors' list and profiles. Patient and Doctors could also communicate via messages and the emergency SOS service provided by the prototype.

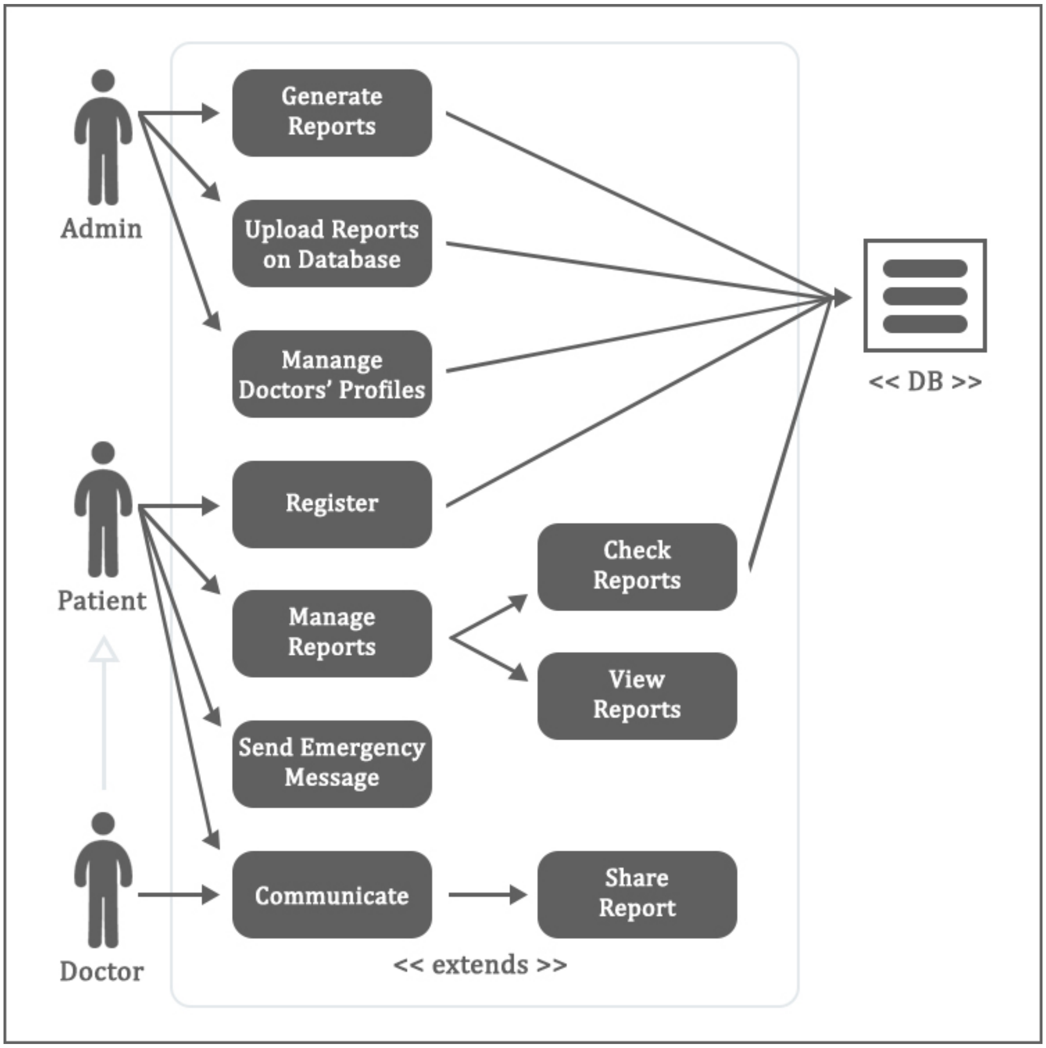


Figure 5.5 MyHealthCloud Use-Case Design

5.4 Mobile User Interface Design

The prototype consists of 22 screens in total. Each has its own purpose and functions. The MUI of the prototype was designed according the UI design guidelines provided by the Apple Developer Program to meet the requirements of users of all ages.

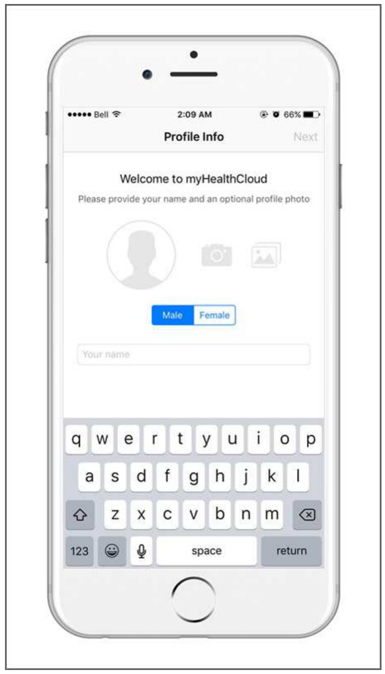


Figure 5.6 Splash **Figure 5.7** Registration **Figure 5.8** Phone Number

Splash Screen is the loading screen of the prototype.

Registration Screen is the first screen of the registration process. It asks the user for his/her name, gender and profile picture (optional).

Phone Number Screen is the second screen of the registration process. It asks the user for his/her phone number and country code that can be used to send him/her the medical reports.

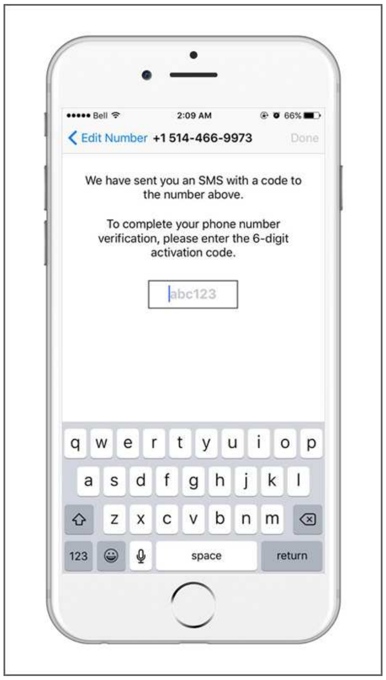


Figure 5.9 Verification

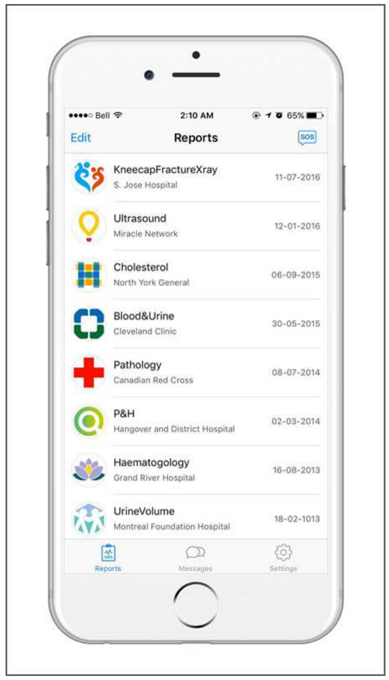


Figure 5.10 Reports

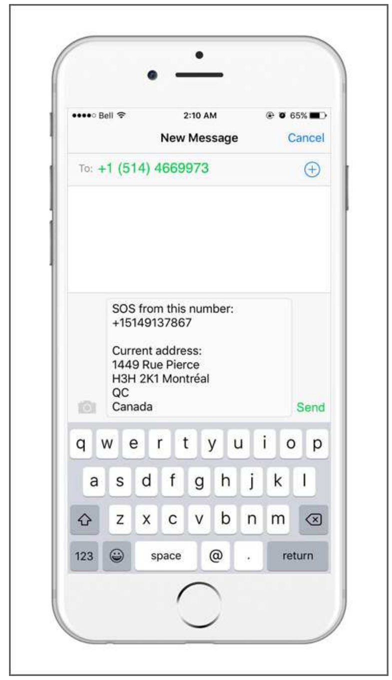
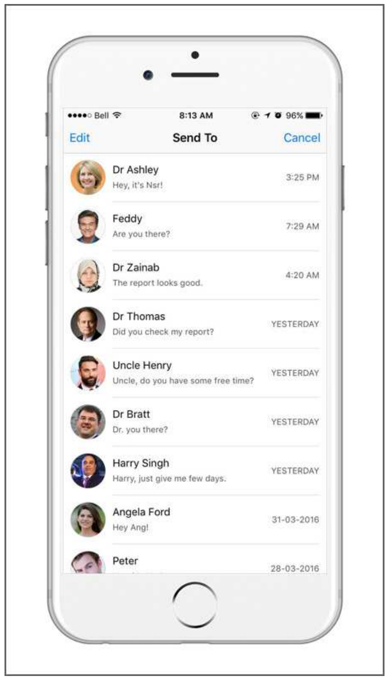


Figure 5.11 SOS Message

Verification Screen is the last screen for the registration process. After entering the phone number, the system sends a verification code to the user's mobile as a security check. The user has to enter that code in order to complete the process.

Reports Screen is the main screen of the prototype that shows the medical reports that a user has received. A user can view any report, edit the reports list, search for any specific report, open the SOS message or go to the messages or settings screen.

SOS Message Screen can be used to send an emergency message with a pre-defined message along with the user's current location to a doctor or caregiver.



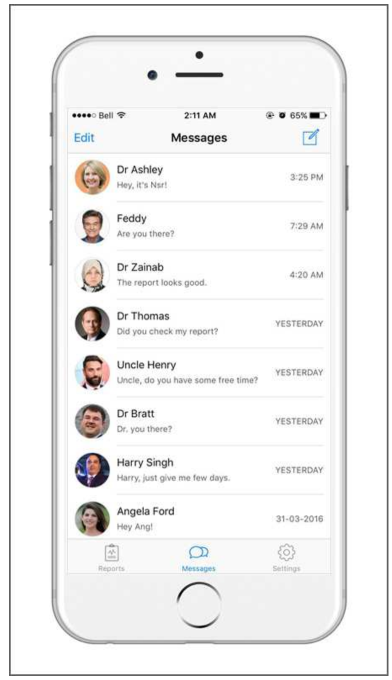
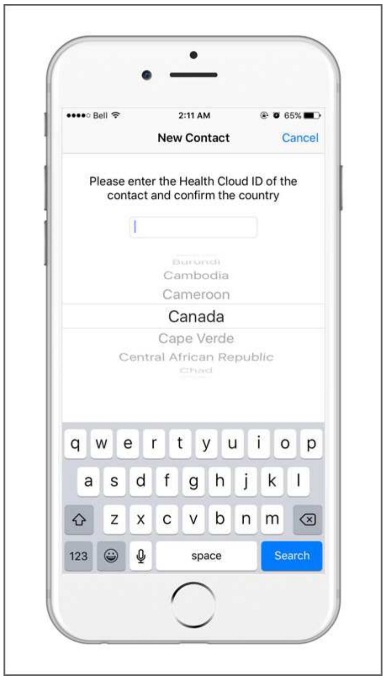


Figure 5.12 Report Detail **Figure 5.13** Send To **Figure 5.14** Messages

Report Detail Screen shows the Electronic Health Record (EHR). It can be an X-ray report, a discharge sheet, a consultation paper, routine check-up data or any other type of EHR defined in section 2.3.3.

Send To Screen shows up when the upload/share button is tapped on the report detail screen. It allows the user to select the contact from the list with whom he/she wants to share his report.

Messages Screen shows the messages history of the user. A user can open the chat screen, edit the list, add a new contact or go to the reports or settings screen.



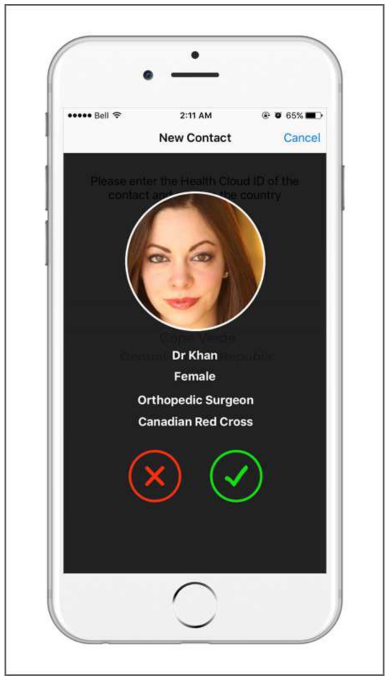
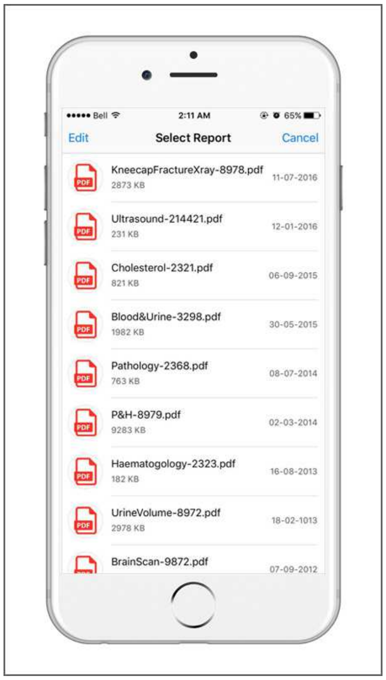


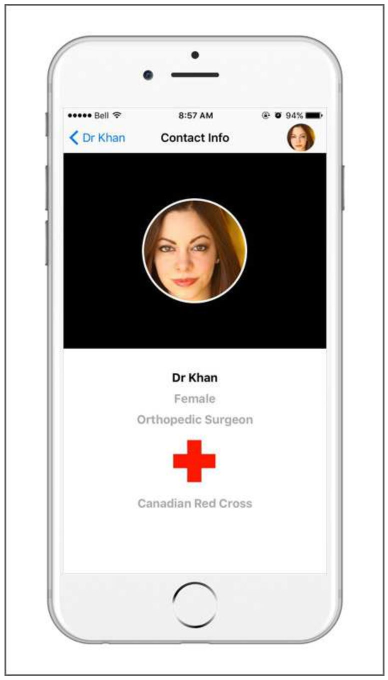
Figure 5.15 New Contact **Figure 5.16** Confirmation **Figure 5.17** Chat

New Contact Screen shows up when the user taps the compose button on the messages screen. It allows the user to add a new contact by asking the specific MyHealthCloud ID and country of the user he/she wants to add.

Confirmation Screen shows the name, profile picture and some basic information of the new contact if the user enters a valid MyHealthCloud ID for that user. It asks for confirmation to either add or cancel the request.

Chat Screen is where patients and doctors can communicate to each other. Patients can even send their report directly from this screen to a doctor by tapping the upload/share button and ask for feedback.





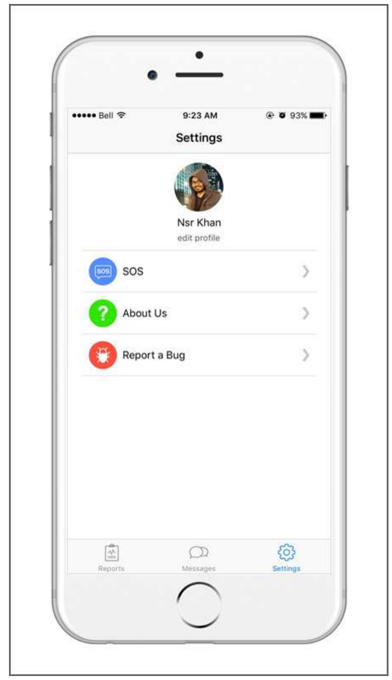
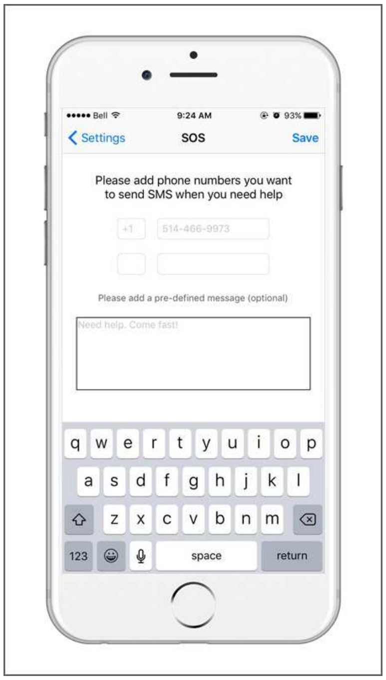


Figure 5.18 Select Report **Figure 5.19** Contact Info **Figure 5.20** Settings

Select Report Screen shows up when the upload/share button is tapped on the chat screen. It allows the user to select the report from the list he/she wants to share.

Contact Info Screen is the profile page of any user. It shows up when the user taps the name of the contact he is chatting with on the chat screen. It shows the name, profile picture and other information of that contact.

Settings Screen allows the user to edit his/her profile information, change the SOS message settings, read about MyHealthCloud or report a bug about the prototype. It also allows a user to go to the reports or messages screen.



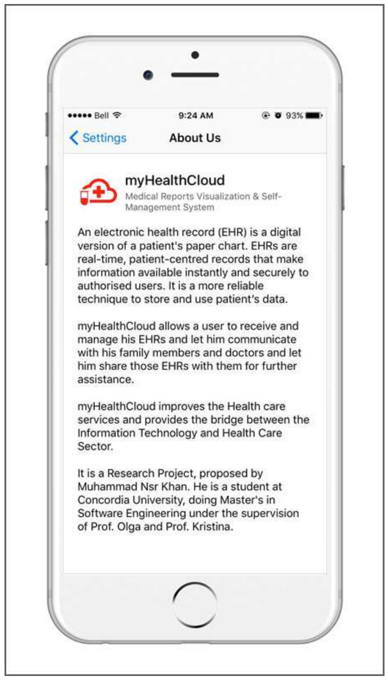
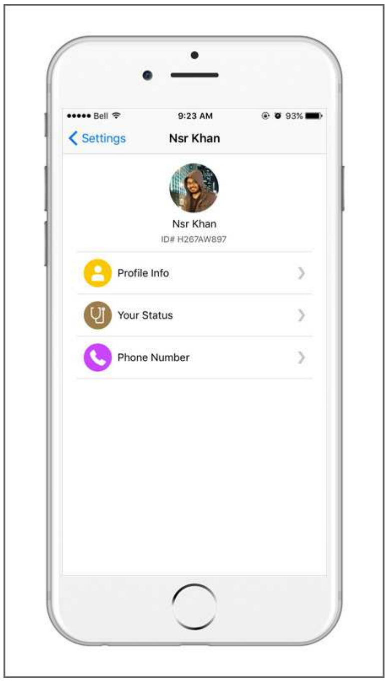


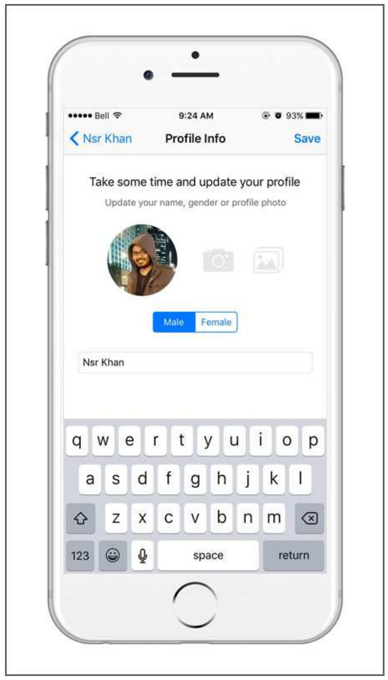
Figure 5.21 SOS Settings **Figure 5.22** About Us **Figure 5.23** Report a Bug

SOS Settings Screen allows the user to add the phone number of his/her doctor, caregiver or any friend or family member to be used to send an SOS message at the time of an emergency. It also asks if the user wants to change the pre-defined message that MyHealthCloud sends along with the user's current location.

About Us Screen shows some basic information about the prototype and how it works.

Report a Bug Screen allows the user to report a bug in the prototype.





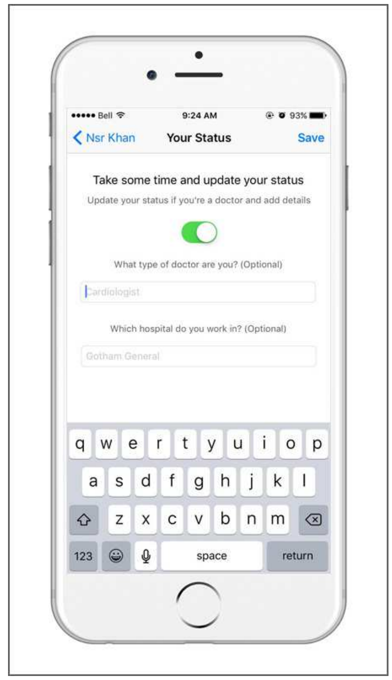


Figure 5.24 Edit Profile **Figure 5.25** Profile Info **Figure 5.26** Your Status

Edit Profile Screen allows the user to change his/her profile information, status, and phone number. It also allows the user to view his MyHealthCloud ID.

Profile Info Screen allows the user to edit his/her name, gender and profile picture.

Your Status Screen allows the user to edit his/her status of being a doctor or not. This option adds a specific value in the database against the user's profile. If the user is a doctor, it asks about his/her field and the hospital he/she works in.

Figure 5.27 Edit Phone Number

Edit Phone Number Screen allows the user to edit his/her phone number and country code.

5.5 Connections Between the Screens

For every application in the world, there are connections between the screens that help users understand the product easily. These connections explain how the system works. MyHealthCloud has 22 screens in total. Fig 2.27 explains the general connections between the screens of the prototype created and used for testing our hypotheses.

Figure 5.28 Connections Between the Screens

5.6 Summary

Fig 5.11 explains how MyHealthCloud helps the patients and doctors view and manage electronic health records (EHRs) on a mobile phone. This platform provides other options as well like sending an emergency SOS message to a doctor, caregiver, friend or family member. It allows the user to share their medical results and get feedback from their doctors without waiting for an appointment. Having MyHealthCloud on their mobile mean that users could even travel to foreign countries with the satisfaction of having their complete medical history in their pocket.

Chapter 6. Empirical Studies

In this chapter, we introduce key concepts underlying the empirical studies, which helped us determine whether the study was appropriate for our evaluation to derive meaningful results. This chapter also contains background information on the user population size, as well as the questionnaires chosen for usability testing. We then describe the experiment's usability testing protocol and issues that were encountered. The results will be discussed in the following chapter.

6.1 Types of Empirical Investigation Used for MyHealthCloud

An experimental design is a complete plan for applying differing experimental conditions to the subjects in an experiment so that researchers can determine how the conditions affect behavior or the results of some activity. In our case, we needed to plan how the application of these conditions would help us to test our hypotheses [77].

In this section, we explain the assessment techniques available, and provide guidelines for applying the scientific method to empirically assess whether or not the research objectives were achieved.

There are different types of empirical investigation, such as: controlled experiments; case studies; survey research; ethnographies; and action research in Software Engineering [77]. But controlled experiments, case studies, and survey research are the methods that we believe are most relevant, as each makes a valuable contribution to the body of software engineering knowledge, and all of them involve careful measurement.

For MyHealthCloud, we used these three empirical investigation methods, case studies, survey research and usability study. The details for these studies are covered in the next section.

6.2 Our Approach

We followed the guidelines proposed by [77] to determine which method would be the best for our research.

Controlled experiments require a great deal of monitoring, and tend to involve small numbers of people or events. For MyHealthCloud, we conducted a **'usability test'** as a controlled experiment.

Case studies usually look at a typical project, rather than trying to capture information about all possible cases. They can be thought of as **'research in the typical'**. As a case study, we met with a team of information security professionals at Dubai, to discuss the vulnerabilities of mobile medical application that can affect the integrity of a patient's data.

Surveys can be referred to as **'research in the large'** because they are used to poll what is happening broadly, over large groups of projects. Before developing MyHealthCloud, we asked a group of doctors for their opinion about the visualization of Electronic Health Records (EHRs) on a mobile device and the sharing of EHRs between patients and doctors.

In this thesis, we focus primarily on controlled experiments. Based on the criteria for defining these methods, we have chosen to apply this method here for the following reasons:

- Our investigation is planned, and not retrospective.
- The treatments that we propose have not been applied previously.
- The level of replication in our study is high, since we conducted the same test many times with different types of users.
- A limited number of participants took part, and they were carefully controlled.
- We had a high level of control over the variables that could affect the outcome.

In this research, we applied usability testing techniques to design our experiments. All these techniques are explained below.

6.3 Case Study

It is obligatory to provide necessary security to mobile medical applications to maintain the integrity of patient's data. For this concern, we contacted a group of information security professionals to look for the perfect security solution for our proposed mobile application. Together we discussed the core security leaks of mobile data and the ways to protect it. The details of security requirements and constraints of a mobile medical application are described in Chapter 4.

6.4 Survey

Before the development of MyHealthCloud, we interviewed eight doctors (6 from Pakistan and 2 from USA) in November 2014, to share their opinion with us about the visualization of Electronic Health Records (EHRs) on a mobile device and patient-doctor sharing of those medical reports. For the sake of our motivation, we asked the following questions:

- First of all, how would you evaluate EHR technology?
- Do you think that improving patient-doctor communication could be beneficial for a patient's health?
- What do you think of a centralized database system for a hospital to keep every EHR with details?
- Which technology or software are you currently using for tracking a patient's medical record?
- Do you think we could save lives if we could provide an additional access to approach health providers at the time of an emergency?

And last but not the least, we asked them for their comments on our hypotheses.

We received positive feedback about our research on the use of EHRs instead of paper based medical charts. But the major concern of almost all the doctors was the security and privacy of EHRs and patient data. Keeping these concerns in consideration, we made a case study on the security of mobile medical applications and met with information security professionals for solutions (See chapter 4).

6.5 Usability Testing

The purpose of this study is to test the usability of a new mobile medical application designed for visualizing, managing and sharing medical test reports using MyHealthCloud. It also covers the emergency message service that includes a patient's current location.

The primary focus of this test was identifying any usability issues in the prototype, potential fixes and potential interests of users. For this we used readily available participants recruited among the general non-technical public and participants with a medical background.

People usually do not get to manage their medical history themselves, as they do not have access to their test reports. We proposed the MyHealthCloud application to the participants and asked them to use the prototype and perform some pre-defined tasks and share their experiences so that we could confirm our hypotheses. We made the following notes for every task:

- Does the participant complete the task?
- How quickly the participant completes the task?
- Does the participant get confused at any point?
- Does the participant makes any mistake?
- Is the participant satisfied with his task performance?
- If the participant has any questions to ask after completing the task?

We asked them to fill a consent form and asked a few demographic questions before starting the test, and then we let them perform the tasks. After performing all the tasks, we asked them to fill a Post-Questionnaire.

6.5.1 Background of Protocol Design

The following section explains the rationale for the sample size used in the usability testing of the prototype, as well as explaining the choice of questionnaires used for the usability testing. The application of these questionnaires, the Usability Metric for User Experience (UMUX) will also be described.

6.5.1.1 Participants

Twenty participants were recruited for usability testing of the prototype. Although twenty is a small sample size, recruiting participants in these fields is difficult given the demands on their time. As will be seen in the following section, UMUX was used to evaluate the system. Since half of the participants have a medical background, this sample of users for the study is sufficient.

6.5.1.2 UMUX

UMUX [78] was chosen due to its reliability, as well as its short length of four Likert-scale questions (see Appendix B). This ensured that the usability testing was kept within an acceptable time frame, while still gathering valuable data. UMUX is a standard set of four Likert-scale questions:

1. The app’s features meet my expectations.
2. Using this app is a frustrating experience.
3. The app is easy to use.

4. I have to spend too much time correcting things with this app.

The questions used a Likert-scale response with a range of 1 through 7, where 1 was Strongly Disagree and 7 was Strongly Agree. Once data is collected, it needs to be properly recoded, with the following scoring:

- First and Third items are scored as [response – 1].
- Second and Forth items are scored as [7 – response].

To calculate the UMUX score, first sum the score contributions from each item. Then multiply that value with 100 and then divide by 24 to obtain the overall value of UMUX; the range will be from 0-100.

The UMUX score provides a single number representing a composite measure of the overall usability of the system being tested.

6.5.1.3 Additional Questions Directly Addressing Hypotheses

We added three additional questions to be answered by the participants after completing all the tasks:

5. It is very easy to view my medical reports on this app.
6. I would prefer to manage my own medical reports with this app.
7. I like the way this app lets me communicate with doctors and caregivers.

The questions above are analyzed between the values 7 to 1 (see section 7.2).

6.5.2 The Experiment

In this section we summarize the experiment and usability testing protocol. The detailed usability Testing Protocol used during usability testing sessions can be found in Appendix A.

6.5.2.1 Participant Profile

Participants were the general public, doctors, research experts, a cardiologist and medical students. Usability testing was performed with twenty participants, where half of them had a medical background. Participants were recruited either by exploring hospitals or through friends, family, and colleagues with acquaintances working in the aforementioned areas of occupation.

Non-medical participants were recruited at random places (like the Concordia Hall Building, Concordia Library, McGill Campus Park, Le Gym, the John Molson Building, Mount Royal, and McDonalds).

Demographics for 20 participants:

- 11 Females, 9 Males.
- 10 with a medical background, 10 without any medical background.
- None of them has any web designing background.
- All of them are smartphone users.
- 8 participants download apps frequently, while 12 download occasionally.
- 10 participants were under 30, 10 participants were above.

6.5.2.2 Usability Testing Session

Each session with a participant followed this approximate schedule of events:

- Participants were contacted and given a brief description of the research and asked if they would agree to participate. If they agreed, a testing session was scheduled.
- Participants were greeted and provided with a consent form, which included asking if they agreed to audio taping of the session and non disclosure of confidential information on the prototype.
- Participants were asked 5 demographic questions prior to starting the test.
- An introduction to the goal of the testing, prototype, and testing procedure was given.
- Participants were then asked to complete the tasks (see Appendix A) and they could ask questions after the completion of each task.
- After completing each task, participants were asked a set of questions. Participants were also asked if they had any comments they would like to provide pertaining to that task.
- After completing all the tasks, participants were debriefed to get their general impressions of the prototype.
- Due to privacy, many doctors did not record their session.

All participants (with or without medical background) were informed that for the purposes of this test, the tester was playing the role of the patient in this session. Participants were instructed that if they had questions they would ask the patient as part of the session, that they could and should, ask them to ensure that the information obtained was as realistic as possible.

The prototype created for testing allows users to log in and view the Electronic health records (EHRs) and communicate with the doctors and caregivers. Note more than one patient file were implemented for the purpose of usability testing.

Participants were also encouraged to talk aloud during the completion of each task, so that the tester could gather information on possible problems, improvements, or elements that should be kept in the prototype. All participants completed the five (5) tasks in the same order to ensure that the results were based on the same criteria.

6.5.2.3 Threats to Validity

No study is perfect. There are numerous ways that a study can give misleading results that could be contradicted in future studies. We have all seen reports about studies with new results that repudiate results reported from previous studies.

With a developing spotlight on empirical research techniques in software engineering, it is essential that each researcher do a validity analysis.

Potential issues with empirical research are classified as categories of threats to validity. In [79], the author describes the following categories of threats to validity:

1. Conclusion validity - In the usability study, we had one primary purpose: to test the usability of the prototype created to confirm a theory by applying UMUX and analyzing our Likert-scale data (see section 7.2). Exploring the relationship among our dataset values confirms the difference between the UMUX score and the possible ideal (maximum) outcome. Our sample size (20 participants) was not very large, so it is hard to validate only upon the feedback received.

2. Construct validity - We have theoretically validated all three measurements (our hypotheses) in a narrow sense, which means a measure is valid if it reflects the real meaning of the concept under consideration (see section 7.3).

3. External validity – It is the extent to which the results of a study can be generalized to other situations and to other people [80]. All the participants recruited for the study use smartphones and do not have any web designing, mobile application development or software development background. This knowledge of using smartphone and ignorance of technical details validates that the result of the usability study can be generalized to any literate person familiar with the operation of smartphones. All participants completed the tasks, which explains the simplicity of the MUI, which means no additional usage explanation is necessary.

From the above discussion, it is clear that both the theoretical and empirical validations, as they are defined, are necessary and complementary.

6.5.2.4 Confounds

- Many of the doctors' sessions were not recorded due to privacy and confidentiality.
- Some participants were not accustomed to working on an iPhone. This was covered at the beginning of the session and explanations were given to these participants prior to starting the first task.
- The following disclaimers were provided to each participant prior to starting the tasks:
  - Please keep in mind that this is a prototype, so not all functionality is present.
  - As we tried to make things as realistic as possible, we added a couple of medical reports in the prototype just for the sake of research.

6.6 Summary

A survey with doctors was conducted in November 2014. It explains the need for EHRs systems and services for emergency. A case study was conducted in January 2015. It describes all kinds of data related security issues for MyHealthCloud and their possible solutions. Usability testing for MyHealthCloud System Prototype was conducted in July 2016. The testing was conducted at a mutually agreed upon location with each participant. Participants were recruited through clinics, as well as through acquaintances of friends and family. The participant profile is provided in section 6.5.2.1. Each session lasted between 15 and 30 minutes and included an introduction, completion of five (5) tasks and associated questions, and a final debrief questionnaire.

Chapter 7. Discussion of the Results

The key results obtained from the usability testing are discussed below. A detailed Usability Report with a more in-depth analysis can be found in Appendix C.

7.1 Summary of Results

The majority of participants completed the session without difficulty. A few participants had difficulty with the technology but everyone was able to complete the session.

- Overall, sixteen (16) out of twenty (20) participants had a very positive reaction i.e. 82% mean score to the MyHealthCloud UMUX Questionnaire.
- Following is the MyHealthCloud Mean Score for the four UMUX (4) questions:
    - Q1 – 4.25 / 6.0 (70% is the average level of agreement percentage)
    - Q2 – 5.50 / 6.0 (91% is the average level of disagreement percentage)
    - Q3 – 4.60 / 6.0 (76% is the average level of agreement percentage)
    - Q4 – 5.30 / 6.0 (88% is the average level of disagreement percentage)
- No participant required specific help with any of the tasks.
- Participants provided numerous suggestions for improving the prototype. We also observed some elements, which could be improved. Those are listed in the Recommendations (see section 7.6).
- Following is the MyHealthCloud Mean Score for the additional three (3) questions (not part of UMUX):
    - Q5 – 5.70 / 7.0
    - Q6 – 5.60 / 7.0

- Q7 – 5.35 / 7.0

7.2 Detailed Results

The UMUX questionnaire was used as a final debrief for the prototype. The UMUX mean score for the overall system evaluation is 82% i.e. most of the participants did find the app an easy-to-use mobile medical application.

The table below gives the participants' responses to the UMUX questionnaire used as a debrief questionnaire after completing all five tasks. A detailed breakdown of the participants' responses, as well as any comment they had while completing the debrief questionnaire, including observations about their experience, are described.

P-IDs	Q1		Q2		Q3		Q4		SUM	UMUX
		R-1		7-R		R-1		7-R		
P1	6	5	1	6	7	6	3	4	**21**	**87.50**
P2	5	4	2	5	6	5	2	5	**19**	**79.17**
P3	7	6	1	6	7	6	1	6	**24**	**100.00**
P4	6	5	1	6	6	5	1	6	**22**	**91.67**
P5	5	4	2	5	5	4	2	5	**18**	**75.00**
P6	4	3	1	6	5	4	2	5	**18**	**75.00**
P7	6	5	2	5	6	5	1	6	**21**	**87.50**
P8	5	4	1	6	6	5	2	5	**20**	**83.33**
P9	5	4	1	6	6	5	1	6	**21**	**87.50**
P10	6	5	1	6	5	4	3	4	**19**	**79.17**
P11	7	6	1	6	6	5	1	6	**23**	**95.83**
P12	5	4	2	5	5	4	2	5	**18**	**75.00**
P13	6	5	1	6	6	5	2	5	**21**	**87.50**
P14	4	3	2	5	5	4	2	5	**17**	**70.83**
P15	4	3	2	5	4	3	2	5	**16**	**66.67**
P16	4	3	4	3	5	4	2	5	**15**	**62.50**
P17	5	4	1	6	6	5	1	6	**21**	**87.50**
P18	4	3	2	5	5	4	1	6	**18**	**75.00**
P19	6	5	1	6	6	5	2	5	**21**	**87.50**
P20	5	4	1	6	5	4	1	6	**20**	**83.33**
SUM	**105**	**85**	**30**	**110**	**112**	**92**	**34**	**106**		
MEAN	**5.25**	**4.25**	**1.5**	**5.5**	**5.6**	**4.6**	**1.7**	**5.3**	**19.7**	**81.875**

Figure 7.1 UMUX results for first four questions

Fig 7.1 shows the detailed calculated mean values of the first four questions of the study. Fig 7.2 shows the graph of UMUX Mean values of all participants and their overall ratings.

Figure 7.2 Graph showing UMUX Mean Values between participants and their overall ratings for first four questions

Following are participants' comments and observations made during the debriefing questionnaire.

- Two (2) participants had no comments to add from what they had already provided on the individual task.
- Seven (7) participants (including doctors) gave enthusiastic comments on the system and would like to have such a system in place and at their disposal.

Fig 7.3 shows some other calculations that are also made for confirming the accuracy of the study. The collected data is not normally distributed due to its small size (only 20 participants). Further work is needed to improve these results by collecting data from a larger group of participants in the future.

VALUES	Q1		Q2		Q3		Q4
SUM	85		110		92		106
UMUX MEAN	70.8		91.7		76.7		88.3
STDEV	0.97		0.76		0.75		0.66
SAMPLE SIZE	20		20		20		20
CONFIDENCE COFF.	1.96		1.96		1.96		1.96
MARGIN OF ERROR	0.42		0.33		0.33		0.29
UPPER BOUND	71.3		92		77		88.6
LOWER BOUND	70.4		91.3		76.3		88

Figure 7.3 UMUX values calculating AVG, STDEV, CON COFF, SAMEPLE SIZE, etc

Using a T-distribution to analyze the small amount of collected data (UMUX), the results show that participants found MyHealthCloud a useful and easy-to-use mobile medical application. Fig 7.4 shows the results obtained from usability testing with the twenty (20) participants using a 95% T-distribution confidence level.

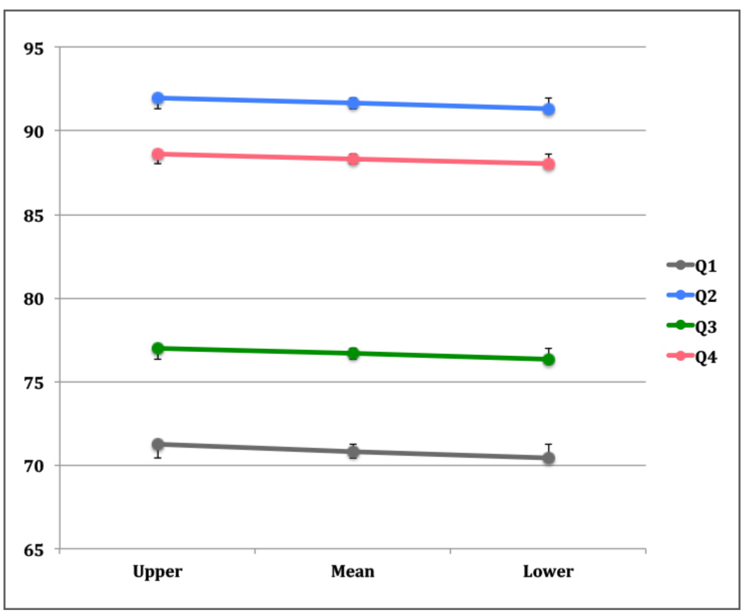


Figure 7.4 UMUX Mean Values with 95% T-distribution with Upper & Lower Bounds

All the values are above 70% with a margin of error less than 0.5 and standard deviation less than 1.0, supporting the validity of the UMUX results.

Following are the Mean, Lower & Upper Bound (Confidence) Level values:

Q1 – Lower CL (70.4), Mean (70.8), and Upper CL (71.3)

Q2 – Lower CL (91.3), Mean (91.7), and Upper CL (92.0)

Q3 – Lower CL (76.3), Mean (76.7), and Upper CL (77.0)

Q4 – Lower CL (88.0), Mean (88.3), and Upper CL (88.6)

7.3 Assessment of Hypotheses

To test our hypotheses, we created a prototype to conduct usability testing (see chapter 6). In Fig 7.2 we can see the graph showing the results for the first four (4) questions that provide the UMUX score.

For the assessment of hypotheses, three (3) additional questions were added to the post questionnaire. Participants were asked to answer these after completing all five tasks. The answers are analyzed between the values 7 to 1 i.e. Strongly Agree (7) to Strongly Disagree (1).

The individual assessment of these questions is described below:

Assessment of Hypothesis H1

Testing the first hypothesis: Patients, doctors and caregivers prefer to use MyHealthCloud to view their medical reports.

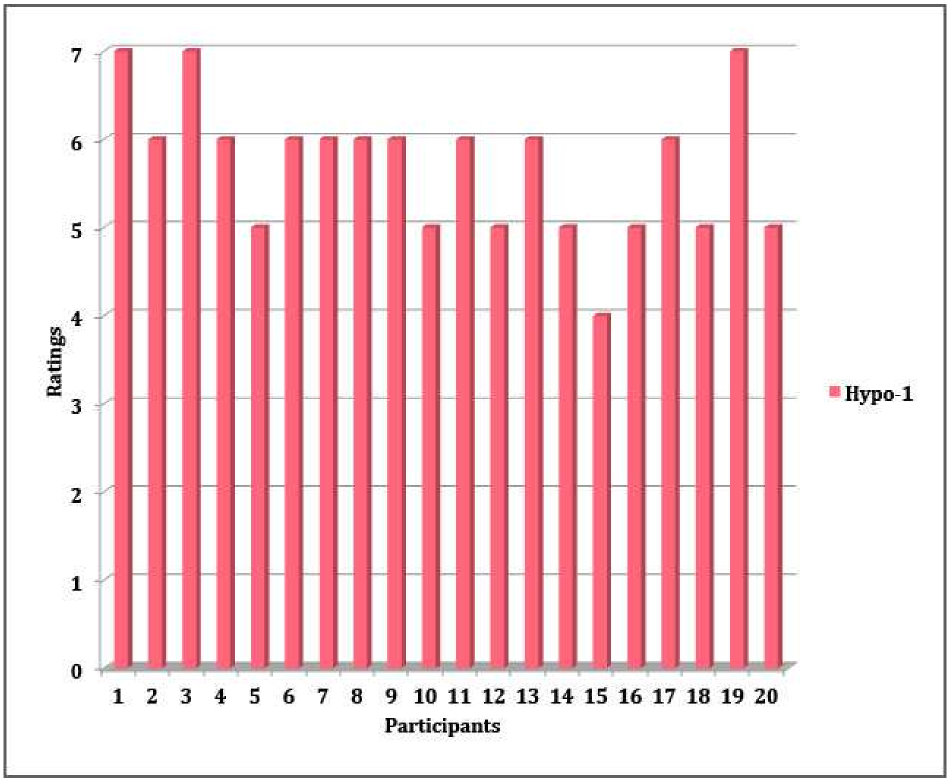


Figure 7.5 Graph showing participants ratings for Hypothesis H1

Supported by Question (Q5): It is very easy to view my medical reports on this app.

Result: Mean Value 81% and Average Value 5.7 / 7.0 with Median 6

In conclusion, the majority of the participants in this study prefer to use MyHealthCloud to view their medical reports.

Assessment of Hypothesis H2

Testing the second hypothesis: Patients, doctors and caregivers prefer medical reports self-management with MyHealthCloud.

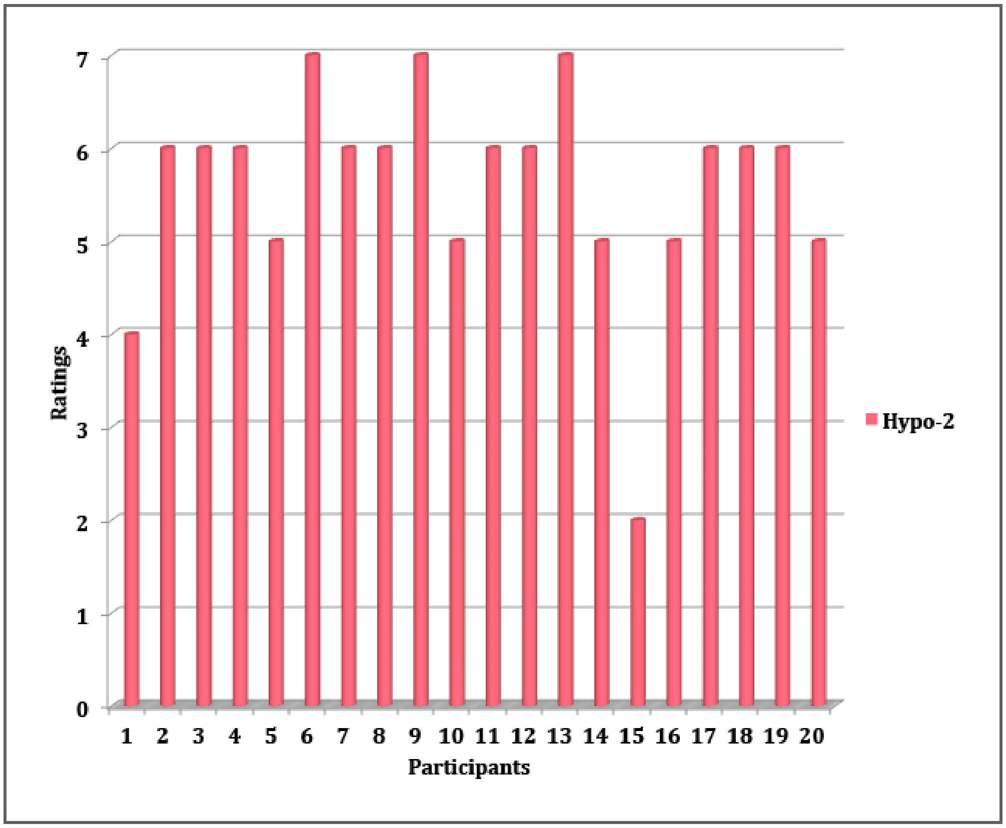


Figure 7.6 Graph showing participants ratings for Hypothesis H2

Supported by Question (Q6): I would prefer to manage my own medical reports with this app.

Result: Mean Value 80% and Average Value 5.6 / 7.0 with Median 6

Based on the above results we can determine that medical reports self-management with MyHealthCloud, is preferred by the majority of the participants in the study.

Assessment of Hypothesis H3

Testing the third hypothesis: MyHealthCloud improves communication and connectivity between patients, doctors and caregivers (including receiving and sending of patient medical health reports and a novel emergency contact to a doctor or friend.

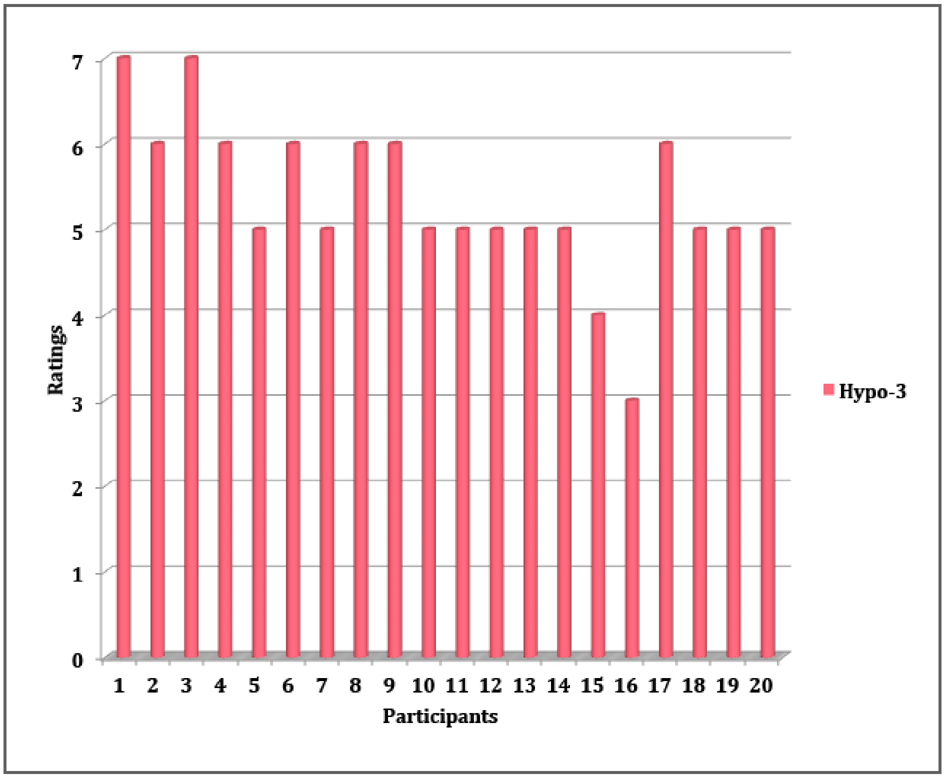


Figure 7.7 Graph showing participants ratings for Hypothesis H3

Supported by Question (Q7): I like the way this app lets me communicate with doctors and caregivers.

Result: Mean Value 76% and Average Value 5.35 / 7.0 with Median 5

Therefore, according to the presented results MyHealthCloud improves communication and connectivity between patients, doctors and caregivers.

7.4 Participants' Feedbacks

We received numerous complements regarding the proposed approach to solve the research questions and the design of the prototype. But with the positive feedback, many participants (including doctors) showed their concerns about the security and privacy of EHRs and medical information. Following is some of the valuable feedback from the participants:

- It's convenient, a good idea. Would this be in other languages as well? Maybe I would need it when I'm older, maybe I'll use it for someone older in my family.
- As a patient I would love this app. As a medical provider I am not so sure due to HIPAA rules and regulations and 24/7 coverage.
- This could be a good technique. I'd like to see such integration of EHRs with mobile.
- Interoperability is the key for EHRs to be successful Data collection activities are in full blow, however connecting them and providing access at point of care would be a challenge.
- Try to make them more easily accessible instead of just scanned documents.
- I think it would be a good a technique of recording patient records as well as easy access to every doctor which is helpful in patient health benefits.
- This app would work if all the hospitals and outpatient clinic apps are connected (universal connection) otherwise it will be difficult to access and send reports to different providers.
- This app has to be completely encrypted to prevent hacking.
- I do not like to download important documents on my smart phone. I worry about hacking.

- Encryption, I worry about security. Patient protected information should be confidential.
- It is a good attempt but needs some work, especially from HIPAA point of view Patient information, results should not get hacked and the risk is high if the app is not fully encrypted.
- This app has great potential.
- It's really super friendly.

7.5 Testing Observations and Remarks

Following are some points we observed during the study:

- A few participants (5/20) commented on a need for an alternative option to add a new contact when sending a report.
- There was a general hesitation among most participants about the security and privacy of EHRs.
- One (1) participant asked if the app is going to be launched in other languages as well.
- Four of the participants remarked that they were uncertain if the prototype met their expectations or not because it was the first time they used any patient-driven health system so they really had no idea what to expect.
- A strong majority of participants (16/20) were very enthusiastic when performing the MyHealthCloud tasks.
- All participants gave suggestions on improving the prototype to ensure that MyHealthCloud is efficient and effective in managing EHRs.

- All participants had an easy time using MyHealthCloud.
    - Only three (3) participants needed an explanation on what MyHealthCloud was and how it worked.
    - Four (4) participants were not familiar with the term Health Cloud.
    - Many participants instinctively learnt how to use it.
- Twelve (12) participants did not take their picture while registering for the app due to either lack of time or since it was not necessary for registering.
- Nine (9) participants said that they would recommend such an app to their friends and family.
- The two (2) oldest participants seemed less comfortable using the prototype and had some minor difficulties in performing the tasks.
- The following issue was noted by the majority of participants:
    - As MyHealthCloud provides only one way to add a new contact, i.e. by tapping on the compose button on the messages page, suppose user opens a report, taps the share button, finds the list of contacts but since the user has to send that report to a new contact, there should be an alternative way on that screen to add the new contact.

7.6 Recommendations

This section lists the suggestions offered by participants when either completing a task or commenting on their answers to the questions.

- The app should be not launched in English language only; it should available in AppStore in all languages.

- The app should be built for all platforms like iOS, Android, Windows, BlackBerry, and Nokia.
- There should be specific timing set for sending messages to the doctors for the integrity of their privacy.
- There should be an alternative option to add a new contact when sending a report.
- Encryption and Security of Data must be the foundation of the app to keep the data secure from hacking.

7.7 Summary

The UMUX mean score of all four answers from 20 participants is 82%, meaning more than 16 out of 20 participants found MyHealthCloud a useful and easy-to-use mobile medical application rather than a frustrating experience. Low values for the standard deviation and margin of error for the UMUX scores show the validity of the study. The additional three questions support the hypotheses with the participants' mean score of 5.7, 5.6 and 5.4 out of 7.0. Based on the results obtained using UMUX and the other questions, we have demonstrated that MyHealthCloud is a useful tool for users who are looking forward to manage their medical history in the form of EHRs on a mobile device. This, combined with the positive comments from users of the MyHealthCloud tool, warrant further investigation of such applications to be used in Healthcare.

Chapter 8. Conclusion & Future Work

8.1 Summary

The growing rate of mobile medical applications and increased pressure on the health care sector for the adoption of Electronic Health Records (EHRs) systems justifies the need for research to be done in this field. In this thesis, we reviewed the related work done in the fields of cloud computing, mobile computing and health cloud technology, the types of EHRs and their visualization on a mobile device via the integration of MyHealthCloud. We proposed a new mobile-cloud-based approach and tool, for viewing and self-management of patients' medical test reports, created a prototype, and conducted its usability testing. We analyzed the different tasks performed by the participants during the study. We also discussed the HIPAA rules and FDA regulations that are obligatory to be taken into consideration before building any mobile medical application. We also discussed the security analysis, constraints and requirements that are considered building blocks for any record-keeping system. Furthermore, the usability of the prototype was tested with 20 participants. The findings demonstrated that the participants prefer the usage of MyHealthCloud to view their medical reports over paper-based reporting. Moreover, medical report self-management with MyHealthCloud was preferred by the majority of the participants, as compared to conventional paper records. Furthermore, the participants agreed that MyHealthCloud has the potential to improve communication and connectivity between patients, doctors and caregivers, as compared to the conventional coordination of healthcare.

8.2 List of Contributions

We propose a novel patient-driven approach, MyHealthCloud, for viewing and self-managing a patient's medical reports (EHRs) on mobile devices.

As a proof of concept, we built a prototype of MyHealthCloud for visualizing, sending, receiving and sharing a patient's medical reports (EHRs).

The prototype was used in a usability study aimed to validate the research hypotheses formulated in support of the research questions outlined in this thesis.

The results of the empirical evaluation of MyHealthCloud show that the system performs tasks very quickly and in an acceptable amount of time, and thus, is efficient and effective (see section 7.1).

A novel approach for patient-doctor communication has also been introduced during this study in terms of the SOS Message Service.

8.3 Impact

The anticipated significance of this research contribution includes:

i) The expectation of having EHR data delivered at low cost has the potential to result in significant cost savings across the health care system.

ii) The advantage of managing EHR data quality on mobile devices, including 24/7 EHR data availability to health professionals and patients. This will facilitate the usage of EHR data for decision-making purposes.

iii) The current trend towards restoring patient control over the quality of their EHR data will allow health professionals to make better clinical decisions with ready access to the full medical histories for their patients.

8.4 Future Work

Given the benefits of using MyHealthCloud with doctors and other medical practitioners shown in this thesis, the approach should be evaluated with a larger group of participants to ensure the validity of the results across demographics within the field. Hospital cooperation would also be required in order to collect a sufficient amount of empirical data.

More user profiles will be defined in future studies to collect more data according to those user profiles.

IBM, Salesforce and other companies are already working on Health Cloud technology to integrate Health Care with Cloud Computing. MyHealthCloud would be a similar project dedicated to the advancement of Health Cloud technology.

In addition, MyHealthCloud could also be adopted by a big company in order to manage large amounts of data and communication between users.

In the future this research will identify and tackle the security issues of EHR data as well as the privacy issues related to visualization of the data.

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Appendices

A. Usability Testing Protocol

Information Access by Naïve Users

Testing Protocol

Session Script, Data-Collection Sheets, and

Participant Forms

Muhammad Nsr Khan, Master's Student

Department of Computer Science & Software Engineering

Concordia University

[Version 1 | 2016-01-12]

Information Access by Naïve Users – Testing Protocol

This document is the testing protocol for the Master's project Information Access by Naïve Users, which Muhammad Nsr Khan, Master's student at Concordia's Computer Science Department, will conduct with up to 25 participants. This document contains all the materials needed for the observation sessions, including the session set-up checklist, the facilitator's script, data- collection sheets, and participant forms.

Session Set-Up

Before a session begins, perform all set-up tasks for the session as follows:

MOBILE	
Switch ON the Mobile	
Set Up Voice Recorder	
Do Test Recording	
Verify Sound in Test Recording	
Set Prototype to Start Usability Test	
PARTICIPANT PAPERWORK	
Consent Form	
Pre-Questionnaire	
Script, Tasks and Observation Sheet	
Usability Metric For User Experience	
Debrief	
Recruitment Script	

Consent Form

TO PARTICIPATE IN STUDY ON VIEWING & SELF-MANAGEMENT OF MEDICAL TEST REPORTS

I understand that I have been asked to participate in a research project being conducted by Muhammad Nsr Khan under the supervision of Dr. Olga Ormandjieva (514-848-2424, ormandj@cse.concordia.ca) and Dr. Kristina Pitula (514-730-6731, pitul_87@encs.concordia.ca) from the department of Computer Science & Software Engineering at Concordia University.

Purpose

I have been informed that the purpose of the research is to test an app that lets you view and manage medical reports on your cell phone and send an emergency message to a doctor or caregiver.

Procedures

I understand that I will be asked to answer some questions about my experiences with the prototype and this will take approximately 15-20 minutes of my time.

Risks & Benefits

I understand that there are no foreseeable risks or benefits from participating.

Conditions of Participation

- I understand that I am free to withdraw my consent and discontinue my participation at anytime without negative consequences.
- I understand that my participation in this study is CONFIDENTIAL
- I understand that the results of this study may be published.
- I understand that the data collected from this study will not be published or used in any publicity.

I HAVE CAREFYLLY STUDIED THE ABOVE TERMS AND UNDERSTAND THIS AGREEMENT. I FREELY CONSENT AND VOLUNTARILY AGREE TO PARTICIPATE IN THIS STUDY.

NAME ________________________________ SIGN ________________________

If at any time you have questions about the proposed research, please contact the study's Principal Investigators: Dr. Olga Ormandjieva or Dr. Dr. Kristina Pitula.

If at any time you have questions about your rights as a research participant, please contact the Research Ethics and Compliance Advisor, Concordia University, 514.848.2424 ex. 7481 ethics@alcor.concordia.ca.

Recruitment Script

Hi. My name's **Muhammad Nsr Khan** and I'm a student at Concordia University. I'm testing a new cell phone app for tracking personal Health Data. This should take around 15 minutes of your time.

Are you interested in participating?

This app lets you do things like view your medical test results on your cell phone and send them to your doctor or a friend.

The app also lets you send an emergency message to someone you've chosen.

Briefing Participants

You'll have to sign a consent form.

Just so you know, if we present this study in a conference or paper, your identity will remain confidential.

If at anytime you feel uncomfortable, just let me know and we'll stop the study.

To help remember your answers I'd like to record this session. Any problem with that?

Do you have any questions before we start?

Pre-Questionnaire (Demographic Information / Profile)

Before we start with the app, I have a few questions for you.

Gender (Mark)

	Male
	Female

Medical background (Mark)

	Medical
	Non-Medical

Pre-Q 1

Are you a web designer?

	Yes
	No

Pre-Q 2

What age bracket do you belong to?

(Show cue card with options)

	Under 30
	Above 30

Pre-Q 3

Do you use a smartphone? (Familiar with an iPhone)

(If not, show some basic operations of an iPhone)

	No
	Yes

Pre-Q 4

Do you download mobile applications?

	Occasionally
	Frequently

Script

Today we're going to run through tasks which are typical things to do with the app. To perform those tasks, you will be using a cell phone that is in front of you.

While you are doing the tasks I'd like you to say aloud what you are doing and thinking so I can follow what's happening.

If you do have any questions, I'll be happy to answer once the task is over.

Tasks

Task 1

You went to see the Doctor at St. Jose Hospital because your knee is sore. The Doctor took an X-ray and put it on the app.

You have just downloaded the app from Apple Store. Now start the app, and view your knee X-ray.

Given Info: Phone Number **+1 514-466-9973**

Verification code **abc123**

Task 2

It's been couple of months, now you have received plenty of Medical test reports. One of those reports is an ECG (Electrocardiogram).

Using the application, find your ECG report and show it to your friend.

Task 3

You met Dr. Khan at Canadian Red Cross Hospital and discussed your sore knee incident. She gave you her app ID and asked you to send her your knee X-ray.

Using the application, send your knee X-ray to Dr. Khan.

Given Info: Dr. Khan's MyHealthCloud ID **khan123**

Task 4

Dr. Khan said that she would send you feedback once she looked at your knee X-ray.

Using the application, check if Dr. Khan has sent you any feedback on your X-ray.

Task 5

Suppose you are having bad chest pain and are not in condition to call someone for help. MyHealthCloud has a feature that lets you send an emergency message to a friend or relative with your location by tapping a single button.

Using the application, try sending an emergency message.

Given Info: Friend's Phone Number **+1 514-466-9973**

Tasks Observation Sheet

PARTICIPANT NAME ____

PARTICIPANT ID ____

Observed Results For Task Number ________

Success ____________ Failure ____________ Time Duration ____________

# of Mistakes ______________________ # of Screens Used ____________

Task-Q: How did that go? Was anything confusing or everything was clear?

____

Observed Results For Task Number ________

Success ____________ Failure ____________ Time Duration ____________

# of Mistakes ______________________ # of Screens Used ____________

Task-Q: How did that go? Was anything confusing or everything was clear?

____

Observed Results For Task Number ________

Success ____________ Failure ____________ Time Duration ____________

# of Mistakes ______________________ # of Screens Used ____________

Task-Q: How did that go? Was anything confusing or everything was clear?

____

Observed Results For Task Number ________

Success ____________ Failure ____________ Time Duration ____________

# of Mistakes ______________________ # of Screens Used ____________

Task-Q: How did that go? Was anything confusing or everything was clear?

____

Observed Results For Task Number ________

Success ____________ Failure ____________ Time Duration ____________

# of Mistakes __________________________ # of Screens Used ____________

Task-Q: How did that go? Was anything confusing or everything was clear?

____

Bonus-Q: (For Task 5)

What do you think of this feature? Would you use it yourself or recommend it to someone else?

____

Final Comments

____

Post-Questionnaire

Now to complete the study, please circle the options for these additional questions.

1. The app's features meet my expectations.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

2. Using this app is a frustrating experience.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

3. The app is easy to use.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

4. I have to spend too much time correcting things with this app.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

5. It is very easy to view my medical reports on this app.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

6. I would prefer to manage my own medical reports with this app.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

7. I like the way this app lets me communicate with doctors and caregivers.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

Debrief

Thank you for participating in this study.

Your **participation and feedback is greatly appreciated** and **valuable.**

and **valuable.**

B. Usability Metric For User Experience (UMUX)

1. The app's features meet my expectations.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

2. Using this app is a frustrating experience.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

3. The app is easy to use.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

4. I have to spend too much time correcting things with this app.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

5. It is very easy to view my medical reports on this app.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

6. I would prefer to manage my own medical reports with this app.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

7. I like the way this app lets me communicate with doctors and caregivers.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

The questions use a Likert-scale response with a range of 1 through 7, where 1 is Strongly Disagree and 7 is Strongly Agree.

Once data is collected, it needs to be properly recoded, with the following scoring:

- First and third items are scored as [response – 1].
- Second and Forth items are scored as [7 – response]

This removes the positive/negative keying of the items and allows a minimum score of zero.

Each individual UMUX item has a range of 0 – 6 after recoding, giving the entire seven-item scale a preliminary maximum of 24.

To achieve parity with the 0–100 range, a participant's UMUX score is the sum of the four items divided by 24, and then multiplied by 100.

These scores across participants are then averaged to find a mean UMUX score. It is this mean score and its confidence interval that become the application's UMUX metrics for a system's usability tracking and goal-setting.

C. Usability Report

USABILITY REPORT

Information Access by Naïve Users

The purpose of this study is to test the usability of a new mobile phone application designed for viewing, managing and sharing of medical test reports. It also covers the emergency SOS service provided by **MyHealthCloud**.
The primary focus will be on identifying any usability issues in the prototype, potential fixes. For this we will use readily available participants recruited among general non-technical participants and participants with a medical background.

1. Planning

1.1 Possible Objectives/Goals of the test

Investigating the usability, effectiveness and efficiency of overall application:

- **High Priority**
  - Can users register successfully for the application?
  - Can users view test reports?
  - Can users search for any test report?
  - Can users share the test reports with doctors or friends?
  - Can users add a doctor or friend to their messages list?
  - Can users access the feedback from their doctors for the test report?
  - Can users send an emergency message?

- **Medium Priority**
  - Can users zoom-in and zoom-out the test report without any trouble?
  - Can users find their MyHealthCloud ID?
  - Can users edit their info, phone number and profile picture on settings page?

- **Low Priority**
  - Can users figure out how to set their status?
  - Can users add phone numbers and a message for emergency purpose?
  - Can users figure out what button to click?
  - What paths users take to do tasks?
  - What errors do they make during the tests?
  - When and where they get confused or frustrated?
  - How quickly do they do the tasks?
  - Whether the users succeed in completing the tasks?
  - How satisfied the users are with the experience?

- **Missing features**
  - Do users want to leave comments or questions?
  - Do users think if anything is missing in the application?

- **Opinion**
  - What do the participants think about this application to keep their medical history?

- **Demographics/Profile**
  - Do the participants use smartphones?
  - Do the participants download mobile applications? If yes, how often?

1.2 Participants

A total of 20 participants will be recruited for the study.

- Male/female (ideally equal number).
- 2 groups of adults aged (under and over 30).
- Non-technical (no specific computer science or web designing background).
- At least half participants with medical background (medical student, doctor or nurse).
- Familiar with smartphones (specifically iPhones).

1.3 Tasks List with related Scenarios and Questions

People usually do not get to manage their medical history themselves, as they do not have access to their test reports. The hospitals keep those records. But what if you also want to keep track of your medical history and reports so you can share it with your doctor or friend anytime you want.

There is a new mobile application for visualizing and managing medical test reports, **MyHealthCloud**. Users will help us in the research by completing a few tasks using the application. We will make the following notes for every task they do.

- Does the participant complete the task?
- How quickly the participant completes the task?
- If the participant gets confused at any point?
- If the participant makes any mistake?
- Is the participant satisfied with his task performance?
- If the participant has any questions to ask after completing the task?

Task 1

You went to see the Doctor at St. Jose Hospital because your knee is sore. The Doctor took an X-ray and put it on the app.

You have just downloaded the app from Apple Store. Now start the app, and view your knee X-ray.

Given Info: Phone Number **+1 514-466-9973**

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Task 2

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Using the application, send your knee X-ray to Dr. Khan.

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Using the application, try sending an emergency message.

Given Info: Friend's Phone Number **+1 514-466-9973**

1.4 Data collection methods

Data collection approaches for qualitative research usually involves:

- Direct interaction with individuals on a one to one basis.
- Or direct interaction with individuals in a group setting.

Qualitative research data collection methods are time consuming, therefore data is usually collected from a smaller sample than would be the case for quantitative approaches - therefore this makes qualitative research more expensive. The benefits of the qualitative approach are that the information is richer and has a deeper insight into the phenomenon under study.

The main methods for collecting qualitative data are:

1. Individual interviews
2. Focus groups
3. Observations
4. Action Research

For the usability testing, we will record the interviews and make as many notes as we can, to collect the data.

1.5 Targeted 'users'

MyHealthCloud focuses the audience ages from 18 - 60 years old. Under age (less than 18 years old) are not legally allowed to manage their medical history all by themselves.

1.6 Location of the test

Participants were recruited either through exploring hospitals or through friends, family, and colleagues with acquaintances working in the aforementioned areas of occupation. Non-medical participants were recruited at random places (like Concordia Hall Building, Concordia Library, McGill Campus Park, Le Gym, John Molson Building, Mount Royal, McDonalds).

1.7 Testing System

We have built a mobile application prototype for conducting this usability test. And we call it **MyHealthCloud** system.

2. Preparation

2.1 Participant recruitment

We checked if we could find the participants who match the profile.

For the study, participants will be recruited under the supervision of **Dr. Olga Ormandjieva** and **Dr. Kristina Pitula** at Concordia University. We will invite the participants belong to different fields and give them a brief explanation before the test of what we are doing and the time it will take for conducting the test. Participation can be on the spot or scheduled for a later time if they are not immediately available.

2.2 Test Protocols

Each test session will last 20-30 minutes, depending on the participants' chattiness. Before they start, if they are unfamiliar with the type of phone (Apple iPhone), they will be shown some basic operations within a standard app (touch, back, home, etc…). Participants will be given a brief description of the purpose of the application and asked to complete some tasks typical of the kinds of things people would do with the app.

They will be asked to try and complete the tasks as best they can on their own, saying aloud what they are thinking as they do so [think aloud protocol]. The facilitator will only intervene if they get really stuck and request assistance (this will be considered a failed task).

During the task, the facilitator will observe, noting or recording everything that they do, where they have problems and whether they complete the task successfully.

At the end of each task, the facilitator will probe them on how they feel about what they have just done [qualitative – open ended probing "So, what did you think of that?] Then probe about any problems they encountered and what they were expecting.

When they have completed all the tasks the facilitator will ask them to rate the application, fill the post-test questionnaire and leave comments.

2.3 Test Script

Hi. My name's **Muhammad Nsr Khan** and I'm a student at Concordia University. I'm testing a new cell phone app for tracking personal Health Data. This should take around 15 minutes of your time.

Are you interested in participating?

This app lets you do things like view your medical test results on your cell phone and send them to your doctor or a friend.

The app also lets you send an emergency message to someone you've chosen.

2.4 Consent Form

TO PARTICIPATE IN STUDY ON VIEWING & SELF-MANAGEMENT OF MEDICAL TEST REPORTS

I understand that I have been asked to participate in a research project being conducted by Muhammad Nsr Khan under the supervision of Dr. Olga Ormandjieva (514-848-2424, ormandj@cse.concordia.ca) and Dr. Kristina Pitula (514-730-6731, pitul_87@encs.concordia.ca) from the department of Computer Science & Software Engineering at Concordia University.

Purpose

I have been informed that the purpose of the research is to test an app that lets you view and manage medical reports on your cell phone and send an emergency message to a doctor or caregiver.

Procedures

I understand that I will be asked to answer some questions about my experiences with the prototype and this will take approximately 15-20 minutes of my time.

Risks & Benefits

I understand that there are no foreseeable risks or benefits from participating.

Conditions of Participation

- I understand that I am free to withdraw my consent and discontinue my participation at anytime without negative consequences.
- I understand that my participation in this study is CONFIDENTIAL
- I understand that the results of this study may be published.
- I understand that the data collected from this study will not be published or used in any publicity.

I HAVE CAREFYLLY STUDIED THE ABOVE TERMS AND UNDERSTAND THIS AGREEMENT. I FREELY CONSENT AND VOLUNTARILY AGREE TO PARTICIPATE IN THIS STUDY.

NAME ______________________________ SIGN ______________________________

If at any time you have questions about the proposed research, please contact the study's Principal Investigators: Dr. Olga Ormandjieva or Dr. Dr. Kristina Pitula.

If at any time you have questions about your rights as a research participant, please contact the Research Ethics and Compliance Advisor, Concordia University, 514.848.2424 ex. 7481 ethics@alcor.concordia.ca.

2.5 Usability Metric for User Experience (UMUX)

Now to complete the study, please circle the options for these additional questions.

1. The app's features meet my expectations.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

2. Using this app is a frustrating experience.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

3. The app is easy to use.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

4. I have to spend too much time correcting things with this app.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

5. It is very easy to view my medical reports on this app.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

6. I would prefer to manage my own medical reports with this app.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

7. I like the way this app lets me communicate with doctors and caregivers.

Strongly Disagree 1 2 3 4 5 6 7 **Strongly Agree**

2.6 Observation equipment

We are testing the usability of a mobile application on Apple Devices, iPhone 6. We are using 1 mobile phone for five different scenarios of the test. Device has 16GB memory. The prototype will only consume 10mb memory overall. iOS version in this mobile phone is 9.3.

We have used our Apple Developer ID for registering these devices on Apple Servers to test the app on these devices.

We also used the voice recorders and lots of papers to collect as much qualitative data as we can.

2.7 Guidelines / Briefing

You'll have to sign a consent form.

Just so you know, if we present this study in a conference or paper, your identity will remain confidential.

If at anytime you feel uncomfortable, just let me know and we'll stop the study.

To help remember your answers I'd like to record this session. Any problem with that?

Do you have any questions before we start?

2.8 Script

Today we're going to run through tasks which are typical things to do with the app. To perform those tasks, you will be using a cell phone that is in front of you.

While you are doing the tasks I'd like you to say aloud what you are doing and thinking so I can follow what's happening.

If you do have any questions, I'll be happy to answer once the task is over.

2.9 Dry-run of the Protocol & Feedback

We have conducted a live end-to-end rehearsal of our protocol couple of times with Dr. Kristina Pitula and Dr. Olga Ormandjieva using the actual test setup. After the success of the

Dry-run, we are now planning to conduct the test with the general public and doctors who match the participant profile.

3. Conducting the Test

3.1 Summary

The majority of participants completed the session without difficulty. A few participants had difficulty with the technology but everyone was able to complete the session.

- Overall, sixteen (16) out of twenty (20) participants had a very positive reaction i.e. 82% mean score to the MyHealthCloud UMUX Questionnaire.

- Following is the MyHealthCloud Mean Score for the four UMUX (4) questions:
    - Q1 – 4.25 / 6.0 (70% is the average level of agreement percentage)
    - Q2 – 5.50 / 6.0 (91% is the average level of disagreement percentage)
    - Q3 – 4.60 / 6.0 (76% is the average level of agreement percentage)
    - Q4 – 5.30 / 6.0 (88% is the average level of disagreement percentage)

- No participant required specific help with any of the tasks.

- Participants provided numerous suggestions for improving the prototype. We also observed some elements, which could be improved. Those are listed in the Recommendations at the end.

- Following is the MyHealthCloud Mean Score for the additional three (3) questions (not part of UMUX):
    - Q5 – 5.70 / 7.0
    - Q6 – 5.60 / 7.0
    - Q7 – 5.35 / 7.0

- The following issue was noted by the majority of participants:
    - As MyHealthCloud provides only one way to add a new contact, i.e. by tapping on the compose button on the messages page, suppose user opens a report, taps the share button, finds the list of contacts but since the user has to send that report to a new contact, there should be an alternative way on that screen to add the new contact.

- Participants provided numerous suggestions for improving the prototype. We also observed some elements, which could be improved. These are listed in the "Recommendations" section at the end.

3.2 Session Schedule

Each session with a participant followed this approximate schedule of events:

- Participants were contacted and given a brief description of the research and asked if they would agree to participate. If they agreed, a testing session was scheduled.

- Participants were greeted and provided with a consent form, which included and asking if they agreed to audio taping of the session and non disclosure of confidential information on the prototype.

- Participants were asked 5 demographic questions prior to starting the testing.

- An introduction to the goal of the testing, prototype, and testing procedure was given.

- Participants were then asked to complete the tasks and they could ask questions after the completion of each task.

- After completing each task, participants were asked a set of questions. Participants were also asked if they had any comments they would like to provide pertaining to that task.

- After completing all the tasks, participants were debriefed to get their general impressions of the prototype.

- Due to privacy, many doctors did not record their session.

Participants were informed that for the purposes of this test that the tester was playing the role of the patient that they were to be treating in this session. Participants were also encouraged to talk aloud during the completion of each task, so that the tester could gather information on possible problems, improvements, or elements that should be kept in the prototype. All participants completed the five (5) tasks in the same order to ensure that the results were being compared based on the same criteria.

3.3 Confounds

- Many of the doctors' sessions were not recorded due to the privacy and confidentiality.

- Two participants were not accustomed to working on an iPhone. This was covered at the beginning of the session and explanations were given to these participants prior to starting the first task.

- The following disclaimers were provided to each participant prior to starting the tasks:
    - Please keep in mind that this is a prototype, so not all functionality is present.
    - As we tried to make things as realistic as possible, we added a couple of medical reports in the prototype just for the sake of research.

4. Data Analysis and Results

4.1 Summary

The UMUX questionnaire was used as a final debrief for the prototype. The UMUX mean score for the overall system evaluation is 82% i.e. most of the participants did find the app an easy-to-use mobile medical application.

4.2 Application Ratings

While completing each task, participants were asked to talk out loud about what they were doing and how they were trying to complete the task. Once each task was completed, participants were asked to answer couple of questions on the interface used to complete the task. Participants were also asked to provide any additional comments they had above and beyond those they mentioned while talking aloud during the task completion.

4.3 Rating Scheme

Final Debrief – Usability Metric for User Experience (UMUX)

After completing all five tasks, participants were asked the following questions from the Usability Metric for User Experience (UMUX) as a debrief questionnaire:

UMUX was chosen due to its reliability, as well as its short length of four Likert-scale questions (see Appendix B).
This ensured that the usability testing was kept within an acceptable time frame, while still gathering valuable data. UMUX is a standard set of four Likert-scale questions:

1. The app's features meet my expectations.
2. Using this app is a frustrating experience.
3. The app is easy to use.
4. I have to spend too much time correcting things with this app.

The questions used a Likert-scale response with a range of 1 through 7, where 1 was Strongly Disagree and 7 was Strongly Agree. Once data is collected, it needs to be properly recoded, with the following scoring:

- First and Third items are scored as [response – 1].

- Second and Forth items are scored as [7 – response].

To calculate the UMUX score, first sum the score contributions from each item. Then multiply that value with 100 and then divide by 24 to obtain the overall value of UMUX; the range will be from 0-100.

The UMUX score provides a single number representing a composite measure of the overall usability of the system being tested.

We added three additional questions to be answered by the participants after completing all the tasks:

5. It is very easy to view my medical reports on this app.
6. I would prefer to manage my own medical reports with this app.
7. I like the way this app lets me communicate with doctors and caregivers.

The questions above are analyzed between the values 7 to 1.

4.4 Overall System Results

The UMUX questionnaire was used as a final debrief for the prototype. The UMUX mean score for the overall system evaluation is 82% i.e. most of the participants did find the app an easy-to-use mobile medical application.

The table below gives the participants' responses to the UMUX questionnaire used as a debrief questionnaire after completing all five tasks. A detailed breakdown of the participants' responses, as well as any comment they had while completing the debrief questionnaire, including observations about their experience, are described.

P-IDs	Q1		Q2		Q3		Q4		SUM	UMUX
		R-1		7-R		R-1		7-R		
P1	6	5	1	6	7	6	3	4	**21**	**87.50**
P2	5	4	2	5	6	5	2	5	**19**	**79.17**
P3	7	6	1	6	7	6	1	6	**24**	**100.00**
P4	6	5	1	6	6	5	1	6	**22**	**91.67**
P5	5	4	2	5	5	4	2	5	**18**	**75.00**
P6	4	3	1	6	5	4	2	5	**18**	**75.00**
P7	6	5	2	5	6	5	1	6	**21**	**87.50**
P8	5	4	1	6	6	5	2	5	**20**	**83.33**
P9	5	4	1	6	6	5	1	6	**21**	**87.50**
P10	6	5	1	6	5	4	3	4	**19**	**79.17**
P11	7	6	1	6	6	5	1	6	**23**	**95.83**
P12	5	4	2	5	5	4	2	5	**18**	**75.00**
P13	6	5	1	6	6	5	2	5	**21**	**87.50**
P14	4	3	2	5	5	4	2	5	**17**	**70.83**
P15	4	3	2	5	4	3	2	5	**16**	**66.67**
P16	4	3	4	3	5	4	2	5	**15**	**62.50**
P17	5	4	1	6	6	5	1	6	**21**	**87.50**
P18	4	3	2	5	5	4	1	6	**18**	**75.00**
P19	6	5	1	6	6	5	2	5	**21**	**87.50**
P20	5	4	1	6	5	4	1	6	**20**	**83.33**
SUM	**105**	**85**	**30**	**110**	**112**	**92**	**34**	**106**		
MEAN	**5.25**	**4.25**	**1.5**	**5.5**	**5.6**	**4.6**	**1.7**	**5.3**	**19.7**	**81.875**

Figure 10.1 UMUX results for first four questions

Fig 1.1 shows the detailed calculated mean values of the first four questions of the study.

Fig 1.2 shows the graph of UMUX Mean values of all participants and their overall ratings.

Figure 10.2 Graph showing UMUX Mean Values between participants and their overall ratings for first four questions

Following are participants' comments and observations made during the debriefing questionnaire.

- Two (2) participants had no comments to add from what they had already provided on the individual task.
- Seven (7) participants (including doctors) gave enthusiastic comments on the system and would like to have such a system in place and at their disposal.

Fig 7.3 shows some other calculations that are also made for confirming the accuracy of the study. The collected data is not normally distributed due to its small size (only 20 participants). Further work is needed to improve these results by collecting the data from a larger group of participants in the future.

VALUES	Q1		Q2		Q3		Q4
SUM	85		110		92		106
UMUX MEAN	70.8		91.7		76.7		88.3
STDEV	0.97		0.76		0.75		0.66
SAMPLE SIZE	20		20		20		20
CONFIDENCE COFF.	1.96		1.96		1.96		1.96
MARGIN OF ERROR	0.42		0.33		0.33		0.29
UPPER BOUND	71.3		92		77		88.6
LOWER BOUND	70.4		91.3		76.3		88

Figure 10.3 UMUX values calculating AVG, STDEV, CON COFF, SAMEPLE SIZE, etc

Using a T-distribution to analyze the small amount of collected data (UMUX), the results show that participants found MyHealthCloud a useful and easy-to-use mobile medical application. Fig 7.4 shows the results obtained from usability testing with the twenty (20) participants using a 95% T-distribution confidence level.

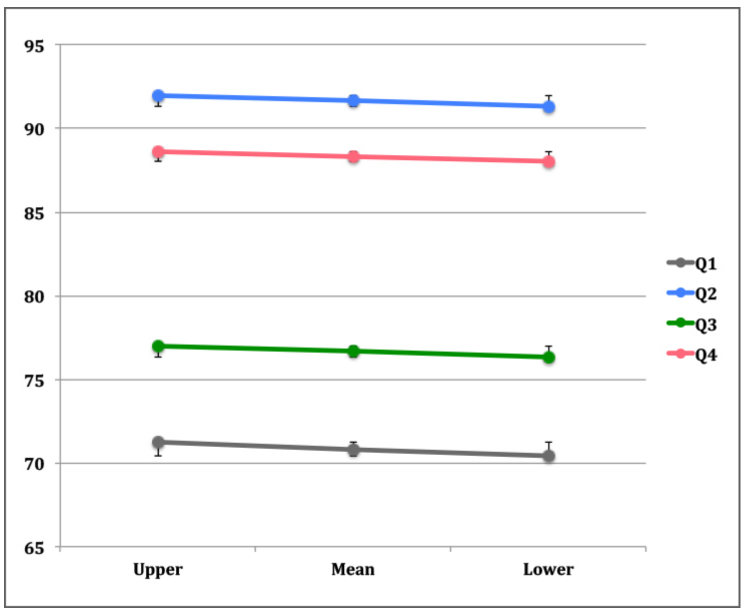

Figure 10.4 UMUX Mean Values with 95% T-distribution with Upper & Lower Bounds

All the values are above 70% with a margin of error less than 0.5 and standard deviation less than 1.0, supporting the validity of the UMUX results.

Following are the Mean, Lower & Upper Bound (Confidence) Level values:

Q1 – Lower CL (70.4), Mean (70.8), and Upper CL (71.3)

Q2 – Lower CL (91.3), Mean (91.7), and Upper CL (92.0)

Q3 – Lower CL (76.3), Mean (76.7), and Upper CL (77.0)

Q4 – Lower CL (88.0), Mean (88.3), and Upper CL (88.6)

The following are participants' comments and observations made during the debriefing questionnaire.

- Two (2) participants had no comments to add from what they had already provided on the individual task.
- Seven (7) participants (including doctors) gave enthusiastic comments on the system and would like to have such a system in place and at their disposal.

4.5 Threats to Validity

No study is perfect. There are numerous ways that a study can give misleading results that could be contradicted in future studies. We have all seen reports about studies with new results that repudiate results reported from previous studies.

With a developing spotlight on empirical research techniques in software engineering, it is essential that each researcher do a validity analysis.

Potential issues with empirical researches are classified as categories of threats to validity. Wohlin et al. (2000) describes the following categories of threats to validity:

1. Conclusion validity - In the usability study, we had one primary purpose: to test the usability of the prototype created to confirm a theory by applying UMUX and analyzing our Likert-scale data (see section 7.2). Exploring the relationship among our dataset values confirms the difference between the UMUX score and the possible ideal (maximum) outcome. Our sample size (20 participants) was not very large, so it is hard to validate only upon the feedback received.

2. Construct validity - We have theoretically validated all three measurements (our hypotheses) in a narrow sense, which means a measure is valid if it reflects the real meaning of the concept under consideration (see section 7.3).

3. External validity – It is the extent to which the results of a study can be generalized to other situations and to other people. All the participants recruited for the study use smartphones and do not have any web designing, mobile application development or software development background. This knowledge of using smartphone and ignorance of technical details validates that the result of the usability study can be generalized to any literate person familiar with the operation of smartphones. All participants completed the tasks, which explains the simplicity of the MUI, which means no additional usage explanation is necessary.

From the above discussion, it is clear that both the theoretical and empirical validations, as they are defined, are necessary and complementary.

4.6 Participants' Feedbacks

Following is some of the valuable feedback from the participants (including doctors):

- It's convenient, a good idea. Would this be in other languages as well? Maybe I would need it when I'm older, maybe I'll use it for someone older in my family.
- As a patient I would love this app. As a medical provider I am not so sure due to HIPAA rules and regulations and 24/7 coverage.
- This could be a good technique. I'd like to see such integration of EHRs with mobile.
- Interoperability is the key for EHRs to be successful Data collection activities are in full blow, however connecting them and providing access at point of care would be a challenge.
- Try to make them more easily accessible instead of just scanned documents.
- I think it would be a good a technique of recording patient records as well as easy access to every doctor which is helpful in patient health benefits.
- This app would work if all the hospitals and outpatient clinic apps are connected (universal connection) otherwise it will be difficult to access and send reports to different providers.
- This app has to be completely encrypted to prevent hacking.
- I do not like to download important documents on my smart phone. I worry about hacking.
- Encryption, I worry about security. Patient protected information should be confidential.
- It is a good attempt but needs some work, especially from HIPAA point of view Patient information, results should not get hacked and the risk is high if the app is not fully encrypted.

- This app has great potential.
- It’s really super friendly.

4.7 Assessment of Hypotheses

To test our hypotheses, we created a prototype to conduct usability. In Fig 1.2 we can see the graph for the prototype showing the results for the first four (4) questions that provide the UMUX score.

For the assessment of hypotheses, three (3) additional questions were added to the post questionnaire. Participants were asked to answer these after completing all five tasks.

The answers are analyzed between the values 7 to 1 i.e. Strongly Agree (7) to Strongly Disagree (1).

The individual assessment of these questions is described below:

Assessment of Hypothesis H1

Testing the first hypothesis: Patients, doctors and caregivers prefer to use MyHealthCloud to view their medical reports.

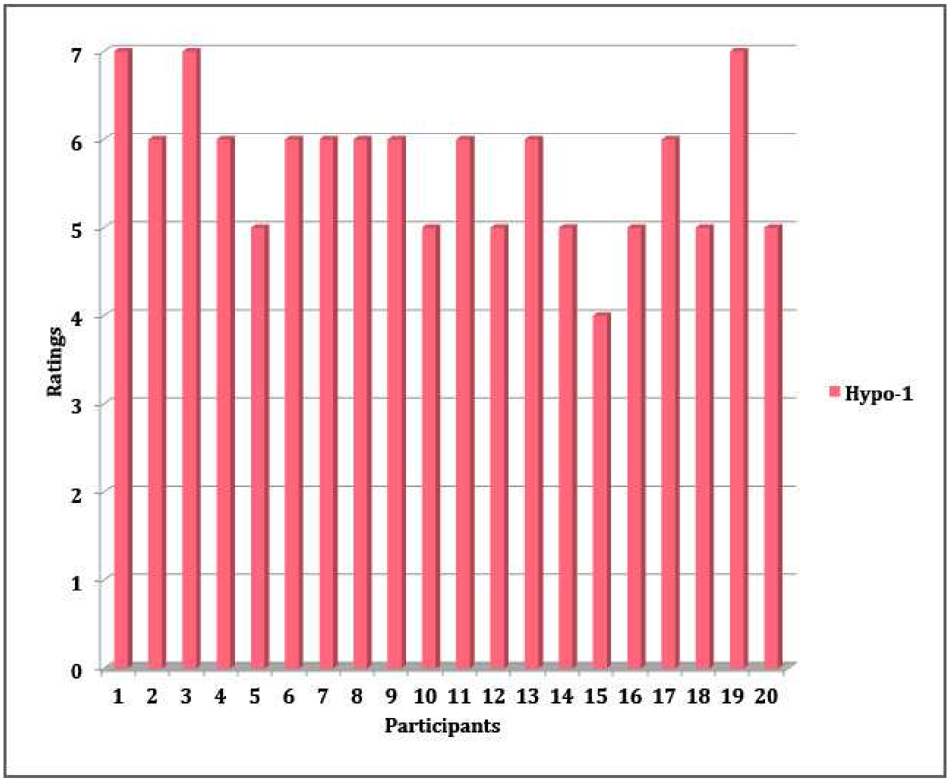

Figure 10.5 Graph showing participants ratings for Hypothesis H1

Supported by Question (Q5): It is very easy to view my medical reports on this app.

Result: Mean Value 81% and Average Value 5.7 / 7.0 with Median 6

In conclusion, the majority of the participants in this study prefer to use MyHealthCloud to view their medical reports.

Assessment of Hypothesis H2

Testing the second hypothesis: Patients, doctors and caregivers prefer medical reports self-management with MyHealthCloud.

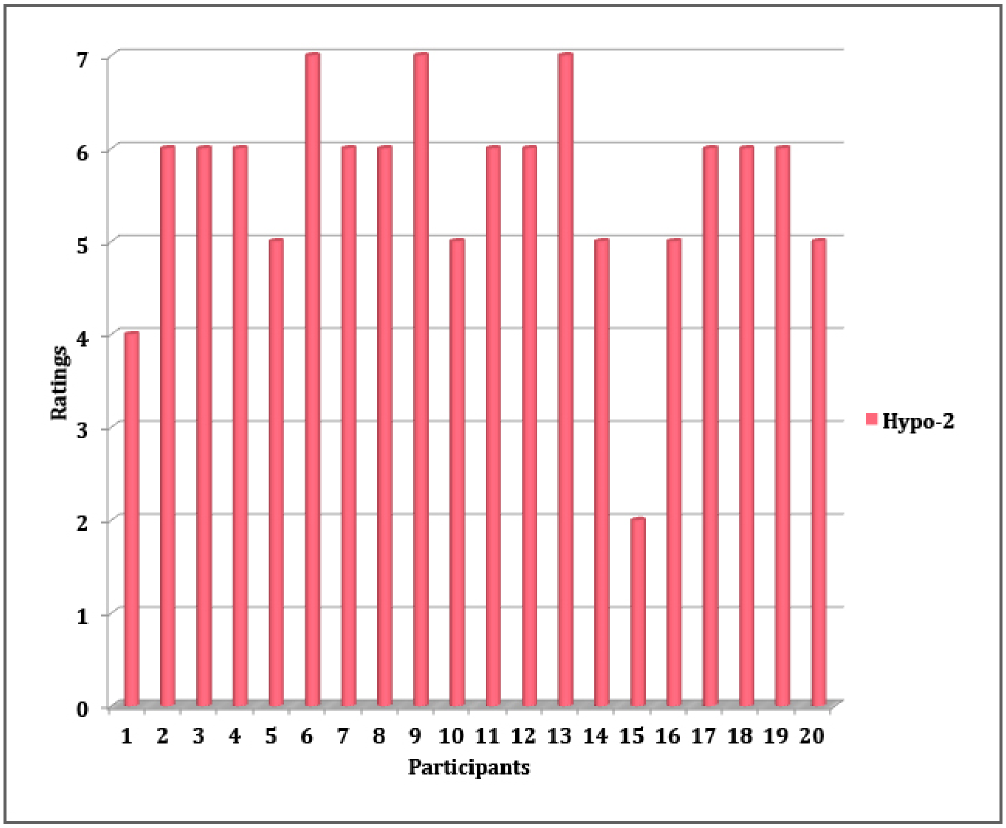

Figure 10.6 Graph showing participants ratings for Hypothesis H2

Supported by Question (Q6): I would prefer to manage my own medical reports with this app.

Result: Mean Value 80% and Average Value 5.6 / 7.0 with Median 6

Based on the above results we can determine that medical reports self-management with MyHealthCloud, is preferred by the majority of the participants in the study.

Assessment of Hypothesis H3

Testing the third hypothesis: MyHealthCloud improves communication and connectivity between patients, doctors and caregivers (including receiving and sending of patient medical health reports and a novel emergency contact to a doctor or friend).

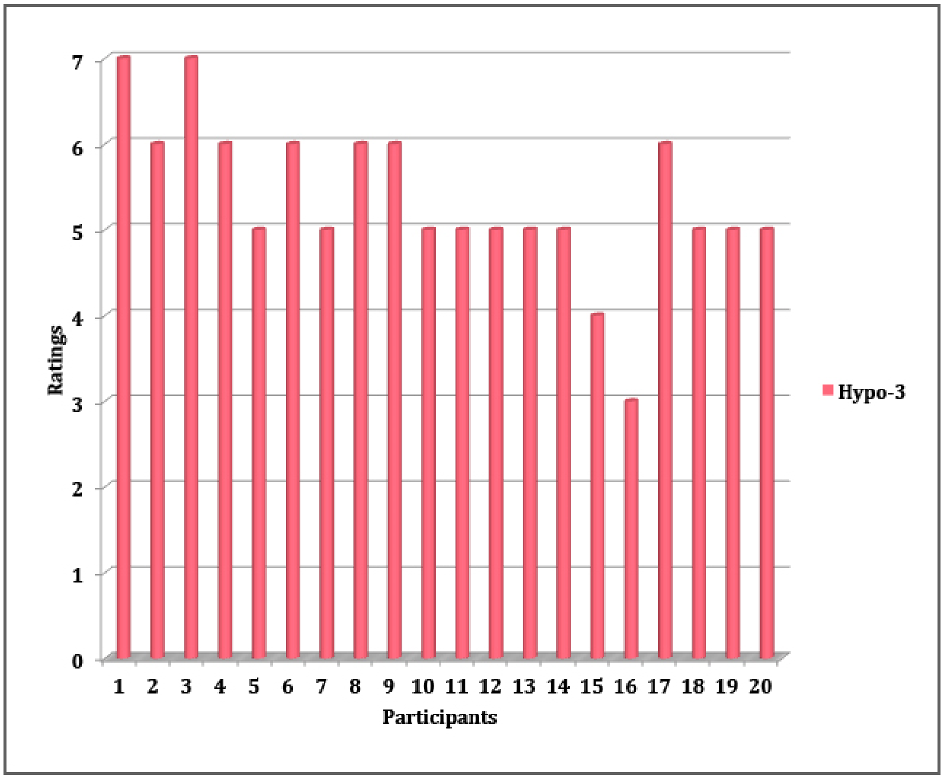

Figure 10.7 Graph showing participants ratings for Hypothesis H3

Supported by Question (Q7): I like the way this app lets me communicate with doctors and caregivers.

Result: Mean Value 76% and Average Value 5.35 / 7.0 with Median 5

Therefore, according to the presented results MyHealthCloud improves the communication and connectivity between patients, doctors and caregivers.

4.8 Observations

Following are some points we observed during the study:

- A few participants (5/20) commented on a need for an alternative option to add a new contact when sending a report.

- There was a general hesitation among most participants about the security and privacy of EHRs.

- One (1) participant asked if the app is going to be launched in other languages as well or not.

- Four of the participants remarked that they were uncertain if the prototype met their expectations or not because it was the first time they used any patient-driven health system so they really had no idea what to expect.

- A strong majority of participants (16/20) were very enthusiastic when performing the MyHealthCloud tasks.

- All participants gave suggestions on improving the prototype to ensure that MyHealthCloud is efficient and effective in managing EHRs.

- All participants had an easy time using MyHealthCloud.
    - Only three (3) participants needed an explanation on what a MyHealthCloud was and how it worked.
    - Four (4) participants were not familiar with the term Health Cloud.
    - Many participants instinctively learn how to use it.

- Twelve (12) participants did not take their picture while registering for the app due to either lack of time or since it was not necessary for registering.

- Nine (9) participants said that they would recommend such an app to their friends and family.

- The two (2) oldest participants seemed less comfortable using the prototype and had some minor difficulties in performing the tasks.

4.9 Recommendations

This section lists the suggestions offered by participants when either completing a task or commenting on their answers to the questions.

- The app should be not launched in English language only; it should available in AppStore in all languages.

- The app should be built for all platforms like iOS, Android, Windows, BlackBerry, and Nokia.

- There should be specific timing set for sending messages to the doctors for the integrity of their privacy.

- There should be an alternative option to add a new contact when sending a report.

- Encryption and Security of Data must be the foundation of the app to keep the data secured from hacking.

4.10 Future Enhancements

IBM, Sales force and other companies are already working on Health Cloud technology to integrate Health Care with Cloud Computing. MyHealthCloud would be a similar project dedicated to the advancement of Health Cloud technology.

In addition, MyHealthCloud could also be adopted by a big company in order to manage large amounts of data and communication between users.

Hospitals cooperation would also be required in order to collect a sufficient amount of empirical data.

Clinics, doctors and hospitals would be the main source of data.

5. Location of Collected Data

The audio recordings are stored on the researcher's mobile phone and all the data collected during the study is stored at researcher's home in Montreal. Few of the sessions were not recorded due to the privacy issue.