

**DE MONTFORT UNIVERSITY**

**Risk Management of Electronic Health Record System in  
Hospitals**

**By**

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**PhD Thesis**

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## *Abstract*

This thesis investigates the use of electronic medical record (EMR) systems and risk management in hospitals. It provides a critical analysis of recognized EMR systems and potential failures and discusses six traditional risk management techniques including brain storming, cause, effect analysis, failure mode effective analysis (FMEA), fault tree analysis (FTA), and Binary Decision Diagram (BDD) in addition, to one of the most recent systematic risk management techniques, Systems Theoretic Accident Model Process (STAMP). The traditional techniques are not as well suited to managing risks and preventing failures in modern information systems with complex software that involves human and machine interaction. The thesis introduces the implementation of common traditional risk management technique such as BDD and FTA which is mostly used in nuclear plants, transportation and medical devices backed by a hypothetical example to help and explain the process of the FTA usage. Most traditional techniques rely on a direct cause-and-effect chain and have no clear formal guidance. The systematic technique introduced and used in this study, is known as Systems Theoretic Accident Model Process (STAMP). It is one of the recent systematic techniques developed and used in many sectors including aerospace.

This study applied the STAMP technique to the EMR system failure at King Khalid General Hospital (KKGH) in Riyadh. One of the reasons for selecting the STAMP technique is that it is based on system theory and established the risk factors that lead to system failure. It also provides guidance for managing and controlling risk factors. This thesis discusses the implementation of STAMP, supported by examples, to explain how the technique conducted.

System failures occur unexpectedly and have the potential to affect health services; they can compromise patient health and sometimes lead to death.

The aims of this study are to explore The Kingdom of Saudi Arabia healthcare usage of EMRs and risk factors that leads to system failure and demonstrate the benefit of STAMP for RM in EMR system, define gaps and provide suggestion based on international best practice

The study was conducted in three phases. The first phase explored EMR system usage and failures. The second phase implemented the STAMP risk management technique at one hospital of our 8 surveyed hospitals, the King Khalid General Hospital's (KKGH), to identify and manage risks. In the third phase, the study modified the STAMP technique and reapplied it. The modified technique STAMP Checklist (STAMPC) was compared with the original STAMP technique. We found that STAMPC is much more usable and subjectively beneficial for the hospital that uses a hybrid system. Data extracted using the modified technique provided more useful information to improve EMR system safety, and prevent potential failures.

This study addresses the challenges of how effectively RM techniques used to reduce the potential risk of EMR system failures in hospitals. It improves the efficiency of the STAMP risk management technique by proposing a new (STAMPC) technique.

There are 3 important implications for both RM and EMRs practice: first, the study suggests that RM and EMRs are integral parts of the management decision-making process; second, they are necessary to improve human health and safety; and, third, RM may minimise the possibility of system failure.

**Key Words:** Risk management, EMR system, Saudi Arabia, IT, STAMP and STAMPC

## *Dedication*

I declare that the work described in my thesis is original work undertaken by me for the degree of Doctor of Philosophy, at the Software Technology Research laboratory (STRL), De Montfort University in Leicester the United Kingdom. No part of the material described in this thesis has been submitted for the award of any other degree or qualification in this or any other university or college of advanced education.

*Abdullah Omar B Al-barnawi*

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# *List of Acronyms*

## *Acronyms*

## *Introduction*

- AECL Atomic Energy of Canada Limits
- ASA American Society of Anaesthesiologists
- BDD Binary Decision Diagram
- BEMRs Basic Electronic Medical Record System
- BNHI Bureau of National Health Insurance
- CEMRs Comprehensive Electronic Medical Record System
- CST China Standard Time
- DT Domino theory
- EBS Electronic Brain Storming
- Echo Electro cardio graph
- eHC Electronic Health Card
- ER Emergency Room
- ETA Event -Tree Analysis
- FMEA Failure Mode Effect Analysis
- FMW Female Medical ward
- FSW Female Surgical Ward
- FTA Fault Tree Analysis
- HACCP Hazard Analysis and Critical Control Point
- HDU Haemodialysis Unit
- HW Hardware
- IC Infection Control Unit
- ISO International Standards Organisation
- IST Information System Technology
- KSA Kingdom of Saudi Arabia
- LAS London Ambulance service
- LR/DR Labour Room/ Delivery Room.
- MD Medical Device

- MMR Manual Medical Record
- MMW Male Medical Ward
- MODA Ministry of Defence and Aviation
- MSPW Male Specialist Ward
- MSW Male Surgical Ward
- NASA National Aeronautics and Space Administration
- NEHR National Electronic Health Record
- NICU Neonatal Intensive Care Unit
- NSWWS National Severe Weather Warning service
- NSY Nursery
- OBW Obi gynaecology Ward
- OPD Out Patient Department
- OR Operation Room
- JCAHC Joint Commission on Accreditation of Health Organisations
- PHC Primary Healthcare Centre
- PHTLS Pre Hospital Trauma and Life Support program.
- PICU Paediatric Intensive Care Unit
- PPS Palin Perspective Scale
- RCA Root cause analysis
- RM Risk Management
- RPN Risk Priority Number
- SANG Saudi Arabia National Guard
- SM Smart Card
- SPSS Statistical Package for the Social Science
- STAMP Safety Theoretical Accident Model Process
- STAMP Checklist Safety Theoretical Accident Model Process and Checklist
- SW Software
- VAS Visual Analog Scale

# Chapter 1

## Introduction and forming Research Problem

### Objectives

---

- State the Research Problem
- Describe Research Questions
- Research Objectives
- Methodology
- Research Plan.



### 1.1 Introduction

Risk management is a demanding and challenging field of electronic government program (Data Computerisation), in many sectors such as the security, banking, business and healthcare domains in Saudi Arabia and elsewhere. In health care, the increasing number and severity of medical errors attributable to interactions with medical equipment has increased the concerns of health care providers about the importance of risk management.

Traditionally, risk has been regarded exclusively as a negative concept that organisations should try to avoid or transfer. The way risk management is set within a hospital context is usually called “*risk management framework*” (Purdy, 2009). This involves a number of elements; risk controlling is an important part of the process. It was created to sell insurance in banking sectors, although this is surely an over simplification and cannot be generalised to other sectors (Talbot, 1981, p. 15). It is true that risk management plays a vital role in some countries’ life insurance, such as in Korea, before the financial crisis in 1998. The risk management system was very frail in Korea but the financial crisis brought changes in risk management. Seven out of 30 insurance companies went bankrupt, the crisis made others realize the importance of controlling risks so they built up a risk management system from their experiences. By this effort, the Koreans have quickly overcome the recent global financial crisis (Huh, 2011).

Risk management is recognised as an essential contribution to business, health and project success (Hillson and Murray, 2007), in terms of saving time, reducing costs and eliminating potential failures before the damage occurs. There are extensive literatures on the benefit of risk management; Lancaster, et al (2003) established that “investment in injury prevention by managing risk results in economic benefits” (Lancaster et al., 2003 in Albert and Hallowell 2013, p. 120). Lins and colleagues stated that an effective risk management process reduces the level of financial cost, allows organisations to better plan (Lins et al., 2011, p. 525). A project with an effective risk management program aims at early identification and recognition of risks and then actively changes

the course of action to mitigate and reduce the risk (Dhlamini, et al., 2009, p. 34). Risk management identifies favourable alternative courses of action, increases confidence in achieving project objectives, enhances chances of success; reduces doubt and duplication of effort (Bannerman, 2008, p. 2118). Therefore, an effective risk management structure programme in health sectors, or elsewhere, allows us to understand the risk in any initiative and helps us to take informed decisions on how the risk should be managed (Holmes, 2004, p. 14).

Furthermore, managing risk of technical error has been established, tested, and approved in the nuclear industry, which known as a high-risk sector (G & Zipper, 2006). Kwiatkowski, (1998) says that "risks are inherent in everything and that no physical work or projects can be considered to be absolutely safe". Likewise, the health care sector represents a sector of high-risk areas (Sara, 2008). Risk management to control errors in healthcare is still missing even though technology has functioned to provide excellent solutions for managing risk and failure; however, health care domains still have difficulty in finding acceptable solutions for identifying and controlling risk in order to prevent failures.

According to researchers, there have been many reports of medical errors, for example, Kohn et al., (2000); Kazley & Ozcan (2008, p. 497) declare that there are about 98,000 American deaths each year as a result of preventable medical errors. A recent study showed that the National Patient Safety Agency's Reporting and Learning System received 129,419 reports of incidents relating only to surgical specialiss across the UK in 2007 (Burbos and Morris, 2011, p. 24). Moreover, Bos et al., (2011) reviewed that the total medical and productivity cost for undesirable events in Utah and Colorado USA was \$662 million a year in 1996, of which \$308 million was due to medical error. Risk can be raised anytime and anywhere, at home, work environments, etc. Therefore, it requires specific and immediate management actions (Office of Government Commerce, 2007). The need is to protect people from threats and injuries in order to achieve acceptable outcomes.

Since we accept the fact that there are no ways to guarantee a completely risk free environment, at the same time we know, every deed we perform in our lives involves some kind of risk thus, developing an effective formal risk analysis and risk management strategy may help us to assess risks surrounding us and can help decision makers to decide on what actions are to be taken in order to mitigate or avoid risk. Therefore, risk management is a fundamental discipline within all businesses, regardless of their market sector or size (Holmes, 2004, p. 9).

Higson (1996) documents patients and the healthcare staff in hospitals, other health care providers should be protected from harm, and injuries at all times. There are incredibly simple procedures for building and equipment to protect customers and staff from harm. In this study, we are trying to protect patients, families, and hospital performance from the impact of EMR system failures by managing risk.

### **1.2 The Scope of the Research**

The scope of this research is to determine; the level and extent of usage of electronic medical record systems (EMRs); identifies risk factors; evaluate and establish STAMP technique; and applying it within the health care domain in order to detect, mitigate, and manage risks to improve safety and quality of health care performance which relies upon the electronic health record system (EHRs) in KKGH Riyadh Region. This is then followed by evaluating the use of qualitative and quantitative methods to enhance the technique (STAMP) to be suitable for hybrid system and reapplied in the hospital.

There are only few risk management studies, related to the Electronic Health Record system in Hospital thus we intend to conduct this research to reviews, EMRs, and RM methodology in the field and shows the viability of STAMP approaches to RM in the hospitals that have recently adopted EMR system for quality improvement of their services.

### **1.3 Statement of the research problem**

Most previous studies in risk management have been focusing on the factors contributing to system failures. Errors are often generated from human acts and system operation. Therefore, building a safe environment for an employee in hospitals, and implementing a secured electronic health record system backed up with properly trained staff are very important issues. Studies have shown that nearly 80-90 percent of all major errors are committed by humans and 10-20 percent by systems (Reason, 1997, p. 25). Researchers learned that errors made by humans were more difficult to predict than mechanical or electronic components (HIMSS, 2009, p. 14). We also know that errors take different forms, different psychological source, and condition in different parts of the system and need different methods to be managed. Having introducing the area of EMR system and RM study, now we are focusing on the research problem.

Weekly, electronic medical record system failure in our hospitals was detected by using mixed methods, questionnaire, and observation in addition to the experience during the first phase of this study, which I called the phase of data collection. The methods used for data collecting and analysing was a part of qualitative and quantitative methodology. During this phase, we adopted many problem related to risk management approach. In one of my personal communication with directors of IT unit in KKGH and Prince Salman hospitals, they cited that they do not know exactly why the system is getting down frequently that means there is need for risk management and improving communication between the managers and heads of departments in order to overcome this type of problem.

Therefore, in hospitals there is no doubt that the electronic medical record department is considered as one of the most important retrieval and communication units. The department has been identified as an essential branch of the health care system due to the increasing requirement of safety and dependability by clinicians, patients, stakeholders, managers and other governmental sectors. This chapter illustrates the structure of the research questions, research objectives, in addition to the research plan.

## **1.4 Research questions**

Research questions exemplify clear direction and scope for the research project Walliman (2007, p. 32). The major question of this research is well developed STAMP enhance risk and prevents system failure in hybrid system? The other following research questions are adapted through experience and reading exploring several books and articles in the area of EMRs, RM and techniques.

1. Can we improve the quality of hospital performance by developing and implementing an appropriate Electronic Medical Record (EMR) system and Risk management technique for example, using STAMP risk management technique to reduce risk?
2. Will managing risks in the health care field by using STAMPC provide a high quality care?
3. How should risk management in an EMR system be carried out?

The answer to the these research questions challenge and evaluate the claim that the implementation of effective EMR system in hospitals and other health organisations will facilitate the achievement of quality of service, increase safety, reduce errors, speed-up services and cut-costs by analysing EMR systems and associated Risk Management process..

## **1.5 Research objectives**

Understandable objectives are the means to success of the whole work (More, 1987). The research objectives of the three phases of this study are; to find out hospitals that use EMRs, measure the level of usage, identify failures and risks, applying appropriate risk management techniques to mitigate risks and prevent system failures and adapting STAMP and introduce checklist to make it suitable for sensing our hybrid EMR system and user behaviour

The EMR system involves different processes starting from deploying the system, data entry, to effective decision making. In addition to a holistic risk management, technique

usage can help to identify potential risks and prevent failures. Therefore, this work intends to approach the following main and specific objectives:

- Classifying hospitals that have Comprehensive EMR, Basic EMR system, and Manual Medical Record in Saudi Arabia
- To find out problems or failures that have occurred when using the system
- To discover the causes of the system failure
- To mitigate risks that lead to major failure.
- To examine the concept of risk and failure
- To describe the most appropriate risk management techniques for managing EMRs failures
- To identify risks in hospital's electronic medical record systems.

The specific objectives can be achieved: by

- applying the STAMP technique developed by Nancy Leveson (2004)
- developing the STAMP technique in order to be suitable for hybrid EMR system
- evaluating the technique in hospitals located in the KSA in order to improve the hospitals ability to deliver a better quality performance
- drawing conclusions on the effectiveness of the risk technique in accomplishing the stated objectives
- supporting decisions makers through a good understanding of threats (risks) and impacts.

## **1.6 Criteria for evaluating the research questions**

Numerous researchers have proposed different criteria for evaluating the quality of research by applying qualitative and quantitative method such as case study. For example, Yin (2009) and Strauss and Corbin (1990) illustrated a set of criteria appropriate for Grounded theory by ensuring that concept categories and theories are fully developed and grounded. A criterion is standard of judgment or rule for principle for evaluation work. The criteria used to evaluate the contribution of this work are:

- To reduce the time takes the patient to see the Doctor
-

- To reduce the Electronic Medical Record system failure by using STAMPC technique
- To safeguard patients data
- To perform good quality services for the patient and families

They are carefully planned to evaluate the objectives, impact, and the effectiveness of this study

### **1.7 Research Methodology**

Different methods have been considered as appropriate for this research, which involves quantitative and qualitative data. A combination of research methods will be used in this study to collect data, more specifically, we will use a cross sectional questions, followed by close observation method and case study to find out sentinel events have previously occurred. For instance, a system failure or serious accident may have occurred due to the ineffective use of medical devices. (Kane, 1990, p. 51) states that a questionnaire tells us what users and providers do and what they say and think. On the other hand, under certain situations, observation can tell us what the users do or what types of accidents occur. He also states observation is a good method when someone trying to learn from scratch by recording everything he/she sees and hears in a situation. However, supplementation is suggested by Moore, (1987) supplementing a research method gives the researcher the required scope to the research project.

Walkman, (2006, p. 37) and Clifford et al., (1997) state that a qualitative research method is concerned with non-statistical phenomena and relies more on language and the explanation of its meaning. Similarly Saunders, Lewis and Thornhill (2009, p. 480) acknowledged that qualitative data refers to all non-numerical data.

According to Silverman, (2000) there are three main methods of data collection; interview, focus groups and observation, and these methods can be used in either quantitative or qualitative studies. Thus, the proposed methodology in this research is quantitative and qualitative in nature (questionnaire, observation and case study). A group of subjects have been selected; hospitals to be investigated and observed in order

to obtain information such as previous system failures and risks to be discovered through questionnaires and reinforced by observation.

We plan to conduct small-scale test (pilot study) earlier to test the research questions and ensure the validity and the reliability of the questionnaire. One of the most important benefits gained from the pilot study that was conducted on June 2010 for a period of two Months acknowledged that, without observation, it would not be feasible to participate in a work or investigate an incident or failure in EMR systems. More benefits and results gained from the pilot study are stated in chapter 7.2. For the main survey the plan was to use mixed methods to survey all hospitals operated and supervised by the Ministry of Health in the Riyadh Region (n = 40) for the presence of comprehensive or basic Electronic Medical Record Systems with specific electronic record functionalities and the usage of risk management techniques to mitigate system failures. Then, we distribute our questionnaires to three of the most knowledgeable personnel in each hospital, namely heads of departments, (experts in the field of EMR system, Quality, Risk Management and Information Technology) to find out more technical information about previous failures. The following section discusses the research plan in detail.

### **1.8 Thesis structure**

This thesis is organised as follows: **Chapter 3** sheds more light on Manual Medical Records, Electronic Medical Record, EMR systems, E H R systems around the world and reviews studies related to system failures in the health care domain. Two examples of system failure are explained and analysed in order to understand the process of system failure. **Chapter 4** provides a critical literature review with focus on the development of health care in Saudi Arabia; **Chapter 5** looks at the concept of risk; risk management; risk analysis; risk control; risk assessment; modelling; goals of risk modelling composition, and quality and risk. **Chapter 6** identifies an appropriate risk management technique for an EHR system, brainstorming, and root cause analysis, fault tree analysis, failure mode effect analysis, failure mode critical effect analysis and System Theoretical Accident Model Process, backed up with some example describe

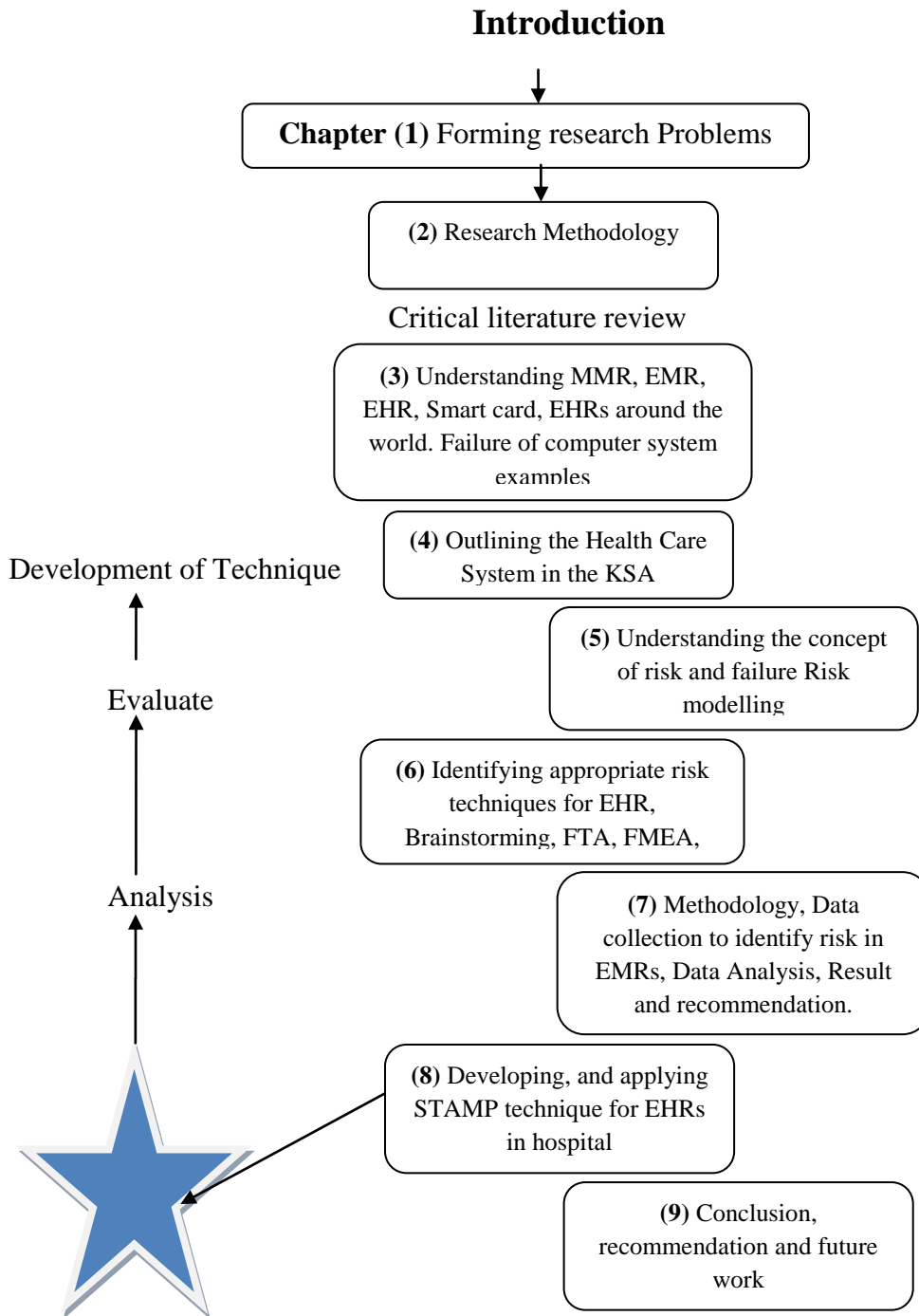
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the usage of STAMP to prevent accidents. The review starts with a definition of all above elements. **Chapter 7** illustrates an exploration of a comprehensive electronic medical record, a basic electronic medical record and a manual medical record system in the Kingdom of Saudi Arabia (KSA). It identifies risks in an EMR system, and categorizes appropriate risk technique for EMRs. **Chapter 8** covers the identification and the application of an appropriate technique in EMRs in the two recognized case studies used during the survey and developing the technique which is based on STAMP. It also establishes a framework for analysing risks, evaluating the technique and demonstrating or applying it in Ministry of Health hospitals as a case study in Saudi Arabia. **Chapter 9** presents the conclusion, recommendations and suggestions for some work worth future investigation.

### **1.9 Research plan**

Figure 1.9.1 depicts the research plan. The research started by forming the research problems, illustrating the healthcare system in the Kingdom of Saudi Arabia (KSA), understanding EMRs, EHRs, identifying errors and risks in the system, understanding the concept of risk, failure, identifying an appropriate risk management technique for EMRs, case studies, developing a technique for managing EHRs failure and finally applying it in one of the hospitals in the Kingdom of Saudi Arabia.



**Figure 1.9.1 research plan (story line).**

## **10. Summary**

This chapter illustrated the research methodology used in this study, which includes the research problems, research plan, questions, hypotheses, and objectives. Most previous experiment and research in risk management have been focusing on factors contributing to system failures these concerns thrown up some unclear area of interest where not followed up. In this study, we are trying to prove the proposed hypothesis “established risk management techniques can be applied to Electronic Medical Record system to prevent failures”. In addition, find answers to the research questions. The specific objectives of the study are measurable, achievable and realistic so, that the research problems were explored effectively.

The following chapter will present research methodology, which begin with an introduction and description of the principal and research models.

## **Chapter 2**

### **Research Methodology**

#### Objectives

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- Justify and state the importance of research
- Describe thesis structure
- To identify appropriate data collection methods to achieve the research objectives and answer the research questions
- Justify the importance of the research
- Pilot study conducted to evaluate and assess the questionnaire design

## 2.1 Introductions

The aim of this chapter is to describe the research methodology adopted by this study to investigate the EMR system usage and risk management technique (STAMP) implementation within public health care sector (MOH) in Saudi Arabia. The chapter introduces the theoretical background of research models namely: Positivism (quantitative) and interpretivism (qualitative) and augmented with the use of case study. Finally, it offers pilot study and data collection

The remainder of this thesis is organised as follows: **Chapter 3** sheds more light on Manual Medical Records, Electronic Medical Record, EMR systems, and E H R systems around the world and reviews studies related to system failures in the health care domain. Two examples of system failure are explained and analysed in order to understand the process of system failure. **Chapter 4** provides a critical literature review with focus on the development of health care in Saudi Arabia. **Chapter 5** looks at the concept of risk; risk management; risk analysis; risk control; risk assessment; modelling; goals of risk modelling composition, and quality and risk. **Chapter 6** identifies an appropriate risk management technique for an EHR system, brainstorming, and root cause analysis, fault tree analysis, failure mode effect analysis, failure mode critical effect analysis and System Theoretical Accident Model Process, backed up with some example describe the usage of STAMP to prevent accidents. The review starts with a definition of all above elements. **Chapter 7** illustrates an exploration of a comprehensive electronic medical record, a basic electronic medical record and a manual medical record system in the Kingdom of Saudi Arabia (KSA). It identifies risks in an EMR system, and categorizes appropriate risk technique for EMRs. **Chapter 8** covers the identification and the application of an appropriate technique in EMRs in the two recognized case studies used during the survey and developing the technique which is based on STAMP. It also establishes a framework for analysing risks, evaluating the technique and demonstrating or applying it in Ministry of Health hospitals as a case study in Saudi Arabia. **Chapter 9** presents the conclusion, recommendations and suggestions for some work worth future investigation.

## 2.2 Research Philosophy and paradigm

All philosophical positions and their attendant methodology implicitly hold a view about social reality (Walliman, 2007. p. 15). This study will determine what can be observed as valid knowledge

In general, research is a word lightly used to describe a great number of activities, such as collecting information regarding accident and producing new products or solution. The term has been defined scientifically by many researchers for instance, Leedy (2001, p. 5) defined it from a more functional point of view saying “ *Research is procedure by which the researchers attempt to find systematically, and with the support of demonstrable fact, the answer to question or the resolve of a problem.* So, research is one of the ways of collecting accurate data about the effectiveness of the researchers’ intervention, and find answers to proposed questions.

Paradigm or a model is a cluster of belief or certainty that influences scientists in a particular discipline what should be studied, how research should be done and how result should be interpreted (Bryman, 2012, p., 630). Others say paradigm is “*A set of assumptions of thinking about some aspects of the word*” (Oates, 2006, p. 282)

There are different philosophical paradigms with dissimilar vision about our nature and the ways to collect knowledge. Epistemology and Ontology are two types of paradigms with the former concerned with how the researchers know things and what they can keep as tolerable knowledge in a discipline. The latter is concern with what exists and needs to be investigated (Walliman, 2007, p. 15).

Our philosophical orientation stems from one of several divisions of paradigms and approaches namely: Positivism, Interpretivism, Realism and Qualitative and Quantitative. Kumar, (2011, p .15) stated that no matter which paradigm a researcher works within, he or she should stick to certain values regarding the control of bias and the maintenance of objectivity in drawing conclusions. In the search of knowledge, we found that these paradigms relate to scientific methods and human subjectivity. Those commonly used in information technology system have been chosen.

## **2.3 Positivism**

Positivism is an epistemological position that advocates the application of the natural sciences to the study of social reality (Bryman, 2012, p. 28 and Walliman, 2007, p. 15). This paradigm lend itself to both qualitative and quantitative research methodology (Kumar 2012, p .14)

### **2.3.1 Interpretive**

Interpretive is a term that usually denotes an alternative to the positivists accepted view that has held influence for decades (Bryman 2012, p. 30). Both can be used within mix methods including case studies.

### **2.3.2 Selection of Model for this study**

The model used in this study is what social science calls the “natural science model of social science" Lee, (1989, p. 34) specified that the natural science is the ideal model to be used in the social science. For example, in the field of management the natural science model is well-known and widely used for conducting studies.

Orlikowsky and Baroudi (1991) argue that the interpretive paradigm is the most appropriate model to adopt for social science research for many reasons: it is more fitting if the researcher is studying people in their natural social environment. On the other hand, positivism lends itself to both qualitative and quantitative research study (Kumar 2012, p. 14). Qualitative research is often associated with interpretivism, whilst quantitative is associated with positivism (Goldkuh, 2012). There are two types of research; filling knowledge gap and problem solving. This study will use the validity of both types to form the most appropriate methodology in detecting the solution information solving the problem of weekly system failure of EMR system in the KSA Hospitals.

Initially, this study will need to find a method of filling gaps in the knowledge of the IST and RM in hospitals. Thus, the most well-known research philosophy paradigm is positivism. It is appropriate for dealing with real situation such as EMR system failures this quantitative and qualitative field study will include questionnaires to get

information, and problems that phased the hospitals EMRs, from the most knowledgeable personal.

Phase two of this study will solve the original problem of the weekly EMR system failure in King Khalid General Hospital (KKGH) in Saudi Arabia through Interpretivism qualitative, deductive research paradigm reasoning to develop a holistic technique based on STAMP for resolving the problem. Therefore, our selected models to conduct this research are interpretive qualitative and positivism quantitative augmented by case study.

### **2.4 Review of the Literature**

One of the vital preliminary task when a researcher thinks to undertake a research study is to go through the available literature in order to know the available frame of knowledge in the area of your work or interest. The literature review is an integral part of research process that makes a valuable contribution to almost every operational step (Kumar, 2011, p. 30). The resources used are books, journals and internet in addition to government reports. The literatures I have gone through helped me to develop the research questions and the research framework in addition it consolidate my knowledge with the existing body of knowledge. The review starts from chapter 3-5. Which involves the following areas: electronic health record system, risk management in healthcare, risk assessment techniques and system failures?

### **2.5 Subject selection**

We have selected all hospitals located in Riyadh region as study population in order to avoid bias and attainment of maximum accuracy .Then we chose the participants in each hospital due to their knowledge about the hospitals units specially the QM, MR, IT units in addition of their participation in quality improvement, patient safety and other hospital's committee meeting

### **2.6 Data collection and analysis**

After formulating a research problem, developed study design and constructing research problems. It is very important to decide how the data will be collected. There are two

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major methods for gathering information; primary sources and secondary sources the former consist of questionnaire, observation, interview and case studies the latest involves documents (Kumar, 2011. p. 139). This section presents and discusses the data collection methods used in this research; questionnaire was used in the phase 1, observation and case study are used in phase 2, a critical analysis of the data and models.

**Questionnaire:** is a written list of questions, respondents' record the answers on the sheet. Because, there is no one to explain the meaning of questions to respondent, it is significant that the questions must be clear and easy to understand (Kumar, 2011, p. 145). The main purpose of using this method is to collect data that is not easily available in the literature (Remenyi et al., 1998). Using this method enables researchers to organize the questions and receive replies without actually having to talk to every respondent in addition of its flexibility (Walliman, 2011. p. 88). The designs of our 36 questions involve two forms of questions open-end and close in order to get the information need easily from the respondents.

**Observation:** is a method of recording conditions, accidents, and activities through looking rather than asking questions (Walliman, 2006., p. 95) it can be used in to record both qualitative and quantitative data. Others said is a focused, systematic and selective method of watching and listening to an interaction as it takes place, there many situations in which observation is one of the most appropriate method of data collection.; for instance, when you want to learn about the interaction between workers or discovering the function performed by workers ( Kumar, 2011., p. 140).

Observation informs us and makes us test our 'common sense' hypotheses (Foster, in Rogers and Victor, 1996, p. 57). Moreover, Walliman (2006, p. 96) states that observation is not limited to the visual senses, and it enables us to gain an overall view of a shared environment. Thus, we used a questionnaire, observation and case study in our study to observe the users' behaviours and their use of existing equipment in their normal environment

**Case study:** thought dominantly a qualitative method, it also common in quantitative research (Kumar, 2011. P. 126). A case could be an individual, a group, an event, or accident. It is a very useful method when, exploring an area where little known about and you want to have a holistic understanding of the situation. Yin (2009) stated that Case study helps researchers to answer "how and why questions. She also suggested five important characteristics for case study design they are as follow: "a study's questions, propositions, units of analysis, logical linking the data to the propositions and the criteria for evaluating the finding" (Yin, 2009, p. 27). The data collection methods used in this study mixed qualitative and quantitative method to understand and explore the usage of EMR system and risk management process in hospitals.

This section includes three main tasks. The first is data collecting from the MOH statistical books. This can be achieved by interpreting the collected qualitative and quantitative data and identifying its solidity. The main data gathering methods was through questionnaire sent to the most experienced subject staff in each hospital. The questionnaire method was selected to gain knowledge, opinions, and information toward the study objective. The collected data is also used for enhancing the hospital staff to use the EMR system and risk management technique effectively in order to prevent system failures. The outcomes of the use of questionnaire have helped us to identify the classification of MOH hospitals in Riyadh, provide us by risks that face our EMR system.

### **2.7 Pilot Study**

A pilot study is small-scale test that is needed to be done before the main study. It intends to measure the sufficiency of the study design and the methods to be used for data collection. Piloting the data is very important, it helps to estimate the rate of data quality, and the sample must represent the diverse individuals that the main study is intended to cover (Wilson, in Roges and Victor, 1996, p. 103). Other authors have suggested the importance of testing the research questionnaire prior to distribution to ensure the validity and reliability of the survey's format and questions. The pilot study is importance of testing the research questionnaire prior to the main study to ensure the

validity and the reliability of the survey, format the question. There are many other reasons motivate us to conduct the pilot study for example, to know how and where good quality information can be founded in hospitals, to make the questions precise and understandable for the respondents Chapter 7.2 shows more reasons, benefits and the main outcome of the pilot study.

## **2.8 Summary**

There are several ways of collecting data, understanding information and finding answers to questions research methodology is one way. The only difference between research and other ways of collecting data and answering questions is that in a process that is classified as research, which work within a framework of a set of philosophical method that has been tested for reliability and validity. Our philosophical direction branches from two of a number of paradigms, interpretive and positivism, the former paradigm lends itself to qualitative research and the latter lends itself to quantitative.

Questionnaire, observation, and case study are used to approach the objective of this study. Pilot study was also presented briefly. Its main outcome can be seen in chapter 7.2

The following chapter will present a brief review of an electronic health record system around the world. It will begin with a description of a Manual medical record followed by discussing the context of our research.

# Chapter 3

## Electronic Health Record Systems

### Objectives

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- To give a brief history of Manual Record Systems
- Describe expressions used to express Electronic Medical Record Systems
- To illustrate the purpose of implementing an EMR system in hospitals
- To present benefits of EMR systems
- To describe the use of EMR systems around the world
- To point out examples of system failures in the health care field
- Methodology for literature review

### 3.1 Introduction

Thousands of patients die every year due to medical errors and improper treatment caused mainly by human and technical factors (Chamberlain, et al., 2012; Pham, et al., 2012). These types of problems could be tackled in many ways, including the use of an effective electronic medical record system (EMRs). The adoption of effective EMR system may lead to major health care savings, reduce medical errors and improve health (Hillestad et al., 2005, p. 1103). It is important to note that Hippocrates developed the first medical record in the fifth century B.C. and the earliest EMRs began to appear in the 1960's (Mclean, 2006, p. 1). Now there is general agreement by system providers and users that EMRs have a potential to improve the quality of hospital service, reduce cost and decrease errors. Researchers have found that the implementation of effective health information technology benefits the hospital management of patients by improving the quality of care provided (Woosley and Khan, 2012, p. 12; Bleich and Slack, 2010; Wills et al., 2012, p. 2832; Taylor et al., 2005, p. 1234). The scope of this chapter is to review and assess the current state of knowledge in the usage of health information technology (HIT) to support hospital's electronic medical record systems. The study is mostly based on literature review and practical work in hospitals.

The literature gives much information regarding unpleasant events in many sectors, including health care, in both the developed and developing world. System users are facing a sequence of catastrophes in many fields. Preventable errors have been threatening the lives of millions of patients around the world, especially in developing countries. Bos, et al., (2011) believed that medical errors are a preventable adverse outcome, which results from inadequate medical management. Similarly later statistics show that Management of information is one of the essential goals of Health care (Fraser, et al., 2005). Therefore, the leading factors for medical errors and infectious diseases are lack of infrastructure, trained, experienced personnel and proper management. According to Kazley and Ozcan (2008), health care delivery has been neglected by the revolution in information technology, which has nearly touched every other field. Since 2001, many efforts have been made to increase the use of health

information technology (Kazley and Ozcan 2008, p. 496-497). From the time when publications showed error could be caused by humans, EMRs and related health information technologies have been encouraged to be used in order to improve patient safety and quality of hospital performance. This encouragement is still largely unfulfilled (Radecki, 2011, p. 92). But the development of health information technology and electronic medical record systems (EMRs) helped health professionals to improve patient's care, patient's safety and to simplify compliance in the use of health care systems, as well as to reduce cost, incidents of adverse drug effects and minimise errors (Venkatesh, et al., 2011; Hess. Cathy. Thomas, 2010 p. 48, Bleich and Slack, 2010, p. 2.). An EMR system plays a significant role in a medical information system; it involves the capability of storing, retrieving patient's information and helps managers to make or choose appropriate decision (Ke, Chiu, et al., 2008, p. 140).

To be a successful health care provider, one has to be concerned about the implementation of a comprehensive and workable electronic health record system that improves and supports the care process. An extensive literature review showed that many hospitals worldwide have used an EMR system, yet in the USA, about 26.1% of hospitals use an EHR system (record about the patient's lifetime) (Li, et al., 2012). In the UK the ambition of providing an EHR system to every patient by the year 2010 has suffered delays due to dilemmas with their software, therefore the project has been pushed back to 2014 (Chen & Akay, 2011, p. 63, Bleich and Slack, 2010, p. 2). Nevertheless, the National Health Service (NHS) is counted as one of the largest National EHR projects currently in the world.

Saudi is a developing country that often uses manual medical records (MMR) that are inflexible to manage. In the kingdom of Saudi Arabia sharing of patient's information between hospital's departments and other health care providers is still performed manually (Al-Sfadi 2009, p. 85). Recently the country started moving from MMR to an EMR system, to overcome the limitations of the paper based Medical Record and to gain the benefit of a computer based EMR system. A study done by Bah and his colleagues to determine the level and the extent of use of EMR systems in governmental

hospitals in the Eastern Province of Saudi Arabia showed that only three hospitals out of 19 use EMR systems (Bah, et al., 2011).

This chapter presents a focused review of the literature on EMR system including the three widely used terms to describe patient health record namely: the manual medical record (MMR); an electronic medical record (EMR) system; electronic health record (EHR) system; components of EMR system in hospital; Smart cards and a brief description of electronic health records around the world in addition to their importance in avoiding unsafe medical services and improving the quality of healthcare provided in hospitals and primary healthcare centres (PHC). However, work to achieve fully comprehensive EHRs all over the world, especially in the developing countries is still far off, effort has been set in motion as long as institutions and governments believe that the use of EHR systems helps health care providers to improve the quality of patient care and the competence of clinical service (Su, et al., 2009, p. 56).

### **3.2 Manual Medical Record (MMR)**

MMR and EMR system are involving the same following information: patient demographics, progress notes, medications, vital signs, medical histories, immunizations, laboratory tests, radiology reports (MITRE, 2006, p. 1). The former is based on paper work, which demographic characteristics of the patient, physicians notes, medication lists, nursing notes, and discharge summaries, referral papers if the patient has been transferred from primary care to hospital, or from one hospital to another, laboratory test results, radiological report, MRIs and dietary list and so on (Kazley & Ozcan 2008 p. 494, Grant, 1979).

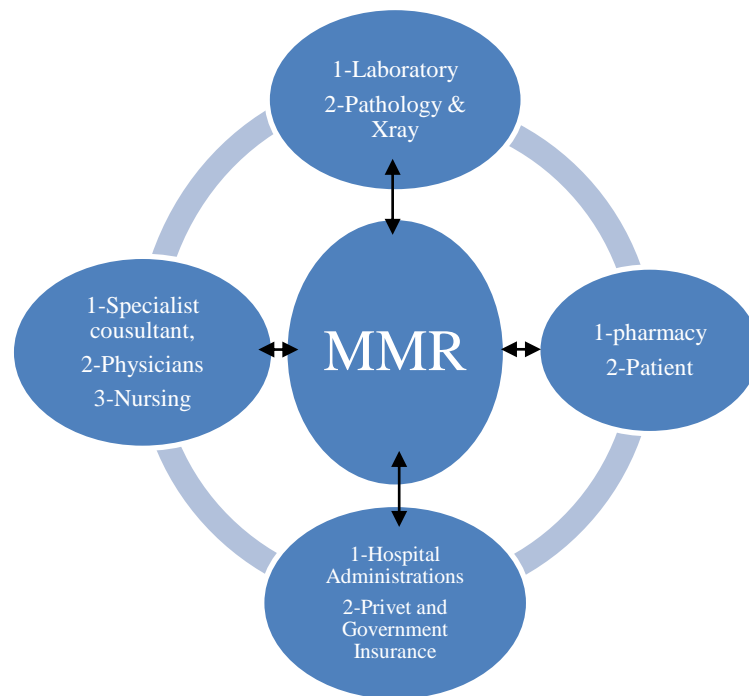
Besides what the manual records involve, the numbers of users and the complexity of medicine have constantly increased the problems that face the users', such as the great amount of time needed to answer specific information queries from other health care providers (Klepack & Neill, 2007; Farsi & West, 2006 p. 17). More problems will be discussed in the following subsection.

Recently, Su, et al., (2009) declared that in hospitals a patient's medical record involves data and information that vitally needed by professionals for treating patients.

Furthermore, Kazley and Ozcan (2008, p. 497) stated that patients cannot transfer their medical record between their health care providers due to the lack of comprehensive, and effective EMR system and this can lead to an incomplete view of their medical history and possible duplication of services . These brief limitations lead many health care providers in developed or developing Countries to move their practice from Manual Medical Record, or a paper based method, to an electronic medical record system, that performs the same functions in a much faster by the use of computers with appropriate input and output terminals and displays. That does not mean the usage of manual medical records has no benefits.

Saudi Arabia is one of the developing countries in the Middle East that has currently started to implement separate Electronic Medical Records system in its hospitals and primary health centres. There is more than one governmental health care provider in the Kingdom of SA. Almost all Ministry of Health hospitals still use manual medical records and a number of other governmental hospitals have already started using some sort of EMR system.





**Figure 3.2.1 MMR Users**

Ministry of Health (MOH) hospitals and other health care providers in Saudi Arabia have almost all noted a number of limitations using MMR, in addition to the extent of medical errors that cause deaths in hospitals. Saudi Gazette Newspaper has currently revealed the death of 21 patients due to medical errors in a report which was released in 2010. In Al-Madina City, an investigation showed 21 death cases out of 43 were due to errors committed by medical professionals. Many believed that errors in medical prescriptions are often correctable. Unfortunately, there are lots of medical errors which are not reported in the media and not effectively documented on the premises. Therefore, the government of Saudi Arabia has been encouraging the health care providers to use EMR system in hospitals and Primary Health Care to improve the quality of care and to support MR safety and security. The following subsection discusses the problems of Manual Medical Record in hospitals.

### 3.3 The problems of Manual Medical Record

In general, the primary Medical Record Department has three functions. The first is to create, store and retrieve the patient records and the second is the provision of statistical information for medical and administrative staff, while the third function is dependent on the hospital type for example, specialist and research hospital provides researcher data. MMR has a long and ancient history extending over thousands of years. But, it is a far cry from the old ideas regarding problems of medical recording to such modern concepts as the total hospital information system (Grant, 1973, p. 191). Before going on to consider the EMRs in detail, discussion the reasons for transferring the MMR to the EMRs is important. We call these reasons problems of the MMR. Besides the benefits that MMR involves in protecting patient information, the number of users and the complexity of medicine have increased and problems of manual record usage start to be revealed. The following are some detected problems from hospitals using MMR. Klepack & Neill, (2007) stated some problems including *growing paper chart in each active file which is becoming thicker, access becomes more difficult for the users, demand for more than one store at one time as regards the number of users in different units, charts lost, misfiled, pages falling out of the files, notes entered in the wrong order and sometimes whole files being misplaced or lost*. Also a great amount of time is needed to answer specific information queries (Klepack & Neill, 2007; Farsi & West, 2006 p. 17). These problems could be mitigated with the deployment of comprehensive EMR system. Many scholars stated that implementation of EMRs in health care has been planned by many organisations as a strategy to reduce cost and improve quality of care (Woosley and Khan, 2012, p. 12)

Recently, Greenberg has said that the use of EMR system in hospitals can reduce the risk of duplication of blood testing by enabling doctors to track patient's care (Greenberg, 2011). In 2005 a report by RAND predicted that the use of EMRs in hospital could save the USA health care system at least 81 billion dollars a year (Taylor et al., 2005, p. 1234; Leshner & Weinstein, 2013). Thus, the automation of hospital's

Manual Medical Records in Saudi Arabia and elsewhere is an essential development to facilitate the successful usage of health care premises.

### **3.4 Electronic Medical Record System**

The term Electronic Medical Record used to represent an automated system based on document image. Electronic Medical Records involve the same information and data that the manual has. Doucette & Ludwick asserted that EMR systems are a computerised health information system where the users record patients detailed such as patient demographics, medical history, allergies, and lab test results (Ludwick and Doucette, 2009 p. 22). Other such Waegemann stated that the EMR system is a record that involves all documentation of care given to a patient (Waegemann 2002, p. 5).

The value of EMRs has been recognised since the early use of computers in health care sectors. It was proposed to improve the quality of patient care, decrease medical errors, and perform the same functions of MMR faster (Li, et al., 2012; Grant, 1973 p. 194). Its usage is the most proficient means of storing, retrieving, supporting and maintaining accuracy of health information (Wossley and Khan, 2012. p. 3). Amatayakul, (2004) documented that the first effort to computerise clinical information was in the 1960s and early 1970s. There is more than one obvious definition for EMRs in literature, among them what Chen and colleagues expressed as ‘a type of medical information system which is dedicated to collect, store, and manage to make the clinical information of patients available to deliver patient’s care (Chen et al., 2011. p. 63).

### **3.5 Electronic Health Record System**

Many health care providers in developed and developing Countries have been using a number of terms to describe the shifting process from Manual Medical Records (MMR) to Electronic Health Record Systems (EHRs). World Health Organisation, (2006) and Amatayakul, (2004) have pointed out some of these terms; patient medical record (PMR), computer-based record (CPR), electronic medical record system (EMRs), automated medical record system (AMRs) and electronic health record system (EHRs)

(WHO, 2006; Amatayakul, 2004). Recently Coiera, (2011) has come up with new terminology, known as summary care record (SCR).

Yet although these terms describe different concepts they are all essential to the success of local and regional goals to improve patient safety, the quality of patient care, as well as to reduce medical errors, support research and education to facilitate disease monitoring and health care delivery costs (Garets, & Davis, 2006; Li, et al., 2012).

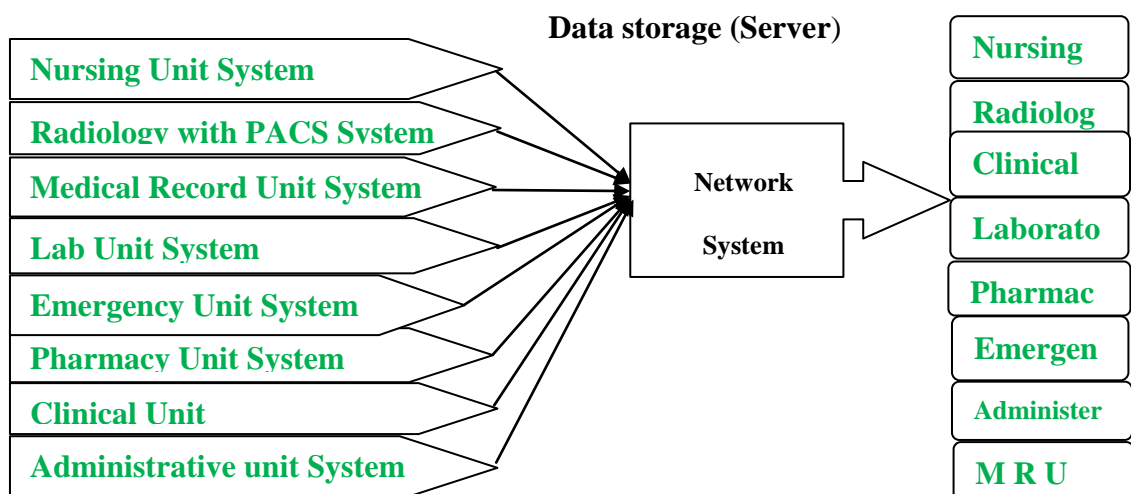
The Electronic Health Record has been defined by Eichelberg, and colleagues as “digitally stored health care information about an individual’s lifetime with the purpose of supporting continuity of care, education and research and ensuring confidentiality at all time” (Eichelberg, et al., 2005). The EHRs involve all information contained in a Manual Medical Record including a patient’s health profile, behavioural, environmental information and others (WHO, 2006; Amatayakul, 2004). According to Rau et al., (2011), EHRs contain more than just a patient’s data; it might also contain dietary and exercise notes.

The term Electronic Health Record is widely used in many countries with a variation in definitions and extent of coverage. It is important to know what definitions are being used and to determine the type and extent of EHRs (WHO 2006). Jha and others have used three definitions for such systems: a comprehensive EHR system, a basic EHR system with clinical notes and a basic EHR system without clinical notes. The former was defined as a system with complete electronic functions in all clinical units, and the latter defined as a system with electronic functionalities in at least one clinical unit (Jha, et al., 2009). Su and others have recognized that comprehensive Electronic Medical Records can potentially lead to better quality and more efficient health care (Su, et al., 2008 p. 140). (EMRs) and (EHRs) are used interchangeably in the USA (Garets & Davis, 2006). However, work to achieve full EMRs in Saudi Arabia is still far off, but efforts are set in motion as long as the health care managers recognise that the new technology helps health care providers to improve the quality of patient's care and the competence of hospital services.

### 3.6 The Components of an EHR system

It seems that an Electronic Health Record system was created to serve each provider and receiver of healthcare. In a hospital all clinical and non-clinical units (departments) are care providers, their main aim is to assist patients. Patients always receive necessary support via Nursing, Laboratory, Radiology, Pharmacy, Emergency and Administration or Admission Discharge Transfer Units, all work as systems.

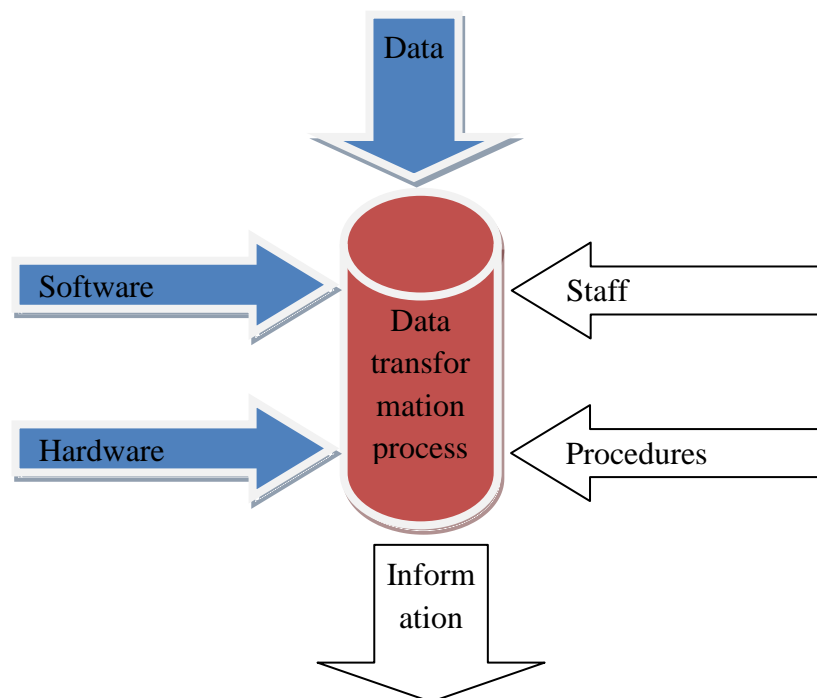
This holistic system should be integrated into a layer to perform the daily task in the hospital. Nevertheless, they are not integrated; they only captured and stored information in a Silo system, so that each system has its own users, with different rules and patient records (Cantrill & Stephen, 2010, Mclean, 2006). The following figure 3.6.1 shows EMRs data storage in a Hospital.



**Figure 3.6.1 EMRs data storage in Hospital**

Each unit has a system to capture patient's data, thus the service provider must open each application to view the specific information according to the policy of the hospital. If the provider needs complete information about patient, he or she must have access to all applications.

On condition that the EMR systems are based on information systems (IS), the providers offer slightly more detailed information concerning the IS components to the hospital's users. Pfleeger and Pfleeger (2007, p. 6) have considered that a computer based system has three separate components: Hardware, Software and Data. Boddy, et al., (2005) stated more detail about the components of a computer stating that they are a set of people, procedures, and resources that collect and change data into information and disseminate the information to others. Similarly, authors such as Sharma and Bhagwat (2005) introduced comparable components of computer-based system saying that a system is a well-organized combination of staff, hardware, software, and communication processes. The network and data resources which collect, transform, and distribute information within an organisation can be seen in the following diagram adopted from Sharma and Bhagwat (2005, p. 200).



**Figure 3.6.2** the components of an IT System. (Boddy et al., 2005, Sharma et al., 2006).

As Wills and colleagues stated, EMRs are not one specific technology. It is often understood as a composite of technologies, including computerised provider order

entry, clinical decision support, administrative, laboratory and imaging systems (Wills et al., 2012. p. 2831). The proper EMRs facilitate the exchange of information across all units within the organisation (Woosley and Khan, 2012. p. 13).

### **3.7 Smart Card to word Mobile health care service**

The smart card is not new technology, its first patent was published in early 1968 by the two German inventors Dethloff and Grotrupp, and they developed the idea of a plastic card containing an embedded chip (Pelletier, et al., 20011, p. 1). In 1992, Germany used the smart card for health care. Later the technology supported a highly mobile health management structure (Chan, 2000, p. 127). Smart cards are commonly used as storage for patient information records and identification purposes in the health care field because of their ability to store text and image (Hsu et al., 2011, Win et al., 2006, p. 311). It is the leading technology for certifying primary user of an EHR system whenever more security is needed (Jacobs and Poll, 2011, p. 1).

However, the use of this technology in the health care domain has fallen behind other industries such as banking, transportation, controlled access to premises and offices as administrative tools for students in universities (Hsu et al., 2011). Chan declared that the delay is almost about 10 to 15 years (Chan, 2000). The smart card is also called an electronic health card; it involves microprocessor-containing information about the patient: emergency data, blood type, drugs used, allergies and other demographic information (Sunyaev and Pflug, 2012). When cooperation between physicians and other health care providers is needed, the patient produces his smart card; the physician inserts the card into a computer in order to have access to the information stored in the card (Aubert and Hamel, 2001, p. 879).

Another purpose of this technology development is to control access to programmes or communications and secure transportation of information like medical data, DNA results, religious affiliation (Jacobs & Poll, 2010 p. 1, Pelletier, et al., 2009, p. 1) furthermore, a smart card usage improves the quality of data provided to the users. The amount of memory on the card when invented was between 2-4 kb, however, nowadays,

there are up to 64 KB (Pelletier, et al., 2009, p. 2). Germany is one of the European countries that use the smart card (SM) nationwide as part of a larger health care reform that took place in 2006 and the ambition was for it to be used in the same year but, due to a variety of problems, the implementation was delayed. The German government's primary goal was to minimise the cost of health care services, but the use also offered an improve method of communication between all parties, and helped patients to utilise their rights. The card served as a key to information stored on the card and online, therefore it contained a microchip, as well as a patient photograph and some readable administrative data. In addition, the back of the card serves as the European health insurance card, which permits all insured citizens of European economic area (EEA) countries to receive medical care in other member states (Sunyaev, and Pflug, 2011). The usage of this technology has various purposes in many sectors; the following subsection describes some of these.

### **3.8 The Purpose of Electronic Medical Record**

Many researchers have asserted purposes of adapting EHR system in hospitals. Solomon, (2005) stated that health care experts predicted that the number of errors could jump in coming years if the providers did not use the EMRs effectively. Chumney, et al.,(2010) believed that the opportunity to reduce costs, errors and to provide more effective and safer health care will be by implementing an effective EHR system, others, such as Waegemann for example, have highlighted on the most significant reasons for adopting the EMR system; professionals are acting blindly, with minimum back ground information of the patient's status, tests are always repeated and the other health care providers also do not know a patient's previously diagnosed condition (Waegemann, 2002., p. 1) . Therefore, the main aim is to provide physicians with information that is easily accessible and fully integrated without delay or requiring excessive navigation in order to prevent events. This is one of the extremely important aims amongst many. In the following section, we will present more advantages that have been found in the literature review regarding EHRs.



### **3.9 Benefits of EHR system in Hospitals**

There are many other advantages that can be derived from a successful usage of EHRs. This could include, but are not limited to, the following: patients will be solely identified at all time; all healthcare information generated within the hospital will be documented at the point of care; standard language will be used to ensure information is commonly understood; all records will be precise, reliable, and completed quickly; information about a patient will be immediately available at all times; quality of health care will be improved by providing better information for physicians to make the right decisions regarding treatment planning; patient confidentiality and privacy will be sustained; morbidity and mortality statistics will be completed precisely and accurately; problems related to the loss of files and replacing notes wrongly will be mitigated; problems related to storage of the records will be solved; reduce health care costs resulting from incompetence; reducing medical errors and inappropriate care; data being available and shared at several sites, several users can enter data at once; data can be stored or backed up automatically at more than one place; physicians can easily access previous records and they can check on the outcome of individuals, or groups of patients, and perform research studies; and uplicate prescribing and testing reduced (WHO 2006; Farsi & West Jr 2006; Fraser et al., 2005; Elchelberg, el at., 2005; Bleich and Slack 2010, p. 3; Coiera, 2011, p. 92; Sunyaev and Pflug, 2012).

Another benefit, derived by Dunham and Baker (2006), is that an effective EMR system leads to simplicity of measuring care quality outcome and errors. Effective use of EMRs is necessary to avoid duplicate tests; improve safety; coordination among units; increase administrative efficiency and improve disease management in hospitals (Taylor, et al., 2005, p. 1237).

In addition to the previous benefits, a survey took place in July 20, 2005 by Accenture ([www.accenture.com](http://www.accenture.com)) and the results revealed that the majority of USA clients believe that effective Electronic Medical Records can provide valuable benefits, particularly during medical emergencies. The survey found that the great majority of respondents believed that effective EMR systems can improve the quality of hospital performance

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(93 percent), 78 percent of respondents said it reduced the time patients spend in the waiting room to see the doctor, and 75 percent of the patients acknowledged that it reduced the health care cost (Al-Safadi 2009, p. 87). Recently, Cantrill presented some potential advantages of using EMRs in hospital in response to the question raised by the author: 'why bother with computers in health care any way'. Due to the importance of potential advantages, such as improving communication between wards, eliminating needless tests, decreasing medical errors, improving quality of service, improving patient satisfaction and improving legibility (Cantrill, 2010, p. 42). Despite this, the effective use of EMRs offers a number of opportunities to improve healthcare services. At the same time, there are potential downsides that have to be avoided. Recently, Leshner and Weinstein reported that the usage of EMRs has added to, not reduced, the cost of healthcare (Leshner and Weinstein, 2013).

Financially, the usage of EMR systems is costly and the failure of such systems in hospitals could have a negative effect on patients, professionals and the hospitals (Wills, et al., 2012. p. 2832). Lauren Weinstein argued that there are remarkable weaknesses with the use of central EMR systems to provide care. For instance, the trap of the online medical records by system encryption or power cut, and she suggested that the healthcare provider should never depend upon central EMRs other than as a secondary access to medical data, because there is no guarantee that the central EMRs will be accessible at any given time, particularly in disaster or other emergency situations (Weinstein, 2007, p. 8).

But the healthcare provider should ensure that the perception of the full EMRs will improve the quality of health care provided, reduce cost and provide humanity with more benefits. The following section illustrates the usage of the Electronic system around the world.

### **3.10 Electronic Health Record Usage in USA**

The implementation of Electronic Health Record system is encouraged in the health care field by many institutions and governments around the world. The United States of

America (USA) is the country where the automation of medical records was developed in the late 1960s (Shortliffe, 2005). The system was used for processing patient's information starting from admission through to discharge. The EHRs in the USA are categorised by three levels according to the study done by Jha, et al., (2009). The first level was classified as having a comprehensive EHR system, and the second level was recognized as having a basic EHR system with Clinical Notes and the third categorised as having a basic EHR system without Clinical Notes. The result of the study was that among the 63.1% of surveyed hospitals, only 1.5% of USA hospitals had a comprehensive EHR system, 17% of hospitals computerised provider-order entry for medication and 7.6% had the third level basic system with no clinical notes (Jha, et al., 2009). Nevertheless, the adoption of EHRs in the USA has been increasing slowly according to Chen and Akay (2011, p. 64). Data from the National Ambulatory Medical Care study showed that about 25% of office-based physicians were using some sort of EHRs. There are many reasons for the slow implementation of EHRs in the USA, among them unawareness of EHR security issues, cost issues and large gaps in knowledge about EHRs (Jha, et al., 2006). The current Obama administration is investing 10 billion dollars a year for five years according to the plan, in an attempt to save up to 77 billion dollars a year through improvements in efficiency of the national EHRs the Obama administration decided in 2008 that the American residents should have an EHR system in ten years' time (Fragidis and Chatzoglou, 2011, p. 475). The government has spent \$36 billion on the project of computerising Medicare and Medicaid motivations for the meaningful usage of certified EHRs.

### **3.11 Electronic Health Record System in Taiwan**

Adapting and enhancing EHR systems in Taiwan was a national goal. The Taiwan's Bureau of National Health Insurance (BNHI), which was owned and run by the government, was aware of the importance of the new technology in health care. The Taiwan Association for Medical Informatics Research group developed the Taiwan Electronic Medical Record model to make available as a basic structure of reference for establishing EMRs (Rau et al., 2010, p. 17). Thus, they decided to replace paper

medical records by EHRs based on the government requirements that data must be processed electronically. In 2002, EHRs were up and started running nationwide for about 22 million people (Cohen, 2003). To enhance the services BNHI distributed smart cards to every individual to reduce fraud and improve health care quality in 2004, in addition to tracking medical information. These smart cards store a great deal of useful health care information including prescriptions, medical procedures; drug allergy history; vaccination records and information about organ donation (Hsu, et al., 2011). At first, the system was tailored to satisfy the requirements of the clinical services, characteristics of the hospital and culture (Chiu and Win, 2008). Even though, the system was affected by the external health care providers such as National Health Insurance, policies and procedures. The total time for the project deployment was only 25 months. The implementing of EHRs in Taiwan helped health care professionals to enhance patient's care and clinical services (Chiu and Win, 2008, p. 140). Moreover, Cohen (2003) stated that the use of EMRs in Taiwan decreased the health care cost and made the treatment more efficient and safer.

#### **3.12 Electronic Health Record System in Oman**

Oman is one of the Middle Eastern Countries that has deployed an integrated Electronic Medical Record system. The system was designed to replace the paper based Manual Medical Record system in health institutions. The Ministry of Health (MOH) of Oman introduced the project in 1990. The deployment was started in Primary Healthcare Centres and then hospitals. Oman EHR's functions involve registration, nursing records, physician entries and other functions such as billing and nursing work reporting (Farsi, West, 2006, p. 18). The EMRs in Oman offers support in medical decision making, encourages use of guidelines, and enhances coordination between different health care providers (Al-Mujaini et al., 2011, p. 324).

World Health Organisation (WHO) categorised Oman's health care system in 2000 as the well-organised system in the world in terms of outcome (WHO report, 2001). Although, the system had been implemented in 1990, still there are areas that need to be improved, such as confidentiality and quality of the outcome (Farsi, West, 2006).

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### **3.13 Security and confidentiality of EMR system**

Confidentiality is a situation of limiting access to a patient's information record system; it relates to a patient's right to determine how, what, why and to what degree information about the patient will be released to users or to other organisations (Yea, 2006, p. 30). The Manual and Electronic Medical Records both contain sensitive information about patients and families. Nowadays, patients and the government are concerned about the privacy and confidentiality of data in health records due to many sensitive issues, such as information about HIV, psychiatric and other inherited diseases. This information in the records is seriously confidential for patients and families. If this information is leaked, the consequences are affecting the patients and family as well as the organisation. For instance, a patient who has been diagnosed as HIV positive and his family doctor has started the treatment plan when unexpectedly the information is leaked, friends and others will start to talk about her/his status. The result will be social and financial damage to the patient and his family as well and the leaked data or information cannot be withdrawn.

Based on the literature review, the data in medical records is useful for the owner and the health care provider from which the patient gets treatment (Win et al., 2006, p. 310). Therefore, to guarantee the security and confidentiality of the patient's sensitive information, the health care providers should offer some general guidelines to enforce the protection of patient's information. Here is a guideline stated by the Health Insurance Portability and Accountability Act (HIPAA) in early 1996: a patient must be able to have copies of their medical records and have the right to request change (HIPAA, 1996 IN Huang, et al., 2009, p. 743). In Canada the Personal Information Protection and Electronic Documents Act (PIPEDA) illustrated some more important guidelines for the protection of patient's electronic records, saying that the sensitive information of the patient must be protected from illegal users during storage and communication; the method of the protection must include a technical method such as providing a special code and password; limited access, who is allowed to read and who is allowed to read and write; the medical record should be protected from loss,

unauthorised access, leaks and modification (Garson and Adams, 2008). In the past, separation of duty (doing one task by one person) was used as a security principle to prevent fraud and errors, followed by implementation of role-based access control (RBAC) principles. According to Eloff (2010, p. 666) the implementation of RBAC are concerned with restraining the associations between users, roles and permissions. It is argued that RBAC does not sustain the complex work processes like IST and EMRs.

The EMR system security is an area that requires further exploration so a number of researchers and working groups have been developing standards for medical data communication. The most useful standards currently used in the field of EHR systems are Health Level 7(HL7) and International Standards Organisations (ISO) (Huang et al., 2009, p. 748). To ensure privacy and security, standards and policies must be implemented effectively and followed by the users. The policy should emphasise the limit of access for each user and who is allowed to access entire applications.

According to Anderson, security consists of two primary components: physical and electronic (Anderson, 2006, p. 15). The physical components can be implemented in the EMR system by physical effort, providing a unique password for each user, implementing security policy, deploying antivirus, firewalls, a proper guide booklet and consent form. EMRs policies have a clear responsibility for physical and electronic security. Overly, (1999, p. 73) stated that users are also responsible for safeguarding their passwords for access to the system (Overly, 1999, p. 73) in addition to the ten important tips of necessity for security of every system announced for further information see (Overly, 1998 “ e-policy how to develop computer E-mail and internet”). Having discussed the concept of security in this section, in the following section we will emphasise the concept of failure and some examples of Information System failure based on the literature review.

### 3.14 The Definition of Failure

In order to be able to discuss risk management of Information System Technology (IST) and Electronic Medical Record systems (EMRs), it is valuable to understand the concepts of system failure and the risk in health.

The concept of failure here denotes technological, computer, communication, network, infrastructure and human behaviour failures or any other threats. Failure has particularly become **precise**; currently everywhere, sectors have become extremely dependent on technological infrastructures to perform services or business, especially in economic and health areas. **Varkey et al (2008)** stated every event in the health care domain is as a result of a failure in delivery or system. As computing technology has increased in sophistication the number and the complexity of dependencies grow larger. This means that any small events can lead to failure in a service or business (Varkey et al., 2008).

There is still no unique definition of the word failure. Oxford dictionary defines failure as “lack of success in acting or approaching the proposed objectives” (Oxford Dictionary). In the same way, but more broadly **Lyytinen, (1988); Lyytinen, and Hirschhein, (1987) and Davis et al., (1992)** also defined the term of failure as “inability of the system to meet a specific stakeholder and user’s expectation”. Both definitions are trying to say “lack of ability to perform a normal function”.

Despite the fact that people are aware that there is no 100% safe project, they believe that failures or errors can cause injuries or harm and sometimes termination to organisations. Lindholm and Host have highlighted the danger of tiny mistakes in health and medical devices as well (Lindholm and Host, 2009). Moreover, Sicotte and others have stated some important reasons for system failures including lack of finance, staff resistance, high cost of network technology and good quality trained users (Sicotte, et al., 2006 p. 557). Lyytinen and Hirschhein (1987), Davis et al., (1992) acknowledge that system failure often occurs due to overrun budgets, frustrated stakeholders and time schedules.

### 3.15 Type of Failures

According to the Reliability Analysis Centre guide (1990, p. 20) failure can be divided into four classes: *Environmental, Human, Component and software failures*. All are explained as follows: the environmental failure is the failure that comes about when a system is over stressed by operating in unsuitable environment, e.g., high temperature or a humid environment. The second class is human failure; it is illustrated as any failure which has occurred due to human error, such as writing the wrong patient's record number or misinterpreting a requested test. This failure is the most difficult to measure, due to the unpredictability of human actions. The third class is the component failure, which is identified as the first level of system failure. The final class is the software failure, known as the failure, which is caused by errors in software.

Moreover, Lyytinen and Hirschhein (1987) presented three types of system failures: **communication failure**: when the established objectives are not met, **process failure**: when the system process cannot construct the planned work and **interaction failure**: once level of use is unstable leading to the lack of satisfaction of users. Consequently, it is very important to be concerned about all type of errors and obstacles that may lead to failures, because the consequences of failure can be severe and according to Bennet and his colleagues, the failed Information System project in the USA accounted for about 81 billion dollars annually (Bennet, et al., 2002, p. 26). In this study, we are going to consider the environmental, human and software failure to conduct this research..

### 3.16 London Ambulance Service Failure (LAS)

London Ambulance Service and emergency dispatch system was founded in the mid-1930s (Hougham, 1996, p. 103). It was the largest ambulance service in the world that provided a free service (Hougham, 1996, p. 103). The L.A.S was established to provide an ambulance service by receiving an emergency call from the users. It services a population of 6.8 million. The service covers about a 600 square mile area LAS. consisted of 318 ambulances and 445 transport ambulances, in addition to one helicopter and a motorcycle response unit. It employed about 2746 staff. The whole



system was managed and controlled from a central location in Waterloo (Musick, 2006).

LAS was totally automated in the 1990s under the director of support services. But the performance was very low and did not meet the nationally agreed standards for ambulance response. So the newly appointed team saw a new computer support despatch system as the primary means to improve the performance and meet the nationally agreed standards. A plan was made to advance the new despatch system, which consisted of three phases: completion of the system requirement order, completion of the system design specification and the target date of January 8th, 1992 for system deployment (Hougham, 1996, p. 106).

The system was fully implemented on 26 October 1992, and, on the same day, it became over loaded with a large volume of calls from users. The Automated Vehicle Location system could not keep track of the location of both callers and the ambulances as well as the status of the ambulance. Thus, it was necessary for the workforce to return to the semi manual operation (Hougham, 1996, p.108; Finkelsten, Dowell, 2010)

Due to the failure, many services were delayed and as a consequence events occurred. The entire system fell into confusion. For example, an ambulance arrived at a scene to find the patient dead and taken away by an undertaker, and another ambulance answered a stroke call later than expected (11 hours) (Finkelsten, Dowell, 2010). Furthermore, it was noted that more than 46 patients died that could have been avoided if the requested ambulance had arrived on time. Other users called the L.A.S. many times every 30 minutes before the ambulance arrived.

There were many documented reasons for the L.A.S. failure. According to Musick (2006), the main root causes of the system failure were a memory loss, an ineffective decision made by the project managers which led to the software failure. It was also noted that L.A.S. was incomplete, untested and had bugs when deployed (Musick 2006, p.3). However, the blame for L.A.S. failure did not lie solely on the single developers

who made the error. The next section provides an example of a medical device failure in a hospital (the case of Therac-25)

### **3.17 Failure of Medical Device Therac-25 (Second example)**

A computer controlled radiation therapy device called Therac-25 had failed several times and killed about six persons in the USA and Canada between 1985 and 1987. The accidents were described as the worst in the medical health field. The device was regulated by the Food and Drug Administration (FDA).

Therac-25 is a medical accelerator electron machine used to destroy cancer tumours or cells with only a slight impact on the surrounding cells. The machine was modified by Atomic Energy of Canada Limited (AECL) and the French company called CGR. They built Therac-6 and followed it by Therac-20. In the 1970s AECL designed and developed the new version called Therac-25. It was more compact, flexible and easier to use and known as the only machine used for electron and photons therapy at the time. Therac-25 was controlled by computer and the software was responsible for maintenance and insuring safety. There were only 11 devices in action, five in the United States of America (USA) and six in Canada. The investigation showed that the Hamilton overdose accident was probably related to software error (Leveson, 2010). Apart from the unpleasant social impact, failed information system projects also hold far-reaching consequences on the sectors and its stakeholders. For example, an inadequate implemented resource planning system has led FoxMeyer Drug, a \$5 billion wholesale drug distribution company in Texas, to file for bankruptcy (Chua, 2009, p. 31).

### **3.18 Summary**

The goal of many health care providers is to use an Electronic Medical Record System, in order to facilitate processes and retrieve patient's and administration's information from a variety of units. Today, hospitals and other organisations use computer systems for almost every aspect of their work. The dependence on the new technology has carried the security and confidentiality issue to be a top priority of many countries. To

improve the safety of EMR systems much has been done to identify the potential system risks that incorporate software, hardware and system users. The effective implementation of EMR system could not be achieved unless its risks were managed and mitigated (Hiller, et al., 2011).

This chapter described a number of EMR concepts. We noted that the EMR system included all patients' sensitive data. Therefore, this data must be stored in a secure and safe environment. Various mechanisms for security and confidentiality were also discussed. The usage of the Electronic Health Record system in many countries was considered and encouraged by many health institutions around the world. Many successful examples have been discussed. Even, the developing countries and some developed countries lag behind the USA and most European Countries when it comes to hospital computing.

The automation medical record was developed in late 1960s in the United States of America (Shortliffe, 2005). Then after about eight years a new storage device (smart card) was published by the two German inventors Dethloff and Grotrupp. They developed the concept of a plastic card that contained an embedded chip. The card was used in the health sector in late 2006 and was shown to be a success in health care sectors and insurance.

We have also discussed some system failures in the health sectors. The term failure has been defined by the Oxford Dictionary, and others researchers; the simplest definition being the lack of success in acting or approaching the proposed objectives. Many Information System projects are successful and few had failed.

The examples of IS and the Medical Device failures has also been discussed in this chapter. High quality IST and Medical Devices with high maintenance levels are important to perform an effective and safe service to patients and users. The London Ambulant service failure in 1992 was the first case described. The causes of the accident were related to the system and vender, in addition to the lack of back up servers in place. The second discussed case was the failure of an electronic device,

which is known as Therac-25. The device had failed several times in Canada and the USA causing injuries and death among the patients. However, the USA and several other European countries have already made great steps in deploying the appropriate EHR system in their health care sectors. The scope of the following Chapter will be Health Care Systems in the Kingdom of Saudi Arabia.

# Chapter 4

## Introduction of Health care Systems in the KSA

### Objectives

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- To describe Health Care Systems in the Kingdom of Saudi Arabia
- To review type of health care providers in the KSA
- To present Medical Record styles in Governmental Hospitals

## **4.1 Introduction**

Hospitals are often thought of as a complicated network of organisation and services that work together in a competent way to provide medical services to the community. Hospitals represent one of the most critical emergency response resources in many countries, along with other facilities. The government of Saudi Arabia has given high priority to the development of health care services at all levels, including Primary Healthcare Centres and hospitals. A Hospital has been described by the Pan American Health Organization (PAHO, 2000, p. 14) as “*a hotel, an office construction, a laboratory and a warehouse*”.

This chapter outlines the historical development and current structure of the health care system in the Kingdom of Saudi Arabia (KSA), including Ministry of Health hospitals, primary healthcare centres and other Governmental health care providers. It reviews the use of manual medical records, electronic medical records, and electronic health record systems in the KSA. The review starts with a brief history of the healthcare systems and is followed by definitions of the concept of an EMR system, with particular emphasis on the usage of new technologies to improve health care services in the Kingdom.

## **4.2 The health care system in Saudi Arabia**

The Kingdom of Saudi Arabia (KSA) is the largest of the six Gulf Cooperation Council (GCC) countries. According to the Ministry of Information Handbook for the Kingdom of Saudi Arabia (2000, p.71) the population of the KSA in 1999 was 19.9 million, in 2006 the population had increased to 24.1 million (MOH, Statistic Year Book 2006). Currently, the population has reached 28.4 million according to the central department of statistics and information ([http://cdsi.gov.sa/Saudi\\_Arabia](http://cdsi.gov.sa/Saudi_Arabia), accessed on 6/12/2012). The inhabitants are predominantly Muslim and have diverse lifestyles and culture. The lifestyle is embedded within the religion of Islam. In terms of health care, the government has given high priority to health care services. During the past few decades, say, before 1950, there was no adequate traditional health care service in Saudi Arabia, or Ministry of Health (Ghaznawi, 1986, pp. 353-354). In 1950 the Ministry of Health

was established and its main objectives were to establish hospitals, dispensaries and others curative facilities (Al maliki, et al., 2011, p. 785). Since then, the Saudi health care system has seen unparalleled growth in resources such as hospitals, and PHC centers. In 1970, the first five years plan to endorse development began, including health care premises. The plan was only intended to establish the needed infrastructure. In 1980s there were only 74 hospitals with about 9039 beds around the country ([www.hziegler.com](http://www.hziegler.com)).

Following the Alma-Ata declaration in 1978, the Saudi Ministry of Health recognized the concept of primary health care and adopted it as an essential part of its policy (Sebai, 1987). Due to the adoption of this concept, all the dispensaries, and the other curative facilities were renamed primary health care centers (PHC). The most needed healthcare provider's facilities were established and the emphasis shifted to improve the quality of care and the scope of specialized field of medicine (Siddiqi, et al., 2012, p. 171). Subsequent to the reform, a new era was started in the Saudi health care system.

In the Kingdom of Saudi Arabia, the health care system is composed of three hierarchal levels. The first level is primary health care centers. The second is general hospitals, and the third is specialist or tertiary hospitals. The government funds these health care providers and their services are free for all Saudi citizens and non-Saudi as well. In 1999 the Ministry of Health has announced to initiate a cooperative health insurance which include all companies have to insure their Saudi and non-Saudi employees on any available health insurance companies in the kingdom, which means the healthcare service will not be free of charge any more ( Al maliki , et al., 2011). The plan is going to cover all Saudi citizens as well in the near future. The following section presents the PHC in the Country.

### **4.3 The primary health care in Saudi Arabia**

Before emphasizing the primary healthcare in Saudi Arabia it is worthwhile to define the concept of PHC in both developed and developing Countries, in addition to the concept of General practice (GP) which is used as the first point of contact in the UK.

At the world health organisation (WHO) conference at Alma-Ata in 1978, the concept of primary health care was defined as “Essential health care based on practical, scientifically sound and socially acceptable methods and technology, made universally available in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development, in the spirit of self-reliance and determination”. It forms an integral part, both of the country’s healthcare system of which it is central function and main focus. PHC is the first level of contact of individuals, the family and the community with the national health care system bringing health care as close as possible to where people live and work, and constitute the first element of a continuing health care” (WHO, 1978).

However, Jepson, (2001) defined the PHC as the most basic and accessible form of professional health care available to all inhabitants of a country. However, this definition does not cover the aspects of PHC in developed countries as WHO stated.

In the UK the concept has been defined by the Commission for Racial Equality’ as the health services provided outside hospitals by: family health services which consist of general practitioners; dental practitioners; pharmacists and opticians; and community health services which involves community doctors, dentists, nurses, and other allied professions ([www.cre.gov.uk/gdpract/health\\_care\\_cop\\_def.html](http://www.cre.gov.uk/gdpract/health_care_cop_def.html))

Moreover, a general practitioner (GP) was also defined by the Royal Commission on the National Health Service (1979, p. 72) as “a licensed medical graduate, that gives personal, primary and continuing care to individuals, families and a practice population irrespective of age, sex and illness”. GPs can attend their patients in many places, for example, in clinics, in the patient’s home, sometimes in hospital. Their aim is to make



an early diagnosis. They include and integrate physical, psychological and social factors into their consideration about health and illness. This will be expressed in the care of their patients. They will also practice in co-operation with other colleagues, medical, and Para-medical in order to provide good services for their patients (RCNHS, 1979).

In the United Kingdom, patients do not normally have direct access to a hospital consultant, and the GP is usually the first point of contact. Similarly, in the KSA the primary health care is the first level of contact. However, some important differences in terms of the function and expertise exist at the primary care level between these two countries.

Primary health care is a part of the entire health care delivery system in the KSA, which includes secondary and tertiary health care. There are 1925 primary health care centres in the Kingdom of Saudi Arabia (KSA), each cover an average of 14,546 people (MOH, 2006, p.105). Every region in Saudi Arabia has a number of primary health care centres and at least one general and one maternity hospital. For example, in 1990 the number of PHC in the Riyadh region was 265. In 1994, the number had reached 276 PHC centres and 26 hospitals. By 2006, the number of PHC had reached 361 and 40 hospitals (MOH, 2006, p. 105). Moreover, the MOH declared that the number of primary health care centres in the whole country had increased gradually, from 1737 in 1997 ,1786 by 2001 to 1925 in 2006 ( MOH, 2006, pp. 105).

PHC centres in the Kingdom of Saudi Arabia offer ordinary treatment for common illnesses and some emergency care. If complicated cases need consultation with the specialists or with a senior general practitioner (GP) with more experience within the unit, or requires investigation with more sophisticated equipment, the primary health care practitioner has to refer the patient to the secondary level (General Hospital). This enables services to be providing to patients whose physical conditions require sophisticated medical technology for diagnosis and treatment. According to Khokar, (1992, p. 33) a systematic referral service needs to be developed. The following section illustrates the second and the third level of governmental healthcare providers.

#### **4.4 Hospitals in Saudi Arabia**

In term of hospitals, there are two types of hospital in the KSA, general and specialist hospitals. The general hospitals are classified as the secondary level of the healthcare system and the latter are classified as the tertiary level.

In the KSA access to a general hospital is usually through manual referral letters from a general practitioner (GP) in a PHC centre, unless in an emergency situation. Patients can be seen easily in the A&E department without referral letters.

The Saudi health care system has witnessed a dramatic expansion in developing facilities in both general and specialist hospitals. For instance, in 1990 the number of MOH hospitals was 163, with a capacity of 26,878 beds (MOH, 1994, p. 103). In 2001, the number of MOH hospitals reached 191, with a capacity of 28,140 beds (MOH, 2001, p. 26) Furthermore in 2006, the number of hospitals had increased to 220 with a capacity of 31,877 beds (MOH, 2006, p. 136). In 2007, the numbers of hospitals were 225 and in 2008, the number reached 231 with an increase of 6 hospitals. A dramatic increase was detected in the following year, 2009, with the total number of hospitals reaching 244, with a bed capacity of 33,277 13 hospitals increase, this being a match of 59.4% of the total beds in the Kingdom. There is an increasing interest in developing new, modern and better hospitals and primary healthcare centres by adopting new approaches such as a comprehensive electronic medical record system, and telecommunication and care closer to home, which will no doubt increase the complexity of health care service and impact on flexibility (MOH, 2009).

The following table shows the increase of population, number of hospitals and primary health care centres funded and supervised by Ministry of Health in Saudi Arabia from 1990 to 2009.

**Table (4.4.1)** Development of Ministry of Health Hospitals and PHC from (1990-2009)

<i>Years</i>	<i>Population</i>	<i>Hospitals funded by MOH</i>	<i>N of people per H</i>	<i>PHC funded by MOH</i>	<i>N of people per PHC</i>
1990	15,187000	144	105,465	1668	9105
1991	16,139000	163	99,012	1692	9538
1992	16,948380	166	102,099	1702	9958
1993	17,189000	170	101,112	1707	10070
1994	17,701000	173	102,318	1719	10297
1995	18,136 000	175	103,634	1725	10514
1996	18,581000	176	105,574	1731	10734
1997	19,037000	180	105,761	1737	10960
1998	19,504000	182	107,165	1751	11139
1999	19,890232	186	106,937	1756	11327
2000	20,474000	188	108,904	1766	11,593
2001	20,976000	191	109,822	1786	11,745
2002	21,491000	195	110,210	1804	11,913
2003	22,019000	200	110,095	1824	12,072
2004	22,678262	213	106,471	1848	12,272
2005	23,119000	218	106,050	1905	12,136
2006	24,122000	220	109,645	1925	12,531
2007	24,941000	225	110,849	1925	12,956
2008	25,787000	231	111,652	1986	12,984
2009	26,167000	244	107,241	2037	12,846

➤ *Source: Ministry of Health Annual Reports (1994-2009) and MOCDSI (2010)*

It can be seen from the above table that there has been an increase in population followed by a gradual increase in the number of Primary Healthcare Centres and hospitals from 1990 to 2009. The total number of PHC Centres in 1990 was approximately 1668 and in 2006, the number had reached 1925, with an increase of 257 PHC Centres during the seventeen years, with an average of 15 PHC Centres in a year. While the number of hospitals in 1990 was 144, by 2009 the number had reached 244. A statistical program SPSS was used to assesses the mean, median, and range of the three variables. Pearson correlation coefficient was also computed to measure the relationship between variable 1 hospitals, variable 2 Primary health care centres and variable 3 the population and a very strong positive correlation between the three variables was found. See the following tables 4.4.2 and 4.4.3 that depict the output of SPSS usage.

**Statistics**

**Table: 4.4.2** depict the Mean, Median, Variance and Rang of health care providers in the KSA

	Hospital	PHC	Population
Missing	0	0	0
Mean	192.0000	1799.7000	20.5043
Median	187.0000	1761.0000	20.1821
Variance	673.474	11046.326	10.498
Range	100.00	369.00	10.98

**Correlations**

**Table: 4.4.3** Shows the correlation between the population and health care providers increase

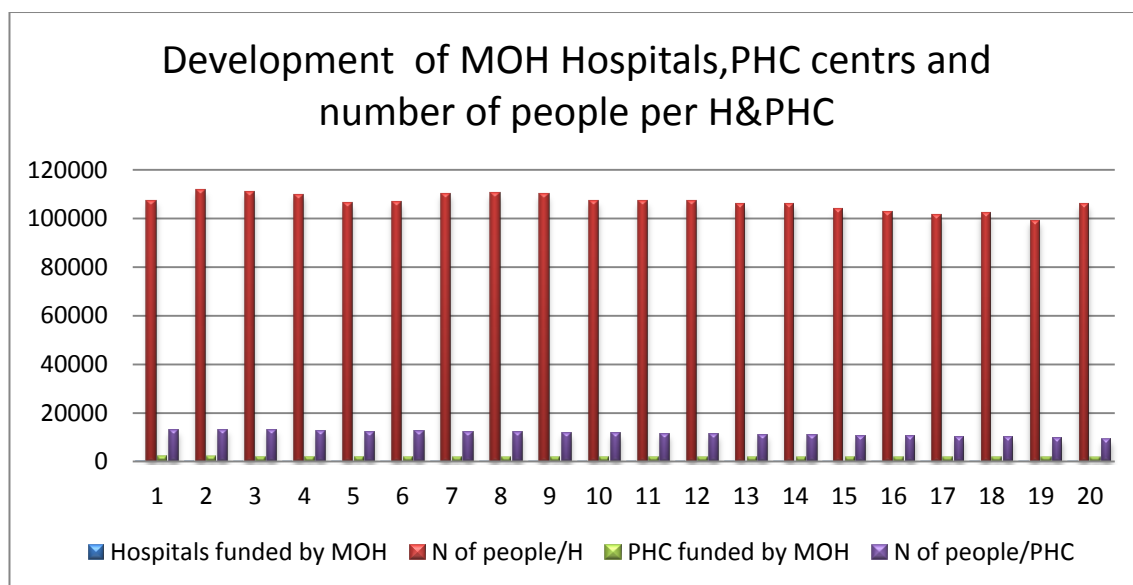
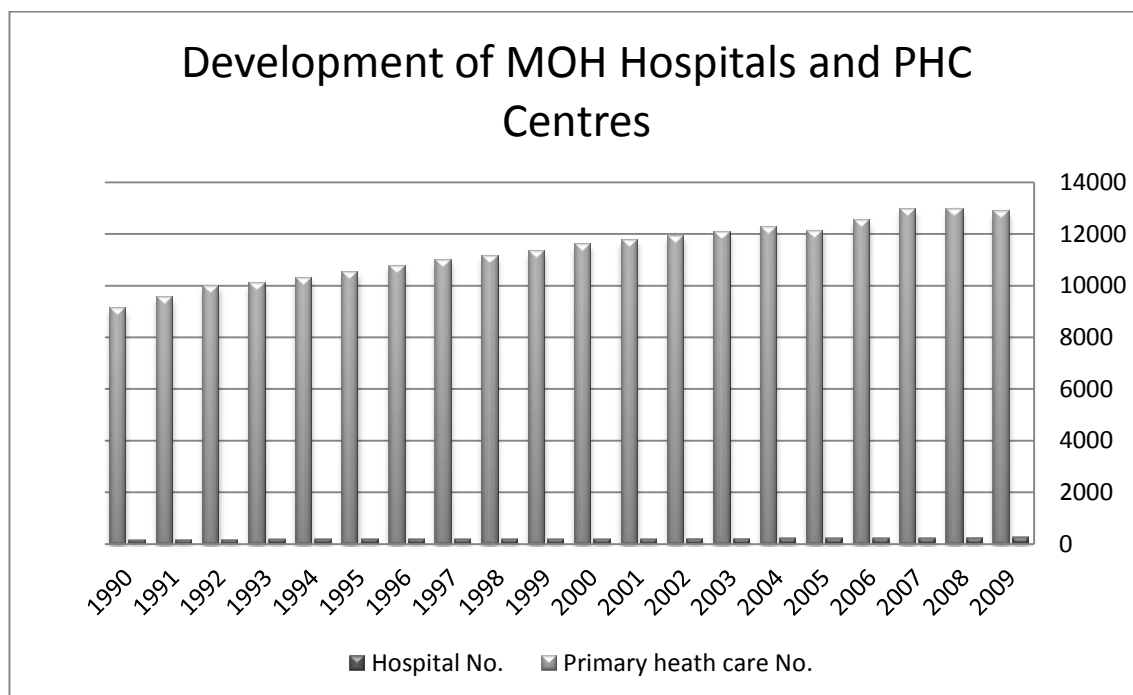
		Population	PHC	Hospital
Population	Pearson Correlation Sig. (2-tailed)	1	.971** .000	.989** .000
PHC	Pearson Correlation Sig. (2-tailed)	.971** .000	1	.980** .000
Hospital	Pearson Correlation Sig. (2-tailed)	.989** .000	.980** .000	1

\*\* . Correlation is significant at the 0.01 level (2-tailed).

The Pearson correlation coefficient for the hospital and the primary healthcare centres is more  $P > 0.9$ . Number of case (n) =20. Hence, this indicates a strong positive correlation between the ranks.

Almost all Medical Record Departments in Ministry of Health Hospital's and PHC in Riyadh cities' and rural areas still perform their tasks manually.

The following graphs illustrates table 3.4.1, that shows the development of Ministry of Health's hospitals, Primary Health Care Centres and the number of people per both organisations over twenty years in the KSA.



**Figure 4.4.1 development of H and PHC**

The MOH is the largest provider and covers 60% of the total health services in the country. The following section presents information about the other health care providers in the Country.

## 4.5 Other Governmental health care sectors in Saudi Arabia

In addition to the Ministry of Health, there are other governmental health care providers in the Kingdom; those going to be described below:

- **Ministry of Defence and Aviation (MODA).** It is the second largest governmental health care provider in the KSA. It runs nine hospitals and provides healthcare to the soldiers and their families. The number of beds in these nine hospitals is about 3,550.

- **Saudi Arabian National Guard (SANG),** is known as the leading health care provider in the KSA, particularly in terms of using Information Technology. In 2010 SANG received the prestigious excellence in EMR system at the Arab health awards in Dubai, UAE, with QuadraMed. SANG is another branch of the Military, has four hospitals and clinics in Riyadh and elsewhere in the Kingdom. It provides healthcare to the National Guard Soldiers and their dependents. The total number of beds for its hospitals is 1,597 spread as follows: King Abdul-Aziz Medical City in Riyadh 847 beds, King Abdul-Aziz Medical City Jeddah 350 beds, King Abdul-Aziz Medical City Al-Hasa 300beds, King Abdul-Aziz Medical City Dammam 100 beds only ([www.ngha.med.sa](http://www.ngha.med.sa) .accessed on 12/12/2012)

The King Abdul-Aziz Medical City in Riyadh implemented an EHR system in July 2008, and provided the lowest morbidity and mortality rates among patients treated on its premises, regardless of the reality that the emergency Care Centre is located close to the Riyadh–Al-Dammam highway and receives allot of patients injured as a result of car accidents. The ECC at KANGC is ranked as the 4<sup>th</sup> Emergency Care Centre outside the USA, to offer pre hospital trauma and a life support program (PHTLS) ([www.ngha.med.sa](http://www.ngha.med.sa), [www.quadramed.com](http://www.quadramed.com)).

- **Security force hospital** (Ministry of Interior). It is the third branch of military hospital in the KAS. It services the security police and other civilian employees supervised by the Interior Minister and their dependents. The total number of beds in this hospital is 500.

- **King Faisal specialist hospitals** and research centres in Riyadh and Jeddah have 950 beds in total 700 in Riyadh and 250 in Jeddah. Services performed by these hospitals are free for every Saudi citizen who needs tertiary healthcare. The Universities hospitals services are also free for all Saudi citizens
- King Khalid University hospital in Riyadh
- King Abdul Aziz university hospital in Jeddah
- King Fahad University hospital in Khobar
- King Fahad University hospital of petroleum and mineral medical unit
- Imam Mohammed Ibn Saud university medical unit
- Medina Islamic university medical clinic
- Institute of public administration medical unit
- School health unit at Ministry of Education
- Saline water conversion corporation medical unit
- Saudi Red Crescent society
- Royal commission hospital
- Youth welfare hospital.

MOH, Health Statistical Year Book. (2006, 2009). Referring to the other previous healthcare provider usage of EMRs in the country is an important motivation for the MOH hospitals to improve their status in the usage of comprehensive EMRs. There was a study conducted by Bah and, et al., (2011) in the Eastern Province of Saudi Arabia regarding the usage of EMRs in this particular area the result showed that only three hospitals out of 19 use EMR systems in addition the study did not categorised the type of EMRs in the studied hospitals. (There are other regions that have more hospitals and PHC centres in the country) thus in view of the facts the scope of that research was inadequate for continued usage. There was a need for studies in other regions in order to know the type of EMRs used and help us for a generalisation for the whole country. Therefore, this study was not sufficient to relay only upon, but it was worthy of being referred to base on its merit.



#### **4.6 Medical record system usage in Saudi Arabia**

In Saudi Arabia, sharing of patient's information between the hospital departments and other health care providers are performed manually (Al-Sfadi 2009, p. 85). This process is obviously uninteresting, expensive in terms of employees, time consuming and it also leads to situations where patients can only get irritated by the slow processes involved in gaining information relating to their medical care in hospitals. This ancient way of documenting patient's information is prone to many problems, such as too much time spent to get information of the chart when needed, and wrong information on charts, etc. (Siddiqi, et al., 2012, p. 175). Thus, nowadays there is an increasing concern about improving the healthcare services in the Kingdom through the implementation of EMRs in MOH hospitals and other governmental health care providers. The usage of EMRs has already started in a number of hospitals, such as King Faisal Specialist hospitals and research centres and the National Guard Hospitals (Al-tuwaijri, 2008). Whereas, the usage of EMRs in MOH hospitals is moving slowly, there are some MOH hospitals operating, but these systems are not connected even with the designated PHC centres in the region or to other private health organisations (Al- maliki, et al., 2011, p. 792).

Electronic Medical Record systems have become a main issue at many health care providers' organisations in Saudi Arabia and elsewhere. Several healthcare providers, including private organisations, started moving from MMR to an EMR system, to overcome the limitation of the paper based MMR and to gain the benefit of a computer based EMR system ( see chapter 3 section 3.9 the advantages of EMRs).

One of the top governmental and military health care providers in the Kingdom of Saudi Arabia is the National Guard Health Affairs (SANG-HA). The core facility of SANG-HA) is the 847 beds academic medical centre in Riyadh which involves 15 medical departments, in addition to its 22 outpatient clinics, or PHC, across the Country that care for National Guard member and other Saudi nationals who need care and are all computerised ([www.ngha.med.sa](http://www.ngha.med.sa)).

The hospital established an EHR system in 2008 to turn quality care into positive financial and service outcomes. King Abdul-Aziz National Guard Hospital has made great improvement in developing an EHR system in all its departments ([www.quadramed.com](http://www.quadramed.com)). The EMRs form an important part of the healthcare problems solution; precise and up-to-date information is necessary for continues quality improvement in hospitals. The implementation of the effective EMRs facilitated the core function of hospitals, and improved the decision making process in the KSA.

### **4.7 Summary**

The health care system in the kingdom of Saudi Arabia is composed of three hierarchal levels, primary health care, general hospitals, and specialist or tertiary hospitals. The government funds these levels, and their services are free for all Saudi citizens. Since 1990, the numbers of hospitals and primary health care centers has been increasing in harmony with the population.

The Kingdom has currently announced starting a new health care reform. The new reform was about implementing a health insurance plan for all non-Saudis and Saudis. All companies have to insure their staff in any available health insurance companies approved by the government. The plan is going to cover all Saudi citizens as well in the near future.

There are also many other governmental sectors as well as nongovernmental such as private hospitals and health centers in the Country. The largest health care provider in KSA is MOH, which hold more than 31,877 beds across the Country and 59.5% of the services, but are still behind track when compared with the other governmental healthcare providers. The leading health care provider in the Kingdom is the National Guard.

The implementation of EMRs in the KSA has started in a number of healthcare organizations, such as KFSH, National Guard, and MOH hospitals. Due to the continued support by the government through using IT, the healthcare services have advanced greatly in all levels.

Despite this achievement, the health care services in the KAS are still facing many challenges, including, lack of effective systematic cooperation between hospitals and their designated PHC centers and MOH hospitals with the other governmental sectors.

# Chapter 5

## Risk Management

### Objectives

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- To define the concept of Risk
- To express types of Risk
- To classify Risk factors
- To describe an effective process of a Risk management program
- To describe Risk Scales
- To express Risk reporting
- To model Complex System

## **5.1 Introduction:**

The scope of this chapter is to review and assess the state of knowledge on the subject of risk management based on the literature review. Risk is an essential part of health care services because organisations cannot work effectively without taking risks. Risk management is not a new concept but its application in the health sector is relatively new in the UK and elsewhere (Holdaway and Kogan, 1997, p. 76). It is a science that has increased the awareness of medical and non-medical errors, but its effect has been seen more broadly than just reducing the error or the cost. Risk is something intangible that can happen in the future, its probability hard to pin down (Raheja, 2011, p. 46). Risk is like investment in car or health insurances; if you get ill you get the assistance; if you do not get sick, you may think that you wasted your cash.

The evaluation of risk was initiated with the development of a numbering system (Holmes, 2004, p. 22). This means without numbers there could be no risk management, because it would be unfeasible to assess the probability of an event. Risk has been defined by various scholars; with 'risk' meaning different things for different people depending on the particular circumstance and context. Hence some types of risky situations have developed into an occupation its self, thus any single definition has become redundant in the field of risk management. Even though, no one can escape the fact that risk is around us. Risk is inherent in activities carried out by organisations, and the health care sectors are not an exception (Holdaway & Kogan, 1997, p. 76).

The identification and management of risk seems to be an emerging area in banking and the manufacturing industry sectors. Recently the subject became familiar in the health sector, thus risk management is needed for acceptance and implementation of an electronic medical record system in order to avoid the occurrence of undesirable events (Hiller, et al., 2011). Risk management processes must have top management support and be an integrated part of a hospital's quality management system. This should help to ensure the security and quality of equipment and services in the hospitals. The process of identifying risks associated with electronic medical record systems (EMRs)

is a challenge for hospital information technology (IT), quality management (QM), and electronic medical record (EMR) managers. Risk management in an EMR system is a complex process and varies in nature, consequence and severity (Pare, et al., 2008). Particularly, the risk and the impact of manmade failures have not been as significant as natural disasters, such as floods and earthquakes, but considerable attention is being given to the former, especially in terms of expenditure (Achour and Price, 2010 p. 264)

There are various ways to identify and manage risks, which include involving top managers and users in risk management activities which would enable better support and to get a comprehensive list of risk factors in order to control and mitigate them. In addition to the clearly defined list of risks, we also have to define risk policies, risk standards and the ability to measure and control them. In this chapter, we intend to give the reader an overview of the different research contributions in risk management literature, starting from a general view of risk (what is risk and how it might be managed?). Hubbard (2009) has stated the simplest definition of risk “*something bad could happen*”. The chapter will also give the benefits of effective risk management, risk scales use, risk reporting and construction modelling.

### **5.2 Definition of Risk**

Naturally, risk has forever been part of human life and the field of risk study started as early as human beings started to reflect on the possibility of their own death and considered actions to avoid dangerous situations (Renn, 1998, p. 50). Most people have a perceptive understanding of risk based on their common sense and skill, but for the principles of academic simplicity, it is significant to agree on a formal definition of the concept. However, there is no wide consensus on the meaning of the term risk except its intangibility (Raheja, 2011, p. 45). Risk has no universal definition; hence, variability of outcome is a common way of expressing (Fadum, 2013, p. 226). There is no commonly accepted definition for the term risk, neither in the sciences nor in public understanding. Wade has defined the term risk, “uncertainty of financial loss that can occur over certain periods of time” (Wade, 1983. p. 33). Smith (2012) indicated, “Risk means different

things to different people which means each individual holds a unique view of the word. However, most individual interpretation of risk regarded as equally real. Mary Sumner came out with simple definition of risk saying “risk” is a difficulty that has not yet occurred but when it occurs, will cause some loss or threaten the success of project (Sumner 2000, p. 317). According to Stranks risk has a number of definitions – a chance of awful consequence (Stranks 2001, p. 72). Chance of something happening that will have a negative impact on achieving one’s objective (Runciman et al., 2007, p. 29). Hoodat and Rashidi, (2009, p. 446) have settled on a more holistic definition for the term risk “as an exposure to loss, injury, thing, element or course that involves uncertain danger”. All risk concepts have one element in common, however, the distinction between reality and possibility. Recently, ISO 31000: 2009 came out with a new standard, with the new definition of risk as “*the effect of uncertainty on objectives*”. The changes in definition shift the emphasis from events to the effect on objectives. Both the new and former definitions undoubtedly place the risk in the context of what organisation wishes to achieve (Purdy, 2009).

Within the context of complex risk, Frank and colleagues stated a useful working definition for risk "risk represents a combination of the probability and severity of an event" (Frank T, et al., 2008) ‘the likelihood of losses in a project’ (Nieto, et al., 2011, p. 220). Inspired by these arguments, the definition of Frank is going to be used for the purposes of this research this definition has been selected for the reasons that when the two factors are multiplied the risk can be characterised as high, medium or low and underlying quantitative relations. However, risk is not a measurable attribute, but it can be derive and ranked according to their probability and severity (Cox & Jr, 2008, p. 498). The severity we use to describe risk may involve, pain, harm loss and detrimental effects. Changing names do not do anything with the logic of this definition

**Risk = Likelihood× Severity**

**Likelihood:** is the state of being probable (Probability)

**Severity:** is the degree of something undesirable; e.g. Pain or cost

Alternatively, you can use graphical representation, such as in Figure 5.8.1, to determine whether a risk is significant or not. Within the context of health, risk management can be defined as "chance of harm or loss" therefore; staff and the stakeholders must be concerned about the safety of the organisation and its objectives. Risks are also known as unexpected events or threats that have negative consequences on projects (Kasap and Kaymak, 2007).

Risks affect the successful completion of a patient's treatment in terms of achieving the best quality outcome. Treatment plans in the health care domain are systematic; likewise risk management, which involves systematic processes including identifying, analysing, assessing, and taking action. It contains reducing probability, consequences of unwanted effects, increasing probability and consequences of positive or wanted events (Kasap and Kaymak, 2007). Despite the differences of detail, some definitions agree that risk has some characteristics.

### **5.3 Characteristic of Risk**

Today, the term risk is used in many speeches to describe the probability of loss or of an accident, threat and vulnerability or uncertainty, while it was used in early 18<sup>th</sup> Century to deal with the problem of chance in gambling (Boehm, 1989). We characterise and describe risk in terms of the consequences of what possibly will happen and the probability of those consequences. A number of authors alleged that the origin of the word risk is uncertain. MacCrimmon et al., (1986) have stated that the origin of the word risk is thought to be derived from Italian word (risco) which means uncertain. And the main cause of uncertain events is absence of information about the process of the events

Risk is well explained by the Oxford English Language Dictionary as "a chance of possibility of danger, injury, and loss". Furthermore, Roberts defined the word risk as "a combination of likelihood (estimation of how likely that something will happen) of occurrence of a defined danger and the severity of the danger" (Roberts, 2013, p. 22). In



actual practice likelihood is regularly taken as the relative frequency for the largest number of any trial (Alder & Rosseler, 1977) while, in risk management terminology “likelihood” is used relatively than “probability” because the probability is often narrowly interpreted as a mathematical term. Likelihood is chosen due to its broader possible application and the frequency as a component of risk is included in the likelihood (Letich, 2010, p. 888). Risk is a future event that may or may not occur; the probability of the future events must be greater than 0% but less than 100% (Nieto, et al., 2011). The future events that have a 0% or 100% chance of occurring are not risks but they are certain. As Jones and Ashenden (2005) said, if there are no severities, vulnerability and impact there will be no risk.

### **5.4 Type of Risk**

Traditionally, concern has been focused on corporation risks and occupational risks (Runciman et al., 2007, p. 29). Nuclear power is one of the domains in which a comprehensive concern for risk management is crucial, because an accident in this field can result in a dreadful disaster. The risk in health care domain is also needs similar concern because, any minor mistake in the patient treatment may leads to the vital complication or death of patients. Several scholars have divided risks in information technology literature into classes: for example, Barki et al., (1993) divides risk into five classes “*application risk, task risk, development team risk, user risk and hospital or an organisation risk*”. Others divided the risk into two types “*Technical and Non-Technical Risks*”. The technical are those risks associated with functions, requirement and performance of the system that consists of hardware and software, i.e., the possibility of technical malfunctions or human errors in handling such machines. Whereas, the non-technical risks are acknowledged and associated to the user interface, staff shortfall (Chittister & Hamies, 1994). Luckily, the technical risk can be mitigated by security activities according to Jone and Ashenden (2005. p. 189).

## 5.5 Risk Factors

There are many risk factors presented in literature, especially in Information System Technology (IST), which includes risk of EMR system failure. Different authors have presented different lists of factors. For example, Pang, et al., (2011) have stated two risk factors in general, *natural* and *human* risk factors. The former is inherent factors, and can be controlled but cannot be eliminated and the latter can be pre-controlled, however, one or some of the human factors may become initiation factors for this study. Sumner (2000) has presented a list of risk factors specifically in Information Systems, namely, *organisational fit, skill mix, management structure and strategy, software system design, user involvement and training, technological planning, project management and social commitment*. Chua Alton (2009) presents a list of risk factors consisting of four main categories namely: people-related, process-related to the project, technical and adding a new feature to the project that revealed factors based on eight well documented and high profile unsuccessful information system technology projects. He also acknowledged that people-related risk factors consist of four categories; inexperienced users, lack of stakeholder involvement, excessively ambitious top managers and users not appropriately trained to use the system. Similarly, Stranks (2006) presents a list of human related risk factors that may contribute to errors, which can be a vital causative feature of events occurrence at a work place. They are as follows: lack of understanding; insufficient information; inadequate design of system; lapses of attention; incorrect actions; misperception; mistaken priorities and inflexibility (Stranks, 2006, p. 121). Besides all these stated factors, human risk factors sometimes can be the main risk factors that cause system failure, such as the official report on the accident occurred in 1979 at the nuclear power station in the USA, which cited human factors as the main causes of the failure among others (Stranks, 2006, p. 122).

## 5.6 Risk Management

An effective process of risk management activities requires a systematic approach to evaluate and control the whole process. A vast number of researchers have proposed

different processes such as Schuster, (2009, p. 15) who stated that the usage of a complete risk management process must be considered first, because it will affect the success of any project. Effective risk management often performed in several steps, which consist of risk identification, risk analysis, risk assessment, risk planning and monitoring (Lindholm, Host, 2009, p. 53; Sun, et al., 2011, p. 22; Fadun, 2013, p. 227). Therefore, it is often described as "proactive and reactive strategies"(Smallman, 1996, pp. 12-26).

There are different approaches proposed for risk management processes in the literature. For example, ISO 31000 has documented seven steps. And others have stated five steps. But the main steps are common in most studies. In this section, we are briefly going to discuss the most common steps found in literature. The following table summarises the main steps of risk management that have been used in many organisations.

**Table 5.6.1: Risk Management Process**

References	1	2	3	4	5	6
<b>Kasap&amp; Kaymak, 2007</b>	R I	R A	R M P	R M & C	Risk Response Planning	
<b>Mattsson &amp;Nyfjord, 2008</b>	RI	R A	R M P	R M & C	Risk Sign Off	Risk Post-Mortem Analysis
<b>Ridley&amp;Chnning,1999</b>	R I	R As		R C		
<b>Boehm, 1989</b>	R I	Risk Prioritisation	R M P	Risk Monitoring		
<b>Thevendran &amp; Mawdesley, 2004</b>	RI	R A	R R	Risk Monitoring		
<b>Vila &amp; Morote, 2011</b>	R I	R As	R R	Risk Monitoring		
<b>Mohanna &amp; Chambers, 2001</b>	R I	R As		R C	Cost Management	

RI= Risk Identification. RA=Risk Analysis. RAs= Risk Assessment. RR= Risk Response. RC= Risk Control. RM&C= Risk Monitoring and Controlling. RMP = Risk Management Planning.

Kasap & Kaymak (2007) divided the risk management process into five steps. The first step is risk identification. Whereas this step is known as the initial phase of risk management process in many studies, it is the process of identifying threats or harm, determines what may happen and how these threats may happen. The final result of this step is to produce a comprehensive list of risk factors (Kasap & Kaymak, 2007). This step is known as the most difficult and important step of risk management (Li, et al., 2006 p .1). The second step in the Kaymak and Kasap study is risk analysis and

filtering, this will be discussed in the next subsection. The Third is Risk Management planning. This involves writing a clear and understood objective of the project, communication to all staff, agreement, and documenting all results. In addition, it is important to define roles and responsibilities to the teamwork.

### **5.7 Risk Analysis**

Making a proper decision to manage risk is not an easy task. Therefore, the identified risk has to be described in an understandable way and then analysed systematically (Li et al., 2006 p. 3). Consequently, each risk, when identified, has to be analysed in terms of probability of occurrence (Talbot, 1981, p. 16). According to Kasap and Kaymak risks are always analysed in term of probability and seriousness of impact and the impact can be rated by given the following rating Low, Medium and High (Kasap and Kaymak, 2007).

There are few well-known types of risk analysis techniques that can be used for analysing risk (Hoodate & Rashidi, 2009). Risk analysis is the third step of a risk management process in the Kasap and Kaymak study. They used the risk analyses step to identify the high-risk elements of the project and grouped the untreated risks that were found from the risk identification process. The purpose of the activity was to give detailed descriptions of risks, so that top risk scenarios and the appropriate risk controlling actions can be planned and implemented. When the risk has been analysed, it needs to be assessed.

### **5.8 Risk Assessment**

Risk Assessment is a process of prioritising risks for future analysis by assessing and combining probability of occurrence and impact (Villa and Morote., 2011). Some researchers have said that risk assessment involves the identification of hazards, the weighing of the hazards, deciding how to control the hazards and implementing control strategies (Stranks, 1996 p. 51). RAs is also known as a step to assessing risk of harm or damage that could result from identified hazard (Ridley and Pearce, 2002, p. 35). This

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process helps to prioritise activities while recognising that not all risk can be mitigated, there will always be a remaining level of risk that has to be accepted if the organisation function effectively. The simplest way to assess and prioritise risk is to use a two by two-risk assessment matrix, described by a risk formula such as one of the following: Risk = Vulnerability  $\times$  Threat. Risk = likelihood  $\times$  Severity. Risk = frequency  $\times$  vulnerability, etc. we will use "vulnerability" or "likelihood", (Cox .Antony 2008, p. 501) such as one shown below in Figure 5.8.1. The matrix ought to enclose threat and vulnerability so that the various possessions that have been assessed can be schemed on a simple and low scale. But, this simple assessment may need additional complex judgment to be ideal. If the threat of any project is 0 by considering the equitation the risk will be 0 so the prioritisation will be difficult to detect. The Oxford English Dictionary defines the word vulnerable and threat the former as ‘unprotected, exposed to danger or attack ‘and the thread as “a real perceived danger”. ISO 2005 defined threat as “The potential cause of an accident associated to the assets in an information system, which may result in harm to a system or organisation”. Four main disconnected types of threats have been identified: *Natural disasters*, *Industrial Origin*, *Errors* and *Unintentional Failures* (unplanned failure caused by human) (Lasheras, et al., 2009, p. 121).

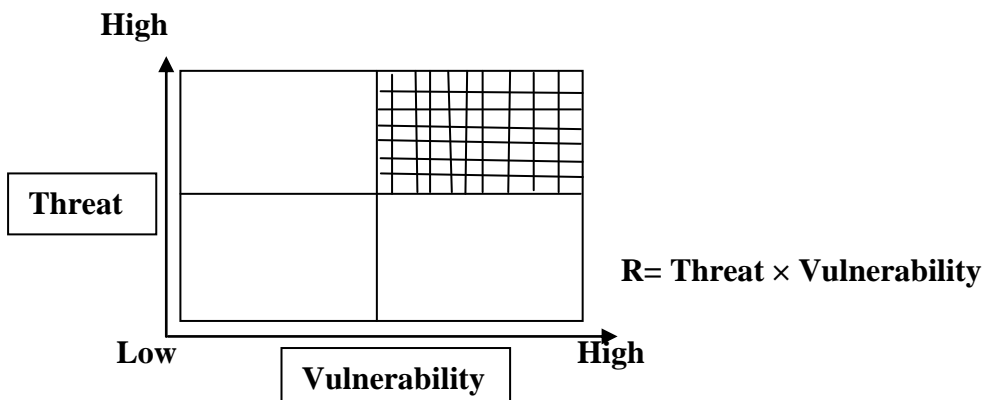


Figure 5.8.1 Risk Assessment matrix is adopted from Jones and Ashenden (2005)

## 5.9 Risk Control

Controlling and monitoring risk are a continuous process with risk management. Reviewing progress continually in order to take proper action to fulfil plan objectives. Risk controlling is a very important stage. It is a systematic approach to the risk identification, evaluating the probability of its occurrence and applying a straightforward process to mitigate, remove or improve the risk (Talbot, 1981, p. 16). Moreover, risk controlling helps in updating the major hazards registration (Tummala & Leung, 1996, p. 61).

Once risks have been identified, analysed and assessed all remaining methods to manage them effectively fall into one or more categories to prevent or control those risks to people or organizations. Dortman (2007) and others have described these categories as follow: *to avoid risk, to reduce risk, to accept risk, to transfer risk and to share risk* (Dortman, 2007; Talbot, 1981; and Mohanna & Chamber, 2001, p. 39). All these categories will be described in more detail independently.

**The first**, risk avoidance, means not to perform any action that could bear risks. It is the answer to all risks. However, all risks can never be avoided because of financial, physical and practical limitations and the nature of people, some are risk avoiders and others risk-takers. According to Williams (1998, p. 45) risk takers will get excitement out of doing risky activities, but will go to a great extent to reduce the risk factors by purchasing expensive safety and high quality equipment to eliminate risks. On the other hand, for instance, a person who was used to crossing the highway every day to reach his work place determined he would resign in order to avoid the risk of being killed by car accident. Similarly, some hospitals managers may say if having an Electronic Medical Record system in a Hospital creates problems, why should we implement one?. We could avoid all the expense and worries very simply by saying just stay as we are. An easy answer does not require any contention.

**The second**, According to Raheja in most systems, the high risk level that exists is about 20% high production and about 80% are minor, this being called the 80-20 rule (Raheja, 2011, p. 134). The minor risk should be passed on to junior employees who want to gain some learning experience since it does not require penalising action. The remaining 20% of the major risks must be delegated to the experienced and innovative team workers in the organisation. There are methods to use in order to mitigate the probabilities and the severities of risk such as FTA, FMEA etc. In other word, actions must be taken to mitigate risks and avoid loss effectively. In many cases, the means of reducing risk are straightforward and do not have considerable cost, if risks are identified and planned for in adequate time. Risk reductions are the result of an effective planning and sufficient cooperation between the system, users and the stakeholders, in addition to adequate periodic maintenance. It is similar in some ways to another e.g. calling IT technicians for emergency to maintain the system when it breaks down suddenly, it may cost a great amount of cash as compared to the cost of the annual periodic service (Guide to Supply Cain Risk Management, 2009). If we have an effective EMR system in a hospital, we also need well-trained computer professionals.

**The third**, risk acceptance, it is a first strategy for small risks, which includes accepting the small damage when it occurs. This will avoid spending time and effort. According to Talbot (1981) acceptance means, exactly what it says. The manager makes the decision to accept this small risk as the impact is very low.

**The fourth**, risk transfer, is a strategy, which is practicable for all unacceptable risks, which organisations cannot go over and would lead to catastrophe. These kinds of risks are normally transferred to insurance companies.

Similarly, Jeremy Stranks,. (2006) presents four important strategies for controlling risk: risk avoidance e.g. (take a clear decision to avoid completely a particular risk by termination of the whole project or process); risk retention with knowledge and without both can be taken within the organisation and any harm or loss must be treated within the organisation; risk transfer assigning the costs of certain future losses from one

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organisation to another. The most common way for risk transfer is insurance, the risk reduction phase takes two stage data collection and data analysis (Stranks, 2006, p.71). He also claimed that adopting and implementing a good standard of risk management may eliminate many predictable risks (Stranks, 2006, p. 68). Almost all of these strategies have a similar framework with different order to prevent or control people and organisations. The following figure shows a risk management process overview.

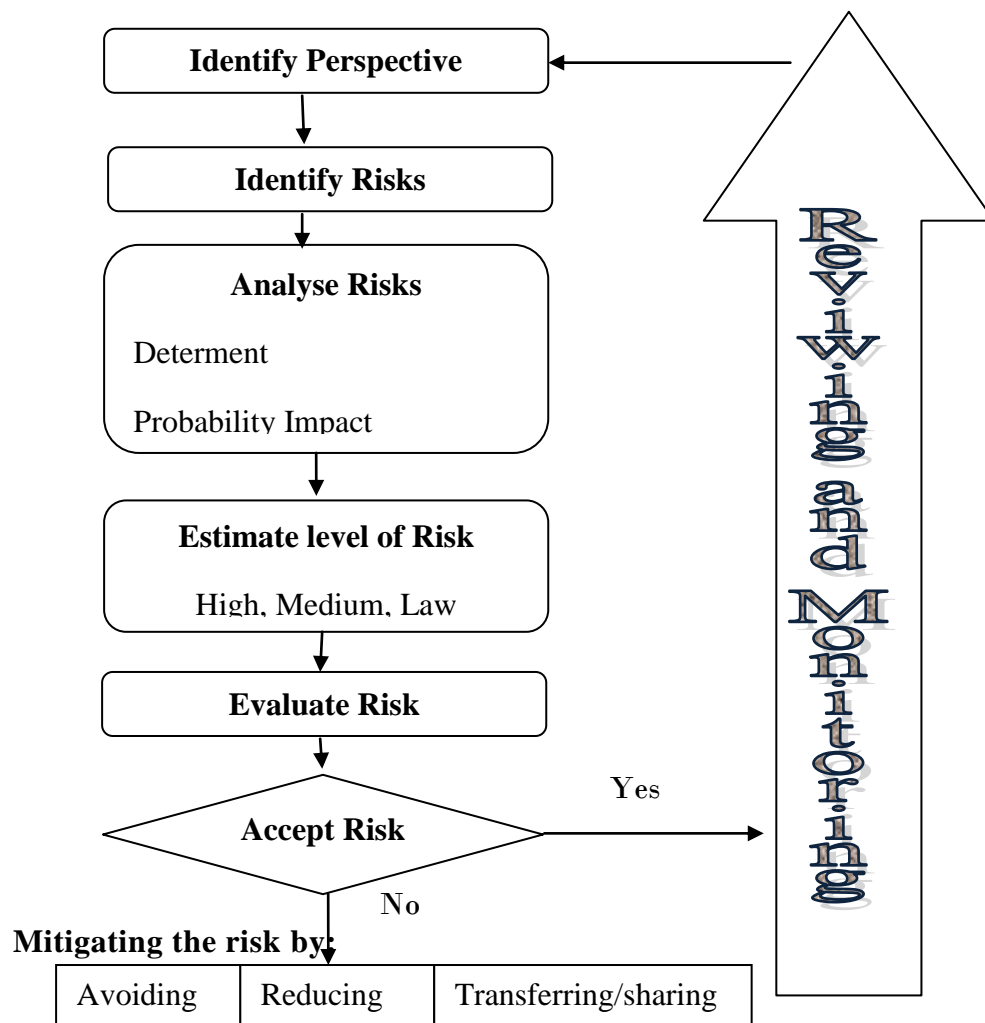


Figure 5.9.1 Risk management process overview

## 5.10 Risk Reporting

Risk reporting is part of the risk management process that involves all steps which have been mentioned in the previous sections of this chapter. The purpose of the reporting is to help identify potential and actual risks and thus mitigate or prevent failure (Raheja 2011, p. 72). Risk reporting means communication between all project teams; each individual in the work chain must be informed about the risk management activities. Reporting to senior managers may consist of a total number of risks, total risk score in each unit, perhaps supported with trend analysis presented graphically (Hillson, 2003, p. 94).

If the report is appropriately designed, written, communicated and documented, in time a clear image ought to be appearing about the achievement of various risk management activities in the organisation. An effective report might increase the level of participation in the future by all members, especially managers.

Risk reporting can be presented orally or as a written document. Whatever medium is used to deliver the report the crucial points are that the report must be documented and communicated effectively to all participants and accompanied by real change or improvement ideas. The reporting and documenting of a risk management process will facilitate potential learning opportunities. Battles & Stevens emphasise that risk reporting must be escorted by improvement and real change in the situation (Battles & Stevens, 2009).

Thomson, et al.,(2005, p. 465) deem that there is increasing evidence that customers or patients who are better informed about their risks and more engaged in the decision are more likely to be knowledgeable and have a better outcome. According to Benn, et al., (2009) effective feedback from a failure reporting system in health care is a crucial matter if organisations are to learn from failures in delivery of care. The successful reporting system used a variety of methods to encourage reporting and enhance usability, provide effective feedback to users, communicate information effectively to

hospital managers and closely link risk reporting with improvement and change (Shojania, 2008, p. 400). However, lack of effective feedback inhibits the willingness of staff to report risks.

### **5.11 Risk Scales**

The literature includes several efforts to set down scales that can increase the understanding of risk. Risk assessment scales for improving the health care service for patients have been used for several years, and different scales have been developed (Fossum, et al., 2012, p. 1). A successful risk assessment scale will facilitate, compare, describe and elevate the understanding for staff and patients about the risks they face. A high-quality Risk Scale should lead to decision-making that staff and patients feel comfortable with. Staff felt that a range of harmonising formats for providing information about risk would be better than a one-person strategy (Mohanna and Chambers, 2001, p. 28). There are several scales used to describe and compare risks. The following is a description of the most commonly used scale in the health sector.

#### **a-The Paling Perspective Scale (PPS)**

The Paling Perspective Scale was proposed by John Paling and devised for when managers are faced with a situation and do not know what to do (John and Paling, 1993). It is a logarithmic scale of risk assessment (Lee and Kehta, 2003, p 779). PPS allows the managers to lay the risks of failures in order along the logarithmic scale for controlling or comparison.

The benefit of this scale is the user can place any unpleasant medical or technical mishaps for controlling or comparing risks. According to Mohanna and Chambers this scale is more useful for irreversible risk than temporary, such as an unpleasant effect of treatment that will vanish when the treatment is closed (Mohanna and Chambers 2001, p. 28). See the following figure which depicts the PPS. This scales show only the probabilities not the consequences of problem occur.

### The Paling Perspective Scale

1in1 Trillion	1in100 Billion	1in10Billion	1in1Billion	1in100Million	1in10Million	1in1Million	1in100,000	1 in 10,000	1in1000	1in100	1in 10	1in1
												Risk of dying
Totally S-For all practical				Effective Zero		Minimum	Very Low	Low	Medium	High	Very High	Extremely High

Figure 5.11.1 the Paling Perspective Scale (John Paling, 2000).

**b- Numerical Scale:**

The numerical scale was developed to measure the probability and the impact in order to prioritise risks. There are a number of different numerical scales, such as the geometrical scale and Saaty scale (Dong, et al., 2011, p. 13). A number of researchers have argued that the choice of numerical scale is an open research issue in analytic hierarchy process discipline (Harker and Vargas, 1987). The choice of any scale is a result of experiment (Finan and Hurely, 1999, p. 365). The following graphs are examples of numerical scale.

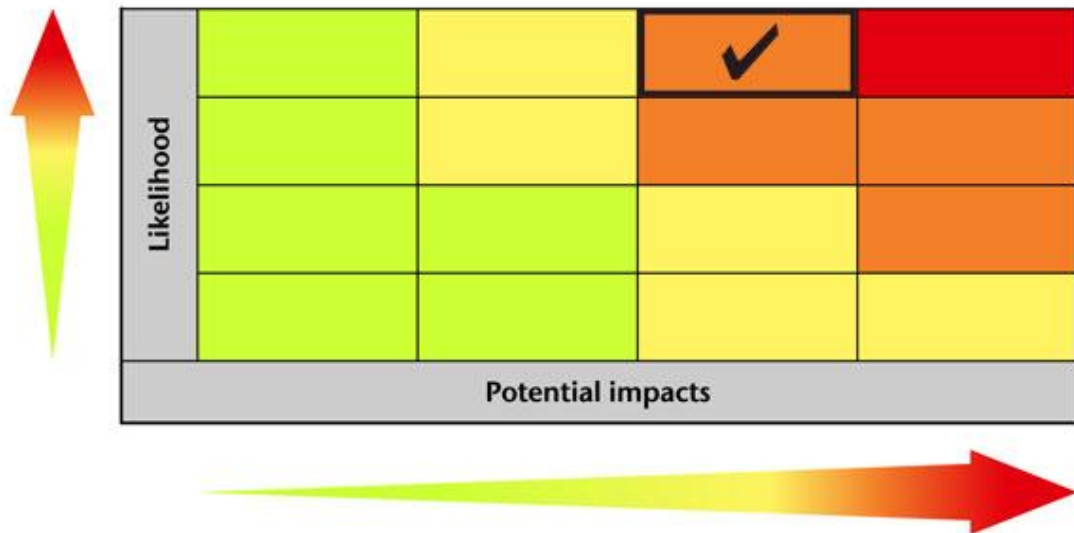
		Impact				
		Very Low 1	Low 2	Medium 4	High 8	Very High 16
Probability	Very High 5	5	10	20	40	80
	High 4	4	8	16	32	64
	Medium 3	3	6	12	24	48
	Low 2	2	4	8	16	32
	Very Low 1	1	2	4	8	16

**Figure 5.11.2 depicts Numeric Scale (JISC InfoNet)**

The numerical scales show a guide for management of an action needed for each combination of probability and impact. For instance, the most harmful combinations are shown in Red and a radical action is required and the least harmful are shown in Green and which may need action as well.

The UK National severe Weather Warning Service (NSWWS) is one of the global organisations which uses a Numerical Scale in weather forecast aims to take account of uncertainty by providing organised forecast scenarios of probability forecasts. The warnings are presented by colour coded all “risk areas” on a map (see the figure below); these colours are based on the probability of a particular severe weather event occurring

and its impact if it does occur. The matrix information below showing how a warning was assigned, the Green describes no severe Weather, the Yellow represents be aware, the Orange give a picture of be prepared and the Red illustrate take action.



*Figure 5.11.3 depicts Weather forecast risk management using numeric Scale. The Matrix adopted from Met office. Available on <http://www.metoffice.gov.uk/research/news/weather-warnings> entered on 12/4/2013*

## 5.12 Modelling

Models are important help to understanding a complex system. They also help problem solvers to detect root causes about the essential features and dynamics of a system (Keppen & Qiang, 2004). Constructing a model is not an easy task, needs more time, effort and may need many disciplines to be involved in the construction process. Here in this research we want to review a well-organised-Risk Management technique and use it as a means of improving the quality of hospital performances, including safety and accident prevention. Models are constantly developed to detect threats, probability and help to provide a reasonable solution to problems.

ORMTM is an acronym for Ordered, Risk, Management Tree, Model, in the Health care domain. Sandres and McCormick (1987) represent model as an abstract that represents a system or process. A model cannot be judged correct or incorrect, and the only criterion for judging is a model's utility (Sandres & McCormick, 1987). Thus, a good model is one that accounts for the process, and can be used to get information in order to facilitate the work or solve problems.

Curwin and Slater (2002) stated that models are of interest to many researchers because they illustrate problems and causes. Renn has stated that modelling is the most necessary step to isolate a causal agent for problems from among several dominating variables (Renn, 1998, p. 52). Modelling for risk assessment can provide an early warning indicator to inform an employee that a specific material may cause harm or damage to them, or to their environment, even if the outcome is not clear for all staff.

There are many examples models, for instance; being in a queue in hospital's outpatient department (OPD) or Emergency and Accident Department (EAD), we all have to wait to see our doctor and other health care professionals. Queuing in one form or another is part of our lives. Even if organisation managers are not directly involved in managing a waiting list or queues, they are likely to be concerned with good quality performance, cost mitigation and satisfaction of patients and families; these can be obtained easily by designing a good model. Waiting in a queue for a long time represents a lack of quality in the service, lack of good quality management, while decreasing the waiting time may increase cost. As mentioned earlier, the purpose of our model is to help the system users in hospitals and other health care providers to detect and mitigate risk in order to provide a good quality service for the clients and prevent future accidents.

Before, we think about building or exploring our risk models in EMR system, it is fundamental to set steps by examining goals related to the modelling attempt. Here, we are pointing up what the model can and cannot be expected to perform. According to Banks (2005), a properly constructed model can afford researcher to estimate the

likelihood of occurrence of accident, event, and estimate the financial loss that will result if an event occurs.

However, a risk model cannot be expected to forecast when or where an accident will occur, forecast the precise intensity of an event in a particular area, effort and exact assessment of the financial losses that may occur and apply commonly to all threats, and locations (Banks, 2005 p. 51).

### **5.13 Summary**

Risk management is a continue process, and not a once in a lifetime activity. Risk is a common and widely used term of today's terminology and it has many definitions but there is still no wide consensus on the meaning of the term, unless its tangibility. Risk process involves 4-6 main steps: risk identification, risk analysis, risk assessment, risk controlling, and so on. When risks are identified and analysed effectively the remaining actions will fall into 5 categories; to avoid, reduce, transfer, accept and share risks.

An effective risk management can reduce costs and allows organisations to plan better. Quality service grows through greater risk taking. This chapter discussed risk management in electronic health record as a holistic issue and explained all its process independently. It also illustrates the importance of using and understanding risk scales and developing Models in a complex system. Models are constantly developed to detect risks, provide, probability and enhance users by reasonable solutions to problems. Models cannot be judged to be correct or incorrect, and the only criterion for judging is the model's utility. Thus, it has been verified to be difficult to model common mode failures, i.e. the simultaneous breakdown of system components. The risk factors discussed in this chapter showed, that there are a variety of risk factors in ITS but there is less attention paid to the EMR systems in hospitals.



# Chapte 6

## Risk Management Techniques (Approches)

### Objectives

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- General overview of risk management techniques
- Detect the strengths and the weaknesses of some common techniques
- To describe the System Theoretic Accident Model Process (STAMP)
- Explore the most appropriate technique for risk management and accident prevention STAMP.
- Explanation of STAMP usage to analyse system Failure

### 6.1 Introduction

A variety of risk management (RM) techniques exist in literature, and scholars have developed their own approaches to failure or accident, investigation, analysis and prevention (Leveson, 2004; Rasmussen, 1997). This chapter considers the value and implementation of some common qualitative and quantitative RM techniques in delivering safe health care services, but it does not attempt to explore each individual risk technique. Rather, it seeks to explore the strengths and weaknesses of these techniques and compare them against each other. We do not claim that the selected techniques are exhaustive with respect to the number of techniques in the safety field. Generally, qualitative and quantitative techniques are suitable for managing risk. For some projects, qualitative methods can be used to provide more information (Jones and Ashenden, 2005, p. 217), however it is also possible to combine the techniques in order to manage the risks of an EMRs system.

Existing literature describe qualitative and quantitative traditional and non-traditional techniques. The Domino Theory (DT) is one of the earliest qualitative sequential accident analysis techniques; it was proposed by Heinrich in the 1940s (Heinrich et al., 1980). In DT, the cause of an accident is seen to be the result of a chain of separate events that occur in a temporal order. The DT model fits in to the first class of accident causation models proposed by Hollnagel; he distinguishes between three types of failure causation models, namely: sequential; epidemiological; and systemic (Hollnagel, 2004). This class views the failure as a result of a sequence of linear events, the last event being the failure or accident (Salmon et al., 2011, p. 2). Ouyang, et al. (2010, p. 544) identify five factors in accident sequence theory: social environment; staff faults; unsafe acts or conditions such poor planning; unsafe equipment; and accidents.

The following sections of this study will discuss the most widely recognised and used RM techniques and present some hypothetical examples. We start with the most traditional techniques, such as electronic brainstorming, root cause analysis (RCA), failure mode effect analysis (FMEA), failure mode effects and criticality analysis

(FMECA), the Binary Diagram model (BD), fault tree analysis (FTA) and System Theoretical Accident Model Process (STAMP). The traditional RM techniques mainly deal with the identification of incident chains; they look for unsafe acts or situations that lead to the failure (Doytchev and Szwillus, 2009, p. 1173). Such methods are used to establish the reasons for past incidents or failures. It is unlikely that any of the traditional techniques that discussed in this chapter be appropriate for an organisation to use without tailoring.

We included literature references in books in our review and used Google Scholar, supplemented by the IEEE digital libraries, as starting points to search for relevant literature about risk and safety techniques.

### **6.2 Traditional Brainstorming and Electronic Brainstorming**

Brainstorming is a traditional technique used for generating creative ideas through idea sharing, such as by identifying potential causes of problems and risks. Idea generation is critical for problem solving steps. Scholars have devoted a considerable effort to establish techniques that can help to identify work processes causes of failures and risks in order to detect perfect solutions (Gallupe et al., 1992, p. 350). In early 1942, Osborn developed the brainstorming technique and described how it could be used to help users to generate ideas (Osborn, 1957). The technique is most effective when used by groups with no more than 12 members (Leggett & Paulus 2005, p. 313; Gallupe et al., 1992, p. 351). Group brainstorming is useful because, they are listening to other group members' ideas, the individuals in the group are prompted to think of new ideas that they could not explore on their own (Wang et al., 2011, p. 265).

Brainstorming has been used by many organisations for almost 60 years. Practical experiences have shown that effective use of this technique generates more unique ideas than would be generated by an individual. Often, a group of people will be given a problem or task to discuss, and every participant will be encouraged to make at least one suggestion (Basu, 2004, p. 36).

New forms of the brainstorming technique have emerged recently, namely, nominal group brainstorming and electronic brainstorming (EBS). Both techniques have been found to be more productive than traditional verbal brainstorming (Dennies et al., 2005). In EBS, contributors collaborate with one another using computer: every contributor types his/her ideas into his computer at the same time as the other participants. In this way, all ideas are seen and shared by all contributors, thus reducing potential duplication of ideas are the results (Gallupe et al., 1992, p. 352). EBS generates more unique ideas; Gallupe and his colleagues (1991) showed that EBS groups with 4 participants out-performed verbal brainstorming groups of the same size (Gallupe et al., 1991).

### **6.3 Root Cause Analysis (RCA)**

The Root cause analysis (RCA) technique is an investigative procedure using a ‘total system’ aimed to explore the root causes of failures. RCA is a useful retrospective technique: it recognises failures as faults in the whole system (White, 1995, p. 37). The technique is recommended when the frequency of the failure is very high; however, if the failure frequency is very low or unknown, the use of this technique is not recommended (Bonnabry et al., 2005, p. 94). For the reason that, the usage of RCA need more time and well-trained personal.

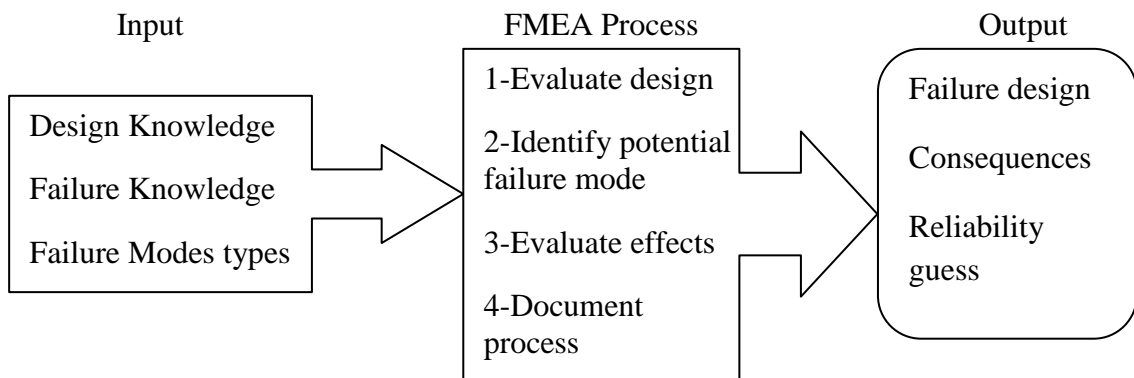
The following subsections introduce the most common risk assessment techniques used in various industry sectors.

As well, as it is not sensible to wait for failure to occur, the use of proactive risk analysis techniques is also highly recommended. For instance, the Joint Commission on Accreditation of Health Organisations (JCAHO) requires each accredited hospital in the United States of America (USA) to conduct at least one proactive risk assessment annually using the FMEA technique. There are number of proactive techniques described in the literature which aim to improve the safety of patients in the health care domain; these include both qualitative and quantities techniques such as the Hazard

Analysis and Critical Control Point (HACCP) technique, probabilistic risk assessment (PRA) and FTA (Kessels-Habraken et al., 2009, p. 427). Despite differences between these techniques, all aim to identify, assess and eliminate risk before or after failure occur.

### **6.4 Failure Mode Effect Analysis (FMEA)**

FMEA is a proactive risk assessment technique; it is a structured approach for forecasting and identifying the consequences of system failures (Win et al., 2004) and is used to identify the possible effects of individual failures within a system (Marx & Solnim, 2003). In the health care industry, the implementation of the technique begins by drawing the process of care. Next, the risks are identified in order to understand how and why failures occur. Finally, mitigating actions are carried out (Shebl et al., 2011, p. 1). Health care providers have more readily accepted FMEA, than other techniques because of its proactive nature. FMEA uses professionals' experiences and skills and takes a positive approach to problems by focusing on the examination of a process as a whole (Chiozza & Ponzetti, 2009). The JCAHO underlines the importance and validity of FMEA in detecting and reducing errors: it requires all health care providers to implement the technique every 18 months (Chiozza & Ponzetti, 2009; Marx & Slonim, 2009; Kessels - habraken et al., 2009, p. 427; Dlugacz, 2006). The International Standards Organisation (ISO) licensed the technical standards specification ISO/TS 22367 for medical laboratories and uses the technique as a proactive risk analysis of high risk processes to do necessary improvement that will mitigate the chance of unplanned adverse events' (Chiozza and Ponzetti, 2009, p. 76). To conduct FMEA, it is essential to understand the basic steps of the technique. The following figure depicts the basic process of FMEA.



**Figure 6.4.1 FMEA basic process (adapted from Ericson, 2005)**

The technique can be easily learned and practically applied to different types of equipment, systems or software and hardware problems. A worksheet is needed to perform the analysis, present the analysis structure and produce reliable documentation. The worksheet usually includes the following information: *component; failure mode; failure rate; causal factors; immediate effect; system effect and risk priority number (RPN)* (Ericson, 2005; Raheja, 2011, p. 12). The last step is calculating the risk priority number. It is the most controversial one for the reason that the participants are required to score the potential failures within a process of care according to the severity and probability of each failure's occurrence (Franklin et al., 2011, p. 1). The following is a brief discussion of FMEA history.

### **6.4.1 History of FMEA**

The USA military standardised FMEA in the late 1940's since then, it has been used as a technique for evaluating the reliability of military systems and has been adopted by many other industries (Rasputing and Opdahl, 2013, p.1128). In 1950, the technique was deployed at the Grumman Aircraft Corporation as an assessment technique for production system safety and reliability (Zhang and Chu, 2011, p. 206). In the 1960s, the National Aeronautics and Space Administration (NASA) formally proposed the technique for their reliability requirement and, since then, the technique has been extensively used as a powerful tool to assess safety and reliability in a wide range of fields (Liu et al., 2011, p. 4403).

Like other RM techniques, the application of FMEA in the health sector lagged behind its use in other industries. Many researchers have acknowledged that the use of FMEA in the health care field started in the 1990s (Chiozza & Ponzetti, 2009; Nada et al., 2012, p.1). In health care, FMEA has been used to ensure delivery of reliable standardised processes, such as those that are used to admit patients into the hospital and to administer medication (Raheja, 2011, p. 122).

### **6.4.2 FMEA Limitations**

Despite its success and popularity, some limitations have been identified. Table 6.4.2 summarises the limitations and strengths of the FMEA technique.

**Table 6.4.2 FMEA limitations and strengths**

Strengths	Weakness	References
Proactive and bottom up Technique.	Cannot identify risk point combination in complex systems	Chiozza & Ponzetti (2009)
Shows the direct relationships between component failures and system failure.		Walker & Papadopoulos (2008, p. 371)
Can evaluate and a Analyse all possible risks in order to eliminate these risks to an acceptable level.		Zhang & Li. (2013, p. 192)
Do not require complicated statistics		MacDermott & Beauregard (1996)
	Cannot capture the dynamic interaction between system component in complex systems	(Qureshi 2007, p. 48)
Helps to identify high risk areas.	Time consuming nature. Neither valid nor reliable.	(Zhang & Li., 2013, p.193; Shebl, et al., 2012, p. 1)



### **6.5 Fault Tree Analysis (FTA)**

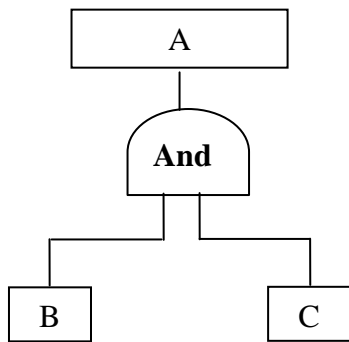
The FTA technique was developed in the 1960s by Bell Telephone Laboratories; since then, it has been used in a variety of fields including the nuclear and aerospace industries. As well, FTA was used effectively in the missile launching safety control system (Park & Lee, 2009; Walker & Papadopoulos, 2008, p. 368).

FTA is an extension of an event tree method that portrays various events and their outcomes associated with particular courses of action and the probabilities associated with each event (Wreathall & Nemeth, 2004, p. 207) and is, according to Reliability Analysis Centre (1990, p. 8), a faster method for analysing failures than FMEA. It is one of the most useful techniques that can be used for qualitative and quantitative analysis in risk (Win, et al, 2004; Doytchev, and Szwillus, 2009 p. 1174). According to Mo and Xiaozong, FTA is widely accepted to assess the probability and frequency of system failure in many industries (Mo and Xiaozong, 2007, p.122). The technique can identify hazards systematically; thus, it is recognised as a reasonable analysis technique. This means that the analysis starts with a system failure and works backwards to determine its root causes (Tummala & Leung, 1996; Walker & Papadopoulos, 2009, p. 1115). FTA identifies events with a high-risk priority depending on likelihood and impact. It is a top-down risk management technique.

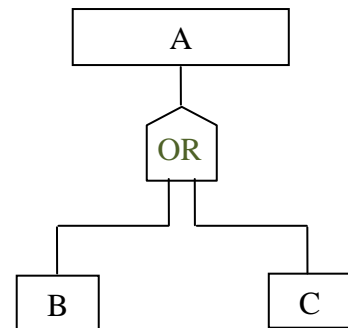
It determines various combinations of system failures and human errors that could lead to the occurrence of an undesirable event or accident which is called 'top event'. Quantitative analyses calculate the probability of the top event occurring from the probability of the other basic events (components). The technique graphically presents the possible normal and defective events that can cause the top level failure (Raspotnig and Opdahl, 2013, p. 1129). Qualitative analysis, on the other hand, illustrates which combinations of failures must occur together to cause a top failure (Mo and Xiaozong, 2007, p. 122).

The FTA's graphic model shows the pathways within a system that can lead to an undesirable event after passing through a 'gate'. The most commonly-used gates are 'AND' and 'OR'. The 'AND' gate means that all of the influencing factors must apply simultaneously to cause the failure; the 'OR' gate means that at least one of the influencing factors must apply to cause the failure (Mo and Xiaozong, 2007, p. 124).

Probability in FTA can be calculated either with the 'OR' gate or with the 'AND' gate (Moriyama and Qhtani, 2009, p. 1383). Examples of 'AND' and 'OR' gates are presented in Figures 6.5.1 and 6.5.2; equations for these are also revealed (Hoodate & Rashidi, 2009):



**Figure 6.5.1 "AND" Gate**



**Figure 6.5.2 "OR" Gate**

$$P_{(A)} = P_{(B)} \cdot P_{(C)} \quad (1)$$

$$P_A = 1 - (1 - P_B) (1 - P_C) \quad (2)$$

$$P_A = P_{(B)} + P_{(C)} - P_{(B)} \cdot P_{(C)} = 1 - (1 - P_{(B)}) (1 - P_{(C)}) \quad (3)$$

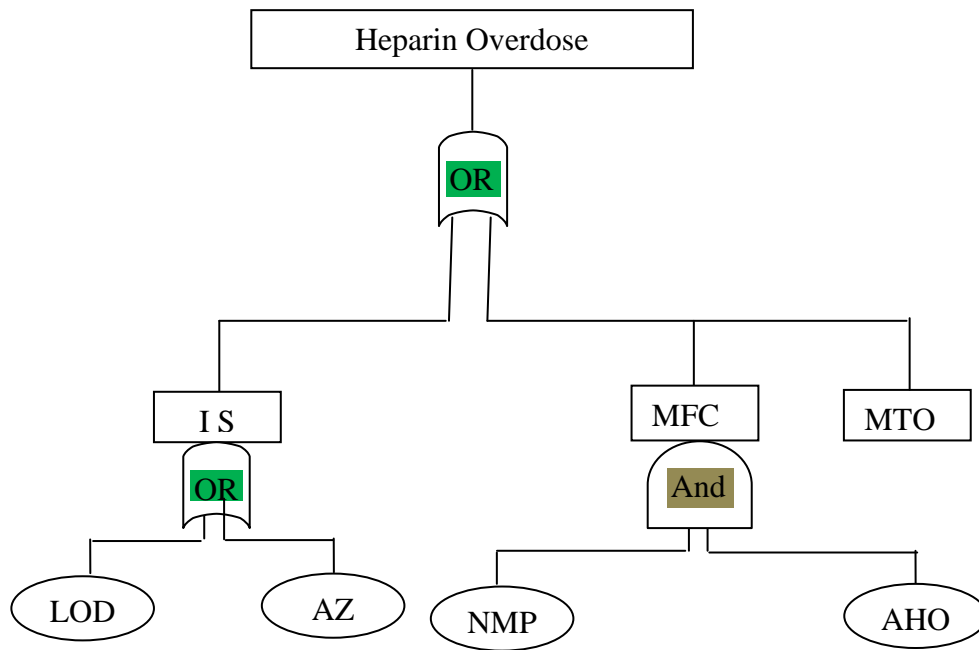
Equation (1) is used for events of an 'AND' gate; equations (2) and (3) are used for events of an 'OR' gate. In the above equations,  $P_A$  is the probability of failure of the input events, and it is assumed that the input events are independent.

FTA is an effective technique for showing how combinations of failures or human errors might lead to a holistic system failure. However, the technique has notable limitations such as some important failure causal factors are difficult to fit into event tree models (Leveson, 2004, p. 240). For example, studies have shown that management commitment to safety in organisations is one of the most important factors in the occurrence of failures. In addition, FTA can only examine one specific event at a time. In order to manage more than one event, another FTA must be constructed. Khan and Abbasi have identified another important limitation of FTA: they note that the technique is sophisticated and requires considerable time and effort as well as skilled staff (Khan & Abbasi, 2000, pp. 1-27). Cai and Wu., (2009, p. 4330) add that ‘ dealing with large FTA, the limitations of the technique in term of accuracy of the solutions and efficiency of the processing time become apparent such as limited ability to handle system accident.

Alsulami et al (2011, p. 140) stated that there are a number of different ways to reduce medication errors include the use of FTA technique, medical devices such as Infusion pumps, city scan, blood gas machine in addition to the action of double-checking by qualified medical practitioners (Alsulaimi et al., 2012, p. 140). Study done by Blank, et al, (2011) shows that most emergency units medication errors do not result in patient harm, but when they do, the impact ranges from slight temporary effects to permanent injury or death. Like other risk management techniques, FTA can be used in hospitals or a combination of techniques can be used to manage risk.

Consider the following hypothetical example that shows a simple analysis of a medical device that is used to provide treatment for patients. The following is an example of using the FTA technique for a medical device; the fault tree (FTA) provides a systematic description of the combination of possible failure occurrences in the device. The FTA technique’s basic procedure is to assume that the failure has occurred and then work backward to determine its possible causes (Cha et al., 1988, p. 378).

Medical devices are developed for many reasons: to treat patient with high quality, to prevent medication errors, patient injury and to intercept overdosing or under-dosing errors while administering intravenous (IV) treatment, among others (Wilson et al., 2004 p. 182). A multi-centre audit in the United Kingdom (UK), France and Germany reported that 81 medication errors events in hospitals were mainly due to incorrect dose administration, which involves 1144 children (Qureshi et al., 2011, p. 141). The Heparin infusion pump is one of the devices, which has revolutionised the way nurses administer intravenous therapy, but these devices may also contribute to causing medical errors or patient harm. Experience and literature reviews have shown that most Heparin infusion pump-related errors occur because of incorrect settings or because the pump was programmed with an incorrect dose ordered by a physician. Wilson and his colleagues state that the infusion pump is capable of delivering as little as 0.05 ml/hr or as much as 1l/hr of treatment; therefore, simply leaving out a decimal point or adding a zero when programming the pump can result in an overdose (Wilson et al., 2004, p. 180). The following graphical figure illustrates the supposed top event Heparin overdose given to a patient via infusion pump.



**Figure 6.5.3 depicts the example:**

**Incorrect Setting (IS)**

- ✓ Incorrect dose adjusted by: adding Zero (AZ) or leaving out decimal point (LOD)
- ✓ The Infusion Pump machine Failed to Close

**Machine Failed to Close (MFC)**

- ✓ No maintenance performed (NMP)
- ✓ Alarm had override (AHO)

**Machine is too old (MTO)**

The overdose can be attributed to one of three causes: the incorrect dose was administered by the nurse; the Heparin pump machine failed to stop or close due to a lack of maintenance or an alarm override; the machine was out of order. The last cause is not considered further because the infusion pump is assumed to be a new brand of

high quality. The first and the second causes were analysed further. We can assess the risk level of an overdose based on the standards in the following table:

**Table 6.5.1 Risk level of Heparin overdose**

Level	Frequency		Probability
Low	Nearly impossible to occur	Less than once a year	[0, 0.00137]
Intermediate	Accidently occur	Once a year	[0.00137, 0.00274]
High		From 1-3	(0.00274, 0.00822)
Extremely High	Frequently occur	From 2-6	[0.00548, 1]

This risk tree model can be converted into a mathematical model to compute the probabilities. The example of ‘AND’ and ‘OR’ are represented in the Figure 6.5.3.

In this example, the probabilities for both gates ‘OR’ and ‘AND’ are assumed to illustrate the use of the FTA technique to manage risks. As depicted above, the probability of an incorrect setting (IS) is extremely high; therefore, immediate action is needed to mitigate the risks and prevent the top event occurrence.

$$P_{IS} = 1 - [(1 - P_{LOD})(1 - P_{AZ})] \quad (1)$$

$$P_{IS} = 1 - [(1 - 0.006)(1 - 0.005)]$$

$$P_{IS} = 0.01097$$

The probabilities and equation for the ‘AND’ gate is illustrated in the following formula:

$$p_{NMP} = 0.00137$$

$$p_{AHO} = 0.00137$$

$$P_{MFS} = P_{NMP} \times P_{AHO} \quad (2)$$

$$P_{MFC} = P_{0.00137} \times P_{0.00137} = 0.00000186$$

The probability of the machine failing to close is low, so the priority for taking action to mitigate the risk is slighter lower than the probability of (IS). The top event probability can be calculated by the following formula:

$$P_{HO} = 1 - [(1 - P_{IS})(1 - P_{MFC})] \quad (3)$$

$$P_{HO} = 1 - [(1 - 0.01097)(1 - 0.00000186)]$$

$$P_{HO} = 0.08972$$

The probability of the top event—Heparin overdose—is high; therefore, the risk should be managed and mitigated in order to prevent patients and similar accidents in future.

The result is suitable that can be controlled and prevent easily. Even though the probability of ‘machine failed to close’ (MFC) due to the lack of maintenance is low, action still needs to be taken because the impact of the medication errors ranges from ‘slight effects’ to ‘permanent injury or death’. In the literature, too many of these types of errors have resulted in death of patients. (See Chapter 2.18 for more information about such errors).

The next section provides brief information of Binary Decision Diagram (BDD) technique, which was used to overcome the explicit limitation of FTA technique.

### **6.6 Binary Decision Diagram (BDD)**

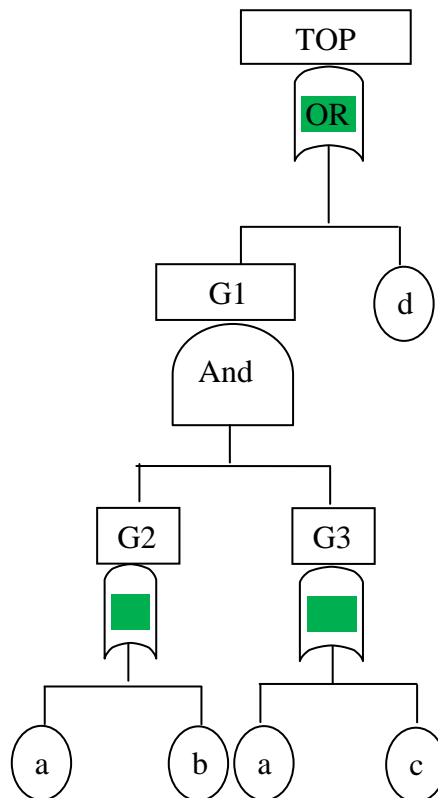
The BDD technique was introduced predominantly by Bryant, and developed by Rauzy to address the weaknesses of the conventional FTA approach (Rauzy, 1993). According to Cai et al., (2009, p. 4330), one of the obvious limitations of FTA was the accuracy of the solutions and the efficiency of its processing time. The BDD technique was created to be used in parallel with FTA (Liu and Wu, 2009, p. 4330). Rementy and Andrews note that the advantages of the BDD technique could be seen by constructing a FTA and then converting it to the BDD technique, nevertheless, the BDD does not analyse the fault tree directly (Rementy & Andrews, 2006). But, sometime problem may occur with the conversion process, if the ordering of the basic events is not selected in order or correctly. All basic events would need to be constructed in sequence throughout the conversion processes to protect the BDD technique's size from growing exponentially. However, it is not simple to identify an optimum ordering scheme to construct BDD for all FTA. Reay and Andrew noted that because there is no general ordering scheme that can be successfully used to create a minimal BDD for all FTA technique (Reay & Andrews, 2002, p. 45).

#### **6.6.1 Construction BDD from a FTA**

As seen in Section 6.5, FTA technique has formed two types of basic analysis method in the process construction: the qualitative analysis: searching for the basic events and their grouping which lead to the occurrence of the top accident and the quantitative analysis which correspond to the calculation and estimating the probability of the top events according to the probability of the basic events (Hu, et al., 2004, p. 360). Fault tree analysis is a quick and accurate for fault diagnosis when the system is simple. The technique is costly, especially for the large scale complex system (Fu, et al., 2013, p. 260). To solve this problem, the BDD is used to simplify the quantitative and qualitative evaluation process. A BDD is a directed acyclic graph, all paths through the BDD in



one direction and no loop can exist (Andrews, 2005) the technique is composed of two end terminal and non-terminal which are linked by branches. The terminal has two end success and failure, the non-terminal correspond to the basic events of the FTA. Therefore, the usual way of taken the advantages of the BDD is to construct FTA and then convert it to BDD. The following figure is an example of a fault tree.

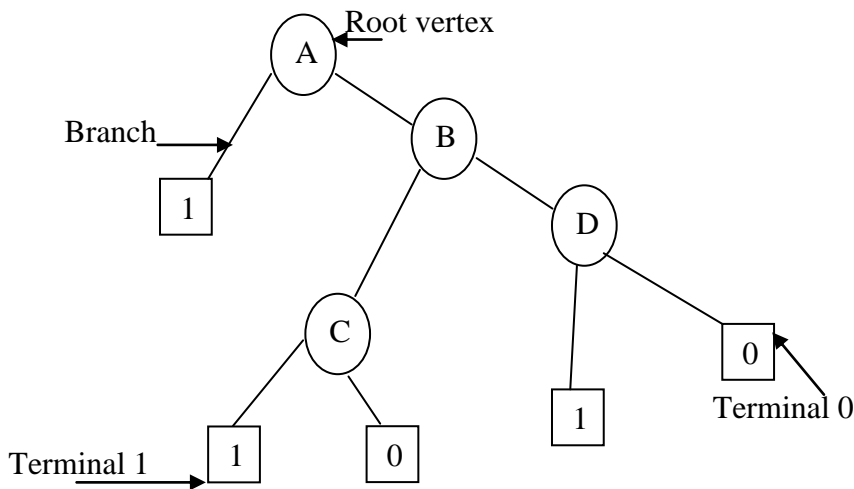


**Fig. 6.6.1 Example of fault tree**

To illustrate the conversion of the above fault tree to the logical BDD with an alphabetical variable ordering  $a < b < c < d$ . See Fig. 6.6.2.

FTA:  $TOP = (a + b) (a + c) + d$ . (Jung, et al., 2004, p. 371).

The transformation from FTA to BDD start from the fault tree's basic bottom events with transforming them to if – then – else structure (ite), then replace all logic gates with basic event gradually ( Hu et al., 2004, p. 362).



**Fig. 6.6.2 BDD structure for the above FT example**

As shown in Fig 5.6.2 three paths from the root vertex (a, b c, d) are constructed from the variables, which represent the occurrence of the basic events in the example of the fault tree above, these events are located in an ordering. The ordering of the basic events can have a crucial effect on the size of the final BDD. Once the ordering is established a set of rules are applied to each gate in the fault tree to generate the BDD. Then the BDD structure for the top event is  $TOP = ite(a, 1, ite(b, ite(c, 1, 0), ite(d, 1, 0)))$ . Jung and colleagues stated that, the size of the BDD construction depends on the variable ordering and the determination (Jung, et al., 2004, p .12). For more information, regarding constricting and investigating the BDD structure to solve large fault tree the reader is referred to the two papers by (Hu, et al., 2013; and Fu, et al., 2013).

The next section provides brief description of the most recent systematic technique used to manage risk and prevent accidents called System Theoretical Accident Model Process (STAMP).

### **6.7 System Theoretical Accident Model Process (STAMP)**

Since most of the previously discussed techniques were traditional and consider the system as static, they fail to identify risks that result from a system moving from a

stable state to unstable state As Leveson, notes traditional techniques do not completely handle systems that have software and complex human decision-making (Leveson, 2003). Systems become more complex as the number of their components and the interactions between humans and the system increase. As a result, researchers sought to develop a functional and effective technique that would overcome the limitations of the existing traditional techniques which were not capable of detecting causes of recent accidents in complex systems.

Professor Nancy Leveson developed the STAMP technique. Unlike most traditional models, it is not based on the premise of a chain of events. Rather, STAMP is based on a constraint-based model, and focuses on the interaction between system components (Leveson, 2004, p. 251; Leveson et al., 2003; Leveson, 2003). The technique has been helpful in assessing, analysing and preventing both past and future accidents in electronic systems, unlike traditional risk analysis techniques, which consider only failure events and work on an existing design (Leveson, 2004, p. 237).

### **6.7.1 The theory and Practical description of STAMP**

The most basic aspect of STAMP is its constraints. In system theory, systems are viewed as a hierarchical structure where each level imposes constraints on the activities of the level below (Leveson, 2003, p. 2). The STAMP accident model is based on three principles: safety constraints; a hierarchical safety control structure; and a process model (Leveson, 2004, p. 66; Leveson et al., 2003, p. 2). STAMP views a system as a set of interconnected components that are engaged in a state of dynamic equilibrium through feedback loops of information and control.

In STAMP, a system is described as a dynamic process that continually changes to achieve its ends by considering all technical, human and organisational factors (Qureshi, 2007, p. 50). The STAMP technique shows that accidents happen as a result of insufficient control or enforcement of safety-related constraints on designs, development and operation (Leveson, 2000, p. 250). Under STAMP, accidents occur

when components fail, internal and external disturbances exist and communication among system components is dysfunctional. In contrast, traditional risk analysis techniques consider the causes of accidents to be a series of failure events or component failures (Leveson, 2003).

In practice, the STAMP technique has been applied in many accident analyses. For instance, in 1994 during the second Gulf War, ‘friendly fire’ caused the shooting down of a Black Hawk helicopter in the ‘No Fly’ zone over Northern Iraq (Leveson, 2002 in Qureshi, 2007, p. 53). All people on the helicopter were killed: 15 USA citizens and 11 others. The technique was also applied to a water contamination accident in Ontario, Canada. The accident occurred in May 2000: 2300 people became ill and 7 died (Leveson et al., 2003, p. 7).

More recently, the technique was applied to analysing a railway accident that occurred in April 2008 at 04:38 China Standard Time (CST) in the Shandong Province China. According to Ouyang and his colleagues, the accident left 72 dead and 416 injured. The accident was investigated officially, and the report released by Chinese government revealed human error as the cause. The analysis resulted in the proposal and adoption of some improvement measures to prevent potential future accidents. For more detail on this analysis, please see (Ouyang et al., 2010).

STAMP as well as other risk management techniques have weaknesses and strengths. Among its obvious strengths are that it provides the users with more information about failures or accidents (Leveson et al., 2003, p. 3). The technique also has a guideline for determining what to model when the goal is to manage risk. Among many other techniques, STAMP was found one of the most relevant to the study of managing risk in health. The Criteria used for the choice are; the technique has been used and shows its effectiveness in many sectors for identifying and managing risk, it considers the entire system operation of our main research question, it reflects the interaction between system and users, and it provides guidance for application, managing and controlling risk factors. Based on these criteria we chose the technique to investigate the risk of EMR

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system failures in our hospitals, see chapter seven. The chapter exemplifies how STAMP can be used in hybrid system events analysis and proposes notations, which might be applicable for representing and communicating the process leading to system failure.

### **6.8 Example of Using (STAMP) to investigate, analyse and prevent systematic accident.**

Accident prevention is one growing area of safety in many industries. Safety of a system can only be inspected by considering the entire system operating in the context of its environment. By applying the STAMP technique we are able to overcome many limitations of traditional techniques. Instead of focusing on linear causation and components failure, STAMP aims to consider interaction between systems components which can come in the form of human, automated, physical design, processes. The system safety depends on imposing constraints on the behaviour of the components in the system (McCarthy, 2013. p, 11). If the constraints are enforced the potential to prevent unsafe condition should be prevented. As mentioned earlier the STAMP technique is better suited for analysing complex systems than more traditional techniques. Therefore, it was chosen to investigate many accidents in various industries. In this section we are describing the application of STAMP in one of the most recent train accidents that occurred in China. The study has been done by Ouyang and colleagues in 2010.

Here we are taken this study as an example, of using the technique with a view to prevent such accident in the future. The technique can explain why the accident occurred and plays a very important role in investigating and analysing accidents or failure. STAMP views systems as hierarchical levels of controls and constraints, with each level in the hierarchy imposing constraints on the level below (Levenson, 2004). Three essential constructs are used by STAMP to decide why control was ineffective and resulted in a failure or an accident: safety constraints, which maintain safety by their presence (e.g. a physical obstacle), hierarchical safety control structures, which

used by STAMP to describe the composition of the systems (see Fig 6.8.1), and process models which integrated into STAMP as an automated or human controller (Underwood, and Waterson, 2013, p.4; Leveson, 2011). The process model considers all technical, human and organisational factors in a complex socio-technical system. In the view point of STAMP an accident occurs from inadequate control or enforcement of safety related constraints on the development, design, and operation of the system (Underwood and Waterson, 2013, p. 4; Ouyang, et al, 2010, p. 545). In the following subsection we will describe the application of STAMP approach to analyse the railway accident for several reasons. It is the most frequently cited and has been applied previously to analyse system accidents (e.g. Underwood, Waterson, 2013; Salmon, Cornelissen, Trotter, 2012). The following Fig. 6.8.1 shows the hierarchical control structure to ensure the safety operation of the trains in China, which has been proposed by Ouyang and colleagues (2010).

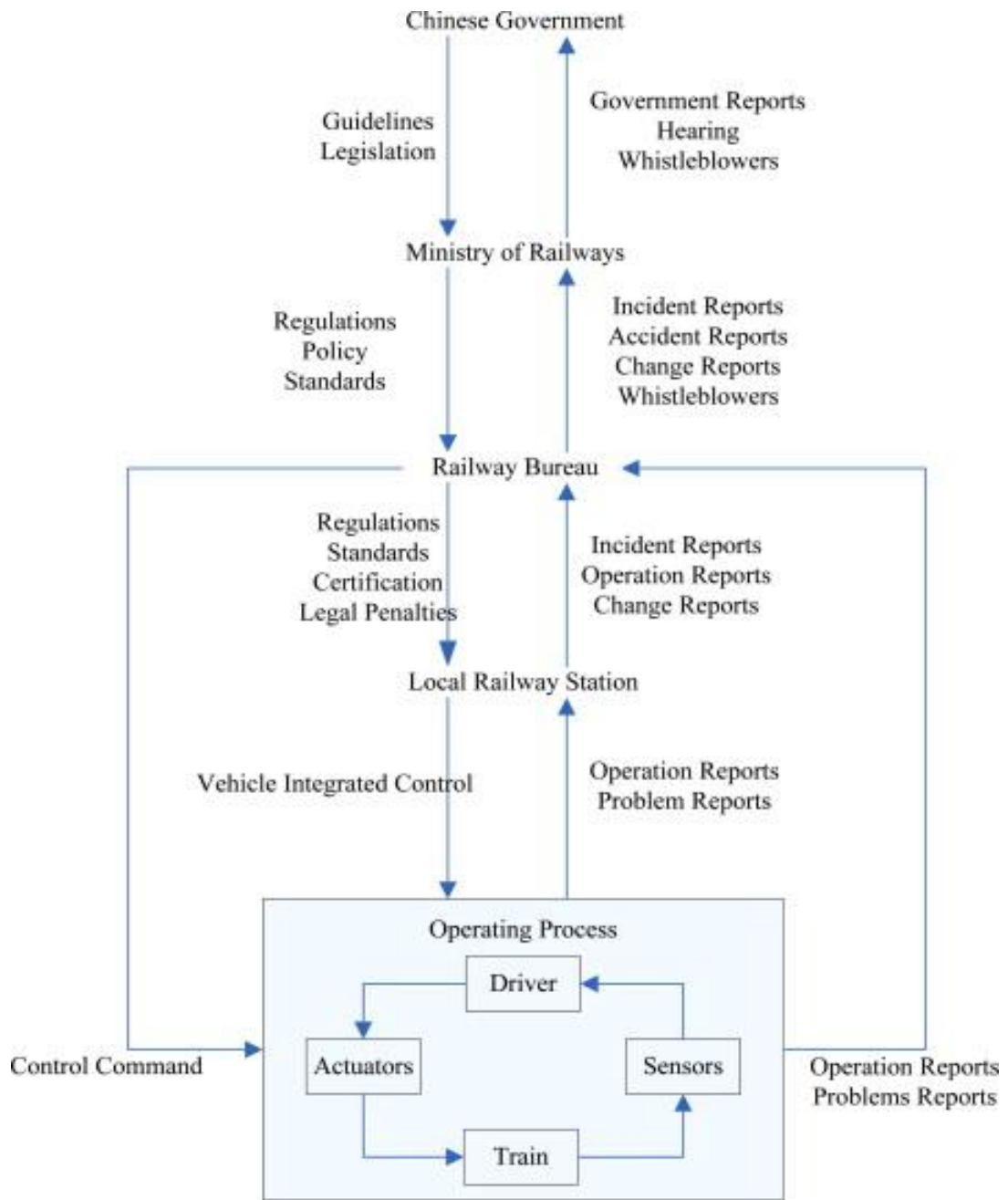


Fig. 6.8.1 .The hierarchical control structure to ensure the safe operation of trains in China

To investigate and analyse the causal factors of a system accident, the procedure of STAMP can be explained as Leveson stated: first to identify the risk involved in the accident. Second to draw the hierarchical safety control structure related to the risk and

constraints needed to control the risk for each controller. Third starting from the technical process and using the recent events and general application knowledge, any accident and impractical interactions involved in the accident are identified. Finally, for every constraint, a determination is made about why it was violated (Levenson, 2002). From the above figure, it can be seen that the essential levels which were started is the Chinese government, who provide the guidelines and the rule to the Ministry of Railway then feeding to each level till it reaches the train driver. Each level has responsibilities, and constraints to be enforced to the level below for example, the local Railway Station is responsible for implementing the “Vehicle integrated control” with the drivers to confirm the safe operation requirement, in addition of reporting of incidents or accidents to the Railway bureau. The railway bureau must send the accident report to the Ministry of Railway; in some special cases they can send commands directly to the drivers. Under the above control structure, Ouyang and colleague had taken the China-Jiaoji railway accident that occurred on April 28, 2008 for this accident they used STAMP technique to investigate and analyse the casual factors of the accident in order to prevent the potential future accident and provide some improvement measures (Ouyang et al, 2010).

### **6.8.1 Accident process**

The accident occurred in April 28, 2008, between the two stations Wangcun and Zhoucun in Shandong region in China. Train T 195 derailed at 04:38 China Standard Time due to excessive speed, carriages from No 10-18 all derailed on the scene those from 1-9 were relatively unaffected. For additional description of the accident process see (Ouyang et al, 2010, section 3.1).

### **6.8.2 Causal investigation**

According to the practice of STAMP the first step is to identify the system hazards. The system hazard related to the accident was derailment of the train. This hazard needs system safety constraints, which is the second step (e.g., the train must not exceed the speed limit: the driver must know the correct speed limits through different kinds of



ways (e.g. IC card, schedule in duty). The third step is the hierarchical control, which used to enforce the constraints and the safety related requirements for each controller the list of the constraints of China railway are as followed:

**China Government:** established rule to ensure the railway safety,

**Ministry of Railways:** establish codes of responsibilities, and accountability for each railways administration; provide oversight and feedback loops to guarantee that each railways management is performing their work adequately; integral legislation, regulations, and policies to protect the safe operation of trains; and ensure employee of each railways administration are capable to carry out their works.

**Beijin Railway Administration:** program for the LKJ transport monitor according to working diagram and control command; confirm the context of received control command with the sender; and set up training requirements for train drivers.

**Jinan Railway Bureau Operation Management:** monitor operations and enforce the legislation, regulations, and policies to safe operation of local railway systems; establish feedback channels for problems found by drivers.

**Jinan Railway Bureau Operation:** regulates the working diagram according to the railway conditions, establish a file for the adjustment, and sends the file to all relative railway bureaus and administrations; track the sending state of the file and control command, and establishes the temporary control command according to the railway conditions and information reported by drivers and staff in the bureau; amend the speed limit signs beside the rails.

**WangCun Railway Station:** Implement the “Coach Integrated Control” carefully with the driver.

**Drivers:** perceive the speed limit displayed on the LKJ transport monitor and operate the train according to the speed limit; pay attention to the speed limit signs beside the rails and run the train according to that limit; run the train according to the control

command issued by the scheduler in Jinan railway bureau; and finally the driver has to confirm the actual speed limit with the assistant in Wangcun station (Ouyang et al., 2010).

The controller in the control structure plays a vital role in enforcing some safety constraints to prevent accidents (Ouyang, et al, 2010, p. 547). However, the train drivers have direct responsibility for the train and passengers safety, because they run the train according to rule, standards placed by the upper decision makers, the speed limit displayed on the LKJ transport monitor, speed limit signs beside the rail and the control command issued by the schedule in the local railway bureau.

### **6.8.3 The role of the automated and human controller in accident occurrence.**

The use of STAMP to analyse and prevent such accidents shows that if the safety constraints are adequately enforced the accident might not occur. The following lines show the inadequate constraints used by the human and automated controller in the control structure:

The driver: did not adhere to the speed limit sign beside the rail, and ran the train at a speed more than the actual speed limit.

The local railway Bureau's inadequate control action: did not carefully check the control command, and amend the program for the LKJ transport monitor; did not amend the actual speed limit for the LKJ transport monitor; did not provide adequate training of all personnel in local railway bureau, inadequate monitoring and supervision of operations; they did not carefully implement the coach integrated control and did not confirm the actual speed limit with the driver.

Ministry of railways, inadequate control actions were: inadequate monitoring and supervision of the safety management for each railways administration, requiring the driver to run the train at speed approached to the speed limit, did not carefully check the

existing problems in the local railway bureau, and did not take further measures to reduce the bad effect of the rumour to close down the Jinan railway station.

### **6.8.4 The results of the usage of STAMP and the improvement measures done.**

In the previous sections the roles of each controller have been analysed and many inadequate actions have been identified to prevent comparable accident in the future. The researchers have proposed the following improvement measure for consideration: the Ministry of the railway must reinforce personal training programs and railway safety culture; more than one train driver and more assistants responsible for “integrated coach control” are needed in order to decrease the probabilities of the error or violation caused by excessive workload; some rules must be added or modified, for instance, drivers should not be penalised due to being behind schedule; all controllers should pay more adequate monitoring and supervision on safety management; and finally many feedback channels in the control structure should be added for example software is needed to automatically send all temporary control command to relevant trains .

## **6.9 Summary**

This chapter has presented a number of the more commonly used techniques to manage risk in the aviation, nuclear, communication and health industries. We described the characteristics of a number of well-known and widely used techniques. These techniques comprise qualitative and quantitative methods. We also described the advantages and the disadvantages of these techniques.

The literature shows that almost all techniques illustrated in this chapter have been successfully used to analyse the risk in real accidents. As well, the notion of probabilities was shown to be fundamental to all risk assessment techniques.

This study selected the STAMP risk management technique to analyse and manage electronic medical record (EMR) system risks. As Leveson (2004) and Rasmussen (1997) highlighted, system accidents are viewed from a theoretical perspective as a

## Chapter 6 Risk Management Approach

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consequence of the inadequate interactions between human and system components in a complex system (Leveson, 2004; Rasmussen, 1997). Having provided an overview of various risk management techniques, the following chapter explores the risks of EMR systems and their associated risks in hospitals.

# **Chapter 7**

## **Exploration of Electronic Medical Record and System failures in MOH Hospitals in Saudi Arabia**

### **Objectives**

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- Provide general overview of pilot Study
- Classify hospitals using EMR systems
- Explore and apply the most appropriate technique for EMR system risk Management and accident prevention

## 7.1 Introduction

There is general agreement that EMR systems have the potential to improve the quality of hospital service (Bleich and Slack, 2010). This chapter will review and assess the current body of knowledge on EMR systems based on a literature review and practical work to identify risks of system failure in the Kingdom of Saudi Arabia.

Countries face similar problems when dealing with EMR system failures such as managing the short-term treatment and long term care programs of a large number of patients. Preventable errors have threatened the lives of millions of patients around the world. Van et al., (2011) allege that medical errors are preventable adverse outcomes that result from inadequate medical management. Recent statistics show that EMR system, which is part of information management technology, is one of the critical requirements for providing excellent health care service (Fraser et al., 2005).

EMR systems play a significant role in any medical information system. They are capable of storing and retrieving a patient's information and help medical practitioners to make decisions or choose appropriate strategies for patient care. The data EMR systems provide is also counted as a basis for scientific research.

It is 'human' to make mistakes, particularly in challenging and stressful environments such as health care; consequently, most Electronic Health Record (EHR) systems and related health information technologies have been devised to improve patient safety and the quality of hospital performance by preventing errors. Recent results by Radecki (2011, p. 92) show that there has been little measurable improvement for preventing errors; however, it is widely agreed that development of health information technology and EMR systems can help health professionals to improve patients' care and other related services (Venkatesh et al., 2011; Hess. Cathy; Thomas, 2011, p. 48; Bleich and Slack, 2010, p. 2; Su et al., 2008, p. 140).

Successful health care providers must support the implementation of comprehensive and workable EHR systems that improve and support the quality of health care process in hospitals. An extensive literature review showed that many organisations worldwide have used EMR systems; some have succeeded, and others are still struggling. For example, in the USA, 83% of the ambulatory care practices have EMR systems (Bleich and Slack, 2010, p. 2). In the UK, a National Health Service (NHS) project targeted to provide an EHR for every patient by the year 2010. This NHS project, one of the largest EHR projects in the world, has suffered delays due to software problems, and the project has therefore been pushed back to 2014 (Chen & Akay, 2011, p. 63; Bleich and Slack, 2010, p. 2).

Some developed and developing countries hold opposing views of EHR system use. For instance, Saudi Arabia is a developing country, which often uses manual medical records (MMRs). This type of record is inflexible; it is difficult tool to use to manage the communication between professionals in health sectors. In Saudi Arabia, patient information is still shared manually, both between a hospital's departments and between the hospital and other health care providers outside of the hospital (Al-Sfadi, 2009, p. 85). Recently, the country has started moving from MMRs to EMR systems in an effort to overcome the limitations of the paper-based MMRs. Starting in January 2007, approximately 30 Ministry of Health (MOH) hospitals participated in a pilot project to implement EMR systems. The MOH and Al-Khaleej Company participated in the project which spanned three years and cost an estimated 64,489,069 Saudi Riyals. When converted to USA Dollar equivalent 11,864,200 \$ .The original scope for the EMR systems was focused on administrative and medical services (MOH and Al-khaleeg Contract Form, 2007).

As part of this study, we identify the use of EMR systems and their effectiveness in improving the safety and the quality of services in hospitals. We also identified the risk factors that might lead to EMR failures.

This chapter explores and describes the use of EMR systems in Saudi Hospitals. It investigates risks in general and risk management in EMR systems in particular. We will reference improvements in the quality of a hospital's performance. The study will be done in two phases: the first phase will be conducted and described in this chapter (Chapter 7), and the second phase will be in the subsequent chapter (Chapter 8).

**Phase One:** In this phase, *we aim to find out the types of EMR systems which are employed in hospitals located in the Riyadh Region of Saudi Arabia.* We will refer to the existing literature and undertake to understand EMR characteristics and system risks in detail. We will measure the level and extent of the use of EMR systems in Riyadh Region. We will introduce briefly the methodology adopted for this phase, which focused on collecting data from the experience of the personnel using EMR systems, conducting risk management (RM) and engaging in quality improvement (QI) efforts in government hospitals in addition of been member of patient and safety and QI committees. These participants were selected because of having detailed information or knowledge about EMR systems, RM and QI and problems in each hospital through attending almost all committee meeting.

A total of 120 questionnaires, with cover letters that described the purpose of the study and included a definition of 'risk' and 'comprehensive EMR', were distributed by mail and facsimile. Data was collected over a two-month period, between 1 April 2011 and 30 May 2011, to ensure that sufficient time was allocated for participants to complete and return the questionnaires. We expected at least 95% of the respondents would return the complete questionnaires on time. Because, of our prior arrangement of risk mitigation The risk of non-returning on time was predicted and managed by scheduled visiting augmented by observing the environment and assuring that participants have understood the purpose of the survey in each hospital in the City .The outcomes presented in this phase include: *a list of hospital classifications and a list of potential risks that may have disturbed the system before, and during the time of, the survey.*



The rest of this chapter is organised as follows: Section 7.2 illustrates the first phase of the research (identification). Section 7.3 shows the methodology of the first phase; Section 7.4 demonstrates data collection; Section 6.6 shows data analysis; Section 6.7 illustrates the results; Section 6.8 (Summary).

## **7.2 Pilot Study**

A pilot study is small-scale test that is done before the main study. It is intended to measure the sufficiency of the study design and the methods to be used for data collection. Piloting the data is very important, it help to estimate the rate of data quality, and the sample must represent the diverse individuals that the main study is intended to cover (Wilson, in Roges and Victor, 1996, p. 103). Other authors have suggested the importance of testing the research questionnaire prior to distribution to ensure the validity and reliability of the survey's format and questions. The questionnaire for this study was designed by the researcher and reviewed by the first and second supervisors who recommended that it be tested in a pilot study.

The pilot study was designed and conducted to prove the useful step in identifying the intervention for EMRs and RM to improve quality of health care services including identifying appropriate outcome measures and high lighting organisational issue. The study conducted at 8 MOH hospitals (with a bed capacity greater than 250 beds) in Riyadh and Makkah over a two-month period. The pilot study sought to differentiate hospitals that use some sort of EMR system from those hospitals that still use manual record systems. Two questionnaires were sent to each hospital; one was to be completed by the head of medical records (MR) and the second by the head of information technology (IT). A total of 16 questionnaires were distributed equally between the 2 cities. All of the distributed questionnaires were received back and analysed. The pilot study was initiated on 29 June 2010 and finished on 1 September 2010.

The main outcomes of the pilot study were as follows. First, the instructions in each part of the questionnaire were deemed to be explicit; however, some of the questions needed

additional choices. For instance, we added one additional option (Nil) to Question 7. Second, a number of respondents, as well as the study's supervisors, suggested that some new questions be added. As a result, Question 3 was split into 2 questions, and 9 more questions were added to the initial number of questions (27) for a total of 36 questions. As well, part of Question 14 (relating to two-part authentication) was deleted.

Of the 4 hospitals that participated in the pilot study in Makkah, 3 of the 4 (75%) use basic electronic records without physician and nursing notes; and 1 of the 4 (25%) still uses manual records. In Riyadh, 3 of the 4 hospitals (75%) in the pilot reported that they use basic EMR systems.

The following table illustrates the main results of the pilot study.

➤ **Table 7.2.1 Main results of the pilot study.**

<i>check sheet</i>					
Collected by: researcher			During: two month		
<i>Number</i>	<i>Hospital Name</i>	<i>Bed capacity</i>	<i>Comprehensive EMR</i>	<i>Basic EMR</i>	<i>Manual EMR</i>
Makkah					
1	King Abdullah Medical City	500		1	
2	Al-Nor Hospital	500		1	
3	Hera Hospital	300		1	
4	King Abdul-Aziz Hospital	250			1
Riyadh					
5	King Saud Hospital (Alshomaici)	1400		1	
6	Al -Yamamah Hospital	310		1	
7	AL - Amal Hospital	507		1	
8	Prince Salman Hospital	300			1
Additional Comment: Size: Small (30-99 Beds): Medium( 100-299 Beds): Large (300≥ Beds)					

**Benefits of the pilot study:**

- We learned a great deal about the use EMR systems in hospitals
- This minor pilot study identified many of the problems relating to the implementation and use of EMR systems in hospitals
- We learned how to elicit information from key personnel in the hospitals
- We familiarised ourselves with where to find information sources in the hospitals and built relationships with personnel

- We learned how to overcome the potential problems that we might face when we conduct the main survey
- We noticed that the information that was obtained from the two most significant staff at an individual hospital were similar

**Conclusion:**

The data and information that were obtained from the pilot study persuaded us that there is a need to conduct a study of risk management as it relates to EMR systems. It also helped us to resolve many small problems with our methodology and approach before we conducted the broader study. The pilot study familiarised us with the characteristics of the managers whom we would be addressing in the main survey. Based on the pilot results, and after making the minor changes that were suggested, the questionnaire was proposed for use for the main study.

**7.3 First Phase: Identification**

The purpose of the survey was to find out the type of EMR systems, which are deployed in hospitals, located in the Riyadh Region of Saudi Arabia, determine the level and extent of EMR system use and discover previous EMR system failures. We expected that hospitals would be using one of the following types of EMR systems: basic and comprehensive (the former have less use of functionalities e.g. without the physicians and nursing notes, the latest has all functionalities in place including physicians and nursing notes) EMR, an MMR or a combination of both. A list of hospital classifications and a list of possible risks that may have impacted the system before, and at the time of, the survey were produced by this phase of the study. The phase also created a direct link with, and source for, the following phase of this research.

In the identification phase, we established a questionnaire that was to be completed by three most knowledgeable individuals in the following departments of each surveyed hospital: Information Technology, Quality Management, Medical Records managers.

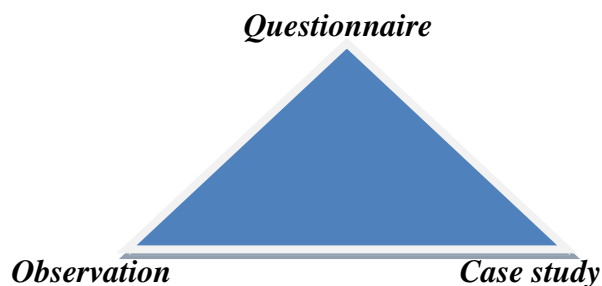
The respondents were selected on basis of having detailed information about risk, safety, EMRs failures and the importance of EMR systems usage in hospitals.

A questionnaire was design and selected as the most appropriate research data collection method to conduct this phase, this was a key learning information detected from the pilot study done earlier (see chapter two). By using questionnaire is possible to draw out information from one or more respondents at the same time. We also noticed that it was important to have the opportunity to explain and clarify the questions to the respondents. Therefore, it was important to be present and available to answer questions while the participants were completing the questionnaires.

#### **7.4 Methodology**

The study in this phase used quantitative method to understand and explore the use of EMR systems and the RM process in hospitals. Varieties of operational method were used to conduct this study in general such as case study, observation and questionnaire. These methods were used to collect data from experienced personnel who were involved in the study.

The literature review showed that observation and interviews are always used simultaneously to examine patients in a hospital. In the pilot study, which was conducted on June 2010 for a period of two Months, we recognized that, without observation, it would not be feasible to participate in the work or investigate an incident or failure in EMR systems.



**Figure 7.4.1 Proposed methods**

Subsequent to developing the questionnaire, we needed to identify the key clinical functions so that the hospital could identify ERM system users. A Consent Letter accompanied the questionnaire; this letter clearly stated that participation in the study was voluntary, and that there was no penalty associated with subjects declining to participate. The Ethics Committee of the De Montfort University approved our protocol. In this exploratory study, conducted in Saudi Arabia, we contacted the managers of each hospital to help us solicit participants for the study. We surveyed all hospitals that are members of MOH in the Riyadh Region by questionnaire. We asked respondents to answer all 36 questions starting from question number one point to the presence or absence of an EMR system in their hospitals; later we asked them to report on the presence or absence of 18 clinical functionalities of an EMR system and whether the hospitals had fully implemented these in their facilities. We then calculated the percentage of hospitals that were using a basic EMR system. In each of these hospitals, the EMR system was developed by a leading vendor and was tailored to fit the needs of the individual hospital. The respondents were also asked to state whether they were using any RM techniques to identify, control and mitigate potential EMR system risks.

### **7.5 Data Collection Procedures**

This section describes our study's first phase of data collection process and the experience of participating personnel with regard to the application of RM for EMR systems in the hospitals. The first data collection phase started on 1 April 2011 and continued to 31 May 2011; (phase one identification) the second data collection phase began on 28 July 2011 and continued to 24 August 2011(phase two case study 2)

Due to the absence of internet services in many hospitals in rural areas, we sent the questionnaires and the explanations letter for conducting the first phase of this study by mail. For those hospitals located in the City of Riyadh, the questionnaires and the Consent Letters were handed to participants personnel 'in person', and the purpose of the study was explained. The Questionnaire Package consisted of the following:

- Covering Letter explain the purpose of the study
- Consent Letter
- Three copies of the Questionnaires (in English and Arabic)
- Return envelope

See appendix C

Two weeks after the package was distributed, we placed a reminder call to those who had not returned the questionnaire. Only 20% of the questionnaires were collected through mail; the remaining 80% were received back by the researcher ‘in person’ during the visit. It should be noted that some participants in the rural areas did not have e-mail addresses.

In the survey, the first question was about the present or absent of EMRs in their hospital we asked the respondents to confirm that. In addition, we asked about the functionalities of the system and whether the hospitals had fully implemented these functionalities in all clinical and non-clinical units. We asked questions regarding the use of authentication mechanisms to protect the confidentiality of patient’s information. We also asked respondents to specify the factors that had been the main causes of the EMR system’s failure in the hospital. The survey instrument can be found in Appendix C.

### **7.6 Data Analysis and Results**

Data analysis can be defined as ‘a way of making sense of patterns that can be imposed on sets of figure’ (Nolan, 1994). The data in our study was analysed using the SPSS statistical software package; it helped to identify various issues from the respondents’ answers and to interpret and organise our findings.

First phase of our study achieved a 100% response rate: this was managed by mitigating the risk of delaying to send back the answered questionnaire through scheduling visits to each participant hospitals in the Region. 120 questionnaires were distributed and all

were returned 24 (20%) questionnaires were received by mail and facsimile, and 96 (80 %) were received by the researcher directly from the respondents during the site visits.

Of the total returned questionnaires, 96 (80%) were returned with uncompleted questions due to the absence of EMR systems in the respondents' hospitals. Parts of these questionnaires were excluded from analysis because most of the questions were related to the availability of an EMR system in the hospital. In addition, the essential aim of this phase is to find out the hospitals that use EMRs in the Region. The 24 (20%) questionnaires that were returned with almost completed questions were used in the analysis process.

We found a large variation in the implementation and usage of EMR system functionalities in the responses from the 40 MOH hospitals surveyed in the Riyadh Region. Only 8 (20 %) hospitals had implemented a basic EMR system without physician and nursing notes, and none had a comprehensive EMR system at the time of our survey. However, larger hospitals regardless of whether they were located in urban or rural areas were more likely to be using basic EMR systems, whereas almost all small hospitals are still using manual medical records.

Respondents also answered that there were many different reasons for EMR system failures. They identified the primary barriers against the continuity of EMR system operations as follows: *incomplete specification of the system operation requirements; inadequate periodic maintenance; lack of an effective project manager; and instability of power supplies.*

The study revealed that one of the eight hospitals using a basic EMR system had abandoned the entire project in 2008, three years after its implementation. The reasons included: poor maintenance, poor management and lack of proper training for users. The remaining 7 hospitals met between 50 and 75% of their performance goals. As noted earlier, 32 small to medium size hospitals are still using MMRs. See Table 7.6.1.



**Table 7.6.1 Calcification of hospitals as having a comprehensive (CEMR), basic EMR system (BEMR) and manual medical record (MMR) in KSA**

<i>List of hospitals</i>					
Collected by: researcher. During: 60 days					
<i>N</i>	<i>Hospitals Name</i>	<i>HBC</i>	<i>CEMR</i>	<i>B EMR</i>	<i>MMR</i>
1	King Fahad Medical City	850	0	2	
2	King Saud Medical City (Alshomaicy)	1400	0	2	
3	King Khalid Eye Specialist Hospital	250	0	2	3
4	Al –Yamama Hospital	310	0	2	
5	AL- Ammal Hospital	507	0	2	
6	Prince Salman General Hospital	300	0	2	3
7	Al-Iman General Hospital	250	0		3
8	AL-Naqaha Hospital	150	0		3
9	King Saud Chest hospital	150	0		3
10	King Khalid in Al-Kharj	400	0	2	
11	Horaimela General Hospital	50	0		3
12	Hotat-Sodair Genera Hospital	100	0		3
13	Shaqra General Hospital	150	0		3
14	Hotat-bany Tameem General H	100	0		3
15	Al-Artawiya General Hospital	50	0		3
16	Temair General Hospital	50	0		3
17	Al-Rowadah General Hospital	50	0		3
18	Al-queyah General Hospital	200	0		3
19	Wady Al-dawaser General Hospital	150	0		3
20	Naffi General Hospital	50	0		3
21	Al-Aflaj General Hospital	100	0		3
22	Affif General Hospital	110	0		3
23	Sajer General Hospital	50	0		3
24	Al-Zulfi General Hospital	231	0	2	
25	Thadiq General Hospital	50	0		
26	King Khalid Al-Majmaah General H	200	0		3

## Chapter 7. Exploration of Comprehensive Basic EMRs and Failures

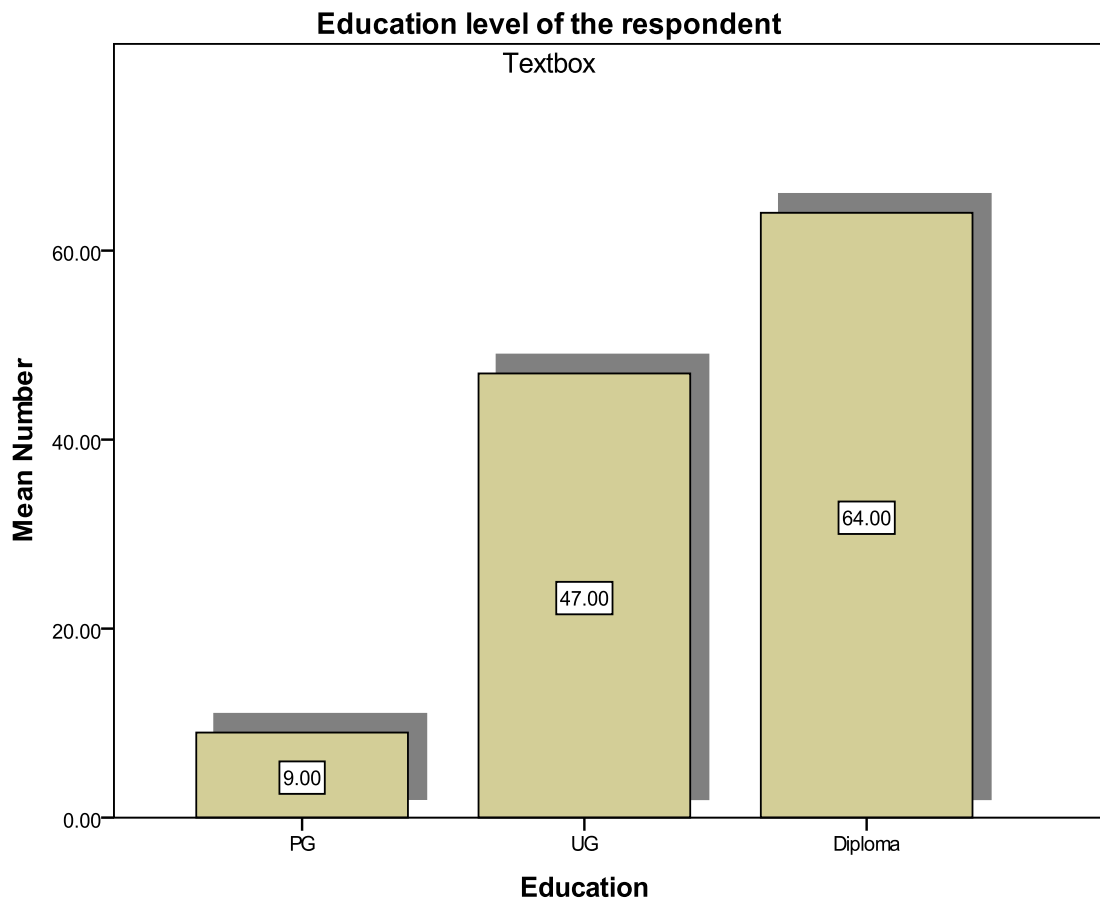
27	Al-Mozahemia General Hospital	30	0		3
28	Duromah General Hospital	50	0		3
29	Al-Dawaddmi General Hospital	200	0		3
30	Al-Celaiyel General Hospital	80	0		3
31	Al-rain General Hospital	50	0		3
32	Wothailan General Hospital	50	0		3
33	Romah General Hospital	50	0		3
34	Prince Selman Ben. Mohamed in –Al-Delam G H	70	0		3
35	AL-Khasera General Hospital	50	0		3
36	Al-bijadia General Hospital	50	0		3
37	Al-refayea in Gimch General Hospital	50	0		3
38	Al-Hareeq General Hospital	50	0		3
39	Al-Ghat General Hospital	50	0		3
40	Morat General Hospital	50	0		3
Additional Comment: HBC ( Hospital Bed Capacity) Size: Small hospital (30-99 beds):Medium hospitals(100-299 beds): Large hospitals (300≥) (1) Comprehensive Electronic Medical Record (2) Basic EMRs (3) Manual MR					

- **This classification was adapted from a previous study done in the USA by Jha and colleagues (2006); it amended to suit MOH hospitals in Saudi Arabia.**

### 7.7 Results

This section presents the outcomes derived from the data collected via questionnaire and analysed using the SPSS tool.

Approximately 53.3% of the respondents did not have a university degree, 39.2% had undergraduate university degrees and only 7.5% had postgraduate education (Figure 7.7.1).



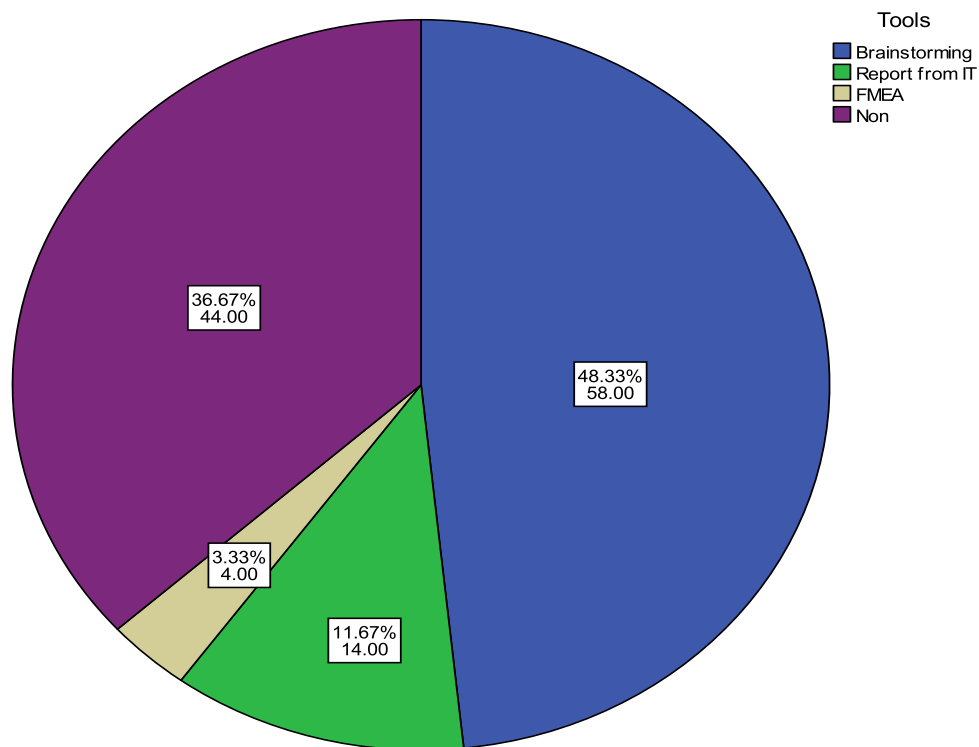
***Figure 7.7.1 Education level of survey respondents.***

In response to question number one 96 (80%) responded that their hospital use MMR and 24 (20%) said that their hospital use BEMRs. Nearly the 26 consequence questions are based on the first close question. Therefore, 96 respondents reacted negatively to these while the remaining 24 respondents reacted positively

In response to the question of whether or not they were using any RM techniques, 63.3% responded positively and 36.7% responded negatively. Respondents identified the techniques that they used as follows: 58 said that they used brainstorming as a tool to identify risks, 14 used checklists, 4 used FMEA and 44 said that they were not using any tool to identify risks because they were not aware of any RM techniques. In a separate question, after describing some of the traditional and systematic risk

management techniques to the respondents, we asked if they would consider the use of risk management techniques in the future; 95% said ‘yes’.

Brainstorming tools are widely used to identify risk in general, and to do problem-solving in particular. Brainstorming is one of the best ways for a group of diverse individuals to identify what can possibly go wrong (Raheja, 2011, p. 123). Previous research has revealed that a brainstorming is one of the most commonly-used techniques for risk identification (Kaymark & Kasap, 2007, p. 246). Other choices include the use of checklists. The survey shows that the use of FMEA is very low (see Figure 7.6.2) even though JCAHO has been recommending the proactive use of FMEA internationally.



*Figure 7.7.2 the application of risk management tools to identify EMR risks in hospitals*

Respondents were asked how they measure the severity of risks. The majority (58.3%) reported using past experience to detect and measure severity, 41.6% reported using ‘common sense’, and none of the respondents reported using a risk equation (for example, Risk = Likelihood × Severity or other method (see Table 7.7.1).

**Table 7.7.1 Methods used to detect and measure risk severity**

Methods	Numbers of Respondents	Percentage %
Past experience	14	58.3%
Commonsense	10	41.6%
Equation (R=F×S)	0	0%
Total	24	100%

In response to the question of how often the system fails, the vast majority of the respondents (41.7%) said they faced monthly failures of the EMR systems in their hospitals and 12.5% reported weekly failures (see Table 7.7.2).

**Table 7.7.2 EMR system failure rate**

Failures	Number of Respondents	Percentage %
Daily	5	20.8%
Weekly	3	12.5%
Monthly	10	41.7%
Once a year	06	25%
Total	24	100%

We asked the respondents to rank the risk factors in term of their significance for EMR system failure; almost all respondents reported that the most serious factors which lead to system failures are *poor system security leading to viruses and spyware* and *computer hardware failure*. About 79.2% of the respondents stated that *incomplete software* was the next crucial factor to cause concern. As well, 62.5% of the respondents considered *unstable power supplies* and *ineffective project managers* to be catastrophic. *Lack of cooperation from the other users* was ranked as one of the most critical risk factors, followed by factors 10 (*lack of onsite technician*) and 8 (*lack of trained and experienced users*). *Lack of catching up with rapid development in technology* was ranked as a minor risk factor.

Note that these results do not mean that the other risk factors are unimportant in the process of failure prevention. The ranking were based on the responders answer to the question number 35 which involves 13 sup questions see the following table (7.7.3) which presented the results of the ranking process.

**Table 7.7.3 Ranking risk factors**

<i>Risk Factors</i>	<i>Ranking Minor #%</i>		<i>Critical</i>	<i>Catastrophic</i>
<b>1-Lack of suitable infrastructure</b>	05	20.83%	12 50%	07 29.17%
<b>2-Poor system security leading to viruses and spyware</b>	0	0%	0 0%	24 100%
<b>3-Unstable power supplies</b>	02	8.33%	07 29.17%	15 62.5%
<b>4-Incomplete software</b>	0	0%	05 20.83%	19 79.17%
<b>5-Computer hardware failure</b>	0	0%	0 0%	24 100%
<b>6-the current server is not appropriate to the number of users and application</b>	08	33.33%	09 37.5%	07 29.17%
<b>7-Stress from over work</b>	09	37.5%	06 25%	09 37.5%
<b>8-Lack of trained and experienced users</b>	04	16.67%	13 54.17%	07 29.17%
<b>9-Lack of cooperation from other users</b>	05	20.83%	16 66.67%	03 12.5%
<b>10-Lack of onsite technicians</b>	05	20.83%	14 58.33%	05 20.83%
<b>11-Lack of catch up with rapid development in technology</b>	13	54.17%	09 37.5%	02 8.33%
<b>12-Unrealistic schedules and budget</b>	06	25%	09 37.5%	09 37.5%
<b>13-lack of effective project manager.</b>	01	4.17%	08 33.33%	15 62.5%
<b>Total</b>	58		108	146

A majority (13) of the 24 respondents said that the most common problems that they face with the EMR systems are: *hardware failure due to lack of periodic maintenance* (8) reported *power failure* (3) testified *ineffective IT manger*.

In response to Question 36 (*the availability of policies recommended by the MOH*) almost all respondents declared they had seen the documentation and that the policies had been implemented. See Appendix C, Question 36.

In order to effectively conduct RM for EMR systems, the probability and the severity of risks must be assessed. Refer to the operational definitions in Chapter 5 of this study. Before using the STAMP technique to detect the causes of system failures, we need to define the probability and severity levels of the major risk factors. See Table 7.7.4

which shows an example of probability and severity description levels that are used as the basis for many risk assessment models.

**Table 7.7.4 Probability and severity of risks**

<b>Probability</b>	
Low	Uncommonly or Never occurs
Medium	Occurs Irregularly
High	Frequently Occurs e.g. weekly
<b>Severity</b>	
Minor	The lost data is not vital and might restore easily
Critical	The information is important to the care providers and may have some impact on the patient and the providers.
Catastrophic	Misplace of information can cause a harmful effect on patient and the hospital.

**Table 7.7.5 Risk score**

<b>Score : Descriptive</b>	<b>Categorise</b>	<b>Probability</b>	<b>Severity</b>	<b>Risk Score</b>
<b>Low / Minor</b>	<b>(1)</b>	1	3	3
<b>Medium / Critical</b>	<b>(2)</b>			
<b>High / Catastrophic</b>	<b>(3)</b>	3	3	9

It is generally understood that risk assessment can either be qualitative or quantitative. Many disciplines use qualitative or semi-quantitative modes to prioritise risks and decide upon the actions that need to be taken to reduce risk and prevent future failures.



It is critical for hospitals to manage risks properly. In each example below, the risk was identified by the hospital prior to the failure, but the risks were inappropriately managed. We will use it as an example

**Example 1:**

**Risk Factor:** Computer hardware failure leads to the loss of whole system

The severity of this risk (computer hardware failure leads to the loss of whole system) can be categorised as ‘catastrophic’: the patient’s information is not able to be retrieved, and this may delay patient treatment for example, specially, if the HR has information about drug levels, and affect other hospital services. As well, there is a requirement to retain duplicated records as the hospital returns to manual records. Since a high percentage of survey respondents reported weekly hardware failures, the probability of risk occurrence is high. using the scores in the Table 7.6.5 above, we establish this risk as a high risk ( $3 \times 3 = 9$ ); this means that urgent action needs to be taken to eliminate the risk and prevent future system failure. The recommended mitigation for this example is to document, implement, communicate and activate a periodic system maintenance plan.

**Example 2:**

**Risk Factor:** Unstable power supplies

The potential failure mode in this example relates to unstable power supplies. In this case, patient records could not be retrieved and, since the system was unavailable, there was a delay of services and the potential for permanent data loss. In addition, the absence of a backup system for the data made it difficult to trace back the patient’s information in both basic and comprehensive EMR systems. Therefore, the severity of this risk will be deemed to be ‘catastrophic’.

In our examples, the severity of these risks was deemed to be critical (in some hospitals) and catastrophic (in others) since the EMR systems in the chosen hospitals were hybrid

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systems (using both manual and electronic formats). The probability of the risk was very low because these hospitals had backup power generators. The risk score for this example is 3 ( $1 \times 3 = 3$ ): action is urgently needed.

## 7.8 Summary

The survey results show that different types of EMR systems have been used in different hospitals. There has been a very low rate of adoption of EMR systems despite the MOH target to implement Comprehensive EMR systems in its hospitals and primary health care centres (PHC); this was revealed after we examined the number of EMR systems adopted by MOH hospitals in the Riyadh Region. We also found that many hospitals still use MMRs.

All hospitals that were chosen for this study use a hybrid approach currently that is, they use both manual and electronic record formats and users received appropriate training for the EMR programme in the early stage of the system implementation. Nonetheless, the EMR systems are still not mature due to the lack of periodic maintenance and effective management. An effective strategy for deploying EMR system on a national basis has not yet been achieved.

In terms of respondent's education level, 53.3% of respondents had an education level below university level, and 7.5% had postgraduate. The hospitals whose management had higher-level of education were more successful in the usage of EMR system. The survey also showed that the use of the FMEA risk management technique was very low as compared to the use of traditional brainstorming techniques. Based on this study's results, it is recommended that the nearly all end users should cooperate with IT administration effectively in order to prevent EMR system and mitigate failures it also, recommended the MOH undertake training programs for risk assessment technique as part of their programme. EMR system end users and IT Managers must be aware of EMR system risks. The hospital IT Administrator should consider the users' feedback as input for system improvement efforts rather than as criticism; the IT Administrator

should support users by focusing on continuous education of information technology and by seeking financial support for training and support.

# Chapter 8

## Exploration of an appropriate RM techniques and application of the STAMP technique in hospitals

### Objectives

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- Explore and apply the most appropriate techniques for RM and accident prevention in hospitals
- To use STAMP technique for identifying EMR system failure case study
- Enhance the STAMP technique to make it more appropriate for application to hybrid system
- To use the modified technique (STAMP Checklist, or STAMPC) in a second case study
- Report on STAMPC usability
- Compare the results of the two techniques (STAMP and STAMPC)
- Offer d recommendations for risk management technique usage in the Kingdom of Saudi Arabia (KSA)

## 8. Background (Phase 2)

Understanding the reasons for system incidents and failures is important for safety and quality programmes in hospitals and other organisations. A number of techniques have been developed to achieve this understanding. Many of these techniques have been described in Chapter 6: we gave a brief overview of the importance of almost all traditional and non-traditional popular techniques for risk and safety management.

Internationally, the rapid advancement in technology and the appearance of new types of compound failures has directed researchers to seek to develop new techniques for managing complex organisations operating in highly unstable environments. Several RM techniques have been developed based on the belief that the most common reasons for accident or event occurrence involve the failure of humans, equipment or environments to act or behave as expected (Doytchev and Szwillus, 2009, p. 1172). Unfortunately, the researchers do not address procedures for assessing the interaction between human and machines, nor for assessing human-related elements (Moriyama and Qhtani, 2009, p. 1380). In 1997, Rasmussen found an approach based on theoretical control concepts and proposed his technique for modelling organisational, operational and management structures that generated the preconditions for failures (Rasmussen, 1997, in Qureshi, 2007, p. 51). Rasmussen also addressed social and technical aspect of overall failure in his technique (Venkatasubramanian, 2011, p. 5).

STAMP is another notable system modelling technique; it characterises all risks to humans, organisations and equipment. The STAMP technique is a comprehensive approach, and it is often chosen to show the risks associated with accidents (Hardy & Guarnieri, 2011, p. 737). Nancy Leveson developed and proposed the STAMP technique, building upon Rasmussen's and Svedung's technique. It was developed to overcome the limitations of traditional risk management techniques. See Chapter 6 of this study for a discussion of the STAMP technique and for details on the limitations of Rasmussen's technique. According to Leveson, one of the clear limitations of

Rasmussen's technique is that it contains only one control structure that focuses on operation rather than development (Leveson, 2004, p. 256-266).

This research proposes to use STAMP for RM of EMR systems. The STAMP technique has been applied to many accidents, including railway, water and sanitation accidents as well as by organisations such as NASA. The STAMP technique is currently being applied to the oil production accident in the Gulf of Mexico and in removing contaminated sediments (Hardy and Guarnieri, 2011). The most important reasons for our choice of the STAMP technique to conduct this study were: 1) the technique focuses on unsafe conditions or actions; 2) it incorporates the notion that a safety accident may include external disturbances; 3) it includes both developing and operational structures (Leveson, 2004, p. 250). In addition, to the popularity and effectiveness of STAMP usage in many other sectors.

Researchers had often thought that there might be more to be gained by studying unsafe conditions or system failures rather than stable and safe systems; however, STAMP can be applied to both safe and successful systems as well as to those requiring improvement. According to Holmes (2004), not many individuals try to learn from successes; learning from success is much harder than failure (Holmes, 2004, p. 175). Qureshi notes that the STAMP technique also considers accidents that occur as a result of a faulty process caused, for example, by interactions among staff, social conditions, organisational structure, engineering activities and software system components (Qureshi, 2007). The literature review, however, shows that there is little information about how this technique has been applied in the health care field.

The aim of this study was not to generate a new technique, but to make the existing technique relatively good for hybrid system when needed, to persuade stakeholders and end users to implement and use it in their organisations, to provide additional information about the technique, and to demonstrate the validity of the STAMP approach for EMR system failure prevention.

This chapter is organised into sections and subsections. *The first* subsection introduces the STAMP technique. *The second* describes the application of the STAMP accident model to identify risks associated with EMR system failures in the King Khalid Al-kharj General Hospital in Riyadh in order to mitigate risks and avoid future failures (Case Study 1). *The third* subsection discusses our reasons for modifying the STAMP technique. *The fourth* describes the application of the modified STAMP technique (STAMPC) (Case Study 2) in the same hospital where Phase 1 of this study was carried out see Chapter 7 for details about the goals for Phase 1. Finally, this Chapter compares and contrasts the original and modified technique used for EMR system failure analysis purpose.

### **8.1 STAMP-based accident analysis**

To understand how to manage EMR system failures, researchers need to know how different organisations, individuals, stakeholders and governmental bodies recognise and utilise the RM process and the results of failure investigations (Hovden et al., 2011, p. 98). Having used the STAMP technique in our study, we can clearly show that the technique involved all stakeholders in the study in order to identify the root causes of failures. STAMP views a system as a hierarchy of control levels: each level in the hierarchy imposes constraints on the level below (Salmon et al., 2012, p. 1159). STAMP also provides a useful classification for controlling the flaws that lead to events. A constraint is the most basic concept in the STAMP technique, and a failure is said to be the result of a lack of constraints imposed on the system's design and operation (Leveson, 2004). Risks are identified and mitigated or controlled through system planning. Rasmussen (1997) assumes that RM must be modelled by cross-discipline studies. He considers RM to be a control structure involving all levels of each particular risk category.

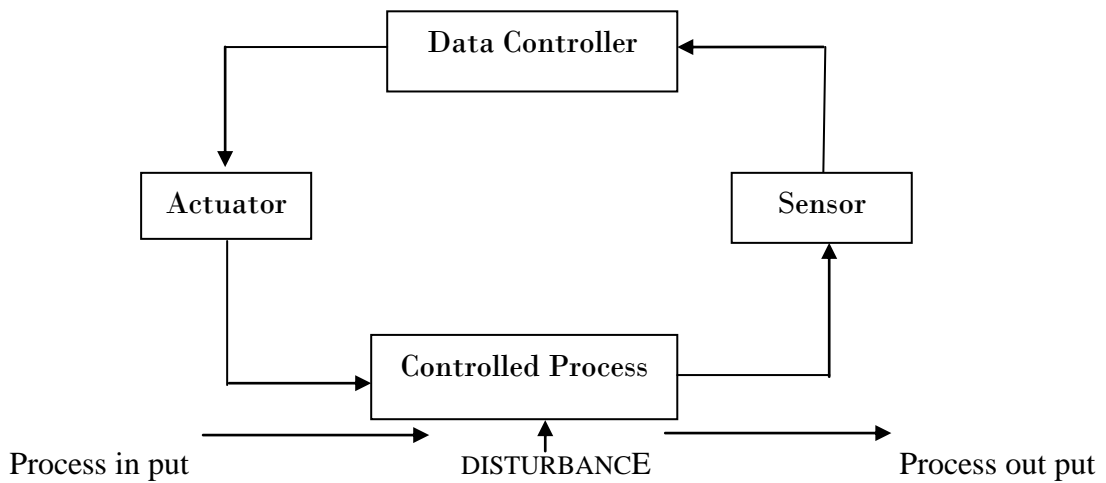
Many studies have shown that human errors are a key-determining factor in hospitals (Rasmussen, 1997, p. 188). Moriyama & Ohtan (2009) concluded that approximately 80.5% of accidents triggered by some sort of human act (p. 1381). Many other

researchers support this argument. Leveson (2011, p. 61) states that ‘most accidents are caused by human errors’. In the United States, between 44,000 to 98,000 deaths are said to occur in hospitals as the result of medical errors each year (Kazley & Ozcan 2008, p. 496; Pronovost et al., 2009, p. 330; Sun et al., 2011, p. 26). A study done by Sandars in 2003 shows that medication errors related to the processes involved in treatment occur between 5 and 80 times per 100,000 consultations (Qureshi et al., 2011, p. 141). In 1995, the Canadian Institute for Health Information reported a 16.6% adverse event incident rate in Canadian hospitals (Sun et al., 2011, p. 26).

To eliminate or control the number of human errors by using STAMP in hospitals, users and stakeholders must understand the policies, procedures and constraints of the MOH, as well as how to enforce them. The proposed technique for this research concerns the interaction between human and machines cooperation, and therefore involves users and system operation policies. ‘Policy’ has been defined by Buse as a ‘decision taken by an individual, group, and organisation responsible for a particular task or area’ (Buse et al., 2007, p. 8). According to Deleon (1999), the implementation of policies is intended to turn them into actions (1999). We will apply the STAMP technique in our analysis of an EMR system’s failures in the health industry. Using the STAMP approach, we expect to be able to identify the primary constraints that may help the system to work properly.

It will be helpful to first consider the original STAMP technique’s goals and structure as developed by Nancy Leveson. Leveson states some important goals of STAMP, including that ‘the technique assists understanding why failure or accident occurs and to apply this understanding we have to create a new and better taxonomy to prevent losses’ (Leveson, 2004, p. 89). Figure 8.1.1 illustrates the basic general process of a control loop in STAMP.





**Figure 8.1.1 Basic process of control loop in STAMP (Ouyang et al., 2011).**

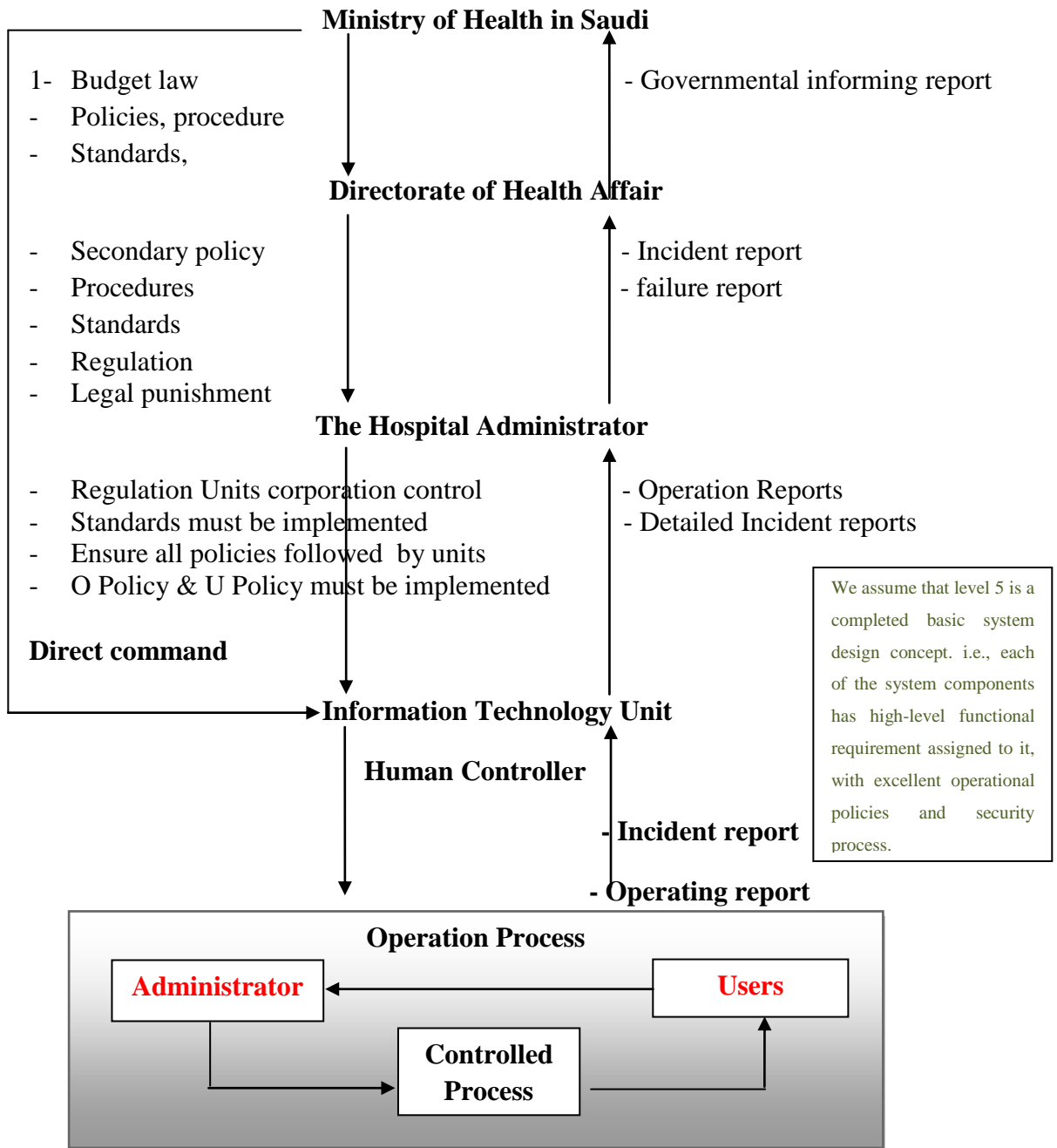
In the control loop illustrated in Figure 8.1.1, some information was obtained through direct input and output from the indicator (Users), whereas other information could be obtained from the stakeholders in the sequence levels. See Figure 8.1.2.

The entire system in STAMP is based on a system control loop idea, and the requirements of the system control loop must be fulfilled. Leveson highlights these requirements as follows: the data controller (automated or manual) must have goals; the data controller should be able to affect the condition of controlled loop; the data controller must be a model of the controlled loop; and finally, the data controller must be able to estimate the condition of the controlled loop (Leveson, 2004; Ouyang et al., 2011, p. 545).

In the following paragraphs, we will illustrate an example of the current conceptual hierarchical control structure to ensure safe operation of a hospital's EMR system. In the end of the control structure, I used the same as actuator IT Administrator, as Sensor the Users, and as Data controller Operation process. This conceptual hierarchical structure consists of five levels, as follows: 1) the MOH, which provides rules (recognized as primary rules), budgets and standards; 2) the Directorate of Health

Affairs (DOHA); 3) the Hospital Manager; 4) the IT Unit; and 5) the end users or 'human indicator, Administration and the automated loop control (Process). All policies are established by the top level (MOH), and these are communicated to the lower levels. This approach is useful for finding, describing and analysing the reasons why failures occur for the reason that of lack of communication between levels (Hoden, 2011, p. 99).

**CURRENT STAMP SYSTEM OPERATIONS**



**Figure 8.1.2 Classification of control flaw leading to failure**  
 General form of socio-technical control, adopted (Leveson, 2004; Ouyang et al., 2010).

Figure 8.1.2 depicts a hierarchical conceptual structure, where each stage imposes constraints on the activities of the stage below. We are applying STAMP to ensure the safe operation of our EMR system, quality service in hospitals and to identify risks that lead to system failure. The downward communication channels provide the information necessary to impose behavioural constraints on the stage below; the upward feedback channels provide information about how successfully the constraints were imposed, as well as information about reported incidents.

One of the large health care providers in Saudi Arabia, the MOH, is at the top of the hierarchy. The MOH provides budgets, laws, standards and policies and procedures to the Directorate of Health Affairs (DOHA) of each of the five regions. The budgets, laws, standards and policies and procedures, in addition to any guidelines, must be imposed on Hospital Managers who must ensure the implementation of these elements in all hospital departments.

The lower levels in this conceptual control structure include the IT Administrator and the system's end users, both of whom are responsible for providing all types of reports, in addition to having direct control of the entire automated system. The IT unit is responsible for operating the system and providing the safe operation requirements. The users are responsible for using the workstations and equipment correctly, in accordance with the training provided by the IT department. They must also convey information about incidents to the IT Administrator or to the corresponding Hospital Manager and cooperate in the correction of the incidents.

The Hospital Manager is responsible for establishing, implementing and controlling the regulations, rules and guidelines that are to be followed in the hospital. In addition to making sure that the standards are effectively implemented, the Hospital Manager must also report any uncontrollable accident to the DOHA. In turn, the DOHA must send report of the accident to the MOH. The MOH is also responsible for making changes to the policies, standards and regulations and communicating these changes to the DOHA. In some special cases, the MOH sends direct commands to the IT Administrators. Based

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on what has been stated above, we can assert that each level has a clear mission and responsibility to perform high quality services. However, the question is whether these missions and responsibilities are effectively implemented. We assume that the use of the STAMP technique will help us to answer the above question.

Hospitals need resources such as money, high quality medical equipment, rules, procedures, standards, effective managers and well trained staff to manage their day-to-day activities. In many cases, rules are provided by governmental bodies, stakeholders and others. In our case, all rules are provided by the upper level or stage and imposed on the stages below.

Using the STAMP conceptual control structure, this study used the failure of the EMR system at King Khalid Al-Kharj General Hospital (KKGH) in October 2010 as a first case study of EMR system failure in Riyadh. The researcher, supervisors, Hospital Manager, Quality Manager, IT Manager and EMR Manager has agreed this case study. The case study was carefully selected: the EMR system failure was among the most recent and had the longest duration of any EMR failure obtained in the phase one of the research.

The case study method is one of several ways of conducting social science research; it is the preferred method when ‘how’ and ‘why’ questions are being posed (Yin and Robert, 2009, p. 4). The case study method allows researchers to maintain a holistic overview of a ‘real life’ incident; for this reason, we have selected the case study method for the second phase of this research

This study will use the case study method to employ the STAMP technique and analyse the usefulness and sufficiency of the technique, identify risks, manage causal factors, mitigate or control risks and provide solutions to avoid future failures. We will achieve this by utilising several parts of the proposed original conceptual structure model which we call our ‘operational structure model’ starting from level one through to level four (IT Administrator and end users). See Figure 8.1.2. The control process is assumed a

complete automated basic system design. Each of the system components is assumed to have high-level development and functional requirements assigned to it and includes operational policies and security processes to ensure safety. Moriyama and Ohtani (2009, p. 1380) state that both hardware and software designers in Japan and elsewhere are aware of the need to reduce risk, and that design is the most critical factor in ensuring machine safety. Safety is known as a ‘growing theme’ that exists only at system level, according to Leveson (2011, p. 58).

## **8.2 Applying STAMP to the EMRs failure in KKGH: Case Study 1 (CS1)**

### **Case Study Introduction:**

The original STAMP technique described in chapter 6 section 6.8.1, will be used in this case study to find out the causes of the EMRs failure in KKGH in order to mitigate the risk of the system failure and prevent future failure. There some amendment done in stage five, the users used as sensor and IT administrator as actuator and the rest remain same.

King Khalid General hospital (KKGH) is one of the MOH hospital located in Al-kharj in the Southern Riyadh City. The hospital is physically located in two buildings: an old ‘main building’ with two floors and the new one with three floors. KKGH services more than 650,000 people and has a capacity of 400 beds. It has been designated as a referral hospital for 6 other general hospitals and 20 Primary Health Care Centres (PHCCs) in the area. Not all of the facilities are electronically connected: in other words, communication between the hospitals and the PHCCs is still performing manual. Recently, however, the MOH decided to computerise 30 hospitals throughout the kingdom of Saudi Arabia and a project was initiated on 29 January 2007 to accomplish this. KKGH was one of the hospitals chosen for this project (see EMR Project in MOH Contract Form, 2007).

KKGGH started using an EMR system in 2009 in almost all of its 28 clinical units (for example, in its emergency, outpatient, in-patient, radiology, laboratory, pharmacy and medical record departments). They also utilised the EMR in non-clinical units, such as the patient registration, administration and discharge units. Contracts for the implementation and operation of the EMR were finalised through the formal hierarchical structure (MOH, DOHA, Hospital Manager, IT unit and IT provider).

This study took place not long after the implementation of the EMR system. The study's first phase survey showed that nearly all EMR system users in the hospitals were trained, an initial 'username' and complex password was assigned to each user and security measures were established to protect the system. The study also shows that, despite these measures, the system was deteriorating weekly in various departments; this is a sign that risk management was not conducted by the hospital. Failures that appeared to be preventable occurred repeatedly and were deemed to have similar systemic causes.

The hospital uses Oracle as its database system, and our investigation shows that there was no 'fault report' component in the automated control loop of the system; therefore, telephone confirmation was the only method of communication between the clinical and para-clinical departments and the IT providers when there was a fault or system failure. The survey in phase one also revealed a lack of documented incident reports and feedback. Constraints were not effectively imposed (see Chapter 7, Phase 1). A brief description of the failure process follows.

### **8.2.1 The Failure at KKGGH**

The EMR system was implemented through a formal hierarchical approach, not by direct command of MOH. A programme was initiated to review the system with the Hospital Manager and to determine whether the hospital could continue to monitor and control the system with the staff provided by the system supplier and the technicians that had been recruited by the hospital administration. The training programme for

developers, programmers and the users had been deemed adequate. However, the training program was inadequate for some end users: they had little knowledge about the EMR system in the hospital, including policies and responsibilities relating to its operation.

At 6:30 am on 26 October 2010 the EMR system suddenly failed. The end users informed the IT department immediately by telephone and requested that the system be restored. The night duty technicians endorsed the incident verbally to the staff who starts at 7:30 am) an action was immediately initiated to restore the system. At about 7:40 am, the IT Administrator sent a request form to the provider asking for more qualified technicians to determine the root cause and risk factors of the failure; as a result, actions to restore the system were delayed for about 2 hours. Other factors contributed to the delay, including the lack of experienced computer technicians in the unit. The appointment of insufficiently-experienced technicians points to serious problems in human resources management in the hospital. The system was finally operational again approximately three hours after the incident had been reported. Fortunately, there was no serious impact on patients; however, serious attention needs to be given to investigating the failure, its causes, and the ineffective response to the failure.

Unfortunately, KKGH does not have properly documented incident reports for every incident. This means that it is difficult to effectively determine the causes of the failure. Also, no RM techniques were used to identify risks and prevent failure. The initial cause of the system failure was attributed to damage to some part of the server: this damage resulted in the server breaking down. The technicians changed the damaged parts and restored the system with the help of the IT equipment provider. Fortunately, according to the IT department's report, no data were lost because the last backup had been performed at 12 am after the night duty started about six hours before the failure was reported.



According to the hospital's Quality, Medical Record and IT Managers, the root causes for this system failure were not investigated and were still not clear at the time that our study was done. However, many department heads did not accept that the damaged components were the only cause for the failure: they questioned why the system was failing almost every week. As researchers, we do not assume that the immediately identified cause is necessarily the only cause. There are potentially many other factors involved in the failure, which are beyond the control of the IT department or the end users. Therefore, we used the current structure of the STAMP technique to find out the external and internal root causes of the system failure at the KKGH in order to mitigate or control risks and prevent future failures of the EMR system.

### **8.2.2 Causal Investigation**

According to Leveson (2003, p. 9), the steps in applying STAMP are to identify the system risks, identify the system constraints and establish a control structure to impose the system safety constraints. Anecdotal evidence has shown that most projects do not fail for technical reasons only; sometimes the failures are due to human mistakes.

In this study, the system risks related to the failure were identified as follows. First, patients were facing service delays. Second, there was a lack of information exchange between care providers. Complications might also occur as a result of late medical action. Therefore, we need to understand the system safety policies, constraints and standards that should be followed. For example, the system must not be turned off during busy working times; the system must not be run by untrained users. As well, the users must understand policies, procedures and guidelines, and they must follow them. They must report incidents immediately. Finally, according to the system failure process introduced in section 8.1.2 of this study, the 'human controller' in the control structure plays a role in imposing the above-mentioned policies and constraints to prevent failures.

By using the STAMP technique, we found that the failure was not solely because of technical errors. Other factors contributed to the system failure, such as the lack of periodic and timely maintenance. Our investigation shows that there was no documented maintenance schedule for the hardware and the infrastructure. As well, users did not formally document the incident report and submit this report to the upper level; consequently, the upper levels of the hierarchy did not receive feedback from the lower levels. We noted that mistakes were made at all levels in the hierarchy. The following subsection illustrates the policies and constraints that the MOH needs to develop and mandate for implementation at hospitals in the KSA.

### **8.2.3 Adequate policies mandated by MOH (identified using STAMP).**

Well-developed policies are a fundamental requirement for health care and related activities to ensure safe and effective patients care and proper and appropriate RM by hospitals. This subsection identifies and discusses the existing MOH policies for EMR systems and RM. These policies are directed to the equipment providers and addressed in the RM and failure prevention processes to detect factors that may lead to system failures.

Many have defined the word ‘policy’. Smith (1976) says that the term policy denotes ‘a planned choice of actions, before the effects of related forces occur’. This definition highlights the fact that attention should not focus solely on decisions which produce change. Rather, one must also be sensitive to those who refuse to accept change. This is often hard to ‘see’, because such people are not necessarily represented in the policy-making process (Smith, 1976, p. 13).

Following are the existing MOH rules that are imposed on the lower levels of the hospital organisation. These rules are at the core of the hospitals day-to-day operations. Moreover, we have identified rules have not been followed at the hospital. Therefore, we have distinguished and illustrated them as adequate and required MOH’s rules:

- + The IT providers must train all users about the use of the system and its safety

- + The IT providers are responsible for fixing any defects in the system for the entire period of the contract
- - The operation and maintenance contract must be renewed every three years, before the end of the previous agreement; this rule is currently not followed
- - A supervisory and feedback loop must be provided to ensure that each health care provider's managers are doing their job adequately; this rule is currently not followed
- + An electronic medical record must be generated for every individual seen at the hospital
- - The periodic maintenance report must be sent from lower level (IT) Department to the higher levels; this rule is currently not followed as well
- + Any additional system enhancement requests by key hospital personnel should be developed and implemented in the system by the IT providers
- - Feedback about the system operation and its faults must be reported to the higher levels in the organisational hierarchy; this rule is currently not followed
- - Risks must be identified and treated; this rule is currently not followed
- + Correct modification or enhancement of the EMR system is required

#### **8.2.4 Inadequate Policies Enforced by MOH and IT Unit (Identified using STAMP)**

The MOH policies in Section 7.2.3 are weak; there is general lack of information about the IT system and its location in the hospital. Specifically, there is:

- Inadequate incident reporting to the Hospital Manager from the IT Department and end users
- Inadequate constraints imposed by the IT Manager to the users
- Inadequate periodic maintenance for both hard/software and other infrastructure
- Lack of feedback between the IT Departments and other hierarchical levels
- Improper identification and management of risks

In this investigation we determined some of the most likely direct causes of the EMR system failure at KKGH. They are: an incomplete risk identification process, inadequate

periodic maintenance; lack of effective feedback from managers to the lower levels; lack of effective policies; and inability to identify serious potential risks.

The responsibility for a system failure generally lies with the top-level manager of the hospital; in this case, the top level had not paid much attention to RM and failure prevention processes. In this subsection of our study, the causal factors have been identified are used to prevent system failure in the future.

During the course of our case study analysis, we concluded that we needed to improve the current STAMP technique by adding a checklist to the model. The completion of the checklist needs to be mandated, and its completion should be overseen by the IT Department and Quality and Safety Committee in the hospital. The checklist should initially be completed weekly; this frequency can be gradually decreased to quarterly with the help of Department heads and system users. One reason for decreasing the frequency is to prevent ‘checklist fatigue’ (see Hales and Pronovost 2006, p. 232).

### **8.3 Reasons for Enhancing the STAMP Technique with a Checklist**

A review of the literature shows that many high-technology industries, such as aviation and manufacturing quality control, rely heavily on checklists to help reduce human and technical errors. Ziewacz et al (2011) state that checklists are standard in managing aviation and other high-reliability industry emergencies: their use helps to prioritise and standardise actions (Burbos and Morris, 2011., p. 24). However, checklists have not achieved wide-spread use for health care failures (Ziewacz et al., 2011). Learning is always improved through documented analyses of failures and literature review (Hovden et al., 2011).

Hales and Pronovost summarize some of the benefits of using checklists, saying that they: can provide guidance to users; act as verification after finishing a task to ensure failures are avoided; and provide a framework for evaluating and regulating a process. In addition, checklists help to ensure adherence to ‘best practice’ as documented by the

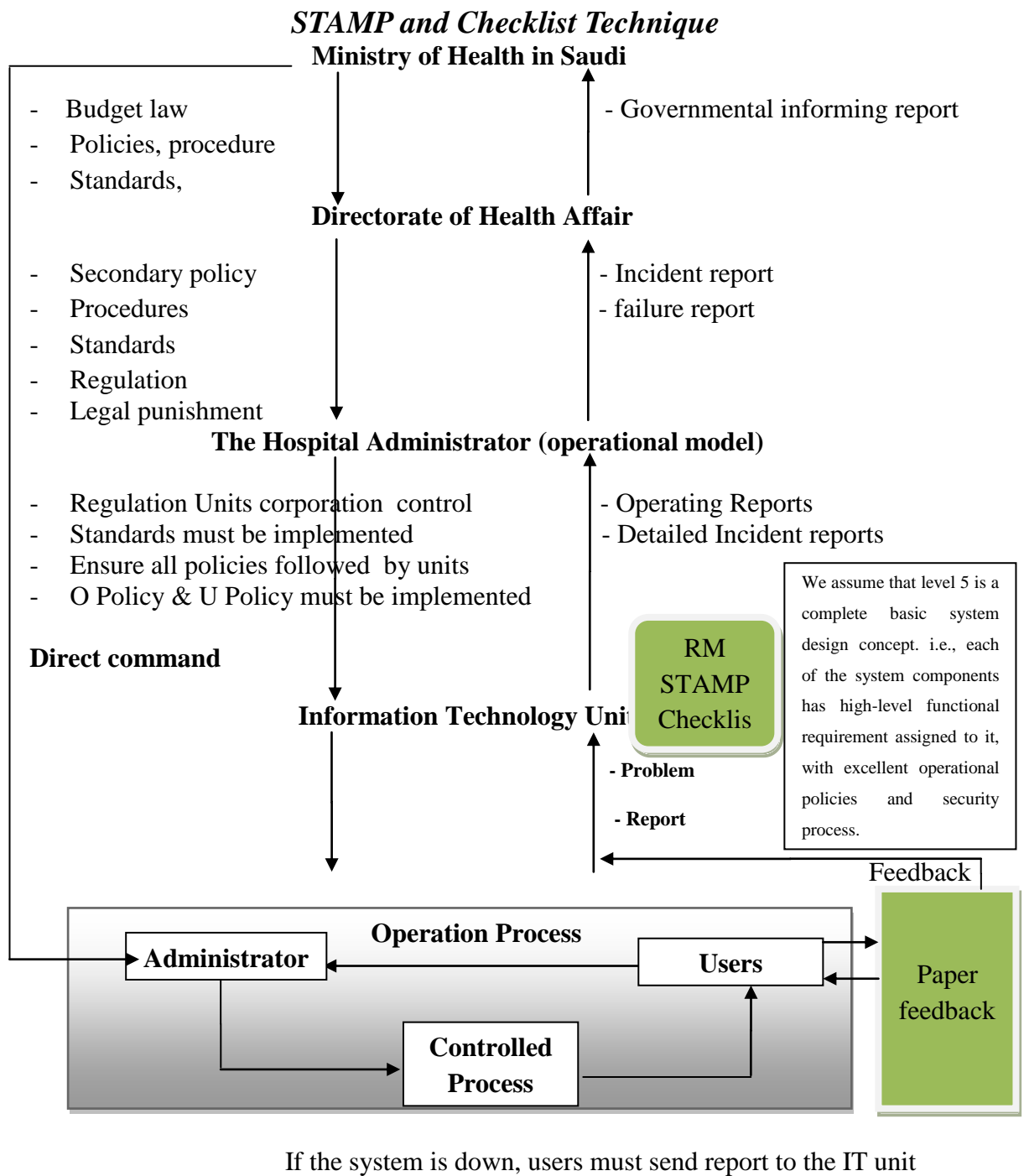
checklist (Hales and Pronovost, 2006). Therefore, we intend to modify the STAMP technique by adding the concept of a checklist to ensure that this amendment be incorporated without affecting or interfering with the design methods of the original technique.

Our idea to enhance the STAMP technique by adding a checklist was prompted by our investigation at KKGH. The checklist is designed to address the specific deficiencies that were identified during the implementation of the original STAMP technique as part of Case Study 1. The deficiencies we found were lack of formal incident reports; lack of feedback to the incident reporters, lack of adequate constraints on the lower levels in the hierarchy and lack of periodic system maintenance. Despite the fact that an established incident reporting form was in place, it was not successfully used to record past accidents.

As mentioned earlier in this chapter, the goals of the original STAMP technique are ‘to assist and understand why incidents occur in order to prevent accidents’ (Leveson, 2004, p. 89). Our main aim of adding the new component (checklist) to the original STAMP technique is to enhance the technique’s ability to identify and manage risks and prevent potential failures and address the specific problems highlighted in the previous paragraphs. We also aimed to improve the completion and consistency of incident reports, ensure that feedback flows to the higher levels in the organisation hierarchy, guarantee steady process improvement, enhance and encourage users and the unit’s directors for reporting incidences, reduce complications and prompt the appropriate management at each level to reduce variations in service delivery and error rates.

Figure 8.3.1 illustrates the main features of the STAMP Checklist. The structure takes into account the EMR system operations and shows the communication between hierarchical levels. This new structure was designed and developed by the researcher, as part of the present study and will be implemented with support from the IT, Quality Improvement and EMR Unit Managers and others users at the KKGH in Al-Kharj.

These departments were not directly involved in the study, but they do influence the activities of the system users in the hospital. See Figure 8.3.1.



**Figure 8.3.1 Classification of control flaws leading to failure (STAMP Checklist based on STAMP); an analysis of EMR systems using the STAMPC technique.**

The above structure takes into account the operation of EMR systems and reveals the communication between organisational levels.

#### **8.4 Usability of the STAMPC Approach for an EMR System Failure: Case Study 2 (CS2)**

Risk management and failure prevention is a central part of many high-risk organisations and key to a successful project (Nurdiani et al., 2011, p. 36). Hospitals or health care providers are like other high risk sectors: a minor error can endanger patients and medical equipment as well as increase the cost of error management. In this case study, the checklist be an essential additional component of the original STAMP technique in identifying risks and preventing potential EMR system failures.

This subsection discusses the application and validity of the STAMPC RM technique to the EMR systems failure at the KKGH. The overall goals are: to apply the technique throughout the EMR system implementation process, including the policies, procedures, standards and incident reports; to help to avoid failures; to decrease the number of EMR system failures (as reported in the previous survey, see Chapter 7) by systematically documenting and implementing regulations; to detect and mitigate the risks that can lead to system failure; and to demonstrate the feasibility and effectiveness of the modified technique by comparing the results with the previous results from using the original STAMP technique.

Hales and Pronovost have already demonstrated the value of using checklists as effective tools in the field of medicine for situations such as trauma and anaesthesia (Hales & Pronovost, 2006, p. 233). Hundreds of organisations, including the American College of Physicians and Surgeons (ACP&S) and the American Society of Anaesthesiologists (ASA), have supported the use of checklists to reduce errors, morbidity and mortality (Styer et al., 2011, p. 591; Pronovost, 2011, p. 162).



### **8.4.1 Methodology**

The STAMP technique was modified and validated in two phases. First, we designed and developed the checklist to become a part of the STAMP technique. Second, to use the checklist at the KKGH in Al-kharj, which is one of the MOH hospitals in Saudi Arabia? We assumed that, by adding and using a checklist to the STAMP technique, we would be able to mitigate risks, prevent incidents, improve the quality of services, considerably reduce the rate of system failures in EMR systems and provide additional information to support the original STAMP technique.

The results of the previous application of the original STAMP technique for Case Study 1 were helpful in establishing the steps that were taken during the design and development of the checklist. First, we developed a set of improvement suggestions to modify the STAMP technique for application in a hybrid system.

We named the modified technique the STAMP Checklist (STAMPC) Risk Management technique. Next, we illustrated the process we followed in developing the technique. Finally, we applied the technique to an EMR system failure, compared, and contrasted the results with the results from our application of the original technique. This evaluation revealed significant differences across the two techniques results.

### **8.4.2 Development of the STAMPC Risk Management Technique.**

The STAMPC development was based on literature search that aimed to identify the usefulness of the proposed technique and the importance of checklist tools in eliminating risks and preventing human and machine errors. The technique is depicted in Figure 8.3.1. Its development was stimulated by the need to analyse and manage component failures. The analysis of organisational factors was assumed to be important for these types of system failures.

Subsequent to conducting the first case study and the literature review, we developed the STAMPC technique.

The initial draft of the technique was documented and circulated for comment throughout software Technology Research Laboratory (STRL) to improve its design and development. The draft was reviewed by this study's first and second supervisors and a local expert in KKG hospital. A few modifications were made to the first draft. The form for the approved STAMPC technique involves 15 questions (Appendix A). The model was proposed at the De Montfort University's Research Degree Students' Poster competition and on Research Open Day on 15 April 2012. This motivation encouraged us to trial the STAMPC technique and publish the results. STAMPC was also presented to an audience at the Saudi Scientific International Conference at the Brunel University in the UK in October 2012.

### **8.4.3 STAMPC Technique and its Practical Application for EMR System Failures**

King Khalid Hospital in Al-kharj successfully passed a 'mock survey' for accreditation, in October 2011 by Central Board for Accreditation of Health care (CBAHI). Therefore, we assumed that the implementation of STAMPC would be relatively straightforward because the quality management program, EMR system and safety policies and standards were effectively endorsed, implemented and communicated to users and staff in the hospital. The trial was conducted over a period of two months, from 1 January 2012 to 31 March 2012.

The steps of this trial were as follows: 1) We organised a meeting with the unit heads, who volunteered to participate in the study and to provide feedback on the content; 2) We gave a presentation on the value of the STAMPC technique for managing risks and preventing failures. We made sure that the policies, standards and the incident reporting forms were in place, that the users were aware of them and that the EMR system provider was informed about the importance of periodic maintenance. A formal schedule was proposed and agreed upon; the Hospital Director agreed to verify and follow up on the application of the checklist.

Before the formal launch of the checklist, we gave a short slide presentation that described the background for the technique and provided some basic guidelines for the use of the EMR system. Nearly all EMR system users in the hospital received this overview. The Quality and Safety Committee team members at the hospital were asked to volunteer for a series of tasks, for example, to assist the researcher in distributing and collecting the completed checklists weekly and to make sure that the IT Department reported feedback. Once the checklist and the implementation process had been introduced and had been mandated in all departments, a copy of the checklist was sent to each department with a request that it be filled in and returned to the researcher for analysis. The units were given the option to store the forms in a box at the site which would be available to the researcher.

The researcher closely monitored each unit to ensure that the checklist and the incident reports were used when necessary. As well, we also asked for feedback from the IT department after the task was completed. As the coordinator for the programme, we undertook to make sure that every participant was comfortable with his/her role and actions and provided feedback to them. In general, feedback is an important motivator; it can help to persuade users to report incident on time and confirms the importance of doing so. Providing feedback 'on time' is critical for early detection and mitigation of accidents (Ursprung et al., 2005).

#### **8.4.4 STAMPC Usability Results**

This subsection reports on our findings from the application of the STAMPC technique at KKGH. A total of 224 checklists were completed over the 2-month period (112 for each month). Our proposed sampling frame was all departments in the hospital use the EMR system. All completed checklists were collected and analysed using the Pearson correlation in SPSS to establish the strength of the linear relationship between the variables or questions. Person correlation test provides precise significant levels regarding of the distribution from which data drawn (Philip, 2009)

Table 8.4.4.1 shows the units that participated in the implementation of the STAMPC process and the number of checklists that were collected weekly.

### Departments Participated in the Trial

<i>N</i>	<i>Hospital Departments</i>	<i>First Month received Checklist</i>	<i>Second Month received Checklist</i>
1	Out Patient Departments (OPD)	4	4
2	Male Surgical Ward (MSU)	4	4
3	Male Surgical Paediatric Ward	4	4
4	Male Medical Ward (MMW)	4	4
5	Female Surgical Ward (FSW)	4	4
6	Female Medical Ward (FMW)	4	4
7	Emergency Room (ER)	4	4
8	OB Ward	4	4
9	LR/DR	4	4
10	Nursery Ward (NSY)	4	4
11	Paediatric Intensive Care Unit	4	4
12	Neonatal Intensive Care Unit	4	4
13	Intensive Care Unit (ICU)	4	4
14	Paediatric Unit	4	4
15	Operation Room (OR)	4	4
16	Kidney Dialysis Unit (HDU)	4	4
17	Endoscopy Unit	4	4
18	Electro Cardio Graph (Echo)	4	4
19	Physiotherapy unit	4	4
20	Pharmacy	4	4
21	Radiology	4	4
22	Laboratory	4	4
23	Infection Control Unit	4	4
24	Dietary Department	4	4
25	Admission & Discharge Unit	4	4
26	Medical Record Unit	4	4
27	Medical Report Unit	4	4
28	Dental Unit	4	4
<b>Total: Received STAMP Checklist</b>		<b>112</b>	<b>112 = 224</b>

➤ **Table 8.4.4.1 STAMPC output by the participating departments in the trial.**

A total of 28 Departments were included in the survey: 27 (96.4.3%) clinical and 1 (3.6%) nonclinical (the Admission and Discharge Unit).

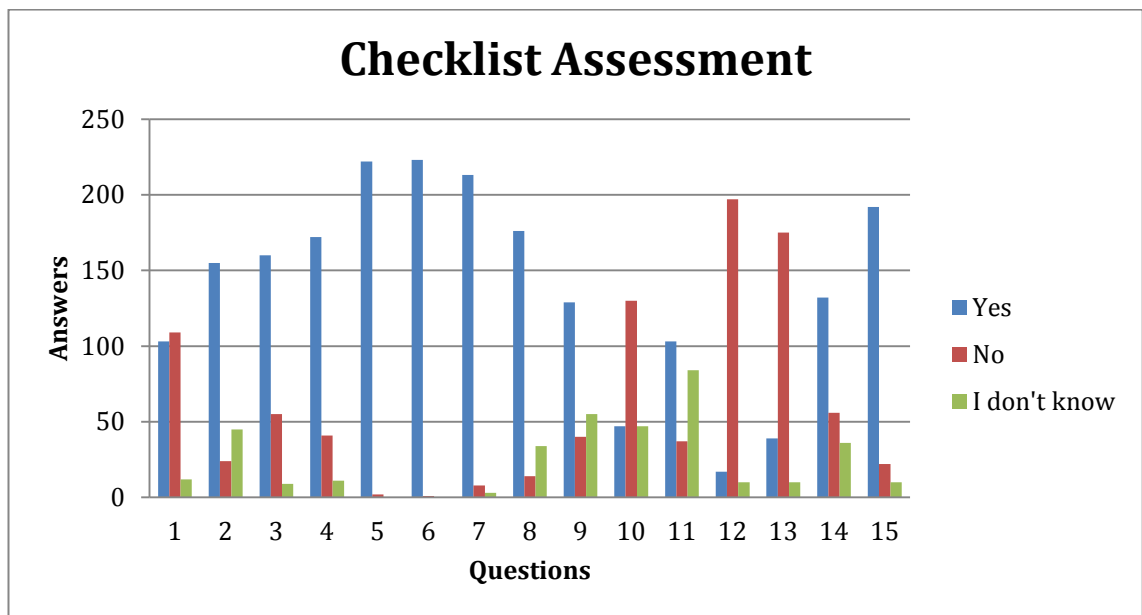
The following is a report of the most important findings related to the causes of the EMR system failure and their correlation to the checklist's questions. Before, using the STAMP Checklist we periodic that system maintenance for a six-month period would

decrease the rate of system failures and maximise the quality of the hospital's performance. Table 8.4.4.2 and Figure 8.4.4.1 show the results gained from the implementation of the checklist.

**SPSS Results**

<i>Questions</i>	<i>Yes</i>	<i>No</i>	<i>I do not know</i>	<i>Total</i>
<b>1</b>	103	109	12	224
<b>2</b>	155	24	45	224
<b>3</b>	160	55	9	224
<b>4</b>	172	41	11	224
<b>5</b>	222	2	0	224
<b>6</b>	223	1	0	224
<b>7</b>	213	8	3	224
<b>8</b>	176	14	34	224
<b>9</b>	129	40	55	224
<b>10</b>	47	130	47	224
<b>11</b>	103	37	84	224
<b>12</b>	17	197	10	224
<b>13</b>	39	175	10	224
<b>14</b>	132	56	36	224
<b>15</b>	192	22	10	224
<b>Total</b>	<b>2083</b>	<b>911</b>	<b>366</b>	<b>3360</b>

**Table 8.4.4.2 Results of the 15 questions in the checklist**



**Figure 8.4.4.1 Results of the 15 questions**

The responses in table 8.4.4.2 show answers of all 28 departments at King Khalid General Hospital in al-kharj to the 15 Questions (Appendix A). The columns show the variables ‘Yes’, ‘No’, and ‘I do not know’. We can see that there is some association between the answers to Questions 1, 2, 3, 4 and 11, 12 and 13. We wanted to understand the nature of the association between these questions, and so we looked directly at the data and concluded that the number of respondents who said ‘Yes’ for Questions 5 and 6 was much higher than for Questions 10 , 12 and 13. Since there are other techniques for analysing data, and could give us more information that we could not get from the table, such as P-values, and the correlation coefficients.

There are different types of correlation coefficients: the two most commonly used are the Spearman’s Rank Correlation Coefficient and Pearson’s Product Moment Correlation Coefficient (Nolan, 1994, p. 147). Goktas and Isci (2011) have stated that Pearson’s Product Moment Correlation Coefficient, Spearman’s Rank Correlation Coefficient and the Goodman-Kruskal Gamma Coefficient are the most commonly used measures of association for double-ordered contingency tables.

In this case study we chose to use Pearson's Product Moment (hereafter, Pearson's) Correlation Coefficient to assess our data for the following reasons; to know the relation between the checklist questions for validation; to show more information to the reader about the important of the checklist usage with STAMP technique in the hybrid system. In addition to the following effectiveness of the usage of Pearson's correlation gained from literature review.

Pearson's Correlation Coefficient is the most commonly used measure of correlation also called Pearson Correlation for short. This test uses probability and tells the researcher the nature of the relationship between the two variables; it also reflects the degree of linear relationship between two variables. The coefficient ranges from 1 to -1. Perfect positive correlation (1) means that X and Y increase in the same direction; -1 indicates a perfect negative linear relation and 0 indicates no relation between variables (Goktas and Isci, 2011, p. 19; Nolan, 1994, p. 147; Hinton, 2004, p. 266).

Therefore, a Pearson's Correlation Coefficient is computed to assess the relationship between the variables. We coded the answers for all 15 questions, using 1 for 'Yes', -1 for 'No' and 0 for 'I do not know'. This coding was suitable for almost all questions except Question 11. Therefore, we coded '2' for maintenance performed every 6 months, '1' for maintenance performed every 12 months and '0' for 'maintenance never done'. The correlation table shows that there is significant correlation between the answers for Questions 1, 2, and 3. There is a weak negative correlation between answers to Questions 11 and 12. This negative value means that any increase in the frequency of maintenance will lead to a decrease in the failure rate. The sample size is 224 and the P-value = 0.276; R = -0.073, N = 224 and P-value = 0.276. See Tables 8.4.4.3 Descriptive Statistics and 8.4.4.4 Correlation.



Descriptive Statistics			
	Mean	Std. Deviation	N
Q11	1.09	.901	224
Q12	-.80	.560	224

**Table 8.4.4.3 Descriptive Statistic**

Correlations						
		Q1	Q2	Q3	Q11	Q12
Q1	Pearson Correlation	1	.454**	.521**	.504**	.021
	Sig. (2-tailed)		.000	.000	.000	.750
Q2	Pearson Correlation	.454**	1	.521**	.377**	.036
	Sig. (2-tailed)	.000		.000	.000	.592
Q3	Pearson Correlation	.521**	.551**	1	.472**	.082
	Sig. (2-tailed)	.000	.000		.000	.222
Q11	Pearson Correlation	.504**	.377**	.472**	1	-.073
	Sig. (2-tailed)	.000	.000	.000		.276
Q12	Pearson Correlation	.021	.036	.082	-.073	1
	Sig. (2-tailed)	.750	.592	.222	.276	

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**Table 8.4.4.4 Correlation between the variables**

The correlation of  $-.073$  indicates that there is a weak linear relationship between the two variables.

The checklist application benefit to the study overall; it was straightforward, usable and beneficial. Additionally, many ‘lessons learned’ are reported and communicated for users and care providers who want to prevent incidents and failures across the hospital. During the period of time that the checklist was used for Case Study 2, the rate of EMR system failure fell considerably to only one per month. This is considered to be a significant achievement for this study. The IT department performs its job perfectly; in particular, periodic maintenance for both hardware (HW) and software (SW) is

performed on time and according to the plan. Users have started to use the formal incident reporting form regularly and all users have received immediate feedback after action is taken.

The use of the original STAMP technique did not reduce the (weekly) system failure rate, and it was inadequate with respect to imposing constraints to prevent incidents. As well, periodic maintenance was not conducted. The differences between the STAMP and STAMPC results are significant. The literature shows and confirms results of many previous studies that have been conducted in other industries and for other applications: the use of checklists can improve safety and help to manage system failures (Ziewacz et al., 2011). One characteristic of the STAMPC technique is that it includes an explicit operational definition of its process and is therefore perceived as a systematic risk management process, unlike the traditional STAMP technique.

The KKGH EMR system failure case study will be a reference document for subsequent investigations of EMR system failures in MOH hospitals and other health care providers in the KSA. In summary, our findings with respect to STAMPC technique show:

- Successful customisation and improvement of the original STAMP technique
- The checklist limits the number of risk factors that lead to failures
- The checklist detects additional information gained to prevent failures.

### **8.4.5 Comparing of the two case studies results**

To generate the result of this study, we have examined the two results of the two case studies with the view of discovering the differences between them. The results of each case study were independently assess and analysed. Case 1 was performed using STAMP technique to identify risks of EMRs, and the causes of failures. The finding of this stage are; Inadequate incident reporting to the Hospital Manager from the IT Department and end users; Inadequate constraints imposed by the IT Manager to the

users; Inadequate periodic maintenance for hardware/software and other infrastructure; Lack of feedback between the IT Departments and other hierarchical levels; Improper identification and management of risks. These finding were the leading factors to the EMRs failure in KKGH in Saudi Arabia

In the Case study 2, STAMPC was used with application of the checklist for a period of two Months to tackle further causal factors in addition to the found in the CS1 in order to mitigate risks and reduce the weekly EMRs failure.

The result of CS2 offered interesting points of the comparison, whereas the main finding was reducing the EMRs failure form once every week to nearly once every Month this result was tackled during the application period. For other two consequence months, the hospital's units continue using the checklist every week as planned by the researcher during the study. The follow up was conducted through the hospital, s quality management team who informed that the EMR system failure in the hospital reduced to nil for two months. Therefore, we expect that the EMRs failure will be reduced to the lowest rate (less than once a year) if the application of the checklist continue as planned. This contrast shows the power of application checklist with STAMP in hybrid system, and data extracted using STAMPC provides users and managers more information to prevent failures and improve safety.

#### **8.4.6 Discussion**

One unexpected finding of the first stage of this study was that only 8 (20%) of 40 MOH hospitals in the Riyadh Region have implemented basic EMR systems. These hospitals use the same software, with similar functionalities. Our efforts show that the application of the enhanced STAMP technique (STAMPC) is not only required for EMR system risk management in hospitals, but throughout the health care environment the technique can be used

In comparing the STAMPC technique with the original STAMP technique, we conclude that the STAMPC technique is more usable and objectively beneficial to a hybrid system. Data extracted using STAMPC provides stakeholders and users with more

useful information that may help to improve safety and prevent potential failures. The STAMPC technique ensures that all probable interactions between the different organisational levels, throughout the EMR system life-cycle, are taken into account by using the checklist. The power of the checklist in general is that it facilitates the identification, development and implementation of the strategies and procedures that are necessary to identify and avoid potential risks (Abdel-Rehim, Morrirt and Perks, 2011, p. 4).

# Chapter 9

## Conclusions, Future Work and Limitations

### Objectives

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- This chapter summarises our conclusions, recommendations for the thesis makes suggestions for future work.
- Discuss the limitation of the research
- Highlight the contribution of knowledge to the research
- Reveals recommendations
- Discusses future work

## **9.1 Introduction**

This thesis examined the implementation and risk management of EMR systems in hospitals in order to improve the quality of service and prevent future system failures. Users, including physicians, nurses and other paramedical health care providers believe that the use of an EMR system and RM practices will improve the quality of patient care, save time, decrease medical errors and improve control and reduce medical expenditures. This study reviewed the current body of knowledge on RM and EMR system usage in health care environments.

This chapter summarises the thesis by reviewing the research problems, research question, research approach, methods used and then presents the significant findings of the study including the impact of the research on academic, social and commercial domain, research contributions, and answer to the research questions and finally draws recommendations for future work.

## **9.2 Research problem and research questions**

EMR systems and RM techniques have been assumed important tools for improving hospital services. The assumption is that the effective use of EMR systems and RM techniques in health care will reduce the rate of system failures and increase the quality of hospital performance. However, RM in EMR systems has received little attention in the literature. Based on the perceived limitations of the literature on RM in EMR systems in hospitals, this study proposed the following research problem and research questions. The answer to these questions will contribute to filling a gap in the body of knowledge on managing risk in EMR systems. The research problem is a weekly electronic medical record system failure in MOH hospital in Saudi Arabia. In addition, the research questions are as follow:

- Can we improve the quality of hospital performance by developing and implementing an appropriate Electronic Medical Record (EMR) system and Risk

management technique for example, using STAMP risk management technique to reduce risk?

- Will managing risks in the health care field by using STAMPC provide a high quality care?
- How should risk management in an EMR system be carried out?

Chapters 7 and 8 answered the questions related to the deployment of EMR systems and the RM technique in order to mitigate and prevent system failures.

### **9.3 The social, academic and commercial, impact of the research**

This section presented the social, academic and commercial impact of the implementation of this research to EMR system failure in KKGH in Saudi Arabia. The positive effect of this research on patients and families from mitigation of system failures are numerous, such as reduction in the length of time patients and families have to wait to see the doctors, which lead to give patients satisfaction. These affect is also benefit the hospital administration and the other health care providers by making their tasks effort easier and cost saving.

Academic impact of this research provided a fulfilment of a gap contributed to the knowledge by expanding the scope of literature based around risk management, technique development, and EMRs usage. By use of original STAMP and the developed STAMPC in hybrid system especially in health care sectors. This is being a unique approach to overcome the problem of EMRs failures in MOH in the Kingdom of Saudi Arabia.

Commercial application of STAMPC technique and its viability of use in consultancy throughout the kingdom and Gulf Countries health care sectors. This could be achievable through targeted planning in the KSA then using such successes as marketing tool to mitigate risk and prevent failures of EMR system. This commercial act may opens up future research opportunity and new research question in other in the countries.

## **9.4 Summary of Significant Findings and Conclusion**

This study set out to tackle important problems such as continuous system failures and lack of RM technique usage in hospitals in Saudi Arabia. The main objective of this study was to detect and measure the rate of implementation EMR systems and RM techniques. STAMP and STAMPC as these may help to prevent system failures in the hospitals. In addition to reducing system failures, use of RM techniques may mitigate risk factors from the perspective of system users. This section presents the significant findings of the two phases of the study including the first and second case studies.

The section also acknowledges the contributions the study has made to the state of knowledge on managing the risk of EMR systems. The implication for the practice suggests that effective EMR system and RMT application are essential for performing high quality hospital services, thereby helping to minimise health care costs.

The study shows very low levels of basic EMR system and RM technique usage in the MOH hospitals in Saudi Arabia. There are only 8 out of 40 hospitals in a region used basic EMR system the investigation revealed. This study found a low level of quality in hospital services; this low level is due to the lack of ineffective risk management policies, risk assessment procedures and effective project management. The existing policies focused on staff training and financial support to implement or adapt an EMR. Thus, MOH hospitals in the KSA faced challenges relating to the continuity of EMR systems operation, including protection of patient's information and continuity of financial support, especially for continuous system improvement and maintenance.

Health care providers need to implement comprehensive EMR systems, in addition to effective RM activities during the design and throughout the operational stages of EMR system implementation. This study found that the lack of RM technique usage in the surveyed hospitals means that users often have no real idea of the risks that they face, and they are not aware of what steps they should take to protect system from failure and patients from harm.



In this study, we applied the STAMP technique to detect risks and analyse the process of system failure using the KKG hospital's EMR system as an example. This is the first time that STAMP has been applied in this hospital's EMR system's failures. The technique is used to identify risks by helping the system stakeholders, including providers and users, to consider the system through its entire life cycle and taking into account all interactions between the different levels. The study also focused on the difficulty of achieving control between the different hierarchical levels of the system. The obvious advantage of STAMP technique is that it provides an opportunity (and reason) to create an overall view of the whole system. In other words, it is the most comprehensive RM technique that deals with interactions between humans, the organisation and technology. The use of STAMP guides its users to find out the causal factors of incidents; it does this better than the FTA and other 'chain of events' models since it provides information about the failures and the modifications that are needed to prevent potential future failures. The STAMP technique makes it possible to identify probable risks by providing detailed scenarios involving incident components before the system formally implemented.

Application of STAMP technique with a checklist, and using the enhanced (STAMPC) technique in a 'real' hospital environment (Case Study 2), we significantly improved the quality of the hospital's performance in general, and the quality of the EMR system in particular by reducing the system failure rate. The incorporation of the checklist with the STAMP technique was integral: by using this straightforward tool, the root causes of failures were established, permitting the hospital to avoid current and future potential system failures and adverse incidents. EMR system failures were analysed in a case study and although the performance improvement was difficult to detect in short term, the checklist was nonetheless considered to be a valuable tool in minimising human and technical errors in hospitals.

Specific conclusions drawn from this study:

- Of the 40 MOH hospitals surveyed in Riyadh Region, only 8 hospitals (20%) have been using basic EMR systems, without physician and nursing notes; the remaining 32 (80%) hospitals are still using MMRs.
- Weekly EMR system failure was detected for many reasons including; incomplete requirement specifications for the EMR system's operation; inadequate periodic maintenance; lack of effective project managers; and instability of power supplies.
- Very low use of RM techniques to detect risks and prevent failure
- The STAMPC analysis outcomes showed component failures as well as interaction failures between machine and human operators within a hierarchical structure.
- STAMPC is like other RM techniques insofar as it must be consistently used in order to accurately and completely identify the risk factors that can prevent system failures.

### **9.5 Recommendations**

The following are some suggestions for improving the use of EMR systems, RM activities and ultimately, the quality of patient care in hospitals. Despite widespread implementation of IT systems in almost all other governmental and nongovernmental health care providers in the country, the failure rate of the EMR systems is still high in many others MOH hospitals. This study suggests that:

- Health care providers be encouraged to use at least one of the RM techniques in their programme in order to detect risk and avoid system failures
- Senior managers at all levels should improve the communication among staff and the system providers by making feedback mandatory at all levels and giving full consideration to the need for management information in connection with RM and EMR policies

- Managers should hold regular meetings with the IT Manager (at least quarterly) to discuss the performance of the users and other related issues, such as training opportunities
- Continue training for staff and managers should be recognised
- The results of all major system failures should be reported to the Hospital Manager and the Quality and Safety Committee
- The rate of the usage of EMR systems in MOH hospitals should be accelerated and hospitals should be given more independence with respect to implementation and maintenance
- High quality EMR and related equipment must be chosen and used

If the MOH desires to use information system and RM effectively in EMR systems, policies and standards must be central to any discussion of project implementation. We also recommend that the human resource management activities in hospitals has to be improved by making EMR training sessions compulsory for all employees. Users must attend the training session and must understand the EMR system functionalities and operations. Equipment and infrastructure must be kept in good condition and be in effective working order. Effective maintenance plans must be in place because the absence of a precise schedule for system maintenance, inspection and repair, together with a failure to understand the risk associated with equipment deterioration has resulted in several fatal system failures. Finally, we suggest the use of STAMPC technique help and provide managers with valuable information to manage risk.

### **9.6 Limitations of the Study and the contribution**

One of the goals of this study was to ensure that findings could be generalised to all MOH and other governmental and private hospitals in the KSA. However, due to the lack of resources, contextual data and the difficulty of getting permission to access all governmental and nongovernmental hospitals, only MOH hospitals in the Riyadh Region were studied, thus results cannot be generalised.

RM studies relating to EMR systems are limited in existing literature and those that exist, were performed by a small number of health institutions using non-hybrid and hybrid systems. The hybrid systems are sometimes incompletely described.

This study only covered MOH hospitals that use hybrid EMR systems. As well, the implementation of the developed checklist was for a relatively short period of time (two months) and not sufficient from the perspective of safety verification. The study would have been strengthened if the STAMPC technique had been implemented for all other governmental and private health care providers.

Despite of these limitations, the study offered the first test of the use of a RM technique on an EMR system in the KSA, it provided a significant contribution in term of reducing the EMRs failure rate in the hospital, introduced checklist and it confirms its validity by the obtained result of the two case studies. The study also contributed to knowledge by broadening the scope of literature on EMR systems and effective RM in hospitals in Saudi Arabia and elsewhere and provided a technique to identify and mitigate the possibility of system failure. The following section reveals future work required in this area.

### **9.7 Future Work**

As the health care sector continues to depend on technology, the problems will become more complex and the need for risk management practices will increase. Risk-aware hospitals will increasingly require units to be staffed with professionals who are socially and technologically aware of how to perform good quality services. We know that there is no perfect RM and total free risk project or environment: ‘Developing a risk management technique is a long way from making it happens’ (Leviton, 2004). The technique (STAMPC) proposed by this study provides suitable mitigation to approach the research goals and makes a significant contribution to existing RM knowledge, but there is always a room for future work.

Further studies should employ larger sample sizes and encompass wider and different geographical health care providers including public and private to detect the rate of the EMRs usage. As well, future studies using the STAMPC model might consider adapting the structure to meet the specific needs of the hospitals or organisations and test the model during EMR system implementation.

Additional recommended actions for future works are listed below:

- Further analysis can be done for non-hybrid EMR systems in hospitals; the STAMPC technique was developed and used for a hybrid system case study.
- More research could be conducted to prove the validity of the STAMPC technique
- The checklist could be converted from paper format to electronic format.

Finally, future project research in enhancing STAMPC would be to develop a comprehensive technique with electronic format of the checklist for easing its application in hybrid systems.

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**Appendix A: STAMP Checklist for RM in EMR SYSTEMS**

<b>STAMP Risk Management Control Checklist Investigation Progress</b>			
<b>Department: ICU</b>	<b>Date: / / 2012</b>		
<b>Case Number:</b>	<b>Collected Case Name :</b>		
<b>Review required</b>	<b>Yes</b>	<b>NO</b>	<b>I do not know</b>
1- Have you received updated EMRs policies and procedure from MOH or the Information Technology unit recently?	1	-1	0
2- Do the policies involve instruction for contacting IT expert 24-hours a day?			
3- Are you aware of the policies, procedures and standards of this hospital?			
4- Have all users been trained, on the hospital and the IT security policies and procedure?			
5- Do only authorised staffs have access to the system?			
6- Do all users have passwords and usernames?			
7- Do you know who to contact in case of system incident?			
8- Is your computer protected by virus protection software?			
9- Does your computer receive virus protection updates?			
10- Has the IT technicians performed system software maintenance this week?			
11- When was the last hardware precaution maintenance done?	6M 2	12M 1	Never heard 0
12- Have you filled in any incident reports this week?			
13- Have you received feedback for previous incident report?			
14- If the IT technician dose not responds, does a procedure exist for escalating the problem to the hospital manager?			
15- Do incident-report form and procedures exist?			
<b>Total</b>			
<b>Approval Name :</b>	<b>Sign</b>		

- This checklist is a subset of whole process from the master list STAMP.
- The use of it has been shown to improve conformity of safety and help to prevent incidents.
- In coding we used 1for yes -1 for No 0 for I don't know
- For question(11) the coding was 2 for every 6month 1 for every 12 month 0 for never

**Appendix B: Classification Checklist of functionalities**

Requirements	Comprehensive EMR System	Basic EMR system	Manual MR
<b>Electronic Requirements for Classification of Hospitals as having C,B, EMR system &amp; M</b>			
<b>Clinical Documentation:</b>	<b>95- 100%</b>	<b>70-90%</b>	<b>1-0%</b>
Demographic characteristics of patient	C	B	M
Physicians, notes	C		
Nursing assessment note	C		
Discharge Summaries	C	B	
Post mortem report	C	B	
Medical report	C	B	
Laboratory reports	C	B	
Radiologic reports	C	B	
Consultation reports	C	B	
<b>Computerized provider- order entry , test and image</b>			
Laboratory tests	C	B	
Radiologic tests	C	B	
Consultation requests	C		
Radiologic images PACS	C	B	
Diagnostic-test results	C	B	
Diagnostic-test images	C		
Medications list in patient	C	B	
Medication lists prescription order	C	B	
Physician Order	C		
Nursing Orders	C		
<b>Decision supports</b>			
Clinical pathways	C		
Drug-allergy alerts	C	B	
Drug-drug interaction alerts	C	B	
Drug-dose support (e.g. renal dose guidance)	C	B	
<b>All 23 functionalities are compulsory, to classified the Hospital as Comprehensive EMR system user.</b>			



This classification adapted from previous study has been done in the USA by Jha, and colleagues (2006). The classification table below was modified to suit MOH hospitals in Saudi Arabia.

A comprehensive EMR system was defined as a system with electronic functionalities in all clinical and non-clinical units. A basic EMR system was defined as a system with EMR functionalities in at least (70 – 90 %) of clinical and non-clinical units. A manual medical records (MR) system was defined as a system with manual functionalities in all clinical units.

## Appendix C: Questionnaire

### Managing Risk in Electronic Medical Record System Survey

#### *Covering Letter*

**Dear:** involver

I am a research student at STR in De Montfort University in the UK. I am conducting research study to detect and distinguish the hospitals that use Manual Medical Record (MMR), Basic Electronic Medical Record (BEMR), and Comprehensive Electronic Medical Record system (CEMR). In addition we want to identify failures or errors that had occurred in the system. Thus, your cooperation by filling this questionnaire is completely voluntary and your respond will be completely anonymous. The information you provide will remain confidential and will only be used for the research purpose. You do not have to answer any question you would rather not answer, and there are no consequences if you decide not to complete the questionnaire. Thanks again for your cooperation for filling this questionnaire and I hope the results of this study will contribute to the improvement of this hospital and all others health care providers in general. If you have any enquiry about the content of the questionnaire please do not hesitate to contact me. Please give the completed questionnaire to the researcher or put it in the envelope and then place the enveloped in the box provided. (At the quality management unit in the hospital)

Yours Sincerely

Abdullah Omar Barnawi

## *Letter of Consent*

I understand that my participation in this study is entirely voluntary and that I am free to reject to participate without consequence at any time prior to or at any point during the activity, and I also understand that any information I provided will be only used for the research purpose. Thus, I confirm that I have completed the questionnaire provided by / Abdullah Omar Al-Barnawi as part of his PhD studies.

I confirm that I give my consent for the information I have provided to be used in Mr / Barnawi's thesis

**Signed by/..... Date / /**

I prefer that the information I have provided remain confidential.

**Signed /.....Date / /**

**The questionnaire consist of two sections**

**Section (1):** demographic information: **Section (2):** main questions. **It takes about 20 minutes** to answer all questions.

Hospital name: ( ) Bed Capacity: ( )

Responder :		Gender:	( )- M ( )-F
Position:		Department:	
Education Level:		E-mail :	
<ul style="list-style-type: none"> <li>• University degree PG ( )</li> <li>• University degree G ( )</li> <li>• Professional- Diploma ( )</li> </ul>			
Other: Please specify			

1. What type of Medical Record system is used in this hospital?(choose one)
  - ( ) – Manual MR      ( ) –Electronic MR
  
2. Which of the following departments use the EMRs?(please tick the a available)
  - ( ) – Administration unit (admission)
  - ( ) – Clinical units
  - ( ) – Radiology unit
  - ( ) – Laboratory Unit
  - ( ) – Pharmacy Unit
  - ( ) – Nursing
  - ( ) – Medical Record Unit
  - ( ) –Others.....
  
3. What type of database for the Electronic Medical Record System is used?
  - ( ) – Oracle
  - ( ) – SQL Server (Structure Query Language)
  - ( ) – Microsoft SQL
  - ( ) – DB2
  - ( ) – Ms Access
  - ( ) – Sybase
  - ( ) – Others:
  - Please specify.....
  
4. Is the existing database sufficient for the hospital service?
  - ( ) –Yes

- No If no please specify.....

5. When did the hospital start using EMR system? And who was the stake holder  
1-MOH. 2- Hospital Manager. 3-Directorate of health affair 4 all 3

6. Choose which EMRs functionalities this hospital uses?

- Demographic characteristic of patient (PMI)
- Medical reports
- Discharge summary
- Physician note
- Nursing assessment note
- Laboratory tests
- Lab report
- Radiology reports
- Radiology image
- Diagnostic test image e.g. using endoscopy
- Medications (given Prescription)
- Medication lists (inpatient)
- Consultations request
- Clinical pathways
- Drug allergy alerts
- Drug interaction alert
- Drug dose support (e.g., renal dose guidance)
- Insurant purpose

7. Is there documented schedule for periodic maintenance for EMRs and other medical devices?

- Yes       - No    if no go to question 9

8. How often does maintenance take place? (Please tick one box only)

- Once a week
- Once a month
- Every six month
- Once a year

9. How often is the system upgraded?

- Once a week
- Once a Month

- Others please specify.....

10. How frequently is the data backup procedure carried out?

- Twice a day
- Once a day
- Every 2-3 days
- Once a week
- Other specify.....

11. Are all users trained to use the system effectively?

- Yes
- No

12. Is there any technical difficulty when using the system?

- Yes
  - No
- If yes please specify.....

13. Do you think users need more training to use the system effectively?

- Yes
- No

14. Are there security standards, access control policies written, documented and implemented to prevent patient's health information from being lost, stolen or misused?

- Yes
- No

15. The EMRs has been protected by providing authentication mechanisms:

Please choose the appropriate mechanisms;

- User name
- Complex Password for each user that only permits access the parts of EMRs they need.
- All log-in and view data are recorded
- Communicated limited application access list
- login timeout
  
- Card
- Others (please specify).....

16 - Choose which security measures are used to protect the EMR system?

- Fire wall (No download permitted)
- Antivirus
- Using Hardware box to protect the system from using portable devices such as USB.
- Download restrictions

- Other specify.....

17 What are the most common problems that faced the system? E.g.: data over load, denial of service and unplanned downtime.  
.....

18-How often does the EMR system fail? Please tick

- Daily  - Weekly  - Monthly  - Yearly Never -  :  
for example; how many time a day

19- Why did it fail?  
.....

20- For how long does the system remain down, when the failure occurred?

- up to 5 minutes
- 10 minutes
- 30 minutes
- 60 minutes
- more than 1 hour
- Whole project failed

21- How often has a patient been misdiagnosed because of inaccurate record?  
.....  
.....

22- What are the impacts of the failure to patient's care and hospital operation?  
E.g. very severe harm  
.....

23- How severe it was? Please rate the severity. One indicates very low. Five indicates extremely severe.

1-  2-  3 -  4-  5-

24- Are there documented incidents reports regarding the failures?

Yes  No

25- Is there a secondary (spare) server when the original server fails?

- Yes  - No

26- What are the causes of the failures?

---

- Technical Factors       - Human Factors       - Both

27- Choose from the following list, the suitable technical factors that cause failures:

- lack of suitable infrastructure
- Poor system security leading to viruses and spyware
- Unstable power supplies
- incomplete software
- Computer hardware failure
- The current Server is not appropriate to the number of users and applications.
- Other      Please specify.....

28- Choose from the following list, the appropriate human factors that cause the failures:

- Stress from over work
- Lack of trained and experienced users involvement
- Poor / inadequate user training
- Lack of effective project management / skills/ involvement
- Lack of catch up with rapid development in technology
- Lack of onsite technicians to perform maintenance
- Lack of cooperation from other users
- Unrealistic schedules and budgets
- Environmental Problem
- other please specify.....

29- What action has been taken to prevent future failures? E.g. implementation of policies, standards, imposing rules.

.....

30- How risks are identified?

- Common sense
- Previous data
- Tools and assist
- Independent judge
- Others    Please specify.....



31- Which of the following tools are used to identify and mitigate risks?

- Brainstorming
- Questionnaire
- Check-list
- Fault Tree Analyses
- FMEA
- Others            Please specify: .....

If you are not using any Risk Management Technique then please answer the following questions?

31, a: You are not using any techniques because:

- you are ignorant about them
- you think techniques do not work in practice.
- the implementation need well trained staff.

31, b: Are you considering to use any Risk Techniques in the future?

- yes       No

32- How do you define and measure risk?

- Common sense
- Past experience
- Using Equations such as Risk= Likelihood × Severity
- Others
- Please specify.....

33- How do you measure risk priority number (RPN)?

- By using RPN equation (RPN= Severity × Occurrence × Detection)
- Other: please specify.....
- None of the above

34 -How do you measure the impact of risk to patient?

- Probability of unwanted even ×Magnitude of loss
- Others            Please specify.....

35 - Please rank the following risk factors in term of their importance for EMR system failure? 1-3 (1= minor 2= Critical 3= Catastrophic)

- lack of suitable infrastructure.
- Poor system security leading to viruses and spyware
- Unstable power supplies

- ( ) - Incomplete software
- ( ) - The current Server is not appropriate to the number of users and applications.
- ( ) - Stress from over work
- ( ) - Lack of trained and experienced users
- ( ) - Lack of cooperation from other users
- ( ) - Lack of onsite technicians
- ( ) - Lack of catch up with rapid development in technology
- ( ) - Unrealistic schedules and budgets
- ( ) - Lack of effective project management / skills/ involvement

36 - Please choose one or more of the following Ministry of Health Policies bellow that imposed to the IT provider?

- (1) - The Patient Electronic Record must be confidential.
- (2) - The IT provider should train all users
- (3) - The provider is responsible to maintain any defect in the EMR system for the entire period of the contract.
- (4) - The periodic maintenance contract must be renewed yearly.
- (5) - Any new staff must be trained by the provider.

***Thank you for your assistance in completing this questionnaire***