CONCEPTUAL DESIGN OF AN AUTOMATIC MONITORING AND REPORTING TOOL FOR ADHERENCE TO TUBERCULOSIS THERAPY IN KIGALI AREA

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CONCEPTUAL DESIGN OF AN AUTOMATIC MONITORING AND REPORTING TOOL FOR ADHERENCE TO TUBERCULOSIS THERAPY IN KIGALI AREA

A dissertation submitted in partial fulfillment of the requirements for the degree of MASTER of Science in **HEALTH INFORMATICS**

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DECLARATION

I, Floribert BIZIYAREMYE, hereby declare that the thesis has been written by me without any external unauthorized help, that it has been neither presented to any institution for evaluation nor previously published in its entirety or in parts. Any parts, words or ideas, of the thesis, however limited, which are quoted from or based on other sources, have been acknowledged as such without exception.

Done on May 2015

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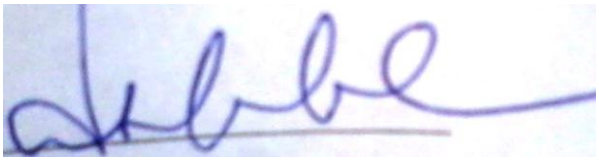
Floribert BIZIYAREMYE

SUPERVISORS APPROVAL

I, **Dr. NGARAMBE Donart**, In my capacity as a Supervisor, I do hereby authorize **Floribert BIZIYAREMYE** to submit his final thesis.

Date: May 2015



Dr. NGARAMBE Donart

ABSTRACT

Efforts to fight tuberculosis have been provided worldwide, monitoring framework has been developed for tuberculosis control in Rwanda but the aggregated data excludes the adherence rate.

Paper based tool doesn't provide alert mechanism to remind patients to adhere on medication. To ensure Direct Observed Treatment (DOT), patients are required to take medication face-face with health providers which interfere with work or travel time and lead to interruptions. Despite presence of Health Management Information System (HMIS), adherence data are not yet reported.

The project aimed to suggest an automatic tool for capturing, reporting and monitoring of data on adherence to tuberculosis therapy.

This study is qualitative in nature and multistage sampling was used. An in depth interview guide was used for 23 informants. Conceptual architectural design was presented using architectures with Microsoft office Visio 2007.

86% of informants highlighted familiarity as benefit of paper based tool while timely data accessibility, lack of analysis, data sharing and tedious works are its major barriers. 87% of informants proposed to use Short Message Service (SMS) for reporting adherence, reminding and alerting patients to take medication. Enabling patients using Video Direct Observed Treatment (VDOT) facilitates monitoring and foresees that distance wouldn't be an obstacle to adherence.

Future research must develop and evaluate the cost effectiveness and user acceptability of automatic tool.

RESUME

Les efforts visant la lutter contre la tuberculose ont été fournis dans le monde entier, le système de suivi est en place pour le contrôle de la tuberculose au Rwanda, mais les données agrégées exclut le taux d'adhérence.

Le system manuel n'a pas de mécanisme d'alerte pour rappeler aux patients d'adhérer au traitement. Pour assurer le traitement directement supervisé (DOT), les patients doivent prendre les médicaments devant les prestataires des soins, ce qui interfèrent avec le temps de travail ou de voyage et peut causer les interruptions. Malgré la présence du système informatique de gestion des données de santé, les données d'adhérence au traitement ne sont pas encore rapportées.

Le projet vise à proposer un outil automatique pour la collecte, le rapportage et le suivi des données sur l'adhérence au traitement antituberculeux.

Cette étude est de nature qualitative et l'échantillonnage à plusieurs degrés a été utilisé. Un guide d'entrevue a été utilisé pour 23 informateurs. Les architectures sont présentées à l'aide de Microsoft Office Visio 2007.

86% des personnes interrogées a souligné la familiarité comme avantage du system manuel alors que l'accessibilité des données à temps opportun, le manque d'analyse et de partage de données, et la charge de travail sont ses principaux obstacles. 87% des interrogées a proposé l'utilisation de SMS pour signaler l'adhérence, rappeler et alerter les patients à prendre des médicaments. L'utilisation de la vidéo par les patients dans le traitement directement supervisé (VDOT) permet le suivi de l'adhérence au traitement et réduire la distance entre les patients et les agents de santé. Les recherches futures doivent élaborer et évaluer l'efficacité des coûts et acceptabilité de l'outil électronique.

DEDICATION

This work is dedicated to the almighty God and to the following Special People:

To my wife MUREKEYITETO Alphonsine

To my daughter BIZIYAREMYE ISHEMA Adora Chloë

To all health professionals committed to tuberculosis control

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LIST OF SYMBOLS AND ABBREVIATIONS/ACRONYMS

AHIMA	American Health Information Management Association
CDR	Central Data Repository
CDT	Centre de Diagnostic et Traitement
CT	Centre de Traitement
CHUK	Centre Hospitalier Universitaire de Kigali
CPOE	Computerized Physician Order Entry
DICOM	Digital Imaging and Communication in Medicine
DOQ-IT	Doctors Office Quality Information Technology
DOT	Direct Observed Treatment
HER	Electronic health Record
EM	Electronic Monitoring
EMR	Electronic Medical Record
e-TB	Electronic TB surveillance system
GOe	Global Observatory for eHealth
HIMSS	Healthcare Information and Management Systems Society
HIT	Healthcare Information Technology
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
IT	Information Technology
IVR	Interactive Voice Response
KFH	King Faisal Hospital
M&E	Monitoring and Evaluation
MDR-TB	Multi-Drugs Resistance Tuberculosis
MENS	Medication Event Monitoring System
mHealth	Mobile Health
MOH	Ministry of Health
NTP	National Tuberculosis control Program
PDA	Personal Digital Assistants

RTMM	Real Time Medication Monitoring
SCMS	Supply Chain Management System
SDE	Structured Data Entry
SMS	Short Message Service
TB	Tuberculosis
UN	United Nations
UR	University of Rwanda
VDOT	Video Direct Observed Treatment
WHO	World Health Organization

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CHAPTER 1: INTRODUCTION

1.1 Definition of key terms

Conceptual design: According to Microsoft, conceptual design is the process of gathering, analyzing, prioritizing business and user perspectives of the problem and the solution, and then creating a high-level representation of the solution (Microsoft, 2003).

System design: It is defined as the process of defining the architecture, components, modules, interfaces, and data for a system to satisfy specified requirements ("Systems design," 2014).

Requirements: Microsoft defines requirement as a formal statement of what the product planners informed by their knowledge of their working place or marketplace and specific input from existing or potential customers believe is needed for a new product or a new version of an existing product (Microsoft, 2003) .

Functional specification: It is the documentation that describes the requested behavior of an engineering system. The documentation typically describes what is needed by the system user as well as requested properties of inputs and outputs. It is the virtual repository of project and design-related artifacts that are created during the planning phase of an application (Microsoft, 2003).

Adherence: "In terms of TB control, adherence to treatment is defined as the extent to which the patient's history of therapeutic drug-taking coincides with the prescribed treatment" (Sabaté and World Health Organization, 2003).

Tuberculosis: It is an infectious disease caused by a bacterium called Mycobacterium tuberculosis, the tubercle bacillus, which can affect almost any tissue or organ of the body, the most common site of the disease being the lungs (Vilchèze et al., 2013).

A case of tuberculosis: is defined as a patient in whom tuberculosis has been confirmed bacteriologically or diagnosed by a clinician (Toman et al., 2004)

Architectural design: The design process for identifying the architectural design subsystems making up a system and the framework for sub-system control and communication (Sommerville, 2004).

1.2 Background to the study

Tuberculosis (TB) has been present in humans since antiquity; it has been called "consumption" because it seemed to consume people from within. It is caused by a bacillus called

Mycobacterium tuberculosis, described by Robert Koch (Esume et al., 2009). Tuberculosis is a contagious disease that can affect almost any part of the body but is mainly an infection of the lungs (Rwanda NTP, 2009). The burden of TB is highest in Asia and Africa. The African Region has approximately one quarter of the world's cases, and the highest rates of cases and deaths relative to population(World Health Organization, 2012a). Rwanda has registered and reported 6780 TB cases all forms in 2011 (Rwanda NTP, 2011).

According to WHO (World Health Organization, 2012a), monitoring and reporting of data is a fundamental component of care of patients with tuberculosis (TB) and control of the disease. Currently monitoring of adherence to TB therapy is paper based system and rely on individual patient cards(Rwanda NTP, 2009). The information kept in paper registry cannot be shared between health providers more easily and are not fast accessed (World Health Organization, 2012b). Rwanda national TB program has more than ten paper tools used for TB detection and care treatment at different levels to capture records and report of TB related data (Rwanda NTP, 2009). Reporting systems rely on quarterly basis reports of aggregated data (World Health Organization, 2012b) and quarterly reporting forms describe aggregated data on notifications and treatment outcomes for all cases within a health facility to higher administrative levels (Sculier et al., 2012).

Using paper based tool requires TB programs to develop and print new forms, registers and reporting templates and ensure distribution to all health facilities. This slow process and lead to the reporting of errors (Rwanda NTP, 2009). TB recording and reporting tools are reviewed periodically (World Health Organization, 2007) and paper-based tools are not flexible to review when recording and reporting data are changed.

1.3. Problem statement

Starting December 2013, quarterly reports of TB surveillance data are copied from paper form to Rwanda's Health Management Information System and TB control program of Rwanda has initiated the development of an e-TB for individual record (Rwanda NTP, 2013a). Despite the effort and progress made so far, data on adherence to TB therapy are not yet monitored or reported neither through paper tool or nor HMIS. The aggregated data excludes the adherence rate which is only measured using outcome oriented definition, these intermediate outcomes

don’t correlate with the actual quantity of prescribed drugs taken (Sabaté and World Health Organization, 2003).

With manual system, there is no any alert mechanism to remind patients to adhere on their treatment, to notify patients to come for laboratory sputum control test or alert health providers on patients lost to follow up and transferred out (Rwanda NTP, 2009).

Consequently, lack of adherence monitoring leads to noncompliance to therapy then causes multidrug resistance which increase treatment cost even death. According to drug resistance survey conducted in 2005, 3.5% of TB cases were resistance (Rwanda NTP, 2005) to the two pillar molecules for treatment of tuberculosis (Rifampicin and Isoniazid). As reported in national strategic plan 2013-2015 of Rwanda NTP, treatment cost for one case with multidrug resistance (MDR) is 86 times the cost for treatment of a susceptible TB case where it require $2136 instead of $ 25 per patient (Rwanda NTP, 2013b). Referring to Ndjeka report (2013) on programmatic management of drug-resistant TB in Rwanda, treatment success was 88% while the 12% represents deaths and not evaluated cases (NDJEKA Norbert, 2013).

Therefore a study on conceptual design of an automatic tool for monitoring and reporting of adherence to TB therapy is conducted to contribute to the development and implementation of an electronic tool for daily management of adherence to TB therapy in Rwanda context by providing elements to be maintained and gap analysis of paper based tool, functional requirements and conceptual design of the system to be implemented. In addition, conceptual design provided architectural design of the automatic monitoring and reporting tool to inform future researchers and developers to avail an electronic tool for improving adherence to TB therapy Kigali area.

1.4 Project objectives

1.4.1. Main objective

The main objective of this project is to avail a conceptual design of an automatic monitoring and reporting tool for adherence to TB therapy in Kigali area.

1.4.2 Specific objectives

1. To determine the advantages and disadvantages of the existing paper tool for monitoring and reporting of TB data;

2. To study the functional requirements of the automatic monitoring and reporting tool for adherence to TB therapy in Kigali area;
3. To provide architectural design of the automatic monitoring and reporting tool for adherence to TB therapy in Kigali area.

1.5 Research question

The study intends to answer the following research questions:

1. What are the advantages and disadvantages of paper based tool for monitoring and reporting for adherence to TB therapy in Kigali area?
2. What should be the functional requirements of an automatic tool for monitoring and reporting for adherence to TB therapy in Kigali area?
3. What should be the architecture of a conceptual design of an automatic monitoring and reporting tool for adherence to TB therapy in Kigali area?

1.6 Significance of the project

Design allows not only finding out how the automatic tool is going to look like, but also allows both software owners and developers to realize how it's going to function (Fielding, 2000).

A conceptual design of an automatic monitoring and reporting tool for adherence to TB therapy will assist in the development and implementation of the tool which will result into the measurement and report on adherence rate to TB therapy, contribute to the solving of problems of data quality and workload. It will also strive to check the errors, inconsistencies in medical records and timely access to historical records on adherence to therapy all of which had impact on planning and decision-making (World Health Organization, 2012b).

The delivery of healthcare services at a distance using an automatic tool once developed and implemented will have the potential to address several deficiencies in the delivery of direct observation therapy(Wade et al., 2012). The proposed Video Direct Observed Treatment which is patient centered will increase adherence to therapy which reduce disease recurrences and prevent development of resistance Mycobacterium tuberculosis strains(Kenneth G., 2012). As the validation checks will be an integral part of the automatic tool, it will contribute to data quality and edit on reporting format will be more flexible (World Health Organization, 2012b).

1.7. Subdivision of the dissertation

The dissertation is mainly divided into the following parts:

- **Chapter 1: Introduction**

The general introduction contains key terms used in the context of the present study and describes challenges health professionals are facing with during the monitoring and reporting of adherence rate to TB therapy and expresses problems of patients to comply on requirements of Direct Observed Treatment (DOT).

- **Chapter 2: Literature review**

The second chapter dedicated to literature review provides details on disadvantages for the use of paper based tools and advantages of electronic software. It presents details on goals of conceptual design and functional process requirements.

In this chapter, a review on existing TB recording and reporting forms used in TB control proram is presented and benefits of automatics tools over paper-based ones detailed.

In addition, the chapter presents the role of healthcare information technology (HIT) in medication adherence with regards to TB treatment in Rwandan context. It also presents a conceptual framework of the automatic tool design.

- **Chapter 3: Methodology**

This chapter describes the approaches and techniques used for the conceptual design of the automatic tool.

- **Chapter 4: Results**

The chapter four presents findings from the informants, showing benefits and disadvantages of paper based tool, and functional requirements to be used for the development of the automatic tool for adherence to TB therapy. This chapter demonstrates features of the conceptual design for the proposed automatic tool.

- **Chapter 5: Discussions**

In the chapter five, results are discussed comparing them with currently used standards and with similar findings from other studies. It states the implications of the outcome of the comparison of the results with the established standards or earlier findings on the use of information technology for adherence to TB therapy and explains how the results fit in with existing knowledge on the present study.

- **Chapter 6: Conclusions and recommendations**

The last chapter of the present study provides conclusions based on dissertations findings compared to the research questions and provide key recommendations for further work to improve or develop and implement the automatic tool for monitoring and reporting of adherence to TB therapy.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

In this chapter, a wide discussion of various scientific views and techniques is made and exposing of the weaknesses and strengths related to the tools under discussion. We demonstrate the relationship between variables based on literature and hypothesized ideas for our topic.

2.2. Advantages and disadvantages of paper based records

The Paper based writing system has been important to our species at least since the time of ancient Egypt, when the papyrus roll was developed. With the introduction of information technology, tendency of policy in health sector is to use new technique to increase quality of service delivery (Hassell et al., n.d.).

2.2.1 Advantages of paper based records

Since evolution of humanity, paper based system has played key role in communication and knowledge dissemination. Paper documents such as schedules and flow charts provide a gathering place for workers to view information and be seen viewing information (Hassell et al., n.d.).

Paper based medical records are still used mostly in developing countries as they do not dependent on computer or electricity and don't require high skills in information technology (Hassell et al., n.d.).

2.2.2 Disadvantages of paper based records

According to Abigail (Sellen and Harper, 2010), paper system has limitations that has been identified include the factor that paper tools must be used locally, can't be remotely accessed; physical space, require physical delivery, hard to revise or integrate into other documents and are static (Sellen and Harper, 2010).

Roukema adds several weaknesses of paper-based medical namely illegibility and data quality, ambiguous and incomplete data, data fragmentation, inflexibility, data access and poor availability. Paper records often become bulky with time, which leads to lack of overview. Paper based records may suit an individual clinician but problems will arise when one patient is seeing more than one medical professional (Roukema, 2006a).

2.3. Advantages and disadvantages of electronic health records

An electronic health record (EHR) is a digital version of a paper chart that contains all of a patient's medical history from one practice. An EHR is mostly used by health providers for diagnosis and treatment. The electronic health record provides the opportunity for healthcare organizations to improve quality of care and patient safety.

2.3. 1 Advantages of electronic health records

According to Roukema (Roukema, 2006a) the implementation of electronic medical record systems promises significant advances in patient care, because such systems enhance readability, availability, and data quality. The electronic applications such as Structured Data Entry (SDE) can prompt for completeness provide greater accuracy and better ordering for searching and retrieval, and permit validity checks for data quality monitoring, research, and especially decision support. They are able to support documentation of patient history and physical examination findings that developed and tailored for the health system (Roukema, 2006a).

Lori presents several distinct advantages over paper health records. One definite advantage is the fact that there are increasing storage capabilities for longer periods of time. Also, the EHR is accessible from remote sites to many people at the same time and retrieval of the information is almost immediate. An EHR also represents a huge potential for cost savings and decreasing workplace inefficiencies. The record is continuously updated and is available concurrently for use everywhere (Lori, 2013).

Computers have obvious advantages over traditional methods of patient tracking. Computers never have bad handwriting (Hassell et al., n.d.)

2.3. 2 Disadvantages of electronic health records

According to Sandy, electronic records have some well-known problems. Critics cite high initial cost, large training investment, hardware crashes and breakdowns, power failures, software glitches, sabotage of the system by disgruntled employees and hackers, unauthorized access, viruses, Trojan horses, reluctance of physicians to use the tightly controlled format for notes, and a host of other real and imagined problems (Sandy, 2006).

2.4 Conceptual design

The Conceptual design is a central stage in product design; it determines the principles that govern the product and decisions made in this stage have impact on the final product quality and cost (Shai et al., 2009).

Its role is to come up with a first proposal that satisfies the functional requirements (Date and Frederik W, 1998). Conceptual design takes statement of the problem and generates broad solutions to it in the form of the schemes. The schemes are worked up greater details, and if there is more than one, a final choice between them is made. The end product is usually a set of general arrangement drawings (Michael, 1998).

2.4.1 Goals of conceptual design

The researcher of the present dissertation creates a conceptual design of an automatic tool purposively for understanding the problem to be solved and framing the future state of the process to the point of improving the system processes. conceptual design embodies a process for refining, documenting, and validating what the users and the business need from the solution (Microsoft, 2003).

The conceptual design also formalizes the target future state of the system activities to describe the target future state of the system which becomes the basis for the next phases of the design process (Microsoft, 2003).

2.4.2 Steps in conceptual design

Any conception has steps to be followed to get to the intending results. For conceptual design, understanding problem space of what you what to create and the assumptions behind as well explain how the proposed design idea must overcome the problems is one of the steps of conceptual design (Kristina Lapin, 2009).

Conceptual model plays key role in conceptual design by expressing ideas about components and processes deemed important in a system, document assumptions about how components and processes are related, and identify gaps in our knowledge (Gross, 2003).

Conceptual modeling is widely recognized to be the necessary foundation for building an automatic system and fully satisfies the user requirements. In particular, from the designer point view the availability of a conceptual model provides a higher level of abstraction in describing

the automatic tool process and its architecture in all of its aspects (Cravero and Sepúlveda, 2013) .

In the last few years multidimensional modeling has attracted the attention of several researchers that defined different solutions each focusing on the set of information they considered strictly relevant (Cravero and Sepúlveda, 2013). Some of these solutions have no or limited graphical support, and are aimed at establishing a formal foundation for representing cubes and hierarchies and an algebra for querying them. On the other hand, distinguishing feature of conceptual models is that of providing a graphical support to be easily understood by both designers and users when discussing and validating requirements (Cravero and Sepúlveda, 2013).

2.5. Functional requirements

In the context of the present dissertation, functional requirements describe the programmatic or projects needs and or required behavior of a system or component. They define the required behavior of the system to be built, it is envisioning the inputs that the future system will be compatible with and the outputs it will produce in response to those inputs (R.Stanek, 2010). Functional requirements may be technical details, data manipulation and processing and other specific functionality that define what a system is supposed to accomplish (R.Stanek, 2010).

As reported by Malan and Bredemeyer, the functional requirements specification documents the operations (Malan and Bredemeyer, 2001) and activities that a system must be able to perform; and are focused on the outcomes required to ensure that the automatic tool is being used and managed appropriately.

Within functional requirements, aspects on data capturing must be considered to ensure that records are reliable and authentic representations of the business activities or transactions in which they were created or transmitted (International Council on Archives, 2010). As the automatic tool will not be stand alone, functional requirement should provide clarification on system organization need to control access to their records and how it should be synchronized with other existing system. Access to records and aggregations should be limited to specific users. Users can then be allocated security clearances to permit selective access to aggregations or records at higher security categories (International Council on Archives, 2010).

2.5.1 Data requirements

The data requirements are directives that define or constitute high quality data instances and values. They describe data by producing a logical data model, which consists of entity relationship diagrams, entity definitions, and attribute definitions (Malan and Bredemeyer, 2001).

The data requirements for a real-time stream processing system is to process messages in stream without having a costly storage operation in the critical processing path or sequence of operations. Ideally the system should also use an active processing model (Stonebraker et al., 2005).

The automatic tool must have built-in mechanisms to provide resiliency against stream imperfections, including missing and out-of-order data, which are commonly present in real world data streams. The stream processing system must process time-series messages in a predictable manner to ensure that the repeatable outcomes are guaranteed (Stonebraker et al., 2005).

The automatic tool must have the capability to efficiently store, access, and modify state information, and combine it with live streaming data. For seamless integration, the system should use a uniform language when dealing with different types of data. To preserve the integrity of mission critical information, the system must ensure that the applications are up to date and available, and the integrity of the data maintained at all times, despite failures. Distribution should be automatic and transparent then deliver a real time response for high volume applications (Stonebraker et al., 2005).

2.5.2 Functional process requirements

The process requirements describe what the application must do. Process requirements relate the entities and attributes from the data requirements to the users' needs. It states the functional process requirements in a manner that enables the reader to see broad concepts decomposed into layers of increasing detail (Malan and Bredemeyer, 2001).

Process requirements may be expressed using data flow diagrams, text, detailed view of the processes, data input and output from processes, logic used inside the processes to manipulate data, accesses to stored data and processes decomposed into finer levels of detail (Malan and Bredemeyer, 2001).

2.6 TB recording and reporting system

The monitoring, recoding and reporting system of TB cases aims to provide a surveillance information system for better management of tuberculosis program at national, district and center of diagnostic and treatment level and is used to evaluate the progress of patient and treatment outcome (Jagannatha, 2002);

A good recording practice is necessary for effective patient management and effective monitoring depends on appropriate recording and reporting systems. The WHO recording and reporting system consists of detailed patients forms that are filled out at the point of care (Organization, 2008).

2.6.1. Recording system

The patient registration is to ensure continuous evaluation of the activities against tuberculosis. The data recorded regularly are transformed into useful information to improve quality of care, management and tuberculosis control. The recording system comprises tools used for TB detection and TB treatment (Rwanda NTP, 2009)

2.6.1.1 Tools used for TB detection

Laboratory register: records all symptomatic patients who have had sputum smear examination. It's maintained at laboratory department by laboratory technician. The results of sputum smear examinations are recorded in laboratory register for either diagnosis or for follow up and then returned to the referring facility (Rwanda NTP, 2009).

2.6.1.2 Tools used for TB treatment

TB Patient treatment card: a patient treatment card is created for each TB case. It records basic epidemiological and clinical information, and the administration of drugs. The health worker uses treatment cards for recording treatment and for follow up (Organization, 2008).

Tuberculosis patient Register: It used to monitor progress towards and treatment outcomes for all patients in the centre of diagnostic and treatment. It provides, the essential information for identification of the patient and status of case management(Rwanda NTP, 2009).

Patient's identity card: an identity card is completed for each patient starts treatment. It records name, age, sex, address, and health facility, type of TB regimen and dates of treatment (Organization, 2008).

TB transfer form: is used to record all patients transferred out or in the health facility. Transfers and referrals of patients aim to improve the quality of their care in facilities offering more appropriate services or services that are more conveniently located, usually closer to the patient's home (Rwanda NTP, 2013).

2.6.2 Reporting system

The reporting system consists of quarterly reports on TB case registration, which summarize the number of TB patients started treatment, laboratory tests performed and HIV tests and results obtained. Quarterly and annual reports provide detail treatment outcome and TB/HIV activities after all patient in cohort have completed their course of treatment then report the contribution of each health facilities, community and private sector in diagnosis and treatment of Tuberculosis (Rwanda NTP, 2009).

In smear positive pulmonary TB patients, the six standard outcomes of treatment for reporting purpose are: cured, treatment completed, treatment failure, dead, default and transferred out.

Cure: A patient who was initially culture or sputum smear microscopy at the beginning of the treatment but who was smear-negative in the last month of treatment and on at least one previous occasion;

Treatment completed: A patient who completed treatment but who did not meet the criteria to be classified as a cure or a treatment failure (World Health Organization, 2013).

Treatment failure is defined depending on patient's category:

A new patient who is culture or sputum smear microscopy positive at five months or later during treatment, or who is switched to Category IV treatment because sputum culture revealed MDR - TB;

A previously-treated patient who is culture or sputum smear microscopy positive at the end of the re-treatment regimen or who is switched to Category IV treatment because sputum culture revealed MDR –TB (World Health Organization, 2013).

Dead: A patient who died from any cause before stating or during the course of treatment.

Defaulted: is defined as a patient whose treatment was interrupted for two consecutive months or more (World Health Organization, 2013).

And transferred out: A patient who was transferred to a health facility in another basic management unit and for whom the treatment outcome is not known (World Health Organization, 2013).

2.7 Data capturing

In computer science context, data capture is any process for converting information into a format that can be handled and interpreted by a computer (UN Secretariat, Statistics Division, 2009). The utility of data capture is the ability to automate the information retrieval where data entry would be inefficient, costly or inapplicable.

There are a variety of methods of capturing data for documenting patient care which is including monitoring and reporting to the adherence of TB treatment. All methods can be used in one or another and in some cases multiple methods can be used to complete each other. Here below, we described different methods which can be used to capture data with their advantages and disadvantages.

2.7. 1 Manual data capturing method

Traditional handwriting: It has been the primary information capture method for thousands of years (Waegemann et al., 2002). The transition to electronic records requires a major change in workflow, habits and skills. Still now, handwriting is popular because of its history and habits of practitioners, it boast the greatest ease of use (Waegemann et al., 2002). Despite this habit, it still have many weaknesses related to illegibility, lacks standardized structure, lacks detail, difficult to recognize lost entries, difficult to reproduce when lost, lacks of analysis, it does not support real time accessibility and lack of information sharing (Waegemann et al., 2002).

2.7.2 Automated data capturing method

To capture data automatically requires technology of different devices which can be used together to complete each other or used alone. We are describing here below some of them which should be used not only by automatic monitoring and reporting tool for adherence to TB treatment but also for TB diagnostic and TB cases management.

2.7.2.1 Interactive voice response

The interactive voice response is a technology that automates interactions with client and computer to achieve defined results, without human intervention (Ministry of Health and Long-Term Care and Registration and Claims Branch Ontario, 2010). It serves as a bridge between people and computer database by connecting the telephone network with the database. The telephone user can access the information from anywhere at any time simply by dialing a specified number and following an online instruction when a connection has been established (Mishra and Swapnil, 2012).

It is also a method of patient communication and data collection that has been increasing utility with advances in health information technology (Androwich and Margaret, 2010). This technology initially used automated interactions with telephones using prerecorded voice prompts and the touch-tone keypad, now advances in technology allow using voice recognition for input and or responses gathered from the spoken word (Androwich and Margaret, 2010). Interactive voice response (IVR) technology is playing a great role in tracking patient information, developing decision support systems by sending automated alerts and reminders, combining with personal health records, using care transitions and linking to education materials (Androwich and Margaret, 2010).

It has been shown that the IVR is used in treatment of patients with chronic health problems such as heart failure, diabetes, hypertension and mental health disorders. This technology has been used also in Rwanda in reporting of HIV data using Tracnet. Adherence to prescribed medications is often suboptimal and it is a good technology for real time data collection, storage and automated reminder (Androwich and Margaret, 2010).

2.7.2.2. Digital imaging and communications in medicine (DICOM)

DICOM is designed to ensure interoperability of systems used to capture, store, display, send, process, retrieve, query, and print medical images as well as manage related workflows (DICOM Standards Committee,, 2005). It also enables the integration of equipment from multiple manufacturers into a picture archiving and communication system. It is mostly used in electronic health records because it is capable to integrate imaging information within patient record (DICOM Standards Committee, 2005).

Data integration within DICOM provides continuity of information along the health care continuum. Clinicians have access to common repository of patient records that is complete and up to date (D. Sluis et al., 2003). In additional the imaging information technology can automate information delivery to streamline workflow and enhance diagnostic quality (D. Sluis et al., 2003). It does have a major advantage in terms of recognizing that the information is indeed shared, and does not vary per frame. The Compression of images takes advantage of the ability of encoder to recognize redundancy within the data (Clunie and Erickson, n.d.).

2.7.2.3. Mobile health

WHO in the survey conducted by the Global Observatory for eHealth defined mHealth or mobile health as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs) and other wireless devices (WHO Global Observatory for eHealth and World Health Organization, 2011). mHealth can be simply explained as the provision of health services enabled by mobile communications (The Boston Consulting Group, 2012). In additional users can interface with mobile devices through software applications that typically gather input from interactive questionnaires, separate medical devices connected to the mobile device, or functionalities of the device itself, such as its camera, motion sensor, or microphone (Hamel et al., 2014).

From text message campaigns disseminating information on health lifestyles to the use of smartphones as medical devices capable of diagnostics and remote monitoring, mobile technology will permeate every aspect of global health system (The Boston Consulting Group, 2012).

The present dissertation shows how mobile devices should be used as solution for health challenges related to the monitoring and reporting on adherence to TB treatment. It has been shown that complexity of mobile health applications help in areas such as training for health care workers, the management of chronic disease, and monitoring of critical health indicators (The Boston Consulting Group, 2012) like it is being used by community health workers in Rwanda through mUbuzima applications. These applications allow access to tools like calorie counters, prescription reminders, appointment notices, medical references, and physician or hospital locators. Applications empower patients and health providers proactively to address medical

conditions, through near real-time monitoring and treatment, no matter the location of the patient or health provider (European Commission, 2014).

The survey of the WHO and GOe, shows that mobile devices are key for treatment compliance, appointment reminder and provide a new communication channel for health promotion and community mobilization (WHO Global Observatory for eHealth and World Health Organization, 2011).

However, in African region it has been identified the lack of infrastructure as one of its top barriers. It is evident that although much work has been done in the region enormous challenges still exist. One indicator of infrastructure is the level of cellular network coverage. The growth of mHealth is dependent on widespread network coverage and access to mobile devices (WHO Global Observatory for eHealth and World Health Organization, 2011).

2.7.2.4 Electronic health record

As defined by WHO, the term Electronic Health Record (EHR) in today's environment is generally accepted as a longitudinal health record with entries by healthcare practitioners in multiple sites where health care is provided (World Health Organization and Regional Office for the Western Pacific, 2006). It contains all personal health information belonging to an individual, also it is entered and accessed electronically by healthcare providers over the person's lifetime; and extends beyond acute inpatient situations including all ambulatory care settings at which the patient receives care (World Health Organization and Regional Office for the Western Pacific, 2006). It includes patient information such as a problem list, orders, medications, vital signs, past medical history, notes, laboratory results, and radiology reports, among other things (Hughes et al., 2008).

Orders for patients are the connective tissue in any EHR. They are necessarily complex, integrating patient-specific interventions across departments. Orders management crosses customary boundaries, and it is just as likely to integrate computerized applications and functions as it is to disintegrate traditions (Hughes et al., 2008).

Error is human focused attention on the frequency of medical errors occurring in hospitals. In response, the health care industry has been counting upon the strengths of technological innovations to improve patient safety and decrease medical errors (Hughes et al., 2008). Medication errors can occur at any stage of the medication administration process, starting at the

ordering of the drug by the physician, followed by dispensing of the drug by the pharmacist, and ultimately ending in the actual administration of the drug by the nurse to the patient. the implementation of Computerized Physician Order Entry (CPOE) systems should be or is targeted to eliminate errors occurring at the ordering phase (Hughes et al., 2008).

On the other hand, barcode medication administration systems work toward decreasing errors that arise further into the medication administration process. Integration of the two technologies, can lead to significant improvements in patient safety and efficiency of medication administration (Hughes et al., 2008).

EHR requires a computer program that captures data at the time and place where healthcare is provided over an extended period of time. It would enable healthcare information, to be readily available at all times to assist with decisions on diagnoses, treatment and medication at all levels of healthcare (World Health Organization and Regional Office for the Western Pacific, 2006).

A good functioning EHR demands interoperability satisfactorily this requires a focus on a concrete application and its healthcare context. It usually involves the preparation of detailed specifications, agreement among users in healthcare on use cases and required results, testing and certification, legal and regulatory compliance (European Commission, 2009).

2.8. Factors contributing to adherence rate

Poor adherence to treatment of chronic diseases including TB is a worldwide problem of striking magnitude (Adane et al., 2013). In addition, poor patient adherence to the treatment regimen is a major cause of treatment failure and of the emergence of drug-resistant TB (Bagchi et al., 2010).

Factors contributing to adherence are patient-related, the characteristics of the disease and its treatment, and attributes of the health care system and service delivery also have great influence (Sabaté and World Health Organization, 2003). Adane added that among the causes of non-adherence includes travel expenses, traveling to treatment centers, male sex, poor patient information and communication, alcoholism and homelessness as the major determinants of non-adherence to anti-TB treatment. The scholarship suggests that patients with TB are expected to have adherence levels greater than 90% in order to facilitate cure and is crucial to achieve cure and avoid emergence of drug resistance (Adane et al., 2013).

2.9 Treatment adherence

In developed countries, adherence to long-term therapies in the general population is around 50% and is much lower in developing countries (Sabaté and World Health Organization, 2003).

Treatment adherence problems are observed in all situations where the self-administration of treatment is required, regardless of type of disease, disease severity and accessibility to health resources. Poor adherence has many consequences and are leading to the defaulters, failure and drug resistance even death (Castelnuovo, 2010).

The World Health Organization (WHO) has recommended the Directly Observed Treatment Short-course (DOTS) strategy for control of TB (Nezenega et al., 2013). The strategy has been promoted widely and implemented globally where it has been adopted by more than 180 countries and is considered as the most appropriate and cost-effective approach for TB control (Nezenega et al., 2013). Up to half of all of patients with TB do not complete treatment, which contributes to prolonged infectiousness, drug resistance, relapse, and death (Munro et al., 2007).

Patient compliance is a key factor in treatment success. In many countries, a significant proportion of patients stop treatment before completion, for various reasons. Promoting compliance through a patient centered approach is much more effective than spending resources on defaulter tracing (Nezenega et al., 2013). Efforts to improve treatment outcomes require a better understanding of the particular barriers on adherence to TB treatment, and of patient experiences of taking treatment (Munro et al., 2007).

2.9.1 Role of healthcare information technology (HIT) in medication adherence

The researchers and clinicians have begun exploring the role of Healthcare Information Technology (HIT) in medication adherence interventions. HIT shows numerous potential applications in medication adherence intervention (Misono et al., 2010). It can support a more engaged approach to medication adherence by supporting consumer decision-making and coordination between patients and health care providers (Aja B., 2014). For example the electronic pharmacy data may allow for identification of non-adherence and facilitate data delivery to prescribers and pharmacists (Misono et al., 2010). Electronic systems might inexpensively remind patients and providers about refills. Interactive electronic systems may be used to educate patients about appropriate medication use (Misono et al., 2010).

There is a number of methods used to measure medication adherence and these methods are categorized as either direct or indirect and both have limitations (Aja B., 2014). Given these limitations, use of electronic monitoring to assess adherence in general medical populations has increased (Byerly et al., 2007). Human interventions that once required direct patient contact can now be performed electronically using HIT. For instance, with the advent of video conferencing and smart phone applications, patients, caregivers and providers are now able to monitor medication adherence through video-logged confirmation of dosage (Aja B., 2014).

Cross validation studies show electronic monitoring (EM) to be the most sensitive method available for measuring medication non-adherence by providing timely data on medication adherence dynamics over time (De Bleser et al., 2010).

Numerous electronic monitoring devices to measure adherence exist (De Bleser et al., 2010); as title of example the Medication Event Monitoring System (MEMS) uses an electronic medication bottle with a microprocessor incorporated into the cap that records the date and time the bottle is opened (Vervloet et al., 2011). The Real Time Medication Monitoring (RTMM) system which is an innovative adaptation of MEMS uses an electronic medication dispenser which monitors patients' medication use; it registers this data in real time at a central server. This real time information is directly available through the internet for patients as well as for their care providers (Vervloet et al., 2011).

Reminders combined with other interventions such as patient counseling have been shown to be effective of improving patient compliance to medication (Arne et al., 2010). Electronic monitoring of compliance has been described as the most accurate indirect approach to compliance measurement (Arne et al., 2010). It enables continuous recording and classification of compliance dynamics. The monitoring device can be used to remind patient taking their medication once per day and electronically monitors patient compliance (Arne et al., 2010). Using HIT increases the feasibility of monitoring medication adherence and promotes technological innovations that are consumer-facing to improve self-management (Aja B., 2014).

2.10 Conceptual framework for the present study

The present study itself aimed at proposing a conceptual design to guide monitoring and reporting within TB treatment adherence in Rwanda especially in Kigali area, the framework presented in the figure1 here below is only a summary of the inquiry steps to guide the

investigator to address research questions as the review of existing conceptual design will be reviewed latter.

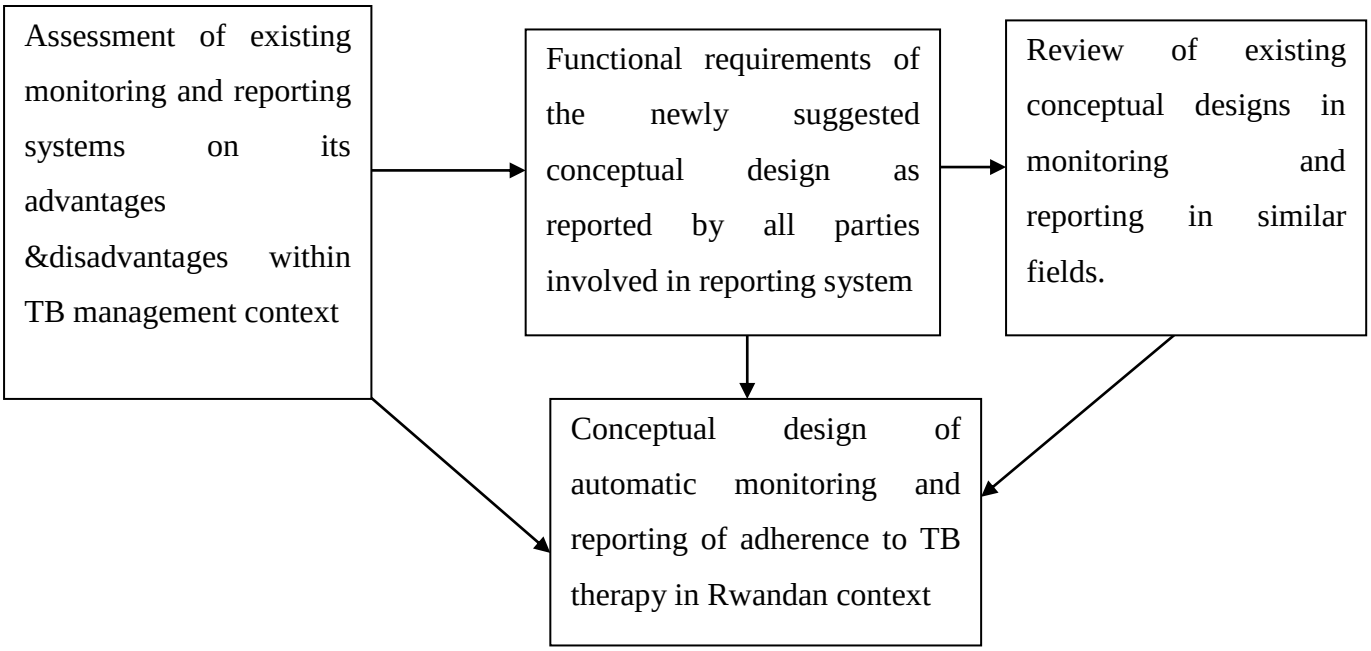

Figure 1: Conceptual framework

CHAPTER3. METHODOLOGY

3.1. Introduction

In this chapter, we discuss the approaches used to achieve the objectives of our research project on design of an automatic monitoring and reporting tool for adherence to TB therapy. The techniques used to attain the user requirement and the technologies used in conceptual design.

3.2 Study area

The study area of the present research is health facilities which are the same time center of TB diagnostic and treatment (CDTs) within Kigali city. The researcher selected CDTs because are specialized in diagnostic, care and treatment of TB patients, and they provide to each TB patient a patient identification number, they keep recording and reporting tools up to date and, in due time, transmit quarterly reports on detection and treatment results of TB to upper level (Rwanda NTP, 2009).

The area is a place of convenience to the researcher to meet objectives of the study because of the fact that the area documents 30% of the total TB cases countrywide (Rwanda NTP, 2013c).

3.3 Study design

A conceptual qualitative research design is used to provide the architectural design used in automatic monitoring and reporting tool for adherence to TB treatment. According to (Greene et al., 1989) a conceptual research design was primarily employed to develop theories on how psychosocial interventions may work, it can also be designed to put in place abstracts ideas or theory about a program or intervention. For the purpose of the present study a new concept about monitoring and reporting of adherence to TB treatment was designed to enable adherence measurement, improve data quality, maximize timely data accessibility and reduce workload of health provider for a better service delivery to a large number of populations with limited resources.

3.4 Study population

The population of interest in the present study comprised of hospital pharmacists, nurse TB focal points from 26 Center of TB diagnostic and treatment (CDT). In addition views of TB services beneficiaries were represented by 1 patient per health center and one community health worker at

each selected CDT. Considering the type of the present research, views of IT specialists were of paramount importance. The CDT includes 5 hospitals, 3 private clinics; 18health centers purposively were selected within Kigali city catchment zone to be the centers specialist in TB management within Kigali City.

3.4.1 Informants

We have interviewed different informants from referral hospital, district hospital, health centre, and at community level as well TB patients using an in-depth interview guide. Interviews were oriented to each participant with respect to his/her role in adherence to TB treatment and to their expertise in information technology.

Pharmacy managers and nurses TB focal point were asked mainly about the advantages and disadvantages of tools they are using in monitoring and reporting adherence to TB treatment and their views on how, when and what kinds information the system should notify, alerts and reminds the users.

Based on their expertise, we interviewed Information Technology (IT) specialists with emphasis on function part of the automatic tool with focus on data capturing, data validation, data synchronization, system accessibility and system architecture of the automatic monitoring and reporting tool.

Referring to health system in Rwanda, community health workers (CHWs) are entrusted to do a follow up of TB cases and ensure that prescribed tablets daily are consumed hence ensure the monitoring of adherence of patients to TB treatment (Rwanda NTP, 2009); therefore, we interviewed the CHWs and TB patients for getting their views where they indicated different elements to be displayed by conceptual system once developed for alerting and notifying patient and users on adherence to TB therapy.

3.5 Sample size and sampling strategy

Multistage sampling was used to meet the objectives of the present study as shown in the table 1 here below.

Table 1: Sampling Strategy

Institution	Service name	Number of institution	Number of informant selected per service	Sample size	Sampling strategy
Hospitals	Nursing	2	1	2	Purposive sampling
	Pharmacy	2	1	2	Purposive sampling
	IT	2	1	2	Randomly selected
Private clinic	Nursing	1	1	1	Convenient sampling
	Pharmacy	1	1	1	Convenient sampling
Health centre	Nursing	3	1	3	Purposive sampling
	Pharmacy	3	1	3	Purposive sampling
Representative of the Community health workers	Community	3	1	3	Census sampling
TB Patients	One stop TB service	6	1	6	Random sampling
Total				**23**	

At hospital level, 2 hospitals one at the district level and one at referral level were selected purposively from 5 hospitals providing TB management in Kigali. At a hospital, 2 units including pharmacy and nursing ensure adherence to TB treatment. Therefore 1 informant was selected purposively to be part of the study and the total number was 4 participants from 2 hospitals. In the two hospitals selected purposively, the Information Technology (IT) unit of each hospital was part of the present research. Thus 1 informant in an IT unit was selected randomly to participate in the present study and total number was 2 participating IT specialists.

On private clinics; 3 clinics provide TB services in Kigali. The researcher selected 1 clinic conveniently comprising of 2 services namely pharmacy and nursing. Therefore, a convenient sampling of 2 participants was chosen to represent the views of others.

Among health center (which are at the same time center of TB diagnostic and treatment), 3 health centers were purposively selected from 18 CDTs, one from each district based on the high number of TB patients enrolled each year. Within each health center, pharmacy and nursing services were chosen to participate in the current study. Hence 1 informant from each service was chosen purposively, and then the total number was 6 informants from 3 health centers.

Representatives of community health workers from each of the selected 3 health centers were part of the current study. We selected randomly one patient from each of the 6 institutions (health facilities) in which the present research was conducted in and at time of data collection, all of CHW and patients were represented respectively. Hence, a census of 3 participants was chosen to present view of other community health workers and 6 participants sampled randomly were chosen to present views of other patients.

3.6 Inclusion criteria

Research participants included in the present study were selected depending on roles they played in adherence to TB therapy. All health personnel in the CDT centers are not actively involved in monitoring and reporting of adherence to TB treatment, one pharmacist or one pharmacy manager and one nurse TB focal point at selected hospitals were included in the study due to the role they play in monitoring and reporting of adherence to TB treatment. At the private clinic level, 2 informants were included in the study: a pharmacy manager and the nurse TB focal point. In addition, the Health centers were represented by one pharmacy manager and one nurse TB focal point. The end user group which is community at large was represented by one CHW in a selected health center and one patient. Considering the nature of the study, the IT specialists were part of the present research.

The above mentioned participants constitute informants who are playing key roles of ensuring adherence to TB treatment. CHWs were among informants because they are heavily involved in supervising treatment for patients entrusted to him/her by the CDT; monitoring and reporting each dose on the community treatment card and accompanying patients to the CDT for monthly control test and follow up with irregular or un-traceable patients

3.7 Exclusion criteria

All health personnel at the site, other than those delivering TB service were excluded in the present study due to the fact that they are not actively involved in monitoring and reporting of

adherence to TB treatment. In addition, patients who were severely ill due to TB or suffering from any other disease except TB were not selected for interview.

3.8 Data collection methods and procedures used

3.8.1 Data collection methods

The present study is qualitative in nature due to the fact that a new concept to be designed depends on views of all parties involved in implementation. Therefore, an in depth interview was conducted to collect views on disadvantages and advantages of paper based reporting tool in comparison to a rapid TB reporting tool, and functional requirements of an integrated concept in adherence to TB treatment. The interview guide was developed based on existing automatic recording and reporting tool and adapted in the context of an automatic monitoring and reporting tool to ensure adherence to TB treatment (Rwanda MoH and SCMS, 2010) See annexes, 1, and2. The components covered were focused on advantages, disadvantages of paper based tools, functional requirements of automatic monitoring and reporting tool as reported by research participants. The interviewer oriented the interviewee on the following key areas:
Strengths of paper based tool; weaknesses of paper based tool; data capturing, data validation, data synchronization, alerts and notification, system accessibility, system architecture.

3.8.2 Data collection procedures

The study proposal was submitted to the research and ethical committee of University of Rwanda /College of Medicine and Health Sciences for approval. After the ethical clearance was obtained the application for authorization to conduct data collection in the selected sites namely Masaka Hospital, Kabuga Health centre, CHUK, Clinic le plateau, Kimironko Health centre, Kacyiru Health centre.

The research categorized the informants into three categories depending on their area of interventions or working position and for each category, the interviewer used specific in-depth interview guide. On health professionals and IT specialists, the researcher used specific interview guide. The in-depth interview guide related to alert and reminder aspect was used for all informants. However, the researcher translated that part in Kinyarwanda only for CHW and patients to facilitate interviewee to answer questions related to the present study. Data was

captured by writing answers on the elaborated in-depth interview guide. The researcher compiled all in-depth interview guides and kept them in secure location.

3.9. Data analysis

Data was analyzed qualitatively. Information collected by means of in depth interview guide was transcribed into themes before being analyzed and it was then categorized by objectives. Finally, views from the respondents were used along with the reviewed concepts from elsewhere in the reporting systems of health care delivery to draw an integrated concept that can be used in Rwandan context to automatically ensure monitoring of adherence to TB treatment.

Referring to the elaborated functional specification according to the 2013 national guidelines of TB for prevention and management and standard operating procedures of the existing paper-based algorithm and written procedures of monitoring and reporting of adherence to TB treatment, we provided architecture and component design specifications of the automatic monitoring and reporting tool for adherence to TB treatment.

To perform analysis, we used a logical reasoning process and presented data using flow charts, diagrams and architectures.

In this dissertation, architectures were represented by box-and-line drawings in which the nature of components, their properties, and semantics of connections and behavior of the system were represented by visual notations with Microsoft office Visio 2007.

3.10 Problems and limitations of the study

3.10.1 Limitations of the study

The limitations were faced in terms of scope as data was collected within the confinements of Kigali city while other centers monitoring adherence to TB therapy exist across the country. Thus generalization of the study results to the country level may be not possible. In addition, the study was qualitative in nature and reflects the views of the respondents at the study setting which limits the generalization of the results to other settings. The second limitation is that the design is limited to the functional requirement and architecture design. We didn’t go to the phases of software development (Programming, implementation, testing and validation).

3.11 Ethical consideration

Before data collection process could start, all approvals were granted by research and ethical committee of University of Rwanda /College of Medicine and Health Sciences. Thereafter, through TB district coordinators permission to collect data from research sites were applied. After permission was granted, study participants were approached and given an informed consent form to be filled as a testimony of the willingness to participate in the study, then, the researcher kept them for further reference. Confidentiality of information and right to withdraw from the study at any time were highlighted in information sheet that was given to the participants prior to data collection process. The information obtained from an interview guide was kept with strictest care.

Neither names nor any other personal identifier were mentioned during the data coding, analysis as well as reporting. All completed interview guides were kept in a secured location.

CHAPTER 4: RESULTS

4.1 Introduction

In this chapter we present results from the research we conducted in line with objectives of the present study. Participants reported many themes unique to the conceptual design of an automatic monitoring and reporting tool. The interview data were initially coded according to a number of themes that corresponded to the focus questions (Pat, 2009). These themes included advantages and disadvantages of using paper based tool, the functional requirements of the proposed automatic monitoring and reporting tool including data capturing, data validation, alert mechanism, data synchronization and system accessibility then conceptual architecture design.

4.2 Advantages of paper based

As Lewis Hassell noted, paper based tools have been important and initially used for religious and administrative record-keeping purposes and later for storing and disseminating knowledge on mathematics, surgery, and Engineering (Hassell et al., n.d.). According to Hersh, most medical encounters are still documented on paper medical records despite the growth of computer technology in medicine (Hersh, 1995).

In a response to the question asked the health professionals and IT specialists: Upon to you what are the advantages of using paper tools for adherence to TB therapy among the following? , the study respondents, in the present case are the informants reported different views organized into themes on the positive role of using paper tool in health system.

The majority of informants (12/14) have reported that:

"*Many of users have familiarity with use of paper based tools."*

"Paper based tool don't require electricity, computer or internet connection to use it or to have access to data recorded on it."

Other part of informants 10/14 added that:

"Users fell accountable when they are signing on paper based tool during the reporting period";

"Paper based records are used as supporting document for evidence during audit";

In relation to the document security, one informant 1/14 argued that: "*Patient cards hold in filling cabinet are secured and ease to retrieve*".

The analysis on the results from the informants on the advantages of paper tool categorizes findings into three groups. Views presented as the real advantages of paper based tool so far; summarized into familiarity, ownership and evidence for audit purpose. The analysis shows another category of views on advantages of paper based tool depending on the context of work or the informants but it is among the disadvantages of paper based tool. Timely file retrieval can be feasible with manual system in health facilities or services with few patient files. However in TB context where there are some health facilities recorded around 5 TB cases per year this may happen but in other health facilities with a huge number of patients, the retrieval of file of last five years ago might be difficult even impossible. Other views are considered among the disadvantages of the paper based tool as when we are analyzing the security in data management context, manual system may not be the best one to be used. Paper based tools don't have validation rules to reduce errors and cannot be relied on to validate data. All views above mentioned are discussed in chapter five where are compared with the existing theories and with the views from the part of disadvantages of paper based tool of the present study.

4.3 Disadvantages of paper based tool

Views from 14 informants on the present theme have resemblance and those with relationship are combined into one to allow the researcher to express all ideas in a focused and concrete way.
The informants mainly reported disadvantages classified in 4 main categories: Data retrieval and share, data quality, cost and safety.
In relation to data retrieval and sharing, the majority of the informants (13/14) reported that paper based tools are not used friendly:

> "*It is time consuming to have access to medical data, tedious to retrieve and share medical data and difficult to conduct rapid data analysis with paper based tool*";

Regarding the data quality, all informants 14/14 revealed that documents may be damaged easily: "*Paper based tools are exposed to damages and expose patient privacy*."
In relation the cost and data safety, the 12/14 of informants highlighted that it is expensive and result into poor data, as respondents mentioned: "*Managing paper tool at health facility is expensive due to inflexibility to editing, to the printing cost and storage space"; "Data with bad and ambiguous handwriting, it leads to poor data quality and irrational use of medicines".*

The analysis on the theme of disadvantages with the use of paper based tool in health system demonstrated inconveniences for using of manual system in health system summarized into limitation to timely data accessibility and retrieval, limitation to rapid data analysis and information sharing, tedious and workload, inflexibility to editing and damages which make paper based system more expensive and illegible handwriting which end up to poor data quality, and irrational use of medicines.

The above mentioned views are in line with others studies which documented that paper based tools are not flexible to editing and is expensive (François, 2008). As paper files cannot be edited directly, it is forcing users to make new copies to update old files and replace lost paper which affect the data quality. As medical records and tools are continually updated(Tsai and Bond, 2007), health facilities are requested to print new registers and withdrawal the old files which requires a lot of physical space to store all the patient records.

4.4. Need of automatic data capturing tool

Data capturing is a process of collecting data and putting it into a database by different methods and techniques which can be manual or automatic (UN Secretariat, Statistics Division, 2010). As there are many methods which can be used to collect and entry data into a database, we have collected views of informants to know which they want to be used in the automatic monitoring and reporting system of adherence to TB therapy.

The suggestions of the informants on how automatic data capturing can be done was basically in relation to abilities of multiple services working together at the same time, and usage of a multitude of hardware to easy the work. In that regard the majority of informants (13/14) reported:

"*Compared to the existing system we wish to have an application which should capture data through multiple data entry tools in which data can be typed into the system and able to work offline*".

All informants14/14 mentioned tools to be used for data capturing as reported in the expression here below:

"*The automatic system should capture data from different tools using different methods like spreadsheets, computer based and mobile application by using SMS and video to record and*

monitor patient adherence to TB treatment and users who should receive notifications and alerts".

The ideas from informants combined together provided a variety of devices for data capturing which can be used each standard alone or in multiple methods for complimenting each other. The proposed methods for data capturing are web applications/computer applications, mobile application which include phone/smart phone, combined method of spreadsheet and computed system where data are captured on spreadsheet and uploaded into automatic system. Video was proposed to be used by patients and viewed by health provider at remote site instead of going every morning to take medication at health facility or Community Health Work (CHW).

According to the literature, the automatic system by means of multiple devices enables the health workers to save time and minimizing retyping errors (Joint Nature Conservation Committee, 2011). In addition, the use of different modern devices like phones to capture the data provides to the automatic tools the capacity of portability and be response to the data capturing for severe ill patients who should take medication at bed set. This method should be used to enhance monitoring and enable reporting on adherence to TB treatment. In African context, mobile phone communication has been suggested as a method to improve delivery of health services especially for antiretroviral treatment adherence in Kenya (Lester et al., 2010) Rwandan health system can adopt the technique whereby the fixed information which is not mostly changing should be entered into the automatic tool once then use update button to resolve the issue of limited access.

4.5 Need of automatic data validation tool

According to SPSS documents, data validation is a process of running basic checks and checks against defined validation rules to identify invalid cases, variables, and data values for ensuring that a program operates on clean, correct and useful data (Inc, 2005). Unreliable data comes from many sources and all of it needs to be validated then we captured views from informants of the present conceptual study, by providing requirement details on data validation at the time of data entry and validation mechanism once the data is already in the system to ensure data integrity. The reported functional requirements on data validation are categorized into the capacity of the

system to record data and provision of error message for data accuracy and rules to ensure the continuity of the data.

In this regards 10/14 of informants reported that:

> "*The automatic monitoring and reporting tool must have a field, record and screen level validations."*
>
> *"The data integrity and completion must be also be verified at field, record and screen level and the automatic tool should provide an error message to users."*".

In additional all informants 14/14 have stated that:

> "*The automatic tool should be able to pre- populate data based on validation rules to reduce data entry effort and the rest of the information must be provided by the users."*

The majority 12/14 of informants suggested saving changes as stated here below:

> *"In case a user makes changes or enter new data, the system should remind here to save changes."*

Validation is key part in data management and there are many fields and records which should be validated before the integration of data into the database, and the system should have a screen level validation for user friendly with system. According to the literature, the validation process should be applied at entry point level of data to assess whether data collected and measured are a true reflection of the performance being measured. The validation techniques are almost common with particularities depend on the domain of the applications. Alerts provide notification of errors, warnings of abnormal values during data entry or information to prevent adverse events such as non-adherence to TB therapy. The automatic tool through its notification capacity should provide feedback to healthcare providers and helps to monitor patient compliance to medications (DOQ-IT, 2005). Therefore, the present functional requirement should also have a data validation framework.

4.6 Need of automatic data synchronization system

Messerschmitt specified that synchronization plays an increasingly dominant role in the system design, it ensures that operations occur in the logical correct order and is a critical factor in ensuring correct and reliable system operations (Messerschmitt David G., 1990). Here below the informants expressed views of the current study on the present functional requirements on data

synchronization which describes the information that must be updated on records if approved on screen by users.

In this regards, all 14/14 of informants mentioned:

> "*For good data management, the data updated from computer, web applications and mobile application must be (inline) synchronized automatically within central database.*

Few informants (2/14) who were the IT specialists added that:

> "*Considering that the internet connection is not always available, the proposed automatic tool should be able to synchronize data both off line and on line".*
>
> *"The automatic tool should be able to keep old version of the updated file automatically".*
>
> *"The data in central database must be able to integrate with other application of the health sector to ensure data sharing and the automatic tool should have an audit trail for all changes made to the data".*

The above mentioned quotes proves the need for functional requirements to automate the synchronization of data into database; maintain old version and be capable to integrate with existing applications of health system and demonstrate audit capability to track any modification on data recorded in the current proposed automatic tool. The present study is the line with McCormick and Schmidt, (2012) who reports that a functional requirement provides an initial step in a larger effort on development of an application for monitoring of adherence to TB therapy and it focuses on guide on data synchronization which involves ensuring consistence among data from different devices or format to a target data storage (McCormick and Schmidt, 2012). Furthermore Agarwal et al., add that the automatic tool and computing devices rely on synchronization protocols in order to maintain data consistency and these protocols operate in environments where network resources such as bandwidth, memory and processing power are limited (Agarwal et al., 2002).

4.7 Need of automatic alert and reminders tool

These requirements describe the alarms and reminders that the system should provide to users to facilitate rapid action. These reminders are notifications which facilitate timely communication to patients and users for various clinical and practical matters (Optometry, 2014). This includes a reminder that a patient has to comply on a comprehensive laboratory control and treatment

adherence within the recommended period (Optometry, 2014). As one of objectives of the present study was to provide functional requirements of the conceptual design tool for monitoring and reporting of adherence to TB therapy, 23 informants have reported their views on this theme related to how alerts and reminders mechanism should be. Almost of the informants 20/23 has suggested to use SMS recording and reporting adherence to therapy as stated here below:

> "*Through SMS, Community Health Workers(CHWs) should record and notify daily adherence to medication into the automatic tool and receive as well as patients, reminder or alert on time of patients to take their medication, clinical and bacteriological follow up*";

> "*The system should have alert and notification capabilities for information, error and warning messages*";

The proportion of 19/23 of informants proposed an automatic tool which should be used for adherence and side effect monitoring:

> "*The system should be able to help users to monitor adherence of patient to treatment and notify patient treatment outcome to all users";*

> "*The system should be used to notify/alert appearance of side effects, aggravation of general health condition or associated pathology*";

Another part of informants 17/23 suggested an automatic tool which should be used by CHWs for request of medicines resupply:

> "*The CHWs should use the automatic system to notify health facility the request for resupply in medicines*";

Twelve informants out of twenty three suggested using an automatic tool for transfer alerts as they stated here below:

> "*In case of transfers, the system should be used to alert CDTs TB cases transferred in to avail medicines required for good continuation of treatment*";

The above reported quotes by the informants show similarities with the existing literature related to functional requirement on the system ability to provide alerts and reminders. The summary below shows types of information the participants to this study want to be alerted and reminded to users of the proposed automatic tool:

- To notify reporting compliance of adherence to TB treatment;
- To receive a reminder for clinical and bacteriological follow up;
- To receive a reminder on time for taking medication;
- To alert CDTs on TB cases transferred in;
- To be notified on time to change treatment phase;
- To use the automatic tool to notify side effect during health facility visit.

Other views are reflecting the expected capabilities of the automatic system by which the system should be able to work with logistic systems to notify health facilities medical request from CHW for resupply.

4.8 System accessibility

Maintaining correct access control to shared resources as database is an important part of an organization (Das et al., 2010). McKinney (1982) recommends that as we developed conceptual design of an automatic tool which should be used in information sharing electronically, a common understanding of what is needed and expected in securing information technology resources is required. In addition, in the contemporary world, shared resources are becoming increasingly prevalent. Managing such shared resources in the context of the present automatic tool requires views of informants which can be used to gain understanding of the basic security and system accessibility requirements most information technology system should contain (McKinney, 1982). Here below are views of the informants in the present study on how the system should be accessible.

All informants to this theme 14/14 suggested having access to the system any time according to their roles and responsibility as they stated here below:

> *"The system should be accessible by different users at elsewhere any time according to their user roles and responsibility and user hierarchy for all system users."*

In additional the 2 IT specialists highlighted that:

> *"Individuals in an organization should have well defined and precise roles, and access control to all resources should be based purely on their responsibilities. In case a user left the organization or changed his role, his access rights to the automatic tool should be automatically changed as is the new role with immediate effect*". And

> "*Data access or modification (Insert, Update, Delete, etc.) should be restricted based on user and organization hierarchy. It should be very useful if all accesses are managed through a perfectly engineered role based access control system*".

The reported quotes show that the suggested system accessibility should relied on hierarchical organization and role and responsibilities of different users. It requires a strong secured and controlled system to avoid unauthorized accessibility and manage the limitations of different users. Access to the system depending on the roles makes users accountable on what they do with the system or data. This is in the line with the study conducted in United States of America which shows that access control still present weaknesses and suggested ways to prevent it by making the automatic monitoring and reporting tool to be uniquely identify the users while logged in the system, restrict access to data by functional, roles and level of users, encrypt records in additional to restricting access (AHIMA and HIMSS, 2011). In addition, for the privacy purpose the unique patient identifier for each patient should be used instead of patient names. These require the tool to have capabilities of identity proofing, authentication and authorization to control and monitor the accessibility to the automatic tool which should containing patients' data. Also each user should read and sign the terms, conditions and sanctions agreement on the use of the automatic tool.

The table 2 here below describes the contribution of the 23 informants interviewed in the present study per theme detailed above.

Table 2: Distribution of theme per informants

Themes	**Category of informants**	**Number of informants**
Advantages of paper based	Health professionals and IT specialists	14
Disadvantages of paper based	Health professionals and IT specialists	14
Functional requirements on:		
1. Need of automatic data capturing	Health professionals and IT specialists	14
2. Need of automatic data validation tool	Health professionals and IT specialists	14
3. Need of automatic notification, alert and reminder tool	Health professionals and IT specialists	14
	Community Health Workers	3
	Patients	6
4. System accessibility	Health professionals and IT specialists	14
5. Need of an automatic system synchronization	Health professionals and IT specialists	14
Total informants		**23**

4.9 Conceptual architecture design

The present conceptual architecture describes the essential elements of socio-technical organization, relationships to each other and to the environment (Alta et al., n.d.). It comprises software elements, the externally visible properties of those elements and the relationships among them"(Northrop, 2010). Considering that system architecture is response to the

conceptual difficulties of description of a complex environments by partitioning the delivery of the end product into discrete internal services that pass work from one to another to accomplish the goal (Northwestern University, 2004), we have passed through views from informants in which they described how the automatic tool shall be physically and logically configured to meet its operations. Also basing on the reported responses from the qualitative data, a conceptual design was proposed to be a guiding tool for reporting and monitoring adherence of TB cases within Kigali City. The conceptual architecture design availed is in line with the literature as it includes ad hoc box and line drawings of the automatic tool to solve the problems articulated in specifications where boxes define elements or parts of the tool and lines the interactions between parts (Northrop, 2010).

The following features are the main components of the design:

- The central data repository hosted central level logistically equipped.
- Health facilities data capturing, analysis and reporting platform logistically equipped.
- End users system (Community health workers as well as patients) logistically equipped.

The researcher used drawing as an aid to visual thinking of the conceptual design of the automatic tool for monitoring and reporting of adherence to TB therapy. The notations here below externalized the design thought where are written down in structure that supports interpretation at a later time by a computerized program (Taylor and Hoek, 2006). These notations are representing also rules which are expressed by means of shape grammar formalism (Kotsopoulos, 2007). The conceptual architectural design is presenting how data on adherence should be captured and reported, how DOT (Directly Observed Therapy) monitors will access and view the information within the system and staff at central level will always analyze all records of the entire system. In additional the figure here below shows also the video, SMS and computer based records flow diagram and flow of reminders and notifications. The figure shows also how the users will interact with the system.

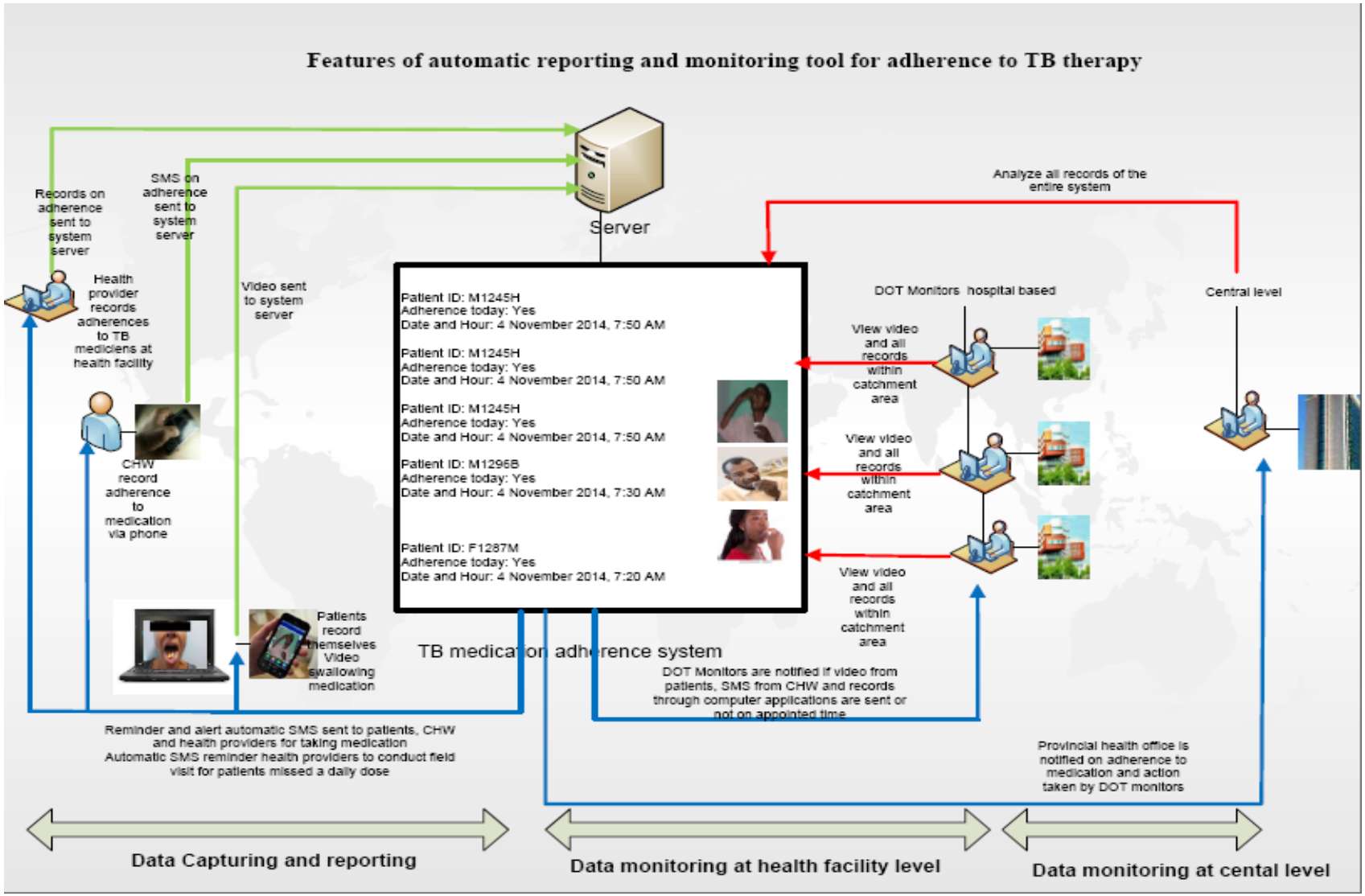

Figure 2: Features of automatic reporting and monitoring tool for adherence to TB therapy

Analysis made to the figure here above is indicating that data capturing should be conducted at three levels depending on the choice of patient and on his capability to comply with the use of video based requirements.

Data on adherence to TB medication should be patient centered where he/she is going to use any mobile device able to capture video while he is swallowing medications and show time (date and hour) even location the video was taken. The video should be sent directly into the automatic tool through the link of patient identification with system server and the DOT monitor will directly observe the patient taking medication at distance. The present technique should be used for patients who have mobile devices (smart phones, laptop using Skype, etc.) and able to comply with the technical requirements of the new technology.

View that all patients will not have or not be able to use mobile devices or comply on its technical requirements; other part of patients will always go to take medication at the community health workers and adhere to the Directly Observed Treatment Short Course (DOTS) at the community level and the CHW will always send a daily SMS (Short Message Service) within system server confirming that the patient with a given ID has received his medications or not instead of waiting for the whole month to know who did or did not adhere to TB therapy for any period.

Considering that TB patients with sputum smear positive are contagious at least up to two first weeks on treatment, to entrust a patient to a trained community health worker will be feasible after that period, and depending on the choice of patients (Rwanda NTP, 2009); there will be always patients who are adhering their TB medication at health facilities. To be able to measure adherence rate to TB therapy, healthcare providers should record through mobile applications or computer based system on daily basis the adherences of patients to TB therapy in the automatic tool through system server.

As the individual data will be recorded into the automatic tool, the system will be able to notify, remind even alert patients, CHW and healthcare providers all information required to be known and action to be taken within one day in case is the clinical and bacteriological follow up and within one hour to remind patients time of taking their medication through their mobile phones or any other devices able to receive the message.

The system should be automatic and once the data is collected it will be reported directly into the database. For decision making, data should be always analysed and monitored by DOT monitors

based on the automated notifications, reminder and alerts through mobile, computed applications or other modern techniques available at hospitals. These analyses will help health facilities to measure adherence rate and to enhance the utilisation of data as well increasing adherences to TB therapy. As the visibility and accessibility to data will based on the user role and hierarchical level, the provincial health office will oversee all data in the province and will play an analytical role at each level within the Kigali city.

The suggested automatic monitoring and reporting tool is in line with the documented literature that it will be used by different entities as should be guided by strict organizing principles that generate systematic and measurable results (Ravasz and Barabási, 2003)and achievable objectives of the system in the most efficient and effective manner(Montana and Charnov, 1993). The notion of responsibility displays different nuances all related with particular aspects of hierarchical organization of the system. System functionality accounts of hierarchy and role of users is relying on level of intervention (Anderson and Brown, 2010).

The figure here above is organizing the automatic tool into two main components which are data collection and reporting, monitoring and data analysis. Responsibilities are shared at different levels; the level of patients using mobile device and video application will be responsible of swallowing medication at home while video is being captured live and monitored by DOT monitor at hospital site. CHW should ensure the compliance to DOT, record and report through mobile applications the adherence or not to TB therapy on daily basis. Recording and reporting compliance to DOT is a shared task of healthcare giver at health centre or hospital. In additional DOT monitor should always view the compliance to treatment of patients entrusted to CHW if is reporting as required and cross check data on adherence of TB therapy from health facilities of its catchment area if are regularly captured during analysis and monitoring activity.

The central level should always keep an eye on the use of the automatic monitoring and reporting tool at different levels. Should also monitor how the hospitals are complying on the system and play a key role of management of entire system specially the maintenance of the system and keep updating the database.

CHAPTER 5: DISCUSSION

This chapter discusses findings of the present study in line with objectives. It gives an insight on the present study in relation to the existing standards and similar studies. It explains the implications of the outcomes with the established standards or earlier findings on the conceptual design of an automatic monitoring and reporting tool for adherence to TB therapy. This chapter aims to answer questions posed in the introduction, explain how the results support the answers and how the answers fit in with existing knowledge on the present topic (San Francisco Edit, 2006).

The objective one was to determine the advantages and disadvantages of the existing paper tool for monitoring and reporting of TB data in Kigali. Basing on the qualitative responses provided by the informants working in different unit which has TB reporting in their hands, it was shown that users have familiarity with paper based tool. As expressed in views of the 12/14 informants, it is physical in nature and therefore tangible and visible, a person who doesn't have any computer proficiency is able to handle and work with paper based documents. Considering that it is physically handled, kept and signed by users, it gives users sense of ownership and they feel accountable of the use of the data recorded on paper tool. The same views were highlighted in the literature that due to the fact that paper is portable; at the bedside, the portability and accessibility of paper form is important in supporting of patient interview process (HARPER et al., 1997).

In addition, these findings are in line with Dick and Steen views where they noted that the traditional paper record is still used due to its familiarity to users, portability, and its browsability for noncomplex patients. The familiarity with the automatic tool is the major implication of its successful implementation. Although the advantages are many, the use of an automatic tool will require sufficient and effective training of the users and portable modern IT equipments.

Regardless the few above mentioned benefits, there are many challenges and disadvantages with the use of paper based tool. Utilization of paper based tools is exposing data to damage as stated by the 14/14 informants and the majority of the participants 12/14 mentioned that use of paper based tool is also stacking users to have timely accessibility, it impedes data retrieval, analysis, information sharing and is inflexible to editing. To aggregate data from different manual forms is tedious and increase workload to health facilities. As in health facility, paper tools are being

handed between different personnel, they have risks to damages due also to unsecured system which expose patient privacy.

Referring to the published journal of Roukema et al. (2006) on paper versus computer; data timely accessibility is one of problems with paper based records as it can only be used in one place at the same time. Paper based tools are bulky with time, this lead to the lack of overview and this impede the continuity and quality of care of patient not to only for the hospitalized or ambulatory patients but also for patients entrusted to community health workers or transferred to other health facility (Roukema, 2006b). It is potentially detrimental to use paper based tool in healthcare because it decreases communication between users and leads to the reduction of physician efficiency (Tsai and Bond, 2007) with paper based tool, physicians or health professionals cannot have always access to the written proof of the medical history of a patient over time which can aid future courses of treatments and provide decision support (Tsai and Bond, 2007).

As it was highlighted earlier the work of François on the other hand shows that paper based tools are not flexible to editing and is expensive (François, 2008). The storerooms with labyrinthine rows of filing cabinets increase the cost for information management kept on paper (François, 2008) in additional to the amount for printing and maintaining all the hard copies (Sreevidya, 2010). It is therefore results into the bulk of work as more, files results into more difficulty to retrieve patient data and medical records are pulled out late which may delayed health professionals to provide a timely healthcare service (Sreevidya, 2010). Using paper based system obstruct the rapid and good analysis of data recorded on it. Paper based tools are always involved in medical prescription and patient transfers but these tools have the potential for misread of data due to illegible handwriting, lost information, delay, and breaches of security (PATH, 2012). The manual calculation of adherence rate to TB therapy for each patient over the treatment period is tedious work that can easily lead to inaccuracies (PATH, 2012).

The second objective was to study the functional requirements of the automatic monitoring and reporting tool for adherence to TB therapy in Kigali area. The conceptual design of the automatic tool for adherence to TB therapy through functional requirement should address the disadvantages of paper records, by providing access to all relevant data from a single location to an automated decision support, maintain the advantages and facilitating communication between users (Wilcox et al., 2005).

The findings on functional requirements for the present conceptual design of the automatic monitoring and reporting tool for adherence to TB therapy are providing theoretical solutions to the challenges with paper based tool which is being used in monitoring for adherence to TB therapy.

All informants 14/14 have proposed to capture data through multiple data entry tools by using a spreadsheet for which the health providers enter data into the appropriate fields and once the network is on, the system should automatically load the information into the database.

In this line the informants suggested to capture data with mobile devices like phones which should provide to the automatic tools the capacity of portability and be response to the data capturing for severe ill patients who should take medication at bed set. This method should be used to enhance monitoring and enable reporting on adherence to TB treatment, as it has been used in other African settings especially in management of HIV cases (Lester et al., 2010).

In Rwandan context when one refers to the article of Jeffrey, the introduction of mobile techniques to implement direct observed treatment through mobile devices with video-capture technology could help patients to capture video during their medication ingestion. Therefore, health providers should directly observe the TB treatment adherence at a distance and should be more useful for contagious patients as it could prevent contamination to health providers and reduce walking distance to health facilities during the initial phase of treatment before they become negative to be entrusted to CHW (Rwanda NTP, 2009). It will also be a solution for patients who want to travel instead of going always to the health facility or community health workers to take medication every morning (Jeffrey et al., 2009).

Nonetheless, the literature suggests that this technique should require advanced technology and patients should be taught how to display the medication in their hand, on their tongue, swallow with a drink and finally open their mouth to ensure that the tablets had been taken (TB Reach, 2013), and all of these steps should be captured in the video while the patient is taking his or her dose of TB medication as prescribed by clinicians through the mobile applications (Jeffrey et al., 2009). By allowing patients to send videos at any time from any location via their mobile device like smart phone, we anticipate that patients will miss fewer observed doses because they may take them on a schedule that better suits their lifestyle and travel time should be no longer a barrier to face-to-face DOT (Kevin , et al., 2012).Advantages related to using automatic tool to report TB cases are enormous , distance between the patient and their health facilities will no

longer be a limitation to DOT, which would make DOT more feasible and reduce number of defaulters even resistance to TB medication (Kevin , et al., 2012). In addition, this technique will reduce sensibly transport cost spent by National TB control program for patients with multi drug resistance who are coming every day at health facilities to take their medications (Rwanda NTP, 2009). Compared to the existing system, the video based should increase time for CHW and healthcare providers to deal with TB prevention and other health activities as one staff at hospital will be able to monitor patients at home of all health centers of its zone. The new technique should reduce stigma felt by some patients while are being monitored by health worker or CHW (TB Reach, 2013).

However the above mentioned technique still has limitation to be used by each patient and this require a concomitant use of other techniques like computer applications and SMS to complete each other. The text message should be used to remind patients to take their medication and by CHW to notify DOT monitors that patients have taken their medication. Studies have shown on the effectiveness of SMS interventions for improving patients' adherence to tuberculosis treatment (Nglazi et al., 2013) and once implemented in Rwanda context it will enable the measurement of adherence rate to TB medication.

With computer applications healthcare providers cannot be worry about monitoring and reporting on adherence to TB treatment, since information concerning TB patient's adherence should be already in database. Furthermore, the computer application makes spelling validity and range checks which prompt users when data entry error is detected (Williams and Boren, 2008).

Depending on the method used to record data in the automatic tool, there may be different sources of error. All informants 14/14 suggested data validation as key element to eliminate data errors before information is generated. It is important to validate data prior to process it. Data validation should be used to prevent unusable results by raging data set into table of exceptions where the users have to decide deleted, changed or used without any alteration. It should lead to the data quality as the quality of output of any data transformation process depends directly on the quality of input data (Berning, 2001). In this dissertation like in the book of Lenhard and Betriebswirt, it has been requested to validate raw data before computing any results (Betriebswirt and Lenhard, 2012). The important implication of data validation in the automatic tool for monitoring and reporting on adherence to TB treatment is that the users should be

vigilant during the data recording to be sure if all mandatory fields are well filled as well other fields especially those which may affect the data quality and read error message generated by the system before saving any change.

Validation is for all data captured using different devices or methods of the automatic monitoring and reporting tool; the synchronization of those data should be primordial as it used for data exchanging and to improve data quality, availability and continuity which attribute to the automatic tool the capacity of monitoring tool at a real time for relevance analytics and decisions. This will help health facilities to improve operational efficiency of adherence to TB therapy whereby any failure or relapse case will be audited upon the adherence rate. To achieve this goal it requires the developers even the health facility to establish a variety of configuration within the health facilities to meet this functional requirements.

Synchronize data makes it to be accessible to many persons, but for security purpose of the system as well for data, it should be handled, viewed, analyzed or managed by key persons in the organization depending on their roles and hierarchies as expressed by the informants the totality of the informants 14/14 of this study. Access to the automatic tool will give right to use data stored in the system and according to Benaloh, it will open potential abuses and threats (Benaloh et al., 2009). The study conducted in the United State of America suggest that access control still present weaknesses, and propose that the automatic monitoring and reporting tool to be uniquely identifying the users that log in the system, restrict access to data by functional, roles and level of users, encrypt records in additional to restricting access (AHIMA and HIMSS, 2011). The safety measures allows the privacy of a whereby a unique patient identifier for each patient should be used instead of patient names. These require the tool to have capabilities of identity proofing, authentication and authorization to control and monitor the accessibility to the automatic tool which should containing patients' data. In additional each user should read and sign the terms, conditions and sanctions agreement on the use of the automatic tool. The same safety measures were proposed to ensure that the suggested reporting system is robust and addressing the client needs.

The 20/23 informants suggested a tool with capability to provide an automated alert or reminders notification systems integrated within the proposed automatic tool which should offer a potential solution. That was supported by the scholarship that communication of adherence to

therapy through reminders can potentially facilitate rapid review of patient information and enhance adherence to TB therapy (Singh et al., 2010). Alerts provide notification of errors, warnings of abnormal values during data entry or information to prevent adverse events such as non-adherence to TB therapy. In addition, the suggested automatic tool through its notification capacity should provide feedback to healthcare providers and helps to monitor patient compliance to medications as it was also supported by the literature (DOQ-IT, 2005).

As presented in the article of Joseph, the use of texting to alert and educate patients is new, indicate that it can be a powerful way to reach people, improved treatment adherence, and were effective in improving patient adherence to medications for chronic diseases and reduce drug resistance through the reduction of defaulters. Also SMS reminders were especially effective, particularly for patients who had simply forgotten to take their medication and respect of bacteriological and clinical control appointments (Joseph C., 2014).

CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

Studies on automatic tool for monitoring of adherence to medication have shown techniques to be used to enable measurement of adherence rate. Findings of the present dissertation show the disadvantages of using paper tool in monitoring patient to adherence to their medication. Functional specifications of the proposed tool are determined and should be based on in developing and implantation of the automatic tool for reporting and monitoring adherence to TB therapy. The features of the architectural design show that the system can improve adherence of patients to their medication, reduce workload of healthcare providers and allow reporting and reduce distance from patient to health facility.

The results of the present dissertation emphasizes (like other existing scientific work) that limitation to timely data accessibility and retrieval, limitation to rapid data analysis and information sharing, tedious and workload are the major barrier of the use of paper based tools. It is time consuming and lead to the lack of overview with consequences of lack of continuity of healthcare between health professionals and impede the quality of care of patient (Roukema, 2006b). It has been shown that there are potential detriments of using paper based tool in healthcare as they decrease communication between users and lead to efficiency reduction among health providers (Tsai and Bond, 2007). Due to inflexibility in editing, storage space and printing cost, paper based tools become more expensive (François, 2008). Illegible handwriting led to the misread of data and irrational use of medicines (PATH, 2012).

The findings of this study on the disadvantages of paper tool suggest that implementing automatic tool to replace paper records may be a fruitful way to advancing the quality of healthcare and improving medication management for TB patients over traditional records (Tsai and Bond, 2007). Thus, functional requirements to be use in the automatic tool development are established. Mobile devices (including smart phones, etc.), computer applications and spreadsheets have been suggested as devices to capture data, to measure adherences to therapy and to improve delivery of health services. Use of SMS was proposed to report adherence, to remind and alert patients to take their medication. It is also proposed to use SMS to notify health providers and DOT monitors on adherence to medication, which contributes significantly to positive intervention for adherence to therapy and to the primary treatment outcomes (Lester et al., 2010) .

The proposed use of video direct observation treatment (VDOT) is patient-centered whereby patients send daily video of themselves taking medication and viewed by DOT monitors at hospital. Enabling patients to use VDOT, it foresees that distance and quarantine habits for tuberculosis which mandate DOT when adherence is a concern (Frederick L.Altice et al., 2004), should be no longer an obstacle to face to face DOT ensured by healthcare providers or CHW. With VDOT, we predict the increase of adherence rate by reduction of defaulters or lost to follow up and decreasing of drug resistance as patients may take medication on a schedule that better suits lifestyle and travel time (Kevin , et al., 2012).

Validation rules are proposed to be applied at all steps of data entry and be mandatory to the records that may affect the quality of data. Synchronization protocols must be mandatory to maintain data consistency, updated, and enable information sharing. System accessibility must be controlled to ensure the security of the entire automatic system for monitoring and reporting on adherence to TB therapy.

The objective three was to provide architectural design of the automatic monitoring and reporting tool for adherence to TB therapy in Kigali area; the suggested design constitutes three main blocks basing on existing health system in Rwanda. Data capturing which will be conducted at community, primary health care and district levels then data monitoring and analysis at district and central level.

6.2 Recommendations

6.2.1 Recommendations for development of the automatic tool and future work

To comply with normal standards for the automatic tool to monitor and report adherence to TB therapy, some recommendations need to be considered to develop and implement an automatic tool based on the findings from the present dissertations.

It recommended to the developers:

- To use the functional requirements from this study to design an automatic;
- To ensure the interoperability of the automatic tool with existing software being used in health sector;
- Include feedback platform between patients and health providers;
- Include component of side effect management, dosage and drug-drug interactions.

It recommended to the future researchers:

- To conduct a cost-effective study of the technology before its implementation and acceptability by end users specifically patients;

6.2.2 Recommendations for future beneficial use of the findings from this study

It is recommended to the Rwanda Biomedical Centre:

- To use the findings of the present study to design the automatic tool for monitoring and reporting on adherence to TB therapy or use these findings as technical specifications to procure an automatic tool;
- To measure and evaluate the impact of using SMS and Video Direct Observed Treatment (VDOT) on adherence to TB therapy;
- To pilot the VDOT in different health facilities and evaluate its cost effectiveness in TB healthcare service delivery;
- To measure user acceptability for its extension;
- To integrate modules for other disease programs like palliative care of patients with chronic diseases.

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ANNEXES

Annex 1: Information sheet

Dear participant,

My name is Floribert Biziyaremye. I am doing a study on conceptual design of an automatic monitoring and reporting tool for adherence TB therapy in Kigali area. The study is in partial fulfillment of a Masters of Science in Health Informatics in the faculty of allied sciences in University of Rwanda College of medicines and health sciences, Kigali Campus.

A key aspect of my study involves an interview with staff of health facilities daily managing TB data/ patients and IT specialists of hospital in Kigali area. It is for this reason that I am contacting you, in your capacity, experience and wishes as health professional, IT specialist, community health workers and Patients, to kindly request your participation in the above mentioned study. The objective is to provide a conceptual design of an automatic monitoring and reporting tool for TB cases in Kigali area. I therefore really value your participation.

The interview will take approximately 15 to 20 minutes to complete. Please be assured that all your responses will be treated confidentially and anonymity of your responses in the final report is guaranteed. Also note that participation is voluntary and that you may withdraw your permission to participate at any stage without any negative consequences.

Although, I assure you that all responses received will only be used for scientific purposes within the framework of this study. The results of the study may be published in a science journal.

Should you wish to enquire about any aspect of the project, please email me at bfloribert@gmail.com. Alternatively you can phone me at +250 788813668.

Thank you for being willing to participate in this study.

Yours Sincerely.

Annex2: In-depth interview guide for medical professionals and information technology specialists

1. **Advantages of using paper based tools for adherence to TB therapy**

According to you what are the advantages of using paper tools for adherence to TB therapy among the following?

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2. **Disadvantages of using paper based tools for adherence to TB therapy**

Basing to your experiences what are the disadvantages of using paper based tools for adherence to TB therapy?

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3. **Data capturing**

According to you what are the devices should be used to enable the system to capture data through multiple data entry tools for monitoring of adherence to TB therapy?

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4. **Data validation**

What should be the function requirements to describe the data validation at the time of data entry and validation mechanism once the data is already in the system to ensure data integrity?

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5. **Alerts, reminder and notification**

Refer to your expectations, what should be the functional requirements to describe the alert, notifications and reminders that the automatic tool should be able to perform?

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6. **Data synchronization**

Refer to your expertise what are the functional requirements to describe the information that must be updated on an existing record if approved on the interface screen by the user?

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7. **System accessibility**

What should be the functional requirements to describe how the automatic tool should be accessible to users based on their roles and responsibilities?

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Annex 3: In-depth interview guide for community health workers and patients

1. **Alerts, reminder and notification**

Refer to your expectations what should be the functional requirements to describe the alert, notifications and reminders that the automatic tool should provide so as to facilitate immediate actions?

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Ubushakashatsi ku gukurikirana uko abarwayi b'igituntu bubahiriza amabwiriza yo gufata imiti mu mujyi wa kigali hakoreshejwe ikoranabuhanga

1. Ushingiye kuri serivisi uhabwa cyangwa utanga, urabone ari ayahe makuru uburyo bw'ikoranabuhanga mu gukurikirana abarwayi b'igituntu bafata imiti bwajya bukwibutsa?

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Annex 4. Consent form

Title of the study: Conceptual design of an automatic monitoring and reporting tool for adherence to TB therapy in Kigali area

I, _____ agree to participate in the study. I am aware that participation in the study is voluntarily and I will not be paid for the participation. In addition, all information provided will be treated with confidence and that my anonymity will be maintained. I am aware that the results of this study may be published but I will not be identified as an individual. I reserve the right to withdraw from the study at any time if I so wish.

_____ …./…../….

Signature of participant Date

Signature

Name: Floribert Biziyaremye
Researcher
E-Mail: bfloribert@gmail.com
Tel: +250 788813668
Kigali, Rwanda.

Annex 5: Selected centre of TB diagnostic and treatment in Kigali city

DISTRICTS	Center of Diagnostic and Treatment
Nyarugenge	CHUK
	Clinic le Plateau
Kicukiro	Masaka Hospital
	Kabuga health centre
Gasabo	Kimirongo health centre
	Kacyiru health centre

Annex 6: Ethical clearance certificate &approval for data collection

UNIVERSITY OF RWANDA — COLLEGE OF MEDICINE AND HEALTH SCIENCES

Research Centre

20th August, 2014

Ref: UR/RECC/171/2014

Dear

BIZIYAREMYE Floribert

Master of Health Informatics Program

RE: ETHICAL CLEARANCE CERTIFICATE & APPROVAL FOR DATA COLLECTION

With reference to the application for Research and Ethical clearance; and approval for data collection for the study entitled **"Conceptual Design of an Automatic Monitoring and Reporting Tool for Tuberculosis Cases in Kigali Area"**

Following the review of your research proposal by Research, Ethics and Consultancy Committee in accordance with the authority granted to it; the reviewers recommended that your study be granted a Research and ethical certificate. It is on this note that the Directorate of Research, Ethics and Consultancy also grants approval for data collection. You will be required to submit the progress report and any major changes made in the proposal during the implementation stage. Also at the end of the study, the Directorate of Research, Ethics and Consultancy shall need to be given the final report of the study.

I wish you success in your study.

Dr TUMUSIIME David

Director of Research Centre

Cc:

- Principal, College of Medicine and Health Sciences
- Director of Postgraduate studies
- Chairperson of Research Ethics and Consultancy Committee