

Chapter 3: Research Methodology

3.1 Introduction

This chapter considers the research methodology used to answer the research question “**what are the barriers to implementing and sustaining an EAIRRS in acute healthcare?**” It considers and justifies the approaches taken with respect to research philosophy, design and methods, organizational context, ethics, and the limitations.

3.2 Research Philosophy

There are two research philosophies which stand out in the literature in management research: positivism and phenomenology (Collins and Hussey, 2003). Positivism assumes that there is an objective reality whereas phenomenology assumes the existence of multiple realities.

Positivists argue that occurrences, experiences, events and trends can be observed and measured objectively (Rubenowitz, 1980; Silverman, 2005, Creswell, 2007). The positivist philosophy presumes that the researcher should not impact on the data being collected or their analysis because objective methods are used. Positivism is inclined towards the use of quantitative data and statistical analysis. This allows the researcher to bring a fresh view within a ‘reality’ setting (Rubenowitz 1980).

Phenomenology is concerned with the study of experiences from the perspective of the individual and as such is subjective in nature. Pure phenomenological research seeks to describe - rather than explain - and to start from a perspective free from hypotheses or preconceptions (Husserl 1970, Lester 1999). Phenomenology is inclined towards the use of qualitative methods and accepts that the researcher can impact on the data being collected and its analysis.

In considering this dissertation and the research question, a positivist would consider the number of adverse incident reports made to be objective reality. The underlying assumption is that increasing the number of incident reports improves patient safety (as measured objectively by the number of accidents and near misses resulting in death or injury). A positivist would also argue that to increase the number of incident reports, an organization needs a reporting system with certain technical characteristics.

To investigate the research question 'What are the barriers to implementing and sustaining an EAIRRS in healthcare?' this dissertation adopted the model of Heeks et al (1999) in Chapter 2. This model is based on socio-technical systems theory and proposes that there are seven characteristics or dimensions which impact on the reporting system:

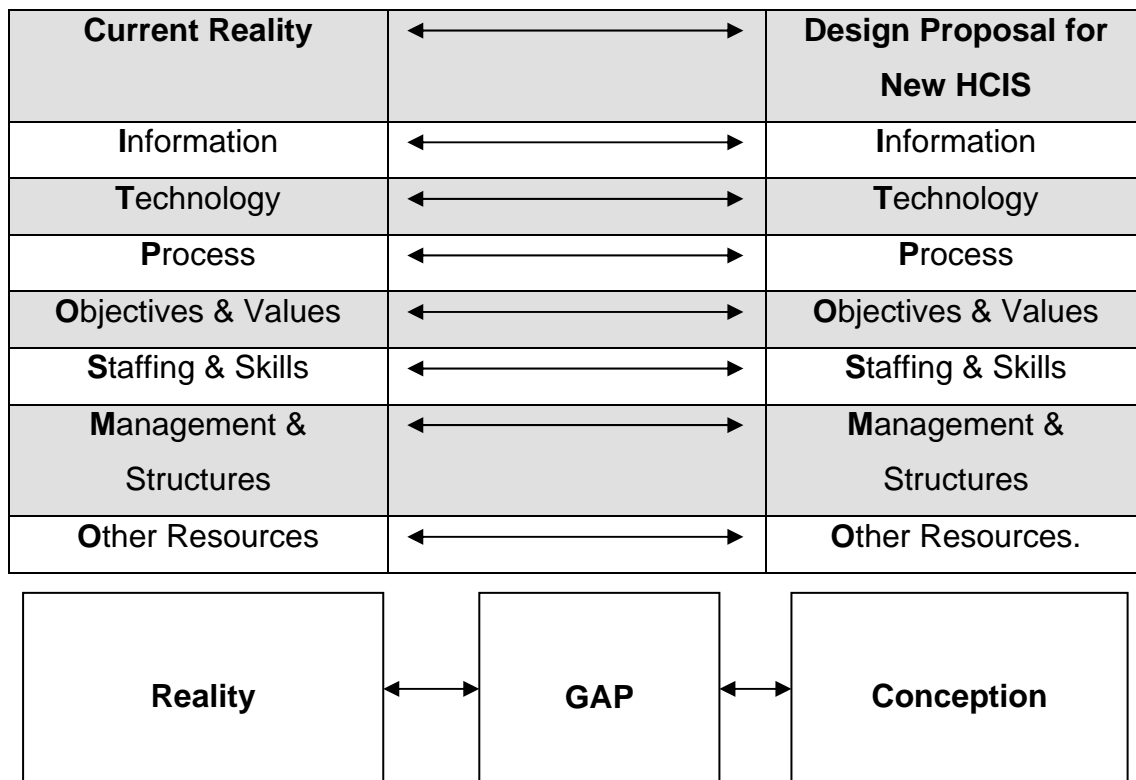
Information,
Technology,
Processes,
Objectives and Values,
Staffing and Skills,
Management and Structures, and
Other Resources.

In Figure 3.1, Heeks et al. (1999) propose that there are two realities:

- 1) the designers' conceptions of the social and technical factors, and
- 2) the users' perceptions of the social and technical factors.

This model is consistent with the phenomenological philosophical approach as it recognizes multiple subjective realities.

Figure 3.1: ITPOSMO Model of healthcare information system. Heeks et al (1999)



Thus, by using this model as the conceptual foundation for the research, this dissertation adopts a phenomenological approach to investigate the barriers affecting the implementation and sustainability of an EAIRRS in healthcare.

3.3 Research Design and Methods

3.3.1 Research Design

There are two main research designs in management research: the survey design and the experimental design (Arnold, Randall, et al., 2010). A survey does not intervene in naturally occurring events nor does it try to control them. It simply takes a snapshot of what is happening - usually by asking people. An experimental design allows the researcher some control over what happens and rules out alternative explanations for the research findings. In order to investigate the research question “What are the barriers to implementing and sustaining an EAIRRS in healthcare?” a

survey design was adopted as it allowed the collection of data about these barriers without trying to manipulate any variables.

3.3.2 Methods

The survey design usually involves the use of questionnaires but other methods including interviews also lend themselves to this research design (Arnold, Randall, et al., 2010). In order to investigate the research question, both questionnaires and interviews were used.

Questionnaires are normally used to assess a person's attitudes, perceptions or experiences by responding to a set of written questions by selecting a response option (usually a number on a Likert-type scale; see Chapter 4). Therefore the results of questionnaires are usually expressed using numbers (quantitative data). The main advantage of questionnaires as a research method is that they can be distributed to a large number of staff within the organisation. A disadvantage is that the lack of personal contact between the researcher and the respondent may lead to a low response rate (Murphy-Black, 2000 Silverman 2001).

Interviews are a particular way of exploring and capturing people's perceptions or opinions on specific matters. The results of interviews are usually expressed verbally (qualitative data). The advantage of interviews is that they allow participants to express their attitudes, perceptions, and experiences in their own words. This can also allow the researcher to explore answers in greater detail and explore causal attributions. The disadvantages of interviews are that they are time-consuming and do not usually include large numbers of participants. One other disadvantage of interviews is that the interpretation of the data is more open to researcher bias and participants may be more inclined to give socially-desirable responses (Arnold, Randall, et al., 2010).

A growing amount of research in the management literature suggests making use of a number of methods using in combination, or sequence to strengthen research designs. This mixed methods approach is used to draw on the advantages of a number of different methods to offset the disadvantages of each. Mixed methods

usually refer to the use of both qualitative (interview) and quantitative (questionnaire) methods in the same study (Arnold, Randall, et al., 2010). In order to analyse the data from both questionnaires and interviews, triangulation can be used to establish the convergence, corroboration, or correspondence of results from different methods. In this dissertation triangulation was used to analyse the questionnaire and interview data in order to improve the validity and reliability of those findings (Stake, 1995; Hussey and Hussey, 1997).

3.3.3 Questionnaire Survey

A questionnaire survey was used at an exploratory stage of the research in order to seek participants' views using the Heeks model (1999) as outlined in section 2.5. A self-completion questionnaire avoids ethical issues around consent as those who do not wish to take part simply do not complete the questionnaire. Saunders et al. (2007) argued that questionnaires are very popular as a large amount of data can be collected in an economical way and the results can be extrapolated to produce generalisations about the population being studied, assuming the sampling is representative. In Chapter 4, the development of the questionnaire is explained further and the results and respective analysis are properly presented.

3.3.4 Semi-structured Interviews

Interviews are an essential source for research as most case studies are about human systems. Interviews can be regarded as 'guided conversations' where the interviewer is concerned with finding out 'why' and there are no set questions to obtain the information; or a 'focussed interview' where there is a set of questions. Both of these are very informal, conversational and the questions predominantly open-ended. A third type of interview utilises a more structured approach, similar to face-to-face interviewing in market research where respondents are chosen according to a sampling frame and the results are more quantitative (Yin, 2003). This research project utilised documentation, questionnaire and semi-structured interviews as the prime data sources. In Chapter 4, there is an explanation of how the review of literature / documentation and the questionnaire findings informed the development of the semi-structured interviews.

3.4 Organisational Context: NHS Ayrshire and Arran Profile

The research was undertaken in NHS Ayrshire and Arran, a Scottish NHS Board. It serves a population of just over 368,000 and contains eleven of the one hundred most deprived social ward areas across Scotland (NHS Ayrshire and Arran Local Health Plan, 2004). In terms of population profile, it is representative of NHS Scotland as a whole. At the time of this research, I held a senior management role with direct responsibility for clinical governance and clinical risk management. This section makes a case for why NHS Ayrshire and Arran was an appropriate context for study.

An EAIRRS was fully implemented in April 2005 across the four acute hospital sites within NHS Ayrshire and Arran. All four acute hospitals participated in this research project. A short description of each hospital is as follows:

Hospital 1 is a general hospital with 350 beds which provides medical, surgical and paediatric services on an in-patient, day case and outpatient basis. The hospital also provides wide services including vascular surgery, ophthalmology and audiology (Internal NHS Board Statistical Department).

Hospital 2 is a hospital with 275 beds and provides area wide Obstetrics / Neo-Natal services and young disabled /rehabilitation services. There are facilities for the Rehabilitation Centre, which is recognised as one of the leading centres in the country. The hospital provides a number of long stay beds for care of the elderly.

Hospital 3 is a general hospital with 564 beds and provides a full range of services and also is the main Accident and Emergency Centre.

Hospital 4 is a local hospital with 166 beds for the care and rehabilitation of the elderly. It provides a wide range of vascular, orthopaedic and Stroke Consultant led rehabilitation and has twenty beds for stroke patients requiring varying degrees of rehabilitation.

Figure 3.2 shows the demographic position of NHS Ayrshire and Arran in which the four participating hospitals are located.

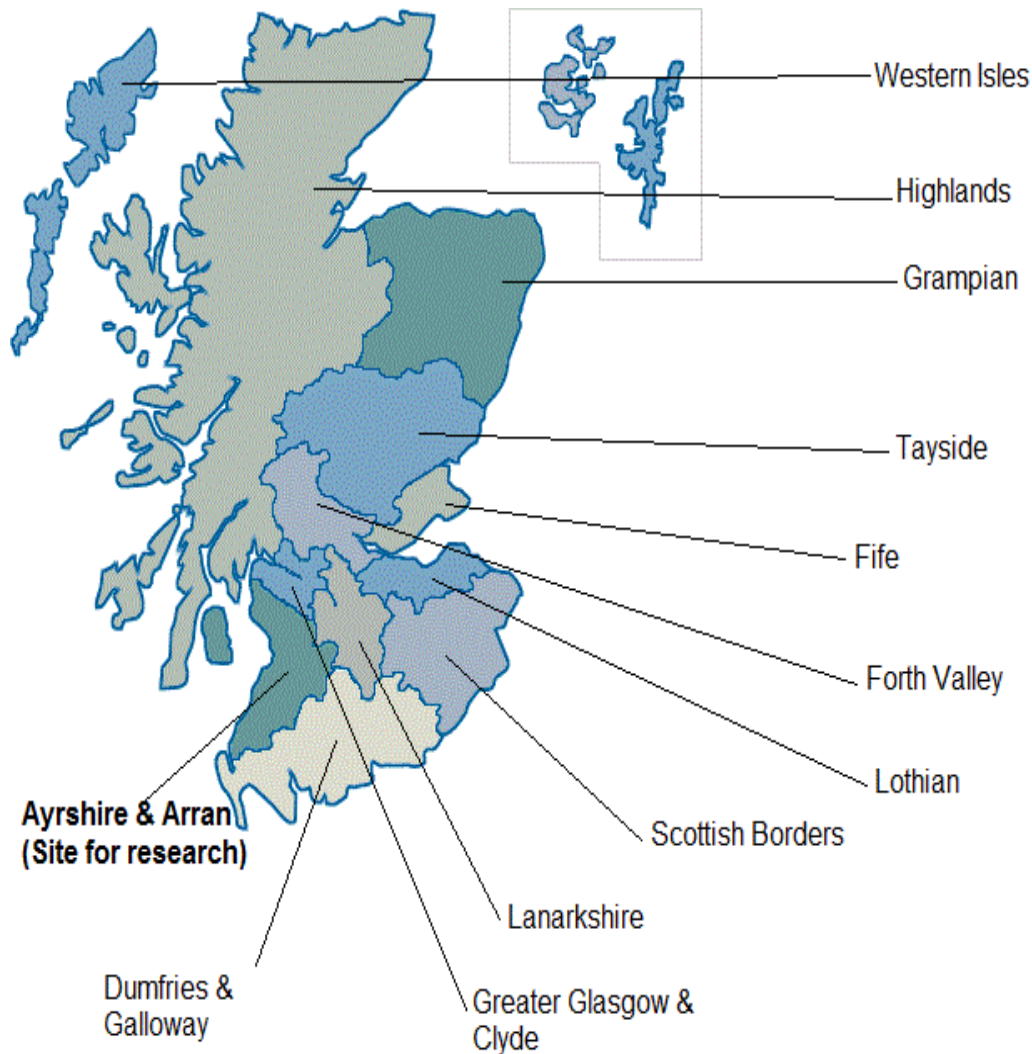


Figure 3.2: NHS Health Boards in Scotland and site of research.

3.4.1. Justification for context

NHS Ayrshire and Arran was constantly undertaking strategic, structural and cultural changes between 2000 and 2005, similar to all other NHS Boards in Scotland and across the UK. These changes were also implemented to meet local and national requirements with the growing importance of risk management, professional accountability, clinical and corporate governance.

The organisation, like all other NHS Boards, was implementing adverse incidents and recording systems in order to be active in meeting political policy, clinical governance, risk management and quality assurance standards. A number of factors and incidents had raised the importance of incident reporting and recording in the organisation by which directors had become aware of the vulnerability of the organisation's ability to understand the level of system failure and individual error in relation to patient care.

In October 1995, a Committee was set up to review the circumstances surrounding the death of a patient and to consider the determination by the Sheriff of a Fatal Accident Inquiry in the former South Ayrshire Hospitals NHS Trust. Because of the sensitivity of the report and despite being ten years old, it has been recommended that details are not recorded in this thesis. The report was not released into the public domain and therefore the information had limited circulation. As a senior manager in NHS Ayrshire & Arran, I was allowed full access to all documentation relating to the adverse incident which included assessors' audit report, NHS Board reports and subsequent action plans for the purposes of this research. However the Sheriff's Determination (1995), which was both detailed and analytical, stated that the 'reporting and acting on adverse incidents were organisationally inadequate'. The Sheriff's Determination also stated that there were organisational system failures which contributed to the patient's death and that the organisation had to be censured and criticised for its failure towards organisational systems and individual failures.

An Audit Report (1996) was made following the Sheriff's Determination by an external assessor. The assessor received and analysed extensive documentation and interviewed senior clinical and non-clinical staff. The Audit Report highlighted organisational weaknesses and fifteen recommendations were made to the organisation. One of the observations recorded from the Audit Report (1996) was in relation to risk management and stated '*it is regrettable that the National Health Record Form does not state that evidence should be retained. However, it is in the guidance notes on completing the form.*'

The organisation responded by making detailed action plans with the clear knowledge that the external assessors would return in six months to review progress. One outcome from the Audit Report was that the organisation should implement an EAIRRS and disciplinary action should be taken by the Chairman of the Trust. The organisation therefore responded to the Audit Report by creating a new management structure with the appointment of new directors. The Audit Report also noted that, on reviewing other incidents, one serious adverse incident involved a student who had given medication orally when it should have been given intravenously. It was also noted by the external assessor that the student was acting unsupervised.

The Audit Report showed that the Director of Nursing was not aware of the incident and acted on the assessor's observation. A local investigation revealed that the Ward Manager had given the medication wrongly while supervising the student nurse. The Audit Report indicated that the organisation was unaware of the level of adverse incidents occurring in clinical areas and that the external assessor did not have an assurance that there were systems to capture adverse incidents in the organisation. Directors accountable for the performance of the organisation did not appear to have service quality measures in relation to risk management already in operation.

The organisation also responded to the Audit Report by introducing a paper based EAIRRS, known as the Information Reporting and Management System (IRAMS) in which clinical and non-clinical staff reported incidents in a book and various carbon copies were forwarded to line managers for action and the Health and Safety Department to be entered into a locally developed database for analysis. Over the years, departments and directorates started to develop separate electronic databases in order to capture adverse incidents. The Pharmacy Department, for example, had collected information on medication errors but did not share the information with the rest of the organisation. The Women's and Children's Directorate had appointed a Risk Co-ordinator to develop a risk management database for the clinical staff to complete which was separate from the rest of the organisation.

By 2005, it was recognized that NHS Ayrshire and Arran still did not understand the level of adverse incidents and ‘near misses’ taking place and thus committed itself to introducing an EAIRRS in line with organisational objectives for clinical governance and quality (NHS Ayrshire and Arran Local Health Plan, 2004). The purpose of an EAIRRS is to provide clinicians and managers with quicker, more up to date and comprehensive information on patient safety issues (Institute of Medicine, 2001).

Figure 3.3 shows the number of recorded adverse incidents from 2005 - 2009, across the four acute hospitals within the organisation. These data are taken from the organisation’s EAIRRS. As can be seen by the number of reports, after an initial start-up period of six months, the EAIRRS had been established. The data for this dissertation was collected during 2008 – 2009, when the EAIRRS had been established. Thus, NHS Ayrshire and Arran was an appropriate organizational context in which to investigate the barriers to implementing and sustaining an EAIRRS.

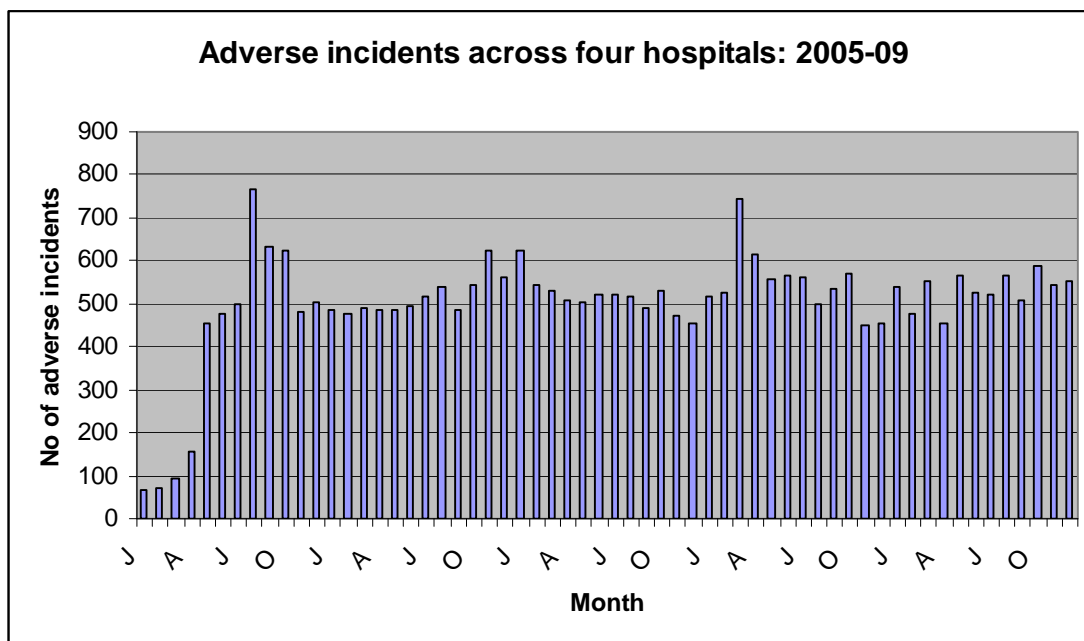


Figure 3.3: Adverse incidents across four hospitals from 2005-2009:
Source: NHS Ayrshire and Arran, Datix Data Base.

3.4.2 Datix electronic software system

The majority of NHS Boards use an electronic computer-based reporting system. Datix is part of a wider Risk Management System; although a key aspect of Datix is to provide access to an electronic incident reporting format for recording adverse events. Datix is the most widely used incident reporting and risk management system in the UK with 75% of NHS trusts and Health Boards using Datix at present and this appears to be increasing each year (Datix 2012).

The Datix software allows incident reports to be submitted from wards, departments by clinical and non-clinical staff. The benefit of this system design is that the company argues that it greatly improves the rates of reporting and promotes the ownership of risk. An online incident reporting form has been designed by the company for both clinical and non-clinical adverse incident recording. The benefit of this approach is that adverse incidents can be submitted by all staff across the Health Board with access to a computer. The process of recording an adverse incident onto the system is outlined in Table 3.1

Each member of staff in each department is given access to the Datix system to analyse and run reports on adverse incidents which are relevant to them. At corporate level, directors and managers can view adverse incidents that occur across the entire organisation. Clinical and managerial reports and information can be presented and developed without using another software package. This can be adapted to meet the organisation and users' requirements. This can be demonstrated by developing and presenting, with trends, detailed reports and statistical breakdowns by wards and departments. The company has designed a security feature which was built into the system in order to restrict access to personal information which can be done on a 'need to know' basis. This complies with the demands of data protection. The purpose is to put into effect safety improvement plans in order to reduce the same incident happening again to another patient or member of staff (Datix 2012).

	Process	Explanatory Comments
1.	Staff member reports and records the details of an adverse incident on the computer system and submits entry to line manager for approval / action.	
2.	Awaiting approval.	The appropriate manager / senior clinician (s) is emailed automatically from system to notify them. The exact location of the adverse incident determines which manager will approve the incident. At this stage the incident form.
3.	The line manager / senior clinician will: <ul style="list-style-type: none"> ▪ Add to / change coding ▪ Start investigation and complete as able ▪ Develop action plan if appropriate ▪ Inform other staff as necessary for appropriate management of incident ▪ Identify Health and Safety requirements 	The nominated manager / clinician must ' approve ' the incident so that it is moved to the main computer system data application. (Reports are mainly produced from the main system application so should be ' approved ' promptly.
4.	Approved: Record is moved into main electronic data base application. Or Saved to complete / review later	The 'approver' can temporary place incidents in an ' under review ' area while they are investigation them. However the adverse incident is not on core system until fully approved.
5.	Reviewed by (Clinical) Manager by: <ul style="list-style-type: none"> ▪ View incidents regularly and when notified ▪ Check appropriate coding and risk grading is appropriate ▪ Look at trends ▪ Run reports ▪ Identify links with risk register ▪ Share with and seek more information from colleagues if appropriate ▪ Close only when fields completed ▪ Check completeness and accuracy 	Basic reports and trends can be done using web, sophisticated reports and trends can be done if incidents have been 'approved' and moved to the main system application.

	Process	Explanatory Comments
6.	<p>Governance, reviewed by Clinical Governance Directorate by:</p> <ul style="list-style-type: none"> ▪ Serious / incidents are subjected to Root Cause Analysis ▪ Review of trends ▪ Share appropriate learning with Risk Committee for organisational –wide learning ▪ Ensure the process is working 	Outcomes of investigations and learning points recorded on electronic adverse incident recording and reporting.

Table 3.1: Overview of the EAIRRS process.

Source: NHS Lothian, Clinical Governance Department.

3.5 Ethics

Before collecting data, I obtained approval from NHS Ayrshire and Arran’s Ethics Committee. I also received approval from a departmental ethics committee at the University of Strathclyde. The main ethical considerations when conducting this research were:

- **Respect for autonomy;** for instance research participants had to be given sufficient information to allow them to make an informed choice about whether to participate in the research and, especially in medical research, to be re-assured that their decision would not in any way affect them or detract from the care they provide;
- **No-maleficance;** where researchers have a duty not to inflict harm on the study participants;
- **Beneficence;** positive beneficence where the research has to have some value either scientifically, particularly, or educationally and utility beneficence where the effort, resource and costs of the research are outweighed by the benefits of the research; and
- **Justice;** for example, treating people equally and fairly.

I provided NHS Ayrshire and Arran’s Ethics Committee with regular annual reports on the progress and conduct of the research against these four main ethical

principles. NHS Ayrshire and Arran's Ethics Committee and Strathclyde University annually approved and commended the conduct and progress of the research timeline.

3.6 Limitations

3.6.1 Hawthorn effect

There is a potential limitation of the study in relation to the Hawthorn effect. The Hawthorn effect can be defined as a phenomenon which occurs when individuals alter their performance or behaviour because of the awareness of being observed. This type of reactivity can be shown in changes of behaviour and can refer to circumstances where individuals alter their behaviour in order to confirm to the expectations of the researcher or observer (Heppner et al 2008). As a Senior Manager responsible for quality and risk, I was aware that participants may only provide me with what they thought the organization wanted to hear (i.e. that the EAIRRS was meeting clinical and non-clinical requirements and that it had been implemented successfully). In order to minimise the possibility of this bias, the data were triangulated (see 3.3.2 above).

3.6.2 Gaining access

Organizational access is often an obstacle for management researchers. Although I was a senior manager within the organization at the time of conducting this research, the length of time it took to gain access to a number of documents and approval from the organization's Ethics Committee was surprisingly long. The Chief Executive allowed full access to NHS Board papers, adverse incident reports, committees' minutes and adverse incident reporting and recording data. Feedback was given to both directors of the NHS Board and staff via conferences and seminars. Contact with staff participants was made indirectly (email, internal post) making it clear that their participation would be on a completely voluntary basis and information obtained would be treated anonymously and confidentially, and that they would have access to the research findings. This is consistent with best practice (Buchanan *et al.*, cited in Bryman 1988).

3.7 Chapter Summary

This chapter considered the research methodology used to answer the research question “**What are the barriers to implementing and sustaining an EAIRRS in acute healthcare?**” It justified the research philosophy and design to investigate the research question. The chapter gave a background to the perceived benefits as outlined by the designers and the process which is required to report an incident. It also made a case for using a multi-methods approach questionnaire (quantitative) and semi-structured interviews (qualitative). This chapter concluded by making a case for why NHS Ayrshire and Arran was an appropriate organizational context for study and some limitations.