Chapter 1: Introduction

1.1 Background

Over one million people are treated successfully per year by the National Health Service (NHS) (National Audit Office, 2005) but there is a hidden level of harm to patients. Kohn *et al., (*1999) shocked the western media into the potential scale of patient harm within health care. The report informed the American public that 44,000 - 98,000 patients a year in hospital were dying with over a million injured as a result of medical error and that about half of those deaths could have been prevented.

In the United Kingdom (UK), the Department of Health (2000) reported the NHS was failing to learn from things that had gone wrong and the systems in place are limited and fragmented for putting things right. They also disclosed the potential levels of harm in the United Kingdom:

Statistics in the report highlighted the extent of the problem.

- *400 patients a year die or are injured in adverse events involving medical devices.*
- *1 in 10 patients admitted to hospital (or at a rate in excess of 850,000 a year) became ill because of medical error and negligent care. Half of these mishaps could have been avoided'.*
- *Nearly 10,000 patients are reported to have experienced serious adverse reactions to medication.*

This report emphasised that too many preventable adverse incidents occur in the NHS and that this level of patient harm required action (Milligan and Robinson 2003). Subsequently, a number of high level public inquiries such as the The Bristol Royal Infirmary Public Inquiry (2001), the Royal Liverpool Children's Public Inquiry (2001), the performance and conduct of Mr. Richard Neal (2004) and Dr.Jayant Patel (2005) all demonstrated organisational, managerial and professional issues regarding patient safety and harm.

1.2 Reporting Systems

The transparency of public healthcare came into question when the potential of withholding information about serious medical errors created a perception that government officials were trying to hide them, or worse, not doing anything about them (Albert *et al.,* 1997; Berens, 2000). Reducing medical errors then become an international concern and healthcare sought to develop better reporting systems (Hudson, 2003). The World Health Organisation (2005) emphasised that adverse incidents are triggered by weak systems, likely to have a history of common root causes, similarities and trends. The WHO (2005) developed standard definitions in the area of reporting and recording. This was an attempt to homogenise reporting and recording of patient adverse incidents and safety experiences to reduce the possibility of it happening to another patient or in another member state.

WHO (2005) described a number of recommendations in order to improve recording and reporting systems within member states. They identified characteristics of successful reporting systems as described below in Table 1.1

Non-punitive	Reporters are free from fear of retaliation or punishment of others as a result of reporting.
Confidential	The identities of patient, reporter, and institution are never revealed.
Independent	The reporting system is independent of any authority with power to punish the reporter or the organisation.
Expert analysis	Reports are evaluated by experts who understand the clinical circumstances and are trained to recognise underlying system causes.
Timely	Reports are analysed promptly and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified.
System-oriented	Recommendations focus on change in systems, processes, or products, rather than being targeted at individual performance.
Responsive	The agency that receives reports is capable of disseminating recommendations. Participating organisations commit to implementing recommendations whenever possible.

Table 1.1: WHO (2005) Characteristics of successful reporting systems.

The WHO (2005) argued that reporting and learning could improve patient safety if:

- '*Reporting is safe for the individuals who report;*
- *Reporting leads to a constructive responsive;*
- *Expertise and adequate financial resources are available to allow for meaningful analysis of reports;*
- *The reporting system must be capable of disseminating information on hazards and recommendations for change.'*

The World Health Organisation (2005) made ten detailed recommendations to member states in order to standardise key changes required to learn from mistakes, justify the resources to encourage reporting and use the results of the data analysis to put together recommendations for organisation / system changes. These recommendations are shown in Table 1.2.

1	'*Adverse event reporting and learning systems should have as their main objective the improvement of patient safety through the identification of errors and hazards which may warrant further analysis and investigation in order to identify underlying system factors.'*
2	*'When designing adverse event reporting and learning systems, the responsible parties should clearly set out:* ▪ *The objectives of the system;* ▪ *Who should report;* ▪ *What gets reported;* ▪ *Mechanism for receiving reports;* ▪ *Sources of expertise for analysis;* ▪ *The response to reports;* ▪ *Methods for classifying and making sense of reported events;* ▪ *Ways to disseminate findings;* ▪ *Technical infrastructure and data security*'.

3	*'Health-care workers and organisations should be encouraged to report a wide range of safety information and events.'*
4	'*Health-care workers who report adverse events, near misses and other safety concerns should not be punished as a result of reporting.'*
5	*'Reporting systems should be independent of any authority with power to punish the reporter.'*
6	*'The identities of reporters should not normally be disclosed to third parties.'*
7	*'Reported events should be analysed in a timely way.'*
8	*'Reported events should be analysed by experts who understand the clinical circumstances and care processes involved and who are trained to recognise under- lying system causes.'*
9	*'The entity that receives reports should be capable of making and disseminating recommendations. Participating organisations should agree to implement recommendations whenever possible'*
10	*'Recommendation for preventive strategies should be rapidly disseminated, especially when serious hazards are identified.'*

Table 1.2: Recommendations to WHO (2005) member states.

Despite the WHO (2005) guidelines different countries have introduced mandatory and voluntary reporting systems to address and improve patient safety and hold organisations accountable to the public they serve. Mandatory reporting systems have been designed to support the legal obligations and professional accountability. This reporting approach is underpinned with penalties and sanctions as leverage to comply with reporting requirements for each country's requirements. The information is available to the public and requires hospitals to take corrective action and also to evaluate the efficacy of the corrective measures taken. Voluntary reporting systems rely on the commitment of individuals who have been involved in or have witnessed an adverse incident to inform the organisation on the patient safety issue.

The WHO (2005) guidelines were based on Runciman (2002) and Leape (2002) which were about important characteristics of successful reporting as shown in Table 1.1 Runciman (2002) argues that using information technology for detecting and monitoring of adverse incidents is essential for improving safety and reducing harm. Runciman (2009) reflects that computerised methods have been used and adopted as a means to improve patient safety. The key preconditions, in his view, for seeing the benefits are the development and adoption of common definitions and data classification. Runciman (2003) also stressed the importance of how an adverse incident is written, and to whom an incident is reported for organisational learning to be achieved. Runciman (2009) argues that more investment in information design is required so system and resources invested can improve the demands of data retrieval and analysis.

Leape (1993, 2002) takes a differing view, in that hospitals have to rethink their approach in how they deal with human error. Leape (1994) argues that hospitals having voluntary reporting systems and having data on incidents is not the main issue. He argues that there are major deficiencies in the techniques in the way doctors are taught, which results in them not recognising adverse incidents. Leape

(1991) recognises the importance of collecting data, and looking at trends, but argues that the socio aspects of reporting and recording need to be part of a number of strategies to deal with the reluctance to report an adverse incident.

1.3 Barriers to reporting

Reporting systems do not provide a reliable index of the rate of adverse incidents as there are many barriers to incident reporting (Vincent *et al*., 1999). A number of studies have identified time constraints, cumbersome forms, lack of knowledge about how and what to report, lack of feedback, and a perceived lack of value in the reporting process as barriers to reporting (Evans *et al*.,2006; Kingston *et al.,2004;* Lawton and Parker, *2002;* Schectman and Plews-Organ, 2006; Taylor *et al.,*2004; Waring, 2005).

Billings (1998) argued that fear of embarrassment, fear of punishment (of oneself and others), and fear of litigation were major reasons why healthcare workers did not report adverse incidents. Barach and Small (2000) identified inhibitive reporting cultures and lack of adequate systems as further barriers to reporting. In the above studies, it is unclear whether the barriers to reporting that were identified were associated exclusively with traditional paper-based reporting systems. It may be the case that additional barriers to reporting may be associated with the use of bespoke electronic reporting systems. A number of studies have also documented that doctors are less likely to report incidents and/or express favourable attitudes about incident reporting than nurses and other types of healthcare workers (Evans *et al.,* 2006; Kingston *et al.,* 2004; Lawton and Parker, 2002; Taylor *et al.,* 2004; Westbrook *et al.,* 2007). This effect has also been demonstrated with respect to electronic reporting systems (Braithwaite *et al.,* 2008).

One reason for doctors' less favourable attitudes and lower rates of incident reporting may be because of the culture of medicine. Rosenthal (1999) argued that its emphasis on professional autonomy, collegiality, and self-regulation is not likely to support error reporting. Leape (2000) supported a call for a more open culture and better reporting in healthcare. Trust (between management, staff, and the public) is needed to create a cultural change in healthcare of increased incident reporting (Firth-Cozen, 2004). In a climate of trust, a reporting culture, a just culture, and a learning culture can interact to create a safety culture (Burns *et al.,* 2006) and incident reporting can then yield greater improvements in patient safety.

1.4 Electronic Reporting System

There has been a focus in healthcare on replacing paper based reporting systems, which are time consuming and appeared to be inefficient with new efficient technology in the form of electronic reporting systems (Braithwaite *et al.,* 2008). The purpose of this approach was to improve delays associated with data entry and other barriers (Allinson, 2004). Researchers have argued that electronic information systems and communication through information technology can be used to introduce new efficiency and services. Taylor *et al.,* (2004) found that 45 percent of doctors and nurses surveyed thought an electronic format for reports would lead to increased reporting of medical errors. Force *et al.,* (2006) suggested that as electronic reporting systems are adopted it is likely there will be increases in the numbers of detected adverse incidents.

Despite these arguments by Allinson (2004), Taylor *et al.,* (2004) and Force *et al.,* (2006), there has been no research undertaken to identify the barriers associated with electronic adverse incident recording and reporting systems (EAIRRS) across an acute healthcare organization. This dissertation undertakes research into barriers associated with EAIRRS in an acute healthcare organization.

1.5 Research Question and Objective

Recent healthcare governance standards have mandated that healthcare organisations are required to implement and use adverse incident recording and reporting systems in the pursuit of improving patient safety (NHS Quality Improvement Scotland 2005). Despite the trend towards using electronic reporting systems in healthcare, there is limited research about barriers associated with implementing and using EAIRRS in acute healthcare organisations. Thus, the research question this dissertation will answer is, **'What are the barriers to implementing and sustaining an Electronic Adverse Incident Reporting and Recording System (EAIRRS) in an acute healthcare environment?'**

As part of answering that question, the objective of this dissertation will be to develop a model based on users' perspectives for implementing and sustaining an EAIRRS in an acute healthcare setting.

1.6 Dissertation Structure

The structure of the dissertation is as follows:

Chapter 1: The purpose of this introductory chapter is to introduce the potential level of harm in healthcare. It also describes WHO reporting guidelines for reporting systems, the potential barriers to adverse incident reporting systems and the move to electronic reporting as a solution to the problem. The chapter makes a case for the research question and presents the dissertation structure.

Chapter 2: This chapter reviews the background literature on adverse incident recording and reporting systems. The chapter describes the reason for adopting a socio-technical systems approach for investigating the research question. This

chapter also introduces Heeks *et al.'s* model (1999) which will be used as the conceptual foundation for the research.

Chapter 3: This chapter considers the research methodology that was used to answer the research question, '**what are the barriers to implementing sustaining an EAIRRS in an acute healthcare environment'?** The chapter considers and justifies approaches taken with respect to research philosophy, design and methods, organisational context, ethics, and limitations.

Chapter 4: This chapter explains the development of a questionnaire survey based on Heeks *et al.'s* (1999) model. It also presents the findings from that questionnaire.

Chapter 5: This chapter explains the development of semi-structured interviews to allow for the exploration of the causal attributions of the attitudes and perceptions expressed on the questionnaire. This chapter also presents the findings from the semi-structured interviews.

Chapter 6: The purpose of this chapter is to extend the literature by proposing a new model for implementing and sustaining an EAIRRS in healthcare based on the research findings.

Chapter 7: The purpose of this chapter is to summarise the practical implications of the proposed model. The chapter reflects on the research limitations and questions for future research.