How will an Electronic Adverse Event Reporting Management System Improve the Time Management and the Quality Processes of the Adverse Event Reporting Process in a Private Healthcare Organisation?

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Declaration

I declare that the work described in this
dissertation is, except where otherwise stated,
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Summary

The purpose of the study was to evaluate if an electronic adverse event reporting management system will improve the time management and the quality processes of the adverse event reporting process in a private healthcare organisation. The aims of this study were to:
- Evaluate how an electronic adverse reporting system will improve the time management of the adverse event reporting process for the Quality Department and departmental mangers due to real time notification of electronic events.
- Evaluate if an electronic adverse event reporting management system will improve the quality of information received and reduce the follow up required by the Quality Department due to missing data.
- Identify the gaps and weaknesses in the paper based process that will improve with the implementation of an electronic adverse event reporting system.

The researcher used a quantitative approach to compare paper based events (n=250) versus a three month pilot study of electronic adverse events (n=35). The time taken from the event to reporting was very similar in both the paper based and electronic events process, whereas electronic reporting appears to address the time management of the time taken from when the event occurred until received by the Quality Department. The average time taken in the paper based process was 14.2 days whereas in the electronic process the relevant managers are informed of the event immediately via email. A noticeable improvement in the electronic reporting is that all the details of the event are available in the database immediately and do not require another individual to enter this information in at a later stage. An improvement was noted in some aspects of the quality of information received; the significant illegibility issue has been addressed as well as the immediate action taken at time of reporting an event, due to the more structured format and mandatory fields. An improvement was noted in compliance with identification of the department reporting the event, whereas identification of where the event occurred requires more training as this is a new parameter. The recording of the date of the event increased to 100% but the time of the event deteriorated in the electronic event from 86.4% to 77.1%, possibly due to the fact that the date and time parameter are reported in the same field.

The study established that an electronic adverse event reporting system addressed the many issues of the current paper based reporting process due to real time reporting, immediate email notification and access. The follow up required by the Quality Department will be reduced due to the more structured format and the mandatory fields. A number of recommendations have been suggested by the researcher in an effort to further improve this process. Further studies will be required to establish if the electronic adverse event reporting system improves the quality and accuracy of the information received, as well as the impact the electronic reporting process has on closing the loop of care in a timely manner.

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Abbreviations

BWH	Bingham's Woman's Hospital
CA/PA	Corrective Action / Preventive Action
CDC	Centre for Disease Control and Prevention
CIS	Clinical Indemnity Scheme
CMS	The Centres for Medicare and Medicaid Services
CQCC	Centre for Quality and Care Coordination
DoHC	Department of Health and Children
EU	European Union
FOI	Freedom of Information
HIQA	Health Information and Quality Authority
HIT	Health Information Technology
HOD	Head of Department
HSE	Health Service Executive
ICT	Information Communication Technology
IOM	Institute of Medicine
IT	Information Technology
JCI	Joint Commission International
KUH	Kyoto University Hospital
PAS	Patient Administration System
QEF	Quality Event Form
RCA	Root Cause Analysis
SPSS	Statistical Package for the Social Sciences
TQM	Total Quality Management
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

Definitions

Accreditation:
Process whereby an organisation is assessed against internationally agreed standards.

Adverse Event / Incident:
Any event or occurrence which was unforeseen and resulted in a person being exposed to injury or a risk of injury.

Closing the Loop:
Is defined as the formal closure of all adverse events. The Quality Department will formally close an event once all the required details, follow up and corrective actions have been implemented. The event is resolved.

Complaint:
Any significant negative comment made by a patient / customer in relation to any aspect of the hospital service.

Electronic Events:
Electronic adverse events are reported on the electronic reporting system; Q Pulse. The electronic events are used in the electronic data collection and analysis.

Follow up:
Is defined as the unnecessary follow up by the Quality Department due to missing or incomplete data on the QEF.

Immediate Action:
Is defined as the immediate action taken at the time of the occurrence by the individual reporting the adverse event.

Legibility of Content of Documentation:
Is defined as the legibility of the details of the event; a description of what, where, when and how the QEF occurred.

Median:
Is defined as situated in the middle.

Near Miss:
An event / occurrence which, but for good fortune, would have resulted in a person being exposed to risk of injury.

Occurrence:
Is defined as when the adverse event occurred.

Occurrence to Reporting:
The time from when the adverse event occurred until the adverse event is reported either on the QEF or the electronic event.

Occurrence to Received by the Quality Department:
Is the time from when the adverse event occurs until the QEF is stamped as received by the Quality Department or an email notification is received.

Parameter
Is defined as a measurable or quantifiable characteristic of a system.

Process:
Is a set of interrelated or interacting activities which transforms inputs into outputs.

Reported By:
The department reporting the QEF or electronic event.

Raised Against:
The department where the QEF or electronic event occurred or the other department involved in the event.

QEF:
The quality event form (QEF) is paper based form used to report all adverse events which includes; actual incidents, near misses and verbal complaints. The QEF is used in the data collection for the paper based adverse event process and analysis.

Thin Client:
It is part of a larger computer infrastructure, where many clients share the same server.

Time Management:
Is defined as the time taken to complete the each step involved in the adverse event reporting process.

Chapter 1 Introduction

This chapter will give a brief outline of the study site involved in the research, the background to the proposed study, the proposed research question and the significance of the study. The author will describe the current paper based adverse event reporting process and will highlight the importance of introducing an electronic reporting management system in an effort to streamline and improve the current adverse event reporting management process. For the purpose of this dissertation the word adverse event will be used interchangeably with the word incident, quality event, occurrence or error reporting.

1.1 Introduction

Patients must be free from accidental injury (Ralston & Larson, 2005). The persistent nature of adverse events and patient harm in hospitals has generated an interest and a desire to understand how the work place contributes to and increases the risk of errors. Analysis of the type of adverse events and near misses are vital in trying to improve care processes and developing successful patient safety strategies (Levtzion-Korach, et al., 2009). The 2000 *To Err is Human* publication stated that approximately 98,000 people die each year in healthcare organisation from medical errors. More patients die from adverse events than from car accidents, breast cancer and AIDS (Kohn, et al., 2000). As a result of this publication quality and safe patient care became a national and international priority for governmental bodies and healthcare organisations. In 2008 *Building a Culture of Patient Safety. Report of the Commission on Patient Safety and Quality Assurance* by the Department of Health and Children (DoHC) stated that every healthcare organisation must

have effective processes in place to ensure the reporting, investigating, learning and the management of adverse events are carried out effectively and must be a priority for the healthcare organisations management team (DoHC, 2008).

As a consequence of the *To Err is Human* report many healthcare organisations conducted a review of their patient care processes and began participating in a formalised accreditation process. In 2002 the study site in an effort to improve their patient's pathways and their increasing commitment to improving quality and patient safety sought formal participation in a voluntary accreditation process. Accreditation is aimed at improving quality and patient safety processes. The primary accreditation body in the study site is the Joint Commission International (JCI). Compliance with JCI standards is mandatory and the Quality and Patient Safety standards require all accredited hospitals to report, monitor and analyse all adverse events in an effort to try and reduce adverse outcomes (JCI, 2008). All departments within the organisation are therefore continuously working together to comply with the JCI standards and the Quality Committees' objectives to meet accreditation requirements.

The study site is a private acute care facility with over 200 inpatient and day therapy beds, 7 theatres and a 9 bedded intensive care unit. The hospital provides a 24 hour, 365 day service by a team of specialists from a wide range of specialities including amongst others cardiac and orthopaedic surgery, oncology and radiotherapy. In addition there are 2 off site outpatient facilities under the hospitals remit.

The Quality Department in the study site has identified the lack of Information Technology (IT) as one of the main barriers to improving patient safety and implementing the Quality Strategy's objectives. The Director of Quality has recently initiated an electronic adverse event reporting management system within one department in the study site on a pilot basis, which will ultimately be rolled out hospital wide. The fundamental aim of electronic adverse event reporting is to improve and streamline the adverse event reporting management process. The impact of these changes on hospital processes and to the staff's workload is significant, therefore the proposed changes must be seen to streamline processes and or improve patient safety.

The research proposal will attempt to illustrate that the current paper based adverse event reporting process in the study site can be streamlined and improved with the implementation of an electronic adverse event reporting management system. It is anticipated that the electronic reporting system will address issues such as improved time management and quality processes from the time the adverse event is reported until the adverse event is formally closed out by the Quality Department. Real time notification and response to an event will significantly improve the current process and will provide departmental managers with the autonomy to manage, trend and track their own adverse events locally as currently they rely on the Quality Department to provide this information. IT can reduce the rate of adverse events; by facilitating a rapid response after the event has occurred, tracking adverse events and providing feedback (Bates & Gawande, 2003). Research has shown that the time required to track adverse events and implement improvements was reduced by 25% to 50% when moving from paper based to electronic adverse event reporting if it allows managers or other responsible individuals to view the reports immediately online and facilitates follow up and actioning (Atherton, 2002).

1.2 Background

The systems used to gather, manage and analyse data on adverse events vary from one organisation to another whether it is a paper based or an electronic system, the fundamental aim is to improve patient safety in the most efficient and effective way possible. Adverse event reporting was first introduced into the study site in 2002 to comply with accreditation standards. Adverse event reporting has increased by 142% from 2002 to 2009 (Table 1.1). This increase in reporting is largely due to the promotion of a "Fair and Just Culture" by the study site. All staff members are encouraged to report all actual adverse events and near misses that occur within the organisation.

Year	2002	2003	2004	2005	2006	2007	2008	2009
Percentage Increase		55%	11%	4%	23%	-1%	12%	23%
Increase 2002 – 2009	142%							

Table 1.1 Percentage Increase in Reporting from 2002 to 2009

Building safe processes in the delivery of care rather than focusing on blame together with analysing all events is an effective way of reducing adverse events and promoting learning opportunities. Adverse events resulting in death or a serious injury must be evaluated to prevent the likelihood of the adverse event occurring again. Events resulting in no harm to the patient also allow for the potential to identify improvements (Kohn, et al., 2000). Hospital employees are familiar with occurrences, incidents and or variances and healthcare organisations use reports to document remarkable events. Analysis and trending of these reported events facilitates patient

safety initiatives and process improvements whilst supporting compliance with requirements by external agency such as accreditation (Dixon, et al., 2002).

The motivation behind this proposal is that the current adverse event reporting system is a manual paper based system which is extremely time consuming and labour intensive. The adverse event reporting process starts at the time of occurrence. All actual adverse events, near misses and verbal complaints must be reported on a Quality Event Form (QEF) (Appendix 1). For the purpose of this dissertation all paper based adverse events will be referred to a QEF. The completed QEF must be signed by the departmental manager, and depending on specific departmental arrangements may also require the Head of Department's (HOD) signature. The QEF is photocopied locally for the departments own records prior to the release of the original copy. The copy is then placed in a risk management box in the department or in specific locations within the organisation where they are collected by the Quality Department approximately once a week, depending on the workload. Alternatively the QEF's can be posted via the internal mailing system to the Quality Department. This process usually results in a number of QEF's gathered together before they are posted.

 One member of staff together with many other responsibilities co-ordinates the adverse event reporting process in the study site; from collecting or receiving the forms, to allocating a unique identification number, to grading the severity, to categorising the event, to notifying the relevant individuals or committee representatives by posting out a photocopy of the QEF, to entering the details of the event onto the excel database, to analysing the data and finally compiling a monthly report on the number of QEF's reported and significant trends identified (Appendix 2). This monthly report goes to the Board of Directors, the Quality Committee and the management team.

The greatest learning opportunity from the adverse event reporting process is analysis and the identification of trends and patterns occurring within the organisation. The quality of the information received and the follow up of immediate and outstanding actions is fundamental to any quality and patient safety strategy. 95% of all reported adverse events in the study site are graded as low or medium risk and do not require formal investigations. Events graded as high or very high risk either due the nature, the severity of the event or the outcome to the patient always require further investigations or a Root Cause Analysis (RCA), in accordance with the Incident Reporting Management Policy (Appendix 3). Due to the high adverse event reporting numbers and the slow and time consuming paper based system, events graded as low and medium risk do not always have the required investigations or resolution. Illegibility and insufficient or missing data increases this already unmanageable workload due to the unnecessary follow up required by the Quality Department in an attempt to get this information.

The manual systems used for error reporting in a number of hospitals are ineffective (Atherton, 2002). Research has shown that paper based systems have their own limitations and risks as data can be lost between time of reporting and receipt which ultimately impacts on time and accuracy (Weber, et al., 2005). Many factors impact the process resulting in a delay from when the event occurred until the information is available electronically for analysis. The form might not be available, as it may be lost or misplaced and the information relating to the event might not be complete or legible. Security of paper based forms is a significant concern as they can be photocopied or misplaced. In 1999 the Centre for Quality and Care Coordination (CQCC) at Baylor University Medical Centre assessed the paper based adverse event reporting process for non medication events and identified that a timely, efficient and effective method of capturing adverse events or occurrences was missing (Dixon, et al.,2002).

IT is a crucial enabler in improving healthcare processes by providing rapid, wide-ranging access to information at the point of care. Healthcare processes have undergone many changes and health information systems are vital in adapting to these changes (Lenz & Kuhn, 2004).

The electronic adverse event reporting system implemented in the study site is Q Pulse, a market-leading software system for managing compliance with quality standards such as accreditation. The Corrective Action / Preventative Action (CA/PA) module will be used hospital wide to report all QEF's and will manage the adverse event reporting process, thereby facilitating resolution, corrective actions, investigations, RCA's and the formal close out of all adverse events (Appendix 4). The user will log in using an assigned username and password to report a new adverse event. The system is designed to ensure the required information is entered by the user at the time of reporting with the assistance of mandatory fields, enforcing compliance. An immediate email notification will be sent to the ward or departmental manager, head of department and the Quality Department once a new adverse event is reported. Managers can also receive email notifications when the electronic event is updated or closed. Managers will log into the Q Pulse database to access their departmental electronic events; events reported by and raised against their department. The follow up of all outstanding actions or investigations is the responsibility of the departmental manager until the event is resolved and the immediate action stage is closed out. The Quality Department will continue to oversee, monitor, categorise and grade all events, monitor trends and patterns within the study site and compile the monthly and annual reports. When no further follow up actions or investigations are required then the Quality Department will formally closed out the electronic event (Appendix 5).

IT is vital in improving quality in medicine especially in relation to patient safety and plays a vital role in the reduction of patient risk by improving care processes, identifying and correcting errors, assisting in decision support and providing feedback (Bates & Gawande, 2003).

The research question for this study is: How will an electronic adverse event reporting management system improve the time management and the quality processes of the adverse event reporting process in a private healthcare organisation?

1.3 Significance of the Study

The aims of this study are to:

1. Evaluate how an electronic adverse reporting system will improve the time management of the adverse event reporting process for the Quality Department and departmental managers due to real time notification all electronic events.

2. Evaluate if an electronic adverse event reporting management system will improve the quality of information received and reduce the follow up required by the Quality Department due to missing data.

3. Identifying the gaps and weaknesses in the paper based process that will improve with the implementation of an electronic adverse event reporting system.

In summary, the drawbacks of the paper based reporting process is that it is slow, time consuming and labour intensive. Lost and misplaced forms, illegible and incomplete documentation all contribute to delaying and burdening an already tedious adverse event

reporting process. Electronic reporting is anticipated to assist in addressing and streamlining this process.

1.4 Conclusion to Introduction

"Accurate, relevant and timely information is not an optional extra but it is essential" (DoHC, 2004). Advances in Information Communication Technology (ICT) allows for a greater ability to generate, access and distribute information. In order to provide a good healthcare system you need good information (DoHC, 2004). The proposed electronic adverse event reporting system is anticipated to significantly improve the adverse event reporting process due to real time reporting, immediate email notification and access of the electronic event. The electronic system will optimistically assist in addressing the increasing onerous workload, the time management, ease analysis and identification of trends and patterns, improve timely feedback and corrective action implementation. The electronic system will potentially assist in addressing the quality of information received due to purposefully selected mandatory fields which will ensure the required data is entered onto the electronic system and should all but eradicate the significant illegibility issues of paper based reporting. Improvements in the well documented paper based process should improve and streamline the current paper based reporting process; addressing time management and quality processes. The overall improvement in the adverse event reporting process will facilitate the Quality Department in meeting their Quality Strategy's objectives, accreditation requirements and most importantly improve patient safety.

Chapter 2 State of the Art

2.1 Introduction

A review of the literature seeks to put the topic under study into context in terms of what has already been established about the subject (Parahoo 1997). Watson, et al. (2008) recommends taking a systematic approach to the search, in addition to the critique of the article found. Whilst Parahoo (1997) would support this concept, it is argued that it is not necessary to be over critical of the research.

A literature review is carried out to identify current state of the art literature. Articles in relation to quality and patient safety in healthcare will be reviewed with a particular focus on accreditation, national and international recommendations aimed at improving and addressing patient safety through adverse event reporting. The review will include literature in relation to ICT in healthcare focusing on ICT and patient safety. The author will evaluate articles in relation to improving and streamlining the time management and quality of information of paper based versus electronic adverse event reporting systems. This evaluation will also include the well documented concerns of paper based reporting and the advantages and barriers of electronic systems. Finally, the review will outline and summarise available literature in relation to the implementation of electronic adverse event reporting systems.

2.2 Search Strategy

Literature reviews are mainly applicable to quantitative research, in an attempt to establish what is previously known, then tested and built on. A quantitative researcher prior to commencing their research needs to establish was has already been done. Qualitative researchers do not want to be influenced by previous work, but require knowledge of their subject (Parahoo, 1997).

Watson, et al. (2008) recommends defining key words and the relationships between variables as a priority in the search strategy. The key words used in the literature search included *electronic, paper based, computerised.* The word *adverse event* is used interchangeably with the word *incident or error reporting,* together with a combination of the following key words; *advantages, time management, quality data, legibility* and *patient safety.* Publications were limited to those written in English. A time frame was specified where possible from 2000 – 2010 otherwise the searches yielded publications from 1993 to 2010.

The following database searches were used; *Emerald, Proquest, Sage Journal Online, ScienceDirect, SpringerLink and PubMed.* The following journals were used; *International Journal of Medical Informatics, Journal of Patient Safety, New England Journal of Medicine, Quality and Safety in Health Care, Advances in Patient Safety, Journal of Medical Informatics Association (JAMIA), International Journal of Health Care and Quality Assurance and Joint Commission Journal on Quality and Patient Safety.* The worldwide-web using the following search engine were used; *Google, Yahoo* and *Metacrawler.* Relevant articles were also selected from citations and references from reviewed literature or articles. The total results of the table below (Table 2.1) refer to the total number of articles available using the keywords listed below.

Database (s)	Keywords	Total Results
Pubmed, Emerald, Sage Journal Online, ScienceDirect, SpringerLink	Electronic incident reporting / adverse event reporting / computerised	5,051
Pubmed, Emerald, Sage Journal Online, ScienceDirect, SpringerLink	Electronic incident reporting / adverse event reporting AND patient safety	5,219
Pubmed, Emerald, Sage Journal Online, ScienceDirect, SpringerLink	Electronic error reporting	29,907

Table 2.1 Summary of Articles identified During the Literature Search

A search using the keywords *paper* versus *electronic* did not yield searches from the above databases. Books in the workplace were reviewed and selected for use if appropriate in relation to quality in healthcare, patient safety and adverse event reporting. Searches continued on an ongoing basis in an effort to identify unpublished work. The searches of databases and journals continued using the selected keywords and continued up until the submission date in an attempt to expand the initial searches and literature review. Duplication of articles occurred across the databases and not all of the articles reviewed were deemed relevant or suitable for this dissertation. The inclusion criteria for the selection of the reviewed literature included current articles in relation to: quality, patient safety and adverse event reporting, ICT in healthcare and electronic adverse event reporting systems. A total of 60 articles and books were deemed suitable for this dissertation.

The first section will discuss Quality in Healthcare.

2.3 Quality in Healthcare

The Quality in Healthcare section will give a brief introduction and background to quality in healthcare, the accreditation process including national and international recommendations on quality and patient safety strategies. The fundamental aim is to address and improve patient safety outcomes by reporting and analysing of actual and near miss adverse events. Accreditation and governmental recommendations provides organisations with frameworks to address patient safety outcomes.

2.3.1 Background to Quality

Total Quality Management (TQM) refers to an organisation's beliefs and attempts to achieve a total quality service through the involvement and participation of the entire organisation from top to bottom; customer satisfaction is the driving force. TQM has revolutionised the way quality is managed and improved (Tiernan, et al., 2001). Organisations must move away from perceiving healthcare errors as an individual's responsibility and progress towards recognising safety as part of a process (Ralston & Larson, 2005).

"First do no harm" has been the mantra for thousands of years for those caring for the sick, but in spite of advances in modern medicine adverse events resulting in patient harm continue to remain a fundamental problem for all healthcare organisations (JCI, 2006). Patient safety and quality is central to the delivery of healthcare and it is fundamental in diagnosis, treatment and patient care. Both national and international healthcare systems face similar challenges in relation to unsafe practice, incompetent healthcare professionals, sub standard governance, errors in diagnosis and

treatment and non compliance with required standards. Patient safety is now a critical component of policy reform, legalisation and the development of standards of care motivated by quality improvement initiatives both nationally and internationally (DoHC, 2008). Quality is a dimension of patient safety and visa versa, of which patient safety is the most discernible component (Ralston & Larson, 2005). The Institute of Medicine's (IOM) publications *To Err is Human* and *Crossing the Chasm* resulted in healthcare organisations being scrutinised, analysed and publicised. These two publications forced healthcare organisations and professionals to be more accountable and responsible to their; patients, employers, the public, other regulatory bodies and governmental organisations (Dlugacz, et. al., 2004).

According to the World Health Organisation (WHO) reducing adverse events is an international concern and studies have consistently demonstrated an unacceptable number of adverse events resulting in injury and death (WHO, 2005). Tens of millions of patients suffer from disabling injuries or death annually due to unsafe medical care or practice, and nearly one in ten patients are harmed while receiving treatment in a well-funded, technology advanced hospital. The economic burden of unsafe care is significant; additional medical expenses due to prolonged hospitalisation, loss of earnings, disability and litigation can cost billions per annum (WHO, 2009). Studies on adverse events around the world demonstrate that between 4% and 16% of patients admitted to healthcare organisations experience one or more adverse events, half of which are preventable (DoHC, 2008). Each year between 8% and 12% of patients admitted to hospitals in the European Union (EU) suffer harm from care they have received, usually from a combination of preventable errors (Tanner, 2009).

Ten years on from the *To Err is Human* publication patient harm continues to remain an issue. A conservative estimate is that preventable medical harm still accounts for more than 100,000 deaths annually; a million deaths over the past decade. The Centre for Disease Control and Prevention (CDC) in the United States of America (USA) estimate that hospital-acquired infections continue to kill up to 99,000 people each year (SafePatientProject.Org, 2009). In Ireland an excess of €60 million was expected to be paid out in 2009 to Irish patients who suffered from serious adverse events; patients receiving the wrong medication (n=6,785), incorrect diagnoses (n=2,051), blood transfusions incidents (n=824) and errors involving the medical record (n=5,070) (O'Cionnaith, 2009). In Ireland the Health Information and Quality Authority (HIQA) under the Freedom of Information (FOI) released a serious incident list where 52 cases of serious healthcare errors and process failures were being reviewed (Centre for Ageing Research and Development in Ireland, 2009).

In Ireland, the States Claims Agency's risk management's goals are to provide State authorities with recommendations on how to prevent occurrences, or reduce the numbers of acts or omissions that may give rise to claims (State Claims Agency, 2010). A review of 108 cases, defined as settled in 2009 by the Clinical Indemnity Scheme (CIS) found 63% of the cases fell into the top three adverse event categories; peri-operative / procedure, peri-natal and diagnosis. Adverse events are associated with multiple system failures and there is the potential for an adverse event to occur at any stage during the patient's journey as interventions occur many times during the patients care. The overall aim is to improve patient care and reduce medico-legal claims (CIS, 2010).

In summary, adverse events have an intense impact on all healthcare organisations. JCI believe that in order to ensure patient safety all organisations must establish a culture in which errors must be identified before they occur and that staff must be comfortable reporting adverse events. Organisations that encourage this will more than likely to develop a culture of patient safety. Healthcare organisations need a clearly defined, coordinated and ongoing quality and safety program to continually address patient safety (JCI, 2006).

The next section will discuss healthcare organisations participation in the accreditation process and the DoHC endeavour to address and improve patient safety outcomes. The discussion will include the private healthcare insurer's attempts to address patient safety, reduce escalating financial costs and enforce accountability by healthcare organisations.

2.3.2 Accreditation, National and International Recommendations

Accreditation is a process whereby participating healthcare organisations are assessed to establish if they comply with pre determined standards which are specifically designed to improve the quality of patient care. This is a voluntary process which guarantees assurance from participating organisations to continually ensure a safe setting for their patients and staff (JCI, 2009). During the past decade accreditation has gained increased international acceptance. JCI is considered a driving force in encompassing all aspects of safe and high quality care in healthcare organisations. JCI assists participating healthcare institutions in providing frameworks to reduce the risk of adverse outcomes, improving patient safety and quality care by ensuring mandatory compliance with all accreditation standards (JCI, 2006). The Quality and Patient Safety standards

provide a framework for developing processes that systematically monitor, analyse and improve performance to enhance safe quality care (JCI, 2008).

The 2008 publication of *Building a Culture of Patient Safety. Report of the Commission on Patient Safety and Quality Assurance* by the DoHC provides recommendations for a framework for patient safety and quality improvement. "Knowledgeable patients receiving safe and effective care from skilled professionals in appropriate environments with assessed outcomes." (DoHC, 2008). The Commission concluded that an effective patient focused approach must be taken in relation to governance, management, reporting and communication following an adverse event. The efficiency, the style and the speed of communication of the local response to the adverse events or near miss is significant from the patient's, his or her family and the staff's perspective. The culture within the healthcare facility will influence this response. An open and transparent culture within the facility will facilitate the communication and learning following such events (DoHC, 2008).

The IOM estimated that medical errors cost $17 to $29 billion annually (National Conference of State Legislatures, 2008). In 2006 the USA spent $5,711 per person on healthcare and the United Kingdom (UK); a nationalised healthcare system spent $2,317 per person (Howie, 2009). In an effort to address these increasing financial costs and patient safety many States in the USA are refusing to pay for medical errors or for never events; preventable hospital errors as their way of addressing quality care and reducing escalating healthcare costs. The Centers for Medicare & Medicaid Services (CMS) originally listed eight hospital-acquired conditions for which they would not reimburse healthcare organisations. This list has since been revised to include additional conditions (Gever, 2008). Events resulting in serious injury to patients are considered

to be costly and frequent. The United States government is shifting healthcare costs further onto healthcare organisations by refusing to pay for medical care that is perceived to be preventable or adverse with serious effect (Chaco, 2009). President Obama's proposed Healthcare Reform Plan argues in favor of adverse event reporting and would actively fund Health Information Technology (HIT) aimed at reducing unnecessary spending resulting from avoidable errors (Howie, 2009). In 2008 VHI Healthcare, a private healthcare insurer in Ireland stated that all new and existing private hospitals that provided care for its customers must achieve international accreditation in an effort to improve the quality of patient care (VHI 2009).

In summary, in an effort to improve patient safety and compliance with accreditation standards and the DoHC's recommendations, all healthcare organisations are required to report, monitor and analyse near miss and actual adverse events occurring within the organisation. The organisation is required to initiate corrective actions in an endeavor to change processes, improve practices and prevent reoccurrence of the adverse event. The next section will discuss adverse event reporting.

2.3.3 Adverse Event Reporting

Healthcare organisations must be proactive in identifying and monitoring adverse events. Preventable events and near misses can only be identified if they are looked for (Ralston & Larson, 2005). Adverse events are defined as; unanticipated, undesirable or potentially dangerous occurrences which may result in a person being exposed to injury or the risk of injury. A critical component of managing patient safety is the accurate reporting and the investigation of all adverse events that result in or potentially result in injury (Mater Private Hospital, 2008).

Adverse events occur with a worrying frequency in healthcare and injuries sustained as a result of medical care received represent an incalculable loss to the affected patients, the treating clinician and the healthcare organisations (Szekendi, et al., 2006).

Adverse event reporting systems were originally introduced 20 years ago following examples in other industries such as aviation, chemicals and nuclear power and were aimed at identifying risks (Hoffmann, et al., 2008). Improving patient safety through adverse event reporting in healthcare originated from the aviation industries' critical incident technique, which was developed to investigate all airline accidents, aimed at reducing human error (Wagner, et al., 2005). Adverse event reporting systems collect information about adverse events with the fundamental aim of identifying risks and assisting healthcare organisation improve quality. It was recommended that reporting should be non-punitive, confidential, anonymous, voluntary, well-timed, system focused, responsive and provide analysis (Hoffmann, et al., 2008). The IOM proposed the implementation of the voluntary reporting of errors that result in no patient or minimal patient harm and mandatory reporting of serious patient harm or death, preventable adverse events. The Joint Commission is one of many organisations lobbying for legislating mandatory reporting in the USA. Mandatory reporting is a component of a system that holds healthcare providers accountable for serious injury or death (Howie, 2009). Several organisations including the Veterans Heath Administration and JCI already require mandatory adverse event reporting (Hoffmann, et al., 2008).

An essential component of a comprehensive patient safety strategy is establishing a setting that encourages healthcare organisations to recognise errors, to evaluate the cause, to take corrective actions and improve performance. The analysis of the information gathered and the identification

of ways to prevent the errors occurring again is the main objective, as merely collecting the data without analysis is of no benefit. Adequate resources and support must be provided for the analysis and response to significant events (Kohn, et al., 2000). Understanding why preventable errors occur in healthcare is fundamental to the development of strategies aimed at addressing and minimising their occurrence (DoHC, 2008). The primary principle of patient safety is the reporting of adverse events in an effort to learn from the experience. Reporting alone does not improve patient safety; it is the response to the adverse event that leads to change. The reporting of serious adverse events should trigger an in-depth investigation to identify causes or possible failures and should result in required system or process redesign to prevent the adverse event reoccurring (WHO, 2005). The focus of reporting and reducing adverse events is the evaluation of the type and frequency of the adverse event and most importantly what is the outcome to the patient. This process is critical in understanding errors in care processes, identifying the root cause and developing actions aimed at reducing and preventing errors (Milch, et al., 2006).

There are a number of barriers to adverse events reporting. Individuals may be concerned with admitting they have made a mistake or may appear incompetent, they may have a fear of reporting confidential information, litigation and or disciplinary action. Organisation may have an inhibitive, blame or punitive culture. Technical issues such as poor system performance and lack of structured reporting mechanisms contribute to IT failure. All of these factors can contribute to under reporting (Braithwaite, et al., 2008). Under reporting can have serious consequences for healthcare organisations as in the case of Dr. Michael Neary a consultant obstetrician. Dr Neary who was struck off the Medical Register in 2003 following an extensive hearing before the Fitness to Practise Committee of the Irish Medical Council, in relation to an

uncharacteristic number of caesarean hysterectomies which went unreported until two midwives voiced their concerns about the number of caesarean hysterectomies performed (Clark, 2006).

Organisations which have high numbers of reported adverse events do not necessarily signify poor or substandard patient care, but rather reflects the organisations culture to encourage reporting of adverse events and the incorporation of reporting in the quality process. The focus is on process change rather than on blame or punitive actions (Milch, et al., 2006). It is suggested that electronic reporting systems combined with relatively blame-free organisational culture will actually increase the number of adverse events as opposed to actually decreasing the number due to improvements (Braithwaite, et al., 2008).

In summary, the quality in healthcare section gives an introduction to quality and patient safety. The organisations compliance with accreditation standards and national recommendations facilitates and directs this process. The adverse event reporting management process is a mechanism used to improve quality and patient safety processes within healthcare organisations. The next section will discuss the importance of ICT in improving adverse event reporting and streamlining patient safety processes.

2.4 Information Communication Technology

If medicine is to make improvements in quality, especially in relation to safety then IT will play a vital part (Bates & Gawande, 2003). The ICT section will discuss the use of ICT in addressing patient safety and will outline the findings of the proposed National Strategy which focuses on

improving HIT in Ireland. This section will also include a review of the literature in relation to the advantages and barriers of electronic and paper based reporting systems.

To perform services healthcare organisations are dependant on rich and accurate information collected and shared between multiple levels within the organisation. To manage data the organisation requires an integrated structure and HIT to disseminate information amongst managers and care providers (Anderson, et al., 2003). IT is a vital enabler in improving healthcare processes by providing rapid and comprehensive access to information at the point of care. Healthcare processes have undergone many changes and health information systems are vital in adapting to these changes (Lenz & Kuhn, 2004). It is fundamental for healthcare organisations to have access to meaningful, accurate and readily accessible information. It is impossible to consider improvements in healthcare, quality and safety, and the development of reliable healthcare systems without considering HIT. HIT is essential in enabling and sustaining the required improvements and advancing the understanding and knowledge of healthcare systems (DoHC, 2008).

The importance of HIT in the wider healthcare reform program, the safety and quality agenda has been described in a number of national strategy documents including the *Quality and Fairness – A Health System for you* and *The National Health Information Strategy and Primary Care: A new Direction*. The proposed Health Information Bill was developed to provide the groundwork for a legislative platform to promote the utilisation of information to sustain safe and high quality patient care. The Health Service Executive (HSE) has the overall responsibility for the development and application of HIT systems within the public sector in Ireland, whereas the HIQA have the statutory responsibility for health technology assessment in Ireland. These

national bodies facilitate HIT and ICT in Ireland in strengthening modern healthcare systems to support accessibility of accurate and meaningful health information (DoHC, 2008).

The introduction of ICT in healthcare has been much slower than any other areas even though ICT has demonstrated a positive impact on patient safety. Timely and accurate information is fundamental in ensuring patient safety (HIQA, 2010). Complex healthcare processes, missing data, interruptions and chaotic communication all contribute to adverse events. HIT solutions are essential in addressing these challenges by directing and assisting workflow processes, improving communication, assisting with accessible knowledgeable information, monitoring and providing decision support. Real time health information contributes to effective prevention and support; by improved information for patients and the public, improved medical knowledge, development of improved guidelines and improved training, all of which contribute to improved patient safety and quality care (DoHC, 2008).

The IOM's report on *Crossing the Quality Chasm* emphasised the importance of IT in creating reporting systems that would effectively reduce medication adverse events. A survey conducted by the Healthcare Information Systems Society in 2003 found that healthcare leaders identified the implementation of patient safety IT as the number one priority at that time (Rudman, et al., 2005). Technology alone can not guarantee reporting numbers; it is merely a tool to assist in the collection of data. Reporting is the responsibility of each individual which is dependant on the culture and values of the organisation and should be viewed as a means of improving quality and safety processes and not as a routine duty. Organisations must focus on process improvement and not blame (Dixon, 2002). Attitudes towards patient safety and adverse event reporting differ between different organisations and cultures (Regenbogen, et al., 2010). Milch, et al. (2006)

discussed the findings of a descriptive study conducted in reported events using a web based reporting system from 26 acute care hospitals in the USA from January 2001 to September 2003. An analysis of 92,547 electronically reported adverse events over a total of 2,547,154 inpatient days, from hospitals ranging from 120 to 582 beds. 674 to 9,617 reports were collected from the different hospitals, a median of 4,237. The range of reports was diverse from 9 to 95 days, a median 35. There was no statistically significant correlation between size of the hospitals, number of months using the electronic reporting system and adverse events reported per inpatient days.

In summary, advances in IT can assist in delivering more efficient and effective care. Reducing the occurrence of adverse events is the only real method of improving safety and quality patient care (JCI, 2006). Organisations must incorporate adverse event reporting into their patient safety programs in an effort to reduce patient outcomes and improve patient safety. The next section will discuss the impact if ICT on patient safety.

2.4.1 Information Communication Technology Addresses Patient Safety

Inadequate information pertaining to adverse events is one of the main barriers to achieving significant improvements in patient safety (Szekendi, et al., 2006). Medical errors occurring in healthcare organisations are a considerable source of preventable morbidity, mortality and healthcare costs (Meyers, et al, 2008). Documentation in patient records must be legible and readable to all users, and has been a longstanding challenge for all healthcare professionals. There are many risks associated with illegible entries which impacts on patient care, drains healthcare resources, impacts on reimbursement and has significant legal implications for all

healthcare organisations. Risks to patient care as a result of illegibility due to misinterpretation can result in significant patient injury. As technology is adopted in healthcare organisations, issues relating to illegibility have improved due to printed documentation. Hand written documentation is the problem (Glondys, 2003).

Electronic adverse event reporting supports the organisations ability to have instant access to explanatory data about the adverse event or near miss, facilitating system improvement and ultimately improving patient safety. The electronic system allows for trending and the analysis of data at local and organisation level and assists with process improvement and risk management. Electronic forms are considered to be more secure, confidential and an accurate way of reporting adverse events than paper based forms (White, 2007). Web-based electronic reporting systems have the potential to overcome barriers to improving patient safety. They are accessible to all relevant members of staff, easy to review, track and trend events. The systems allow healthcare organisations to investigate the root cause of system errors and for real time notification and simultaneous tracking of the events; responsibilities that might not have been easily performed during the paper based reporting process (Milch, et al., 2006).

In summary, international experience shows that the effective use of information systems has the ability to improve patient safety and the patient's healthcare experience. Health information must be relevant and accessible to all healthcare providers. Advances in ICT have improved the ability to generate; access and distribute information (DoHC, 2008). The next section will discuss the well documented concerns of the paper based reporting processes versus the potential advantages of electronic reporting systems.

2.4.2 Paper Versus Electronic Adverse Event Reporting Systems

Inadequate information relating to the adverse event has been identified as a major obstacle to achieving meaningful improvements in patient safety (Szekendi, et al., 2006). The traditional adverse event process in the study site is a paper based reporting system. A paper based form is completed when an adverse event occurs, which is then reviewed by the departmental manager and sent to the Quality Department. The data is then entered onto an electronic system for analysis. Many factors contribute to delaying the process from when the adverse event occurs until it is available for electronic analysis. Some reasons for the delay include the following; forms may not be up-to-date or complete, or available for collection or the information may be illegible. Paper based forms are not secure due the fact that they can be lost, mislaid or photocopied (Dixon, et al, 2002).

Regardless of the medium used whether electronic or a paper based, the key component to reporting an adverse event is that the report is constantly available and must provide individuals involved in reporting the event with equal opportunities to do so. Paper based forms are not considered to be ideal due to legibility issues or interpretation of hand writing. Delays occur as the form passes from one individual to another or sits on a desk waiting for resolution. Experts consider paper based reporting to be ineffective as staff can be confused as to which form to use, how to fill it out, where to send the completed form as well as which individual is responsible for follow up. Error is introduced into the paper based flow process as there are many opportunities for the form to be misplaced or misdirected (White, 2007). The CQCC identified a number of improvement opportunities in the paper based manual documentation process, when converting from a paper based to a web-based adverse event reporting system. Paper forms took more than a

week, 7.6 days for the appropriate department to receive the form, therefore resulting in an inefficient and untimely process. Often there was a delay in data availability and analysis due to illegibility or incomplete data (Dixon, 2002).

Electronic records data is typed text as opposed to hand writing and has a more organised forced structure. The electronic systems can improve completeness and quality due to validity checks on data as it is entered (Tang & McDonald, 2001). White (2007) states that electronic reporting systems ensure comprehensive reporting by eliminating the choice of different forms. The appropriate information can be selected automatically and completed with automated prompting for further information, as well as directing reports to the responsible individuals for evaluation of risks, design and implementation of improvement initiatives.

The electronic record has the capability of storing and retrieving data and allows for flexible queries or analysis. It can retrieve data and arrange data in a number of ways; according to availability, transferring, retrieving, linking incongruent data sources and databases, storing, reporting, data quality and standards and can facilitate audit. This is a significant advantage over paper based records which require substantial sorting to get the full picture. Often paper based data is incomplete, and the risk of misfiling is much higher. The cost of paper health records are not seriously considered for example; stationery, printing, storage, retrieval, re-filing and the cost of transport to and from the clinical setting (Gilles & Holt, 2003).

As ICT pervades healthcare organisations worldwide, hospitals have purchased computerised systems to improve quality of patient care. The IOM's *Crossing the Quality Chasm: A New Health Care system for the 21st Century,* stated IT was one of the fundamental factors required to

improve quality in healthcare. Electronic medical error reporting systems have become more familiar in hospitals. These systems facilitate health organisation in tracking adverse events and near misses in an effort to improve health care processes and prevent errors reoccurring. Findings from the *To Err is Human* report found that errors were generally caused by process failures rather than by individual mistakes, therefore increasing the potential for the error to reoccur. One of the recommendations of this publication was for hospitals to implement computerised reporting systems which would assist in the tracking of adverse events and provide information that can lead to improving patient safety (Roumm, et al., 2005).

The development of new electronic systems allow for many opportunities; to update and standardise data sets, to create risk grading models associated with alert mechanisms, to serve as a mechanism for the identification of trends and the setting of benchmarks or targets, improve the effectiveness and accuracy of the captured patient safety data, facilitates real time data availability for administrators and management and assists with maintaining compliance with regulations, guidelines and standards (White, 2007). IT is proving to be a fundamental component in the administration of healthcare due to its ability to store vast amount of information without the actual need of physical storage space (Hazman, 2008).

Electronic adverse event reporting can be straightforward and cost effective to introduce in healthcare organisations, but there are still significant issues in capturing all adverse events due to under reporting, thus affecting the reliability of adverse event reporting rates (Regenbogen, et al., 2010). Electronic reporting systems continue to challenge healthcare organisations and managers in all aspects of quality and patient safety (Walsh & Antony, 2007). There are many barriers; such as time requirements and the staffs perception that the organisation do not utilise

the data or reports (Mekhijian, et al., 2004). Lack of computer expertise, difficulties in training staff, lack of resources and conflicting pressures all impact on the reporting process (Walsh & Antony, 2007).

In summary, the well documented issues of paper based reporting processes, such as illegibility, delays in the appropriate department receiving the adverse event, confidentiality concerns due to potential unauthorised access of the paper based form appear to be addressed and potentially rectified with the use of ICT. Electronic reporting also appears to facilitate in improving and streamlining the adverse event reporting management process. The next section will review literature in relation to implementation of electronic reporting systems identifying the advantages, disadvantages and challenges these systems pose to healthcare organisation in an attempt to improve the paper based reporting process.

2.4.3 Electronic Adverse Event Reporting Systems

Web-based reporting systems are examples of how IT can assist in improving quality, patient safety and organisational processes. These systems have allowed for anonymous, computerised, integrated reporting and guarantee reporting reliability and quality data. This can facilitate the analysis of trends and generates feedback for quality processes from the quantitative measured data. IT has the potential to improve workflow processes and real time transmission of relevant information. Patient safety may be improved with the use of technology by reducing adverse events due to improved response time in resolving the root cause of adverse events preventing reoccurrence, trends can be tracked and feedback given. Data can be collected from any computer with internet access, from multiple locations while the analysis of data and tracking of

adverse events can be collated centrally. The data can be reported in a timely manner, real time (Rudman, et al., 2005).

Electronic reporting systems have many advantages such as accessibility, easy to use, accessing reports, real time actions, analysing trends and the elimination of illegible forms. It does however have disadvantages as there can be the fear of new technology and the significant cost implications in the purchasing of new applications. The effectiveness of electronic systems should be judged on how well they contribute to improving patient safety (Levtzion-Korach, et al.,2009).

The IOM's *To Err is Human* stated that errors were usually caused from system errors rather than individuals mistakes and recommended two types of error reporting systems. The first was mandatory reporting for all adverse events resulting in serious harm or death. This would ensure all critical errors were reported, investigated and the implementation of appropriate actions, it would provide organisations with the drive to improve patient safety; therefore avoiding penalties, pubic disclosure and healthcare organisations would invest in patient safety. The second recommendation was a voluntary external reporting system. The error would be reported to a national or state body that would analyse the reported errors and suggests improvements. These systems would collect data in relation to non injurious and more serious adverse events. In recent years a third type of error reporting system has emerged in the private sector in the USA. This system allows errors to be reported onto an internal database that is only accessible by hospital staff. The analysis of the adverse events is done within the healthcare organisation and remains confidential as it is never released to any other outside organisation (Roumm, et al., 2005).

To date literature on reporting systems and safety has focused mainly on reporting and not on the actions and follow up as a result of the reporting (Levtzion-Korach, et al., 2009).

2.5 Evidence Supporting Electronic Reporting Management Systems

Levtzion-Korach, et al. (2009) evaluated the rate, the content of the report, the ease of use, the follow up and corrective actions from a web-based electronic reporting system. The study was performed in a 747 bedded tertiary academic hospital, with approximately 52,000 inpatient admissions. The paper based reporting system was replaced 15 years ago by an electronic system, which was upgraded in 2004. The study reviewed all adverse events reported from May 2004 to November 2006. A total of 14,179 adverse events were analysed, focusing on the frequency of the reporting, ease of reporting, the severity of injury, location of reporting, frequency and content by professions, follow up and corrective actions. During the study period the number of submitted reports increased by 206%, 19.7 reports per 1,000 inpatient days or 0.09 per admission. 2.9 per 1,000 inpatient beds involved patient harm. Time was a major issue in the paper based process as it could take 7.6 days for the adverse event to reach the appropriate department. During the research most of the events were submitted within 24 hours of occurrence. Ease of use, the reporter had 53 fields to complete, the number of mandatory fields depended on the classification of the events and generally the reporter only completed the mandatory fields. The electronic system was accessible to all in real time and managers could be notified of the event immediately and concurrently. 70% of reports were reviewed within 72 hours as required by hospital policy. The fundamental goal of the electronic reporting system was to improve patient safety. The delay between the submission of the report and viewing of the

reports by appropriate managers was much shorter than during the paper based process. The reports facilitated managers in the implementation of corrective actions and response to events in real time. A significant limitation of the study was that the study site had an excellent patient safety culture; and this culture could differ in other organisations. The research concluded that web-based reporting system had the potential to gather significant information. Adverse event reporting systems represent a vital safety tool and should be used to directly influence and improve patient safety within a healthcare organisation.

Rudman, et al. (2005) examined the impact of an internet based process for collecting medication adverse events. Data was collected using a paper based system (n=2,965) which provided a baseline for measuring success, identifying needs and prospective actions. The second dataset was collected by means of the web-based medication error reporting system (n=959) which was used to identify whether the issues identified during the paper based collection process where met. Adverse events reported electronically resulted in the risk management department receiving real time notification of all reported adverse events. The risk management department forwarded the details to the appropriate staff for investigation. Once the investigation was completed then the report was returned to the risk manager for analysis. Four areas were identified during the paper based collection to establish a baseline for measuring the web-based system. Significant improvements were observed in all fours areas. The fourth area was to improve the quality and specificity of reported data. 7% of the paper based adverse events reports were categorised as "other" and 11.6% of the data was not recorded, whereas no adverse events were categorised as "other" and only 2.1% of the data was not recorded during the web-based system. Web-based reporting was available through out the hospital and allows for real time reporting. The interval from when the event occurred to when the event reached the risk

management office was reduced from 3-4 weeks to less than 1 day. The positive impact of the web-based medication reporting system found there was an overall increase in reported medication errors. The reporting specificity improved and the volume of not recorded data decreased. The risk manager did not have to collect paper based forms for events requiring further investigation, and the individuals involved in the event could access the event to see what immediate action was taken.

Roumm, et al. (2005) discusses the limited published articles in relation to the effectiveness of internal error reporting systems in relation to reducing errors. The author reviewed state of the art internal error-reporting systems in private organisations to determine whether these systems were effective in improving patient safety. The data was collected through a combination of literature reviews and interviews. A manual search on references in identified articles was used to research other appropriate publications. The internet was used to identify vendors of internal error reporting systems in the private sector. Information pertaining to the systems was obtained through phone or email interviews. The interviews obtained information in relation to the description, marketplace and impact of reporting systems. Initial interviews were conducted in March to April 2005 and follow up interviews in May 2005. 9 vendors were identified suitable for this review. Evidence from the review found that internal error reporting systems that collect data on adverse events have the potential to assist healthcare organisations in addressing patient safety improvements. The systems can be used as more than just a database of stored records if they are utilised for analyses and trending of adverse events. Many private sector organisations have seen the potential in internal reporting systems due to the failures in national and state run systems effectively processing data and addressing the IOM's recommendations. Internal reporting systems allow administrators to track errors in an effort to improve quality without the

fear of hospital data ending up in the public domain. The data is only accessible within the organisation. Error reporting systems can be voluntary, anonymous and free from reprisal. Internal systems allow healthcare organisations to review their own adverse events in a timely manner and focus on identified problems. To reduce errors and increase patient safety healthcare administrators must use the information obtained from adverse events analysis to bring about change to healthcare processes. This is known as "closing the loop" and requires healthcare managers to create a culture of quality in their organisations. Evidence relating to the effects of internal reporting systems is mainly anecdotal. The review of literature did not locate any randomised control trials in determining the reporting systems effectiveness in improving patient safety. This is due to a number of reasons; the infancy of many internal error reporting systems, the healthcare organisations keeping their data private and the vendor's lack of available follow up information. The lack of studies is a serious concern which will need to be rectified especially when organisations are purchasing error reporting systems. Data relating to the impact of these systems is ascertained from subjective accounts and case studies. The limitation of this analysis is the lack of controlled studies measuring the impact of error reporting systems on patient safety. Policies can not be based on case studies or anecdotal reports, and this is the only available data available on the effectiveness of internal reporting systems. There is also the potential for bias, as the data was obtained from the systems web sites, vendor interviews and vendor selected clients. Therefore the negative attributes were not identified. The review concluded that electronic error reporting systems have the potential to significantly improve healthcare quality improvement processes. The data collected can be utilised to bring about change to healthcare delivery and reduce potential adverse events. Reporting alone does not improve safety unless you close the loop. Adverse events must be analysed and change must be implemented. Due to healthcare organisations desire to keep data private it was not possible for the author to determine the

impact of internal reporting systems on patient safety and further research is needed (Roumm, et al., 2005).

Dixon, et al. (2002) describes the improvements in relation to the timeliness, efficiency and effectiveness of a web-based adverse event reporting system. The system was implemented in four different facilities. Adverse event reporting was compared prior to and after the implementation of the web-based form to assess whether the timeliness, efficiency and effectiveness where met. Feedback was also obtained during a campus-based Quality Fair. Prior to the implementation of the web-based system the CQCC received an average of 128 paper based adverse events monthly, 7.6 days after the occurrence. In the twelve months after the implementation of the electronic system they received an average of 175 adverse events and 82% of the events reported within 24 hours of the adverse event occurring. Reporting decreased slightly 13 to 17 months afterwards, but timely reporting was maintained. Anecdotal comments were positive from end users due to ease and speed of electronic reporting compared with the paper based form. Improvements in real time reporting have allowed for quicker corrective actions, notification of relevant individuals, data availability for analysis and issues relating to incompleteness and legibility have been eliminated. Diverse levels of computer competency posed some challenges as well as anonymous reporting as it can result in the inability to obtain sufficient information relating to the adverse event. Regardless of the level of superiority of reporting systems, technology will not guarantee reporting; therefore all organisations must reinforce a no blame or non punitive culture thus enforcing a focus on a culture of quality and patient safety. The objectives in relation to timeliness, efficiency and effectiveness were met by the web-based adverse event reporting system.

Weber, et al. (2005) studied the cost, the accuracy and efficiency of a web-based handheld electronic data collection system versus the traditional paper based data collection and management system. The main areas of discussion were; that computerised data collection provides investigators with maximum control over the data, therefore reducing lost data during transit as data stored on paper can be lost or stolen and can result in privacy and ethical issues. The conclusion of the study was that computerised data collection and management systems ensure data integrity, it increases the accuracy and dependability of the data by reducing the risk of human error.

In summary, electronic adverse event reporting systems potentially address many of the challenges involved in improving the adverse event reporting process. Addressing the time from occurrence until reporting and from occurrence until the event is received by the appropriate department is significant in improving patient safety processes, due to real time notification of the event, timely follow up and corrective action. This change in practice can contribute to improving adverse event reporting process by closing the loop of care and fostering an organisational culture of quality and patient safety. The next section will discuss the positive impact electronic reporting systems have on the time management of the adverse event reporting process.

2.6 Time Management of the Adverse Event Reporting Process

Time management is extremely significant in streamlining the adverse event reporting process and improving quality and patient safety processes. Lag time between the time of the occurrence and the submission of the adverse event provide meaningful insight into the healthcare

organisations patient safety culture and their success of reporting systems. Delays in reporting provide risk managers with the opportunity to improve the timeliness of their adverse event reporting process. Reducing reporting delays is beneficial as timely reporting allows for a speedy organisation response and further prevention of harm to the patient. Consistency with recall is possibly less accurate over a period of time; therefore prompt reporting will enhance the possibility of more complete and accurate details relating to the event. The culture of delayed reporting could increase the chance of the individual failing to complete the report at all (Regenbogen, et al., 2010).

In 2002 the CQCC identified a number of improvement opportunities in the manual paper based process. Paper forms took more than a week for the appropriate department to receive the form, therefore resulting in inefficient and untimely processes (Dixon, 2002). The time required to track incidents and initiate system improvements is reduced by 25 to 50% when moving from paper based to electronic reporting if it allows managers or other responsible individuals to view the reports immediately online and introduce system based improvements (White, 2007).

Regenbogen, et al. (2010) discusses the comparative analysis of adverse event reporting lag times in 2 academic medical centers in the recently on-line published article. The Kyoto University Hospital (KUH) in Japan a tertiary referral hospital with 1,240 beds and a voluntary no blame paper based adverse event reporting system. The Bingham's Woman's Hospital (BWH) in the USA has 747 acute inpatient beds; adverse events are reported electronically since 2003. The collated results were from adverse events reported from May 2004 to August 2005. 4,102 adverse events were reviewed from BWH and 3,084 from KUH. A definition of the lag time;

between occurrence date and reception date of the original adverse event was defined. The overall average lag time between the occurrence of the event and receipt of the event was (mean +- SD) 1.0 (4.1) days at BWH and 3.1 (4.1) days at KUH (p<0.0001). Unadjusted lag times were longer for physicians than non physicians and longer for major harm or injuries than minor injuries. After controlling for profession of the reporter of the event and severity of the injury, the reporting lag times were 2.95 times longer at KUH than BWH. Adverse event reporting systems are a significant factor in organisations patients' safety programs. In most organisations this is the only source of disclosure of adverse events; therefore the organisations risk manger is very dependant on accurate, complete and timely reporting of all adverse events. The difference in the reporting lag times between both organisations, even after controlling for confounding variables, were nearly triple at KUH than those at BWH. This suggested a difference in the performance of the adverse event reporting systems, and could be due to the fact that BWH report adverse events electronically whereas KUH use a paper based process. Possibly electronic reporting has the ability to improve reliability of adverse reporting systems and to decrease factors inhibiting reporting. Longer reporting lag times could contradict differences in organisations attitudes about the significance of patient safety. Previous research has shown organisations wide ranging efforts to improve the patient safety culture was reflected in improved lag times. BWH by comparison to KUH have focused on integrating their reporting systems and patient safety program with a pre-existing quality infrastructure, and developed and maintained a systematic process for swift feedback regarding findings and closing the loop of communication. Potentially this extensive emphasis on safety reporting has reflected in the organisations prompt reporting. This study was observational and can not exclude other important factors to explain these trends. The findings of the study show the potential for using lag times in adverse event reporting as a meaningful measure of different performance in reporting systems.

In summary, improved lags times combined with an effective organisational quality strategy can potentially contribute to improved patient safety outcomes and quality care.

In the main, the articles reviewed for this dissertation used a quantitative approached to compare paper based and electronic reporting systems. Quantitative approaches can be used for exploratory work and generating hypotheses. The main purpose of quantitative research is to measure but this may not always be possible, therefore most studies attempt to explain and or evaluate the degree to which certain phenomena occur; the aim is to quantify (Parahoo, 1997).

2.7 Conclusion to State of the Art

The main purpose of a literature review as highlighted by Parahoo (1997) is to demonstrate why the current study is needed and to show where it fits into in terms of the wealth of knowledge already gathered on the topic. The aim of the literature review is to establish if electronic adverse event reporting management systems will successfully address the well documented issues of the paper based adverse event reporting processes in an effort to improve quality, patient safety and organisational processes. The paper based process is time consuming, burdensome and contributes to ineffectual organisational processes when attempting to implement high level improvements. Reporter confidence in the healthcare organisations response to the adverse events is fundamental for continuous improved reporting (Mekhjian, et al., 2004).

Research has shown that the adoption of electronic adverse event reporting systems assist in addressing many of the well documented issues of the paper based system, while also posing some new challenges. An improvement in the time from occurrence until the event is received is illustrated by the Baylor Medical Centre where 82% of the electronically reported events were received within 24 hours of the adverse event occurring as opposed to 7.6 days in the paper based process (Dixon, et al., 2002). The reporting lag times were 2.95 times longer in the hospital using a paper based system versus an electronic reporting system (Regenbogen, et al., 2010). The time required to track incidents and implement system improvements is reduced by 25 to 50% when moving from paper based to electronic reporting system if managers or other responsible individuals view the reports immediately online and introduce system based improvements (White, 2007).

Paper based forms are not considered to be ideal due legibility issues and a delayed response as the form is passed from one individual to another. Error is introduced into the paper based flow process as the form can be misplaced or misdirected (White, 2007). Data can be lost during transit resulting in privacy and ethical issues, whereas computerised data collection and management systems ensure data integrity, increased accuracy and data reliability by reducing the risk of human error (Weber, et al. 2005).

Improving patient safety and preventing reoccurrence of adverse events is fundamental to all healthcare organisations. All organisations must continually re-evaluate and improve their processes in an effort to comply with accreditation standards and the DoHC's Commission on Patient Safety and Quality Assurance recommendations. IT assists healthcare organisations in addressing many of these challenges and the ongoing issues of the paper based process can no

longer be ignored. Healthcare organisations must move from paper based reporting systems to electronic reporting systems in an effort to address illegibility, real time reporting and notification, corrective action implementation, resolution and prompt analysis. Data integrity and reliability is crucial in maintaining effective and efficient quality processes. Research has shown organisations wide-ranging efforts to improve the patient safety culture are reflected in improved lag times (Regenbogen, et al., 2010).

Time management is essential. Real time reporting, corrective actions and the response, is critical in implementing a quality strategy aimed at addressing patient safety and closing the loop of care. ICT can assist organisations in streamlining the current process by providing access to meaningful, accurate and readily accessible information all of which are fundamental in promoting efficient and effective organisational processes. HIT is essential in enabling and sustaining required improvements and advancing the understanding and knowledge of healthcare systems (DoHC, 2008). Reducing the occurrence of adverse events is the only real method of improving safety and quality patient care (JCI, 2006).

Chapter 3 Research Design / Methodology

3.1 Introduction

This chapter will discuss the research design describing how, when and where the data will be collected, analysed and finally linked to the research question. The following components will be incorporated into the study; the study setting, the approach to the research, the population and sampling, data collection, analysis and ethical considerations. A research design is a plan that explains how, when and where the data will be collected and collated (Parahoo, 1997). The research design will evaluate if an electronic adverse event reporting management system will improve the time management and quality processes of the paper based system in the study site.

3.2 The Study Site

The study site is a private acute care facility with over 200 inpatient and day therapy beds, 7 theatres and a 9 bedded intensive care unit. The hospital provides a 24 hour, 365 day service from a wide range of specialities. The organisation has a dedicated Quality and Risk Management Department, headed by the Director of Quality who is assisted by a number of professional staff. The researcher involved in this study and the individual involved in collecting the data for the steps involved in the QEF process both work in the Quality Department. The Quality Committee (Appendix 6 & 7) is chaired by the Chief Operations Officer who reports directly to the Hospital's Board of Directors. All the hospitals safety and quality committees are represented at the monthly meetings. The Quality Committee is responsible for identifying,

addressing and resolving all quality and risk management issues within the organisation and ensuring mandatory compliance with JCI and other accreditation organisations standards. The fundamental aim of the committee is to continually strive to deliver integrated, safe patient care. The organisation has adopted a systematic approach to addressing quality improvements by adopting the Plan-Do-Check-Act methodology to assist with continuous assessment and quality improvement.

One of the Quality Departments fundamental functions is to collect, collate and analyse data in an effort to improve quality, patient safety, care related services and organisational processes. Data is gathered from a number of sources; key performance indicators as defined by organisational or JCI requirements, verbal and formal complaints, patient focus groups, patient perception surveys, comment cards and adverse event reporting (Appendix 8). Data, if possible is benchmarked against national and international standards and areas identified as requiring improvements are seen as learning opportunities aimed at improving patient care or organisational processes.

3.3 Methodology

Research can be approached in a number of ways and the most common is empirical research using a qualitative or a quantitative approach. Qualitative data originates from the term quality and tends to be subjective and involves the examination and reflection of the less substantial aspects of research such as attitudes; perceptions and values (O'Callaghan, 2007), whereas in quantitative research the data is based on numerical data or quantities (Parahoo,1997). Quantitative data originates from the term quantity and focuses primarily on the collection and

analysis of numerical data. The collated results are usually presented statistically (O'Callaghan, 2007). Statistics is primarily concerned with tabulating data from your research as precisely and accurately as possible. It describes the information collected using tables, diagrams and formulas, the data is presented numerically (Howitt & Cramer, 2005).

The aim of the study is to evaluate if an electronic adverse event reporting management system will improve the time management and quality processes of the paper based system. The researcher will use a quantitative approach using numerical data to collect and measure the time taken to perform various tasks involved in the adverse event reporting process and to measure the quality of the data received. The collated results and findings will be displayed numerically; this approach is best suited for the presentation of the findings.

3.4 Population and Sampling

The term population as described by Parahoo (1997) is the final number of units from which data can potentially be collected. The units could be people, organisations and events. The defined target population is the population from which the data can be potentially collected, of which the sample is a subset. The sample can be selected by purposive sampling which involves the researchers purposefully selecting who to include in the study and the researcher must be directed by the research question and not choose samples out of convenience, whereas systematic random sampling is decided by choosing units on a list at intervals prescribed in advance by the researcher (Parahoo, 1997).

3.4.1. Sampling of QEF's

The sample population of QEF's was randomly selected from QEF's entered onto the Quality Departments database. The number of QEF's selected for monitoring was based on approximately 10% of the 2009 hospital wide adverse event reporting numbers.

3.4.2 Sampling of Electronic Events

The sample population for the monitoring of electronic events was purposefully selected from the department participating in the electronic adverse event reporting pilot. The selection criteria for the pilot study was based on a number of factors; the high number of adverse events reported monthly during 2009 and the wide range of categories of adverse events, the presence of key stakeholders in the department and the eagerness of staff to adopt the new systems. The department consists of a total of 38 staff members, made up of Clinical Nurse Managers (4) and Staff nurses (34). The monitoring of the data from the electronic events will be collected during the three month pilot study.

3.5 Data Collection and Analysis

Selecting the methods of investigation is not an unbiased or a disorganised exercise but rather a choice that reflects the researcher's beliefs and values. The main purpose of quantitative research is to measure but this may not always be possible, therefore most studies attempt to explain and or evaluate the degree to which certain phenomena occur; the aim nonetheless is to quantify (Parahoo, 1997).

3.5.1 Data Collection and Analysis of QEF's

All the data from the QEF's was collected by the researcher, with the exception of the time taken to complete each step of the QEF process which was collected by the colleague working in the Quality Department. An excel spreadsheet was deemed suitable for the QEF data collection and analysis.

The data for the time taken to complete each step of the QEF process was collected by a colleague responsible for the adverse event reporting process in the Quality Department. A time period for the commencement of the monitoring of the QEF's was defined and all QEF's received by the Quality Department from that date forward until the pre determined number of QEF's were received were monitored. A pre designed spreadsheet (Appendix 9) was used to document the time taken to complete each step of the QEF process therefore ensuring all the steps were monitored and recorded. This process occurred during the colleague's regular working hours resulting in non-participant observation by the researcher. Non-participant observation is where the researcher is removed from the data collection or plays an inactive role (Watson, et al., 2008).

The data collection of the quality of information from the QEF's was entered into a SPSS database for analysis by the researcher. SPSS is regarded as a world leader in statistical reporting and analysis (Connell & Rapple, 2010). The following criterion was collected and analysed:

Legibility of author's signature and legibility of content of the documentation

Identification of the department reporting the QEF; reported by

Identification of the department where the QEF occurred; raised against

Immediate action taken at time of reporting the QEF

Date and Time of Event of QEF

3.5.2 Data Collection and Analysis of Electronic Events

The data collection of the quality of information from the electronic events was entered into a SPSS database for analysis by the researcher. The following criterion was collected and analysed:

Identification of the department reporting the electronic event; reported by

Identification of the department where the electronic event occurred; raised against

Immediate action taken at time of reporting the electronic event

Date and Time of Event of electronic event

3.6 Ethical Considerations

During the research process ethical issues are encounted at every stage (Parahoo 1997). The majority of research projects in healthcare organisations require research governance consent and an ethical review prior to commencement (Watson, et al., 2008). The contribution of research to clinical practice is without doubt positive however, in order to ensure that the negative does not outweigh the benefit, ethics committees are relied upon to examine the ethical implications of the study and to ensure that the study is not anyway harmful to the participating client or patient (Parahoo, 1997).

Parahoo (1997) describes the six ethical principles of research aimed at protecting clients or patients from harm.

Beneficence; the colleague involved in the adverse event reporting process and all other hospital staff will benefit from the electronic adverse event reporting system due to a more streamlined and efficient reporting process. Patients will ultimately benefit from quicker reporting times, improved analysis and the formal closure of all adverse events, closing the loop of care. Non–maleficence; the research will not cause harm to the individuals participating in the research. Fidelity and Veracity; developing trust between the researcher and the colleague collecting the data. Justice; fairness and a balance of power between the colleague collecting the data and the researcher. Confidentiality; is governed according to the hospitals code of ethics. The individual participating in the research gave signed consent to participate in the research. The name of the hospital has not been used through out this dissertation and all identifiable names and logos have been removed from the appendices. Confidentiality was maintained at all times as was the security of the researcher's data due to encryption. All paper based adverse events remained in a safe location within the Quality Department and were not removed from this location.

The above 6 ethical principles are merged into the 4 rights of the individual involved in the research; the right not to be injured, the right to full disclosure, the right to make your own decision about participation and the right to anonymity and privacy (Parahoo, 1997).

Approved dissertations are governed by exacting ethical principles which are recognised by local Research Ethics Committees (Watson, et al., 2008). Ethics approval for the proposed research was obtained from the Hospital's Research Ethics Committee (Appendix 10) on condition that research data was encryption protected. Encryption changes data into what is known as ciphertex,

meaning the data can not be understood by unauthorised individuals. The correct decryption key is required to access the encrypted data (Searchsecurity.com, 2010).

Verbal permission was obtained from the Chief Operations Manager and written permission from the Director of Nursing and the Director of Quality (Appendix 11 & 12). The participant involved in the research received a letter and a detailed information leaflet explaining the background to the research and the proposed research process requirements (Appendix 13 & 14). Signed consent was obtained from the participant (Appendix 15). The participant; a colleague involved in collecting the data for the paper based reporting process was fully supportive of the proposed research as the electronic system is anticipated to have a significant impact on streamlining her work processes, improving the colleagues time management and should assist with the follow up and formal close out of all adverse event, closing the loop of care.

The Research Ethics Committee will receive a copy of the findings and recommendations of the research.

3.7 Conclusion to Research Design / Methodology

This research design / methodology chapter covered all the elements involved in the planning of the research study and included the approach to the research, methodology, population and sampling, data collection and analysis and ethical considerations. The results of the analysis of the QEF's and electronic events are outlined in the next chapter.

Chapter 4 Implementation and Results

4.1. Introduction

The purpose of this study was to evaluate if an electronic adverse event reporting management system will improve the time management and quality processes of the paper based system in the study site. This chapter will present the findings of the comparative analysis of the paper based QEF's and electronic events.

4.2 Data Analysis and Results of QEF Process

The collection of the results is a crucial component of the research process; however the data alone will not answer the researcher's questions as set out at the beginning of the study. The researcher is required to present the data so that the data is understood by the reader (Parahoo, 1997).

4.2.1. Time Taken from Occurrence until Reporting of QEF's

Analysis from a total population of QEF's (n=250) found that 76.8% (n=192) QEF's were reported on the same day as the occurrence. The remaining 23.2% (n=58) were reported either the day after or greater than one day after the event occurred (Figure 4.1). 10.8% (n = 27) were reported the next day, 2% (n=5) were reported 2 days after the event, 2% (n=5) were reported 3 days after the event, 3.2% (n=8) were reported greater than 3 days after the event and 5.2%

(n=13) unable to determine due to dates missing; either the date of occurrence or the date of reporting. The minimum time taken from occurrence until reporting was the same day; the maximum time was six days, a median of one day.
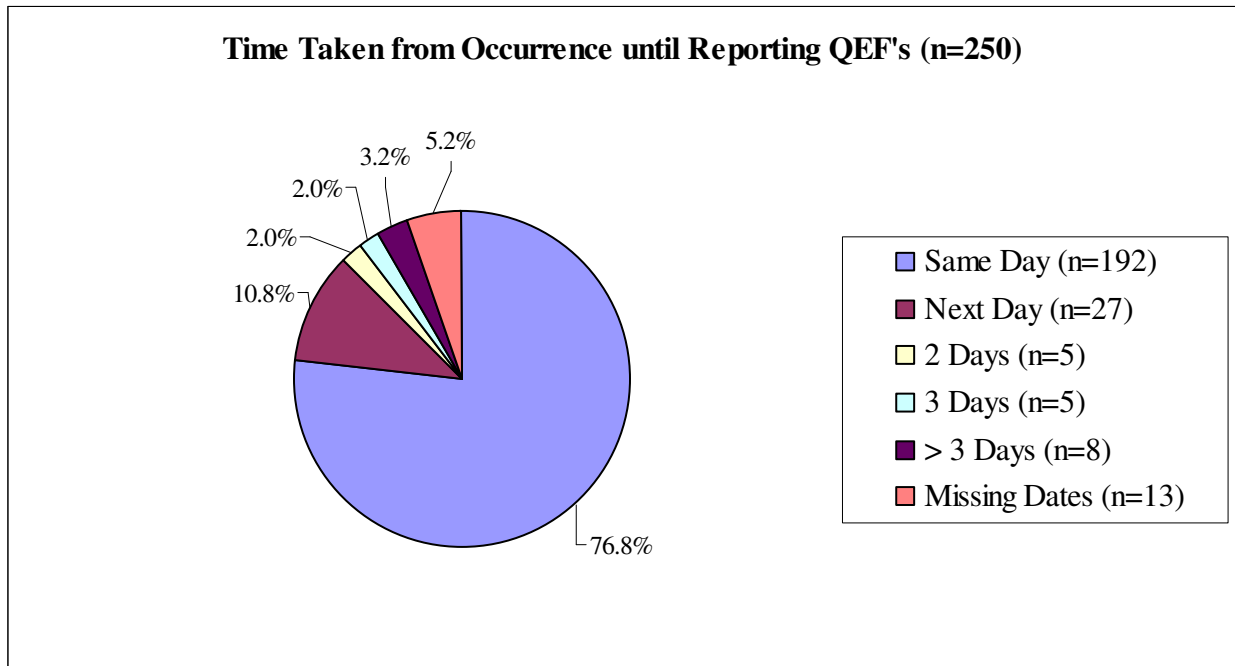
Figure 4.1 Time Taken from Occurrence until Reporting the QEF's

4.2.2 Time Taken from Occurrence until QEF's were received by the Quality Department

An analysis of QEF's (n=250) identified that it took an average of 14.2 days from time of occurrence until the adverse event was stamped as received by the Quality Department. The analysis established the minimum time taken for an event to reach the Quality Department was the day after the occurrence; the maximum time taken was 148 days, a median of 12 days.

4.2.3. Time Taken to Complete Each Step of the QEF Process

The table below (Table 4.1) breaks down the time taken to completed each step of QEF process (n=250).

Steps Involved QEF Process	Time Taken to Completed Each Step
1. QEF's collected or posted to the QD	128 minutes
↓	
2. QEF date stamped as received	11 minutes
↓	
3. QEF read, categorised and graded	234 minutes
↓	
4. Numbering of QEF's	55 minutes
↓	
5. Sorting and filing	36 minutes
↓	
6. Photocopy relevant QEF's	58 minutes
↓	
7. Placing QEF's into envelopes	69 minutes
↓	
8. Selected QEF's reviewed by the Director of Quality	75 minutes
↓	
9. Inputting name, MRN & basic details into database	69 minutes
↓	
10. Inputting remaining details into the database.	377 minutes
QEF's (n=250)	1,112 minutes

Table 4.1 Time Taken to Complete the Steps in the QEF Process

The analysis of QEF's (n=250) identified that the total time taken to complete each step in the QEF process from collection or receipt of the QEF until all the required details were entered onto the database was 1,112 minutes, 18.5 hours, 4.45 minutes per QEF.

4.2.4 Quality of Information from QEF's

4.2.4.1 Legibility of Author's Signature and Content of the Documentation

Only QEF's can be analysed for legibility of the author's signature and content of the documentation.

An analysis of QEF's (n=250) identified that 74.8% (n=187) of the QEF's were compliant with legibility of the authors signature, whereas 25.2% (n=63) were non compliant with the required JCI standard (Figure 4.2).

Compliance with Legibility of Author's Signature (n=250)
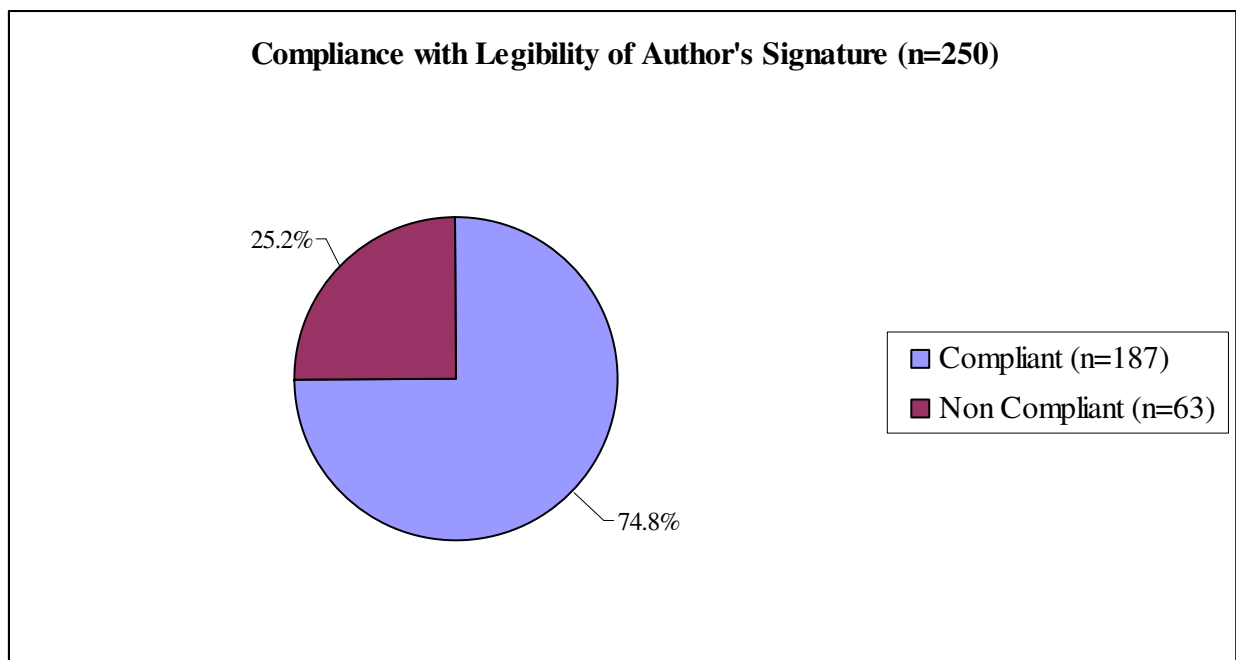
Figure 4.2 Legibility of Author's Signature

Legibility of the content of the documentation was assessed according to the following Legibility Tool Criteria in an attempt to remove bias (St. Albans Hospital & University of Aberdeen, 2008). Maximum score of 3:

1. No illegible words, reads well

2. One or more illegible words but <u>no</u> interference with interpretation of the record

3. One or more illegible words <u>and</u> interference with interpretation of the record.

The analysis of QEF's (n=250) found that 92.4% (n=231) of the QEF's were compliant with legibility of the content of the documentation, 7.2% (n=18) were partially compliant; a score of 2 according to the Legibility Tool Criteria and only 0.4% (n=1) were non compliant with the required JCI standard (Figure 4.3).
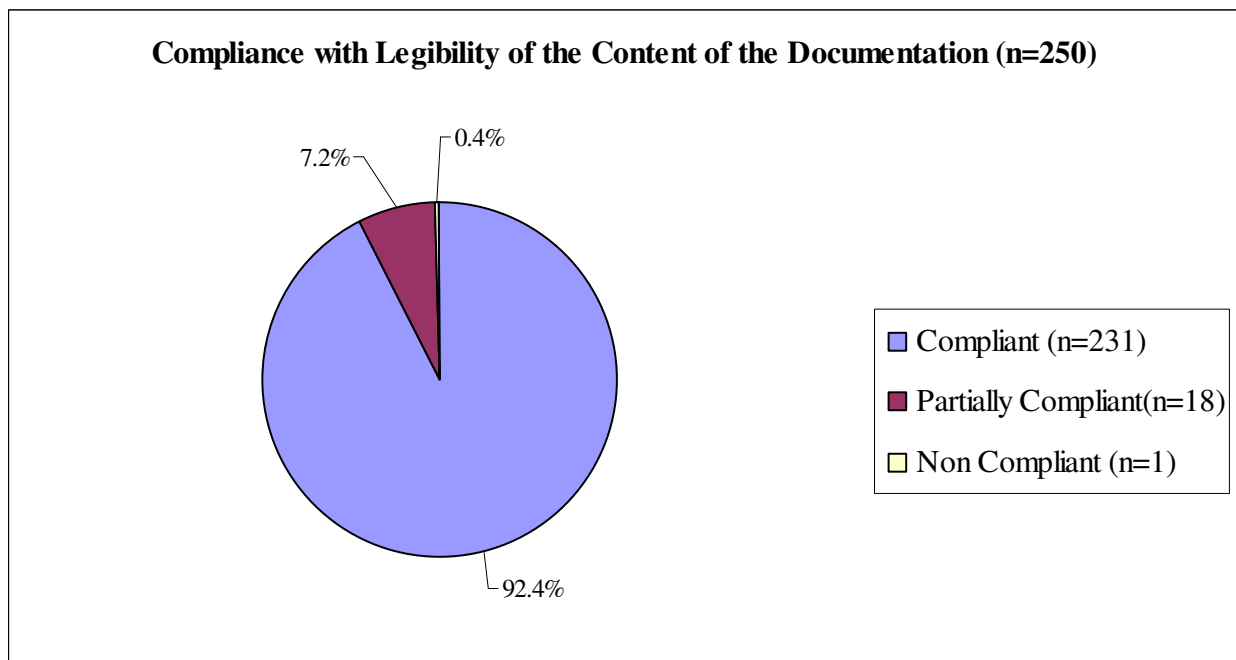
Figure 4.3 Legibility of the Content of the Documentation

4.2.4.2 Identification of the Department Reporting the QEF; Reported By

The Quality Department must be able to identify the department reporting the QEF; reported by.
This is very important in the trending of QEF's. QEF's (n=250) were analysed and 75.6%
(n=189) of departments reporting a QEF were identifiable, whereas 24.4% (n=61) of departments
could not be identified. QEF's occurring in a ward can be identified by the patient label which is
placed on the form at time of reporting. QEF's which occur in all other departments or where the
patient label is not applied need to be identifiable at time of reporting (Figure 4.4).
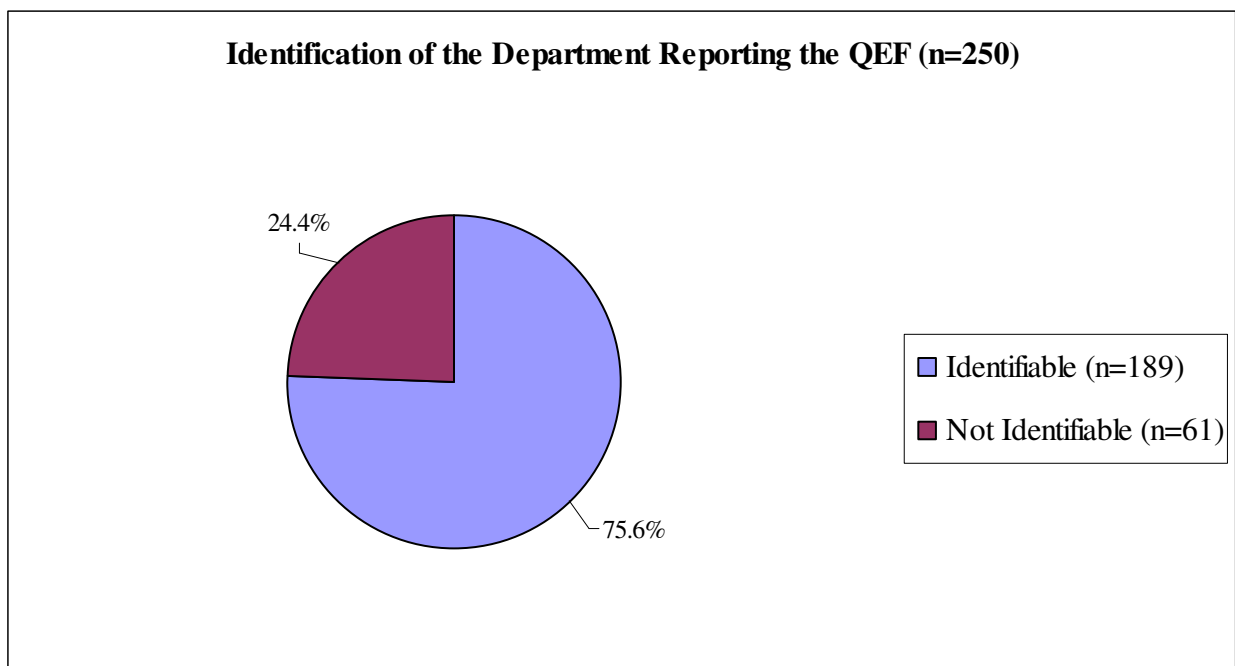
Figure 4.4 Identification of the Department Reporting the QEF

4.2.4.3 Identification of the Department where the QEF Occurred; Raised Against

The Quality Department must be able to identify the department where the QEF occurred; raised against. This is very important in the trending of QEF's. The department reporting a QEF is not always the same as the department where the QEF occurred. The raised by department is often implied in the details of the event, but the QEF does not have a not have a specific prompt at time of reporting. QEF's (n=250) were analysed and the department where the event occurred was identifiable in 74% (n=185) QEF's, whereas 26% (n=65) of the departments could not be identified at time of analysis (Figure 4.5).

Identification of the Department where the QEF Occurred (n=250)

26.0%

74.0%

■ Identifiable (n=185)

■ Not Identifiable (n=65)
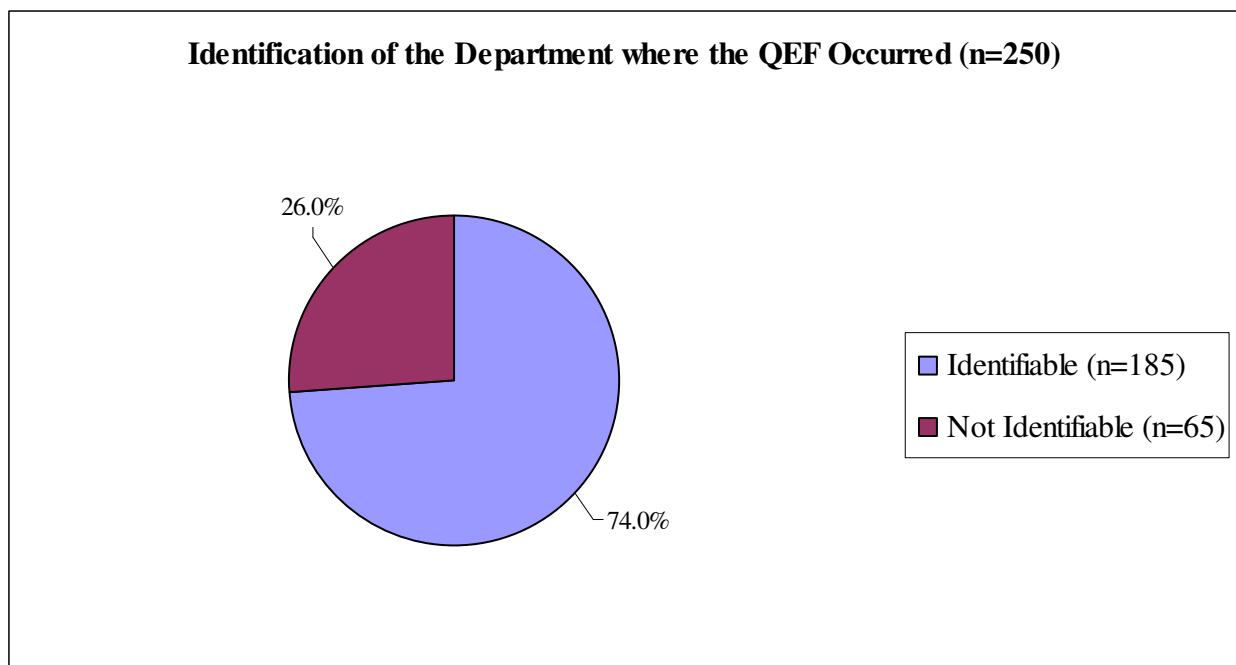
Figure 4.5 Identification of the Department where the QEF Occurred

4.2.4.4 Immediate Action Taken at Time of Reporting the QEF

A total of QEF's (n=250) were analysed. (n=10) were deemed not applicable to the question as an immediate action was not required at the time of reporting due to the nature of the event and were removed from the analysis.

The analysis of QEF's (n=240) identified that 86.3% (n=207) adverse events had the appropriate immediate action documented at the time the QEF was reported. 10.4% (n=25) QEF's did not have an immediate action documented at time of reporting, therefore potentially requiring follow up by the Quality Department. 3.3% (n=8) had evidence of the managers follow up or corrective action documented on the QEF but did not have the immediate actions documented by the individual reporting the QEF.

4.2.4.5 Date and Time of Occurrence of QEF

98.4% (n=246) of adverse events had the date of occurrence documented on the QEF and 86.4% (n=216) had the time documented (Figure 4.6).

Compliance with Date and Time of the QEF (n=250)
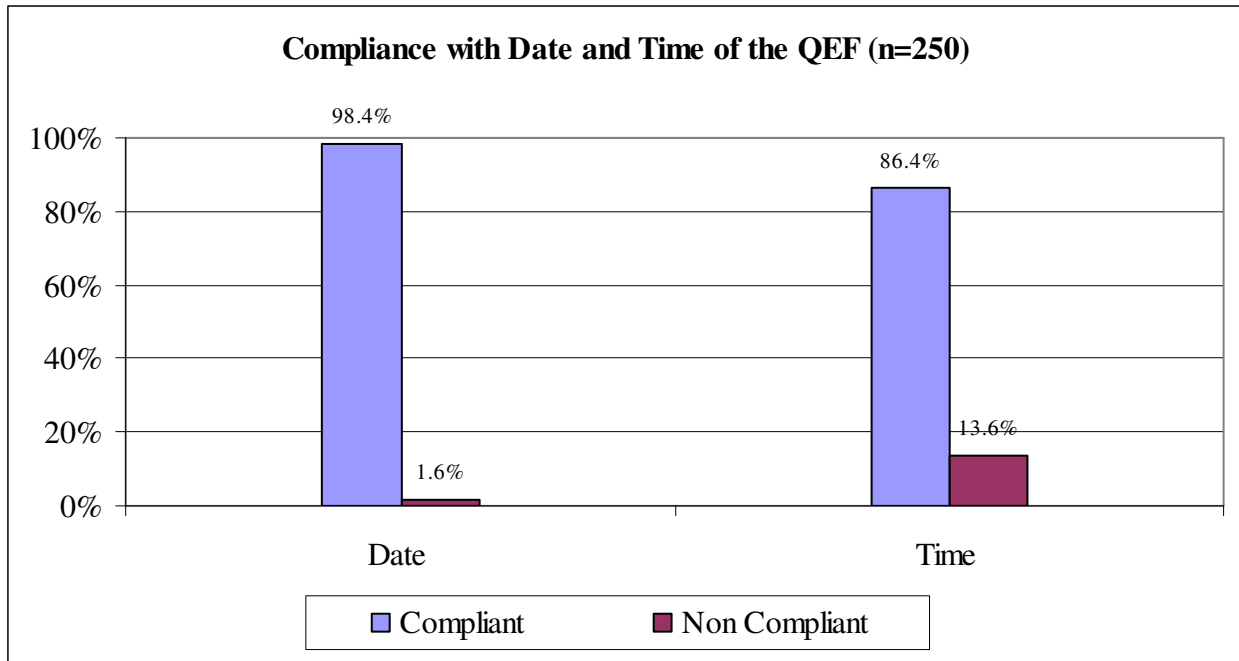
Figure 4.6 Date and Time of Occurrence of QEF

4.3 Data Analysis and Results of Electronic Events

4.3.1. Time Taken from Occurrence until Reporting the Electronic Event

Analysis from a total population of (n=35) electronic events found that 74.2% (n=26) electronic events were reported on the same day as the occurrence. The remaining 25.7% (n=9) electronic events were reported either the day after or greater than one day after the event occurred. 17.1% (n=6) were reported the next day, 2.8% (n=1) were reported two days after the event, 5.7% (n=2) were reported greater than three days after the event. The minimum time taken from occurrence until reporting was the same day; the maximum time was five days, a median of 0 (Figure 4.7).
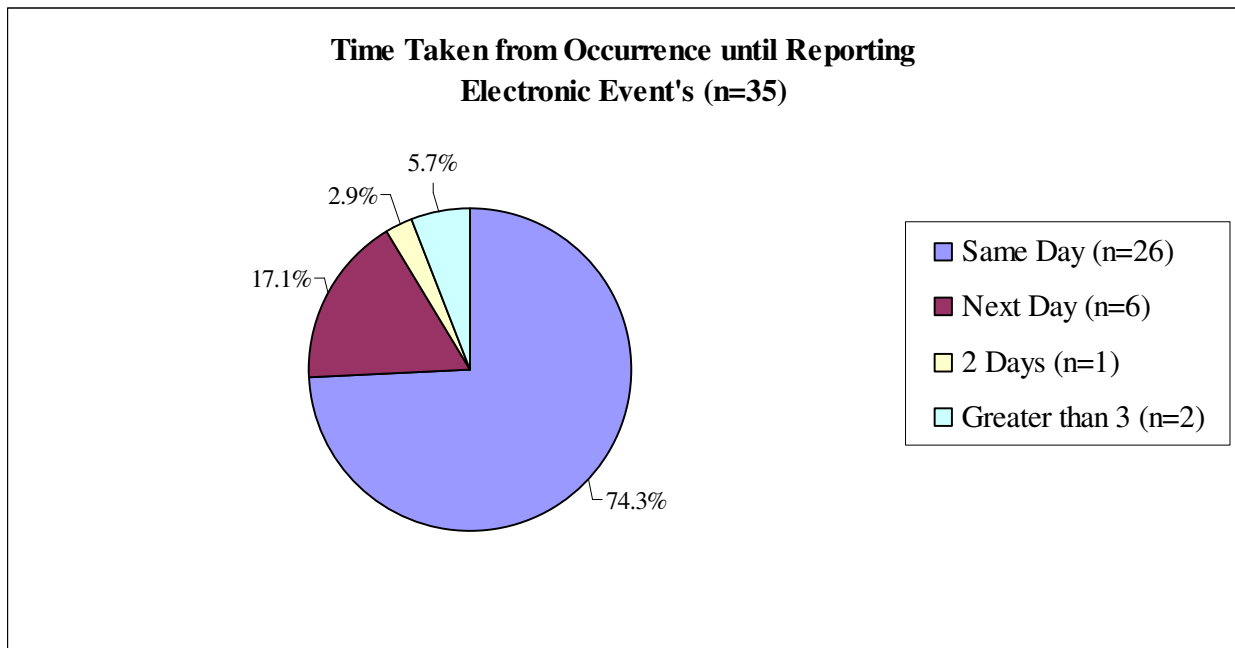
Figure 4.7 Time Taken from Occurrence until Reporting the Electronic Events

4.3.2 Quality of Information from Electronic Events

4.3.2.1 Identification of the Department Reporting the Electronic Event; Reported By

The Quality Department must be able to identify the department reporting the electronic event; reported by. This is very important in the trending of electronic events. 88.5% (n=31) of the electronic events were identifiable, whereas 11.4% (n=4) were incorrectly selected (Figure 4.8).

Identification of the Department Reporting the Electronic Event (n=35)

11.4%

- □ Identifiable (n=31)
- ■ Not Identifiable (n=4)

88.6%
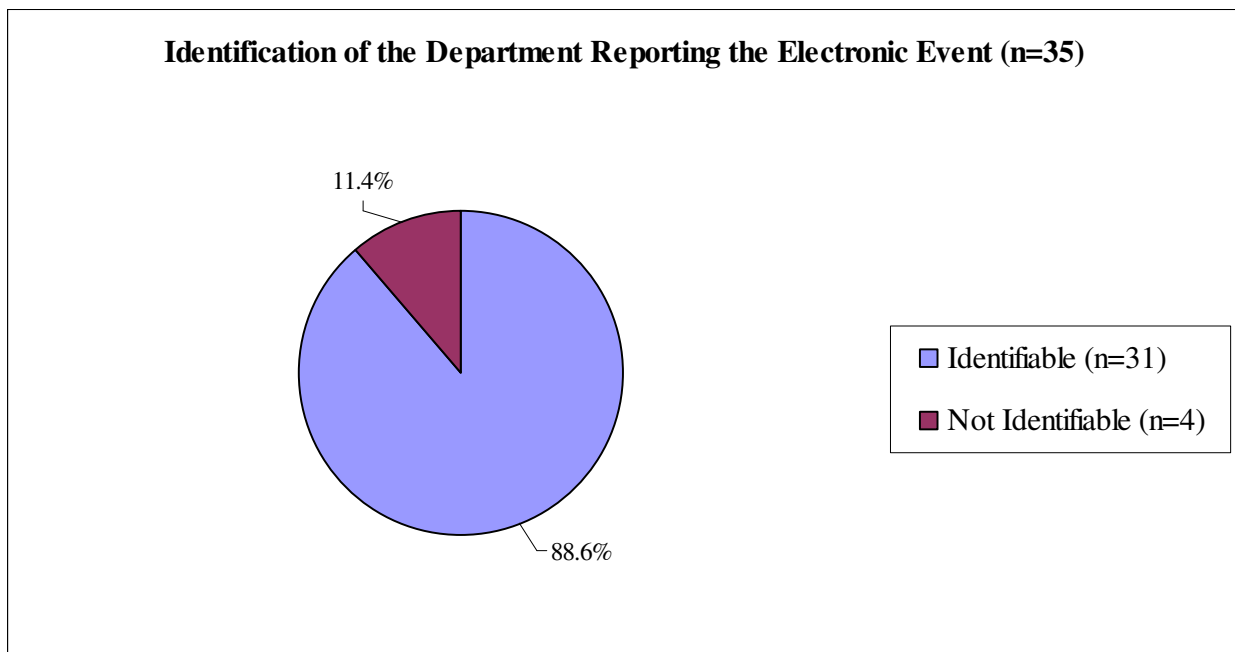
Figure 4.8 Identification of the Department Reporting the Electronic Event

4.3.2.2 Identification of the Department where the Electronic Event Occurred; Raised Against

The Quality Department must be able to identify the department where the electronic event occurred, raised against. The department reporting an electronic event is not always the same as the department where the electronic event occurred. This is very important in the trending of adverse events. The department where the electronic event occurred was identifiable in 80% (n=28) of electronic events, whereas 20% (n=7) of the departments were not correctly selected (Figure 4.9).
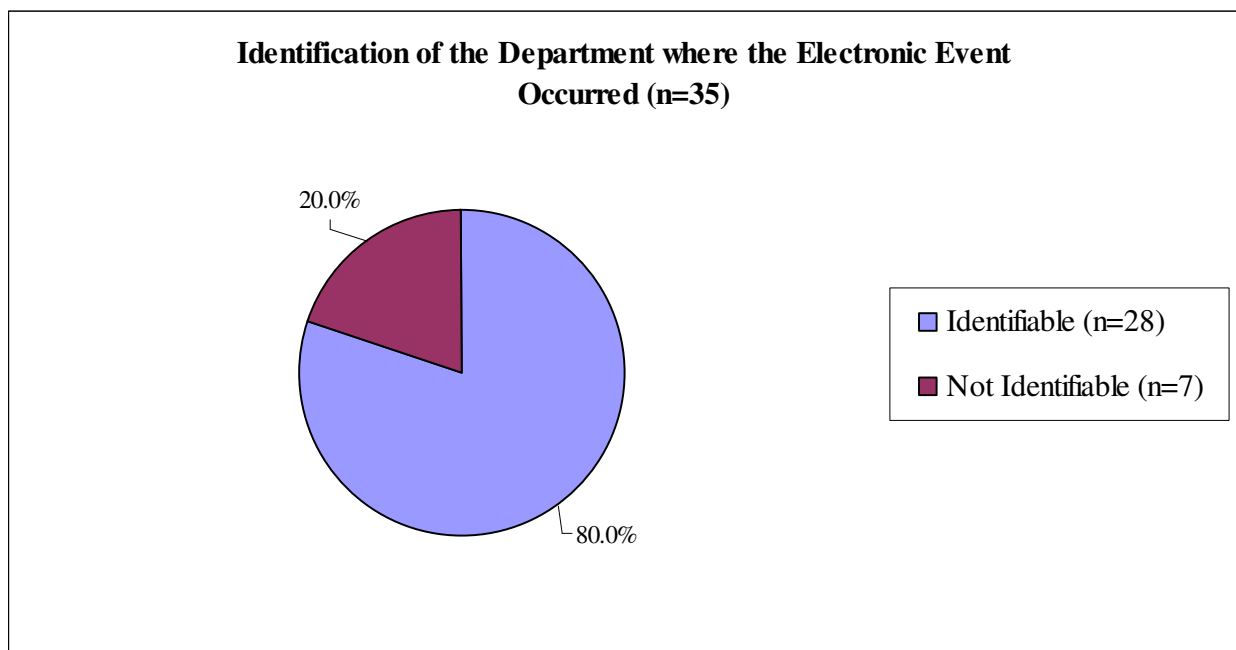
Figure 4.9 Identification of the Department where the Electronic Event Occurred

4.3.2.3 Immediate Action Taken at time of Reporting the Electronic Event

A total of electronic events (n=35) were analysed and 100% (n=35) of the electronic events were compliant with documenting the immediate action taken at the time of reporting the event.

4.3.2.4 Date and Time of Occurrence of Electronic Event

100% (n=35) of the electronic events were compliant with entering the date of the electronic event and 77.1% (n=27) were compliant with entering the time of occurrence (Figure 4.10).

Compliance with Date and Time of the Electronic Event (n=35)
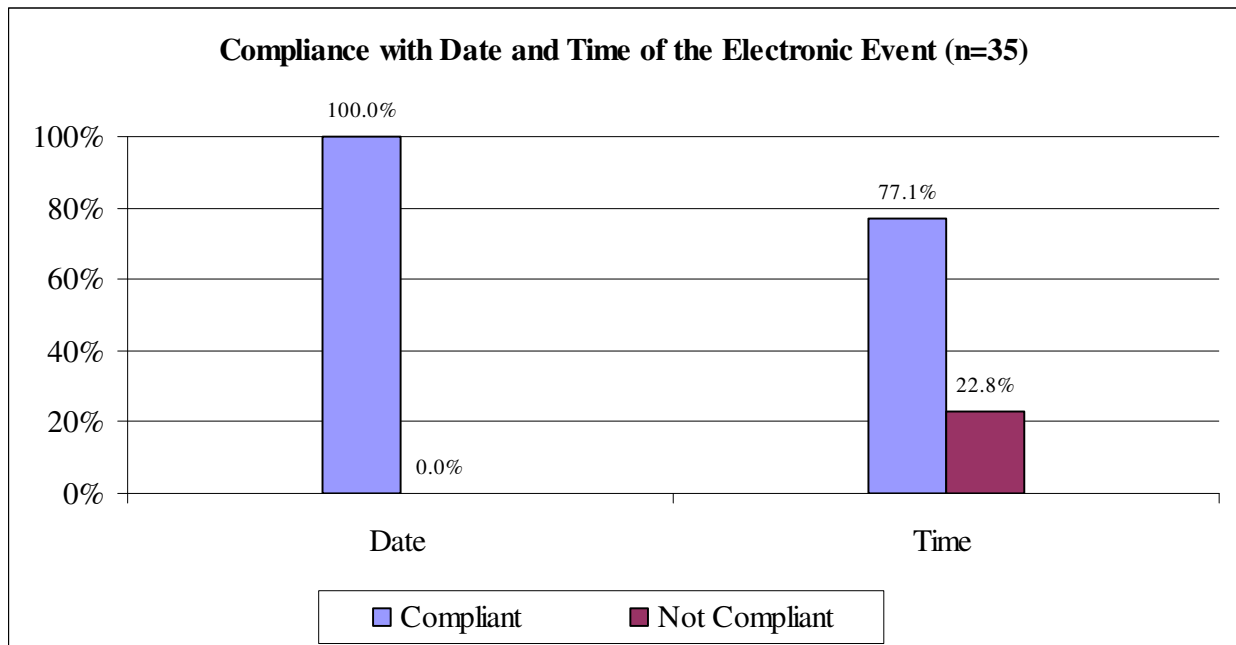
Figure 4.10 Date and Time of Occurrence of Electronic Event

4.4. Comparative Analysis of QEF's and Electronic Events

4.4.1 Time Taken from Occurrence until Reporting of the QEF's and Electronic Events

The table below (Table 4.2) depicts a comparative analysis of the time taken from occurrence until the reporting of both the QEF's (n=250) and electronic events (n=35).

Time Taken in Days	QEF's (n=250)	Electronic Events (n=35)
Same day	76.8% (n=192)	74.3% (n=26)
Next day	10.8% (n=27)	17.1% (n=6)
2 days	2.0% (n=5)	2.9% (n=1)
3 days	2.0% (n=5)	
Greater than 3 days	3.2% (n=8)	5.7% (n=2)
Missing days (unable to determine)	5.2% (n=13)	

Table 4.2: Time Taken from Occurrence until Reporting of QEF's and Electronic Event's

4.4.2 Time Taken from Occurrence until the QEF's and Electronic Events were Received by the Quality Department

The table below (Table 4.3) depicts a comparative analysis of the time taken from occurrence until received by the Quality Department of both the QEF's and electronic events.

QEF's (n=250)	Electronic Events (n=35)
Average of 14.2 days	Immediate email notification once event reported

Table 4.3 Time Taken from Occurrence until QEF's and Electronic Events were received by the Quality Department

4.4.3 Time Taken to Complete Each Step of the QEF and Electronic Event Process

Table 4.4 below depicts the steps involved in the QEF process. Number 3 and 8 are steps that will continue during the electronic process.

Steps Involved QEF Process	Time Taken to Completed Each Step
1. QEF's collected or posted to the QD	128 minutes
2. QEF date stamped as received	11 minutes
3. QEF read, categorised and graded*	234 minutes
4. Numbering of QEF's	55 minutes
5. Sorting and filing	36 minutes
6. Photocopy relevant QEF's	58 minutes
7. Placing QEF's into envelopes	69 minutes
8. Selected QEF's reviewed by the Director of Quality *	75 minutes
9. Inputting name, MRN & basic details into database	69 minutes
10. Inputting remaining details into the database.	377 minutes
(n=250) QEF's	1,112 minutes

Table 4.4: Steps Involved in the QEF and Electronic Event Process

Step number 3; events read, categorised & graded and step number 8; events reviewed by the Director of Quality will continue to be part of the electronic reporting process. If the time taken to complete these two steps was removed from this process and the author was to only include the steps involved in the QEF process, then it would take 803 minutes, 13.38 hours, 3.21 minutes per QEF. If the author speculated that 2,500 QEF's would be submitted to the Quality

Department in 2010 and it took 3.21 minutes per QEF, then a total of 8,025 minutes or 133.7 hours would be saved if the QEF's were reported electronically, a saving of 19.1 working days per year.

The above steps are preliminary steps in the QEF reporting process and do not include; the time taken to format and send the adverse event database to the study sites insurers, sending out follow up and corrective actions forms, emailing staff in relation to an event, collation and trending of data and compiling a monthly managerial report, all of which will remain part of the electronic averse event reporting process.

4.4.4 Quality of Information of the QEF's and Electronic Events

The table below (Table 4.5) depicts a comparative analysis of the quality of information received from the QEF's (n=250) and electronic events (n=35).

	QEF (n=250)	Electronic Event (n=35)
Legibility Author	74.8%	100%
Legibility Documentation	92.4%	100%
Department Reporting the Event; Reported By	75.6%	88.6%
Department where the Event Occurred; Raised Against	74%	80%
Immediate action taken	86.3%	100%
Date	98.4%	100%
Time	86.4%	77.1%

Table 4.5: Quality of Information Received from QEF's and Electronic Events

4.5 Conclusion to Implementation and Results

In summary, the findings of this study show that electronic reporting addresses the time management of the adverse event reporting process. The time taken from occurrence until the QEF reaches the Quality Department takes an average of 14.2 days, whereas the electronic event triggers an immediate email notification of the adverse event to the Quality Department and relevant departmental managers. The time taken from occurrence until reporting is very similar in the QEF and electronic event reporting; events reported the same day 76.8 % and 74% consecutively and event reported the next day 10.8% and 17%. The most noticeable improvement is ability to monitor the date of occurrence and reporting for all electronic events due to the mandatory fields, whereas data can be missing or incomplete on the QEF.

The quality of information received from the electronic reported events compared with the QEF's identified an improvement in some areas. 100% compliance with legibility of author's signature and content of the documentation as expected, as illegibility is addressed due to the typed text. Compliance with documenting the immediate action taken at time of reporting the event and the date of the event improved due to mandatory fields. The name of the department reporting the event improved in the electronic event from 75.6% to 89%. The department where the event occurred; raised by went from 74% to 80%, this is a new reporting parameter. Both the reported by and raised by parameters are more structured in the electronic event as the individual reporting the event has to select a specific department for each parameter of which both parameters are mandatory. The reporting of time was an issue with the QEF's and continues to remain an issue in the electronic event, possibly due to the fact that once the date is entered the mandatory field prompt no longer applies.

In conclusion, electronic event reporting appears to address most areas of the adverse event reporting process but some aspects of the quality of information will need further training and reinforcement to bring about a more significant improvement.

Chapter 5 Evaluation / Analysis

5.1. Introduction

The aims of the study were to evaluate if an electronic adverse reporting system will improve the time management and quality processes of the paper based system. The review of the QEF and electronic adverse event reporting process was achieved by:

1. Evaluating how an electronic adverse reporting system will improve the time management of the adverse event reporting process for the Quality Department and Departmental Mangers due to real time notification all electronic events.

2. Evaluating if an electronic adverse event reporting management system will improve the quality of information received and reduce the follow up required by the Quality Department due to missing data.

3. Identifying the gaps and weaknesses in the paper based process that will improve with the implementation of an electronic adverse event reporting system.

This chapter will discuss the findings of the QEF and electronic events analysis under the comparative analysis headings outlined in the previous chapter. The researcher will attempt to establish if the aims of the study were achieved.

5.2 Time Taken from Occurrence until Reporting of the QEF and Electronic Event

The pilot study yielded electronic events (n=35) whereas the QEF sample was much larger (n=250). The reporting of QEF's on the same day as the occurrence was 76.8% and electronic events was 74.3% (p=0.33 not significant at 5%). QEF's reported the next day was 10.8% and electronic events was 17.1% (p=0.38 not significant at 5%). 2% of QEF's and 2.9% electronic events were reported 2 days after occurrence, 2% of QEF were reported 3 days after the occurrence, 3.2% of QEF and 5.7% of electronic events were greater than 3 days after the occurrence and 5.2% (n=13) QEF's had dates missing and could not be included in the analysis. All the data was available in the electronic events. The adverse event reporting process within the study site is considered to be excellent. All staff are encouraged to report an event as soon as possible; however specific emphasis has not been placed on the time taken from occurrence to reporting as the main priority is to get staff to report the event. As discussed by Regenbogen, et al. (2010) reducing the delay in reporting is beneficial. Timely reporting allows for a swift organisational response and further prevention of harm to the patient. Consistency with recall is possibly less accurate over a period of time; therefore prompt reporting will enhance the possibility of more complete and accurate details relating to the event. The culture of delayed reporting could increase the chance of the individual failing to complete the report at all. Further research will be required to establish if there is a significant improvement in the time of occurrence to reporting in electronic reporting using a larger electronic sample size, however, the most notable aspect of electronic reporting is the availability of the required data in relation to the date of occurrence and date of reporting the electronic event.

5.3 Time Taken from Occurrence until the QEF and Electronic Events were Received by the Quality Department

The analysis of QEF's (n=250) and electronic events (n=35) identified that it took an average of 14.2 days from time of occurrence until the QEF was stamped as received by the Quality Department. The minimum time was the day after the occurrence, the maximum time was 148 days, a median of 12 days. As discussed by Dixon, et al. (2002) paper based forms might not be available, as they may be lost or misplaced. Research has shown that paper based systems have their own limitations and risks as data can be lost between time of reporting and receipt which ultimately impacts on time and accuracy (Weber, et al., 2005). Electronic events trigger an immediate email notification to the relevant managers as soon as the event is reported. This is a noticeable improvement in the time management of the adverse event reporting process due to real time reporting, email notification and access. The CQCC identified a number of improvement opportunities when converting from a paper based to a web-based reporting system, as paper forms took more than a week, 7.6 days to reach the appropriate department resulting in an inefficient and untimely process (Dixon, 2002). As described by Levtzion-Korach, et al. (2009) electronic systems are accessible to all in real time and managers can be notified of the event immediately and concurrently. An independent study conducted by the researcher identified that it took an average of 21 days from date of occurrence of the QEF until all the required details were entered on the Quality Departments database. The electronic event is available immediately in the Q Pulse database for analysis and trending therefore improving the timeliness and accessibility of the current QEF process.

5.4 Time Taken to Complete Each Step of the QEF and Electronic Event Process

A estimated saving of 19.1 working days per year will be made by eliminating the manual steps involved in the QEF process. This will significantly improve the adverse event reporting process as this time will be better spent on the required follow up and formal close of all adverse events; closing the loop. The electronic system facilitates a more formalised, structured and efficient process, therefore streamlining the adverse event reporting process. The data collection for the time taken to complete each step of the QEF process was collected by the participant involved in the adverse event reporting process therefore the researcher had to take the Hawthorn effect into consideration when analysing the results. The Hawthorn effect can be a potential threat to quantitative research as the participant knows they are being studied resulting in a behaviour change, to please (Watson, et al., 2008). The awareness of being observed may influence behaviour (Parahoo, 1977).

5.5 Quality of Information from QEF's and Electronic Event

5.5.1 Legibility of Author's Signature and Content of the Documentation of QEF's

The analysis of legibility of author's signature and of content of documentation can only be analysed from QEF's and not electronic events. Paper based forms are not considered to be ideal due to legibility issues or interpretation of hand writing (White, 2007). Legibility, an ongoing issue with paper documentation yielded a 74.8% compliance rate with legibility of author's signature. 92.4% of QEF's were fully compliant and 7.2% were partially compliant with legibility of content of documentation of the QEF's. Often there is a delay in data availability and

analysis due to illegibility or incomplete data (Dixon, 2002). This can result in a potential delay in follow up and close out of the event. Illegibility is addressed with electronic reporting with the use of typed text and a more organised, forced structure (Tang & McDonald, 2001). JCI require the monitoring and compliance of legibility of content of documentation and author's signature. The researcher assessing legibility of author's signature and legibility of the content of the documentation of the QEF's has extensive experience in dealing with illegible documentation and could have therefore unwittingly lent herself to a degree of bias.

5.5.2 Identification of the Department Reporting the QEF and Electronic Event; Reported By

The analysis of QEF's (n=250) and electronic events (n=35) yielded an improvement from 75.6% to 88.5% in the identification of the department reporting the adverse event (p=0.04 significant at 5%). The reported by parameters is far more structured in the electronic event as opposed to the QEF which could be identified from the patients sticker if one was placed on the QEF at time of reporting. When reporting an electronic event the individual must select the specific department they are working in from a drop down list. Even though this is a mandatory field the staff are able to select "quality event" instead of their department. If "quality event" was selected instead of the department then the QEF was classified as non compliant. This parameter is required in the trending of all events and ongoing education is required to improve compliance.

5.5.3 Identification of the Department where the QEF and Electronic Event Occurred; Raised Against

The analysis of QEF's (n=250) and electronic events (n=35) yielded results of 74% and 80% respectively in the identification of the raised against department (p=0.22 not significant at 5%). The reported by parameters is far more structured in the electronic event as opposed to the QEF and is a mandatory field. The individual reporting the event has to select the specific department where the event occurred from a drop down list. Compliance is measured according to the department selected and if "quality event" was selected instead of the actual department then the QEF was classified as non compliant. The department where the event occurred is often implied in the details documented on the QEF or could be ascertained from the patient label. Staff members were not formally required to document this information on the QEF. This parameter is now a new, forced parameter for all staff reporting an electronic event and a learning curve is expected. The departmental manager will have oversight of this parameter to ensure the correct department is selected, ensuring the correct email notification trigger. The electronic version can improve completeness and quality due to validity checks on data as it is entered, and an interactive system can ensure additional information is obtained with the use of prompts (Tang & McDonald, 2001). This parameter is required in the trending of all events and ongoing education is required to improve compliance.

5.5.4 Immediate Action Taken at time of reporting the QEF and Electronic Event

The immediate action taken at the time of reporting has improved from 86.3% in QEF's to 100% in the electronic event due to mandatory fields (p=0.009 significant at 5%). This ensures the

individual reporting the event documents the immediate action taken at the time of the occurrence. This parameter will facilitate a reduction in the follow up required by the Quality Department as the required information is available at time of reporting. As described by Levtzion-Korach, et al. (2009) generally the reporter only completed the mandatory fields. The quality of the details of the event and immediate action taken at time of reporting will require further research.

5.5.5 Date and Time of QEF and Electronic Event

The analysis of QEF's (n=250) identified 98.4% compliance with the date of the occurrence and electronic events 100% (p=0.23 not significant at 5%). The analysis of date in QEF's 86.4% and electronic events 77.1% in the recording of the time of the occurrence (p=0.06 not significant at 5%). The date and time parameter in the electronic event is set up as one parameter and is mandatory. This is possibly due to the fact that once the date is entered into the date and time parameter then the mandatory field prompt no longer applies. Compliance in relation to the time of occurrence was an issue in the QEF process as well. This area of non compliance can be corrected by the departmental manager at time of reporting due to real time email notification and access. Ongoing education is required.

5.6. Additional Comments

One of the most significant considerations for healthcare organisations when implementing an electronic reporting system is to ensure that there is not a decrease in the reporting numbers. The

table below Table 5.1 compares the numbers of QEF's reported by the pilot area in 2009 with the electronic events numbers in 2010 for the same time period; May – July.

Month	May	June	July	Total
QEF's reported in 2009	9	15	10	34
Electronic Events Reported in 2010 (Pilot Study)	8	13	14	35

Table 5.1 2009 QEF Numbers versus 2010 Electronic Event Numbers

It is suggested that electronic reporting systems combined with a relatively blame-free organisational culture, will actually increase the number of adverse events as opposed to actually decreasing the number due to improvements (Braithwaite, et al., 2008). Technology alone can not guarantee reporting numbers; it is merely a tool to assist in the collection of data. Reporting is the responsibility of each individual which is dependant on the culture and values of the organisation and should be viewed as a means of improving quality and safety processes and not as a routine duty. Organisations must focus on process improvement and not blame (Dixon, 2002).

5.7. Conclusion to Evaluation / Analysis

The findings of this study were discussed in detail in this chapter. The study identified that electronic reporting addressed the time management of the adverse event reporting process for both the Quality Department and the Departmental Managers. Real time email notification, access and availability of the adverse event facilitates the immediate response and corrective action taken by the appropriate managers. This is an effective means of addressing patient safety

and preventing reoccurrence of the event. The electronic event addressed and improved most aspects of the quality of information received during this study, therefore reducing the follow up required by the Quality Department. The recording of the time of occurrence will require further training and education in an effort to improve compliance and reduce the follow up required due to the incomplete or missing data. The reported by and raised against parameters will require further training in an effort to ensure staff are familiar with selecting the correct department, especially as this triggers the initial email notification. There are many weaknesses in the QEF process that are addressed with an electronic reporting system; illegibility or misinterpretation of the details of the event, missing or incomplete data, lost or misplaced forms, confidentiality issues as the QEF can be viewed of photocopied by unauthorised staff. The follow up or corrective actions taken are available for viewing by all the appropriate individuals due to real time access and update of the event. Analysis and trending of events facilitates patient safety initiatives and process improvements, as well as assist with compliance with requirements by external agency such as accreditation (Dixon, et al., 2002). Finally, electronic reporting appears to improve and or at least attempts to address the time management and quality of information received from the paper based reporting system. The recommendations drawn up as a result of the study are discussed in the next chapter.

Chapter 6: Conclusion and Future Work

6.1 Introduction

This chapter outlines the strengths and limitations of the study and explains how the findings will be disseminated to both the research participant and the study site. The details of the findings will bring together the implications for management and the Quality Department and finally, this chapter will provide recommendations for future research.

6.2 Strengths and Limitations of the Study

This study provided the researcher and the Quality Department with the opportunity to identify the gaps and weaknesses in the existing QEF and pilot electronic event reporting process. The recommendations will be based on the findings of the study and are anticipated to facilitate improvements in the time management and quality process of the electronic adverse event reporting process. The support and enthusiasm of the departmental staff and managers participating in the pilot study was greatly appreciated. The department had the increased burden of running a concurrent adverse event reporting system; completing a QEF and electronic event for each adverse event occurring in the department during the three month pilot study. Additionally the unanticipated increased pressure on the staff due to the limitations of the study made this process more onerous than originally anticipated. No study can answer and address all the questions posed and all research has limitations

There were a number of limitations encounted during the study. Firstly, the size of the electronic event sample. The researcher initially anticipated implementing the pilot study in two different departments within the study site in an effort to increase the sample size and highlight the different issues encounted in the two different departments. There were a number of reasons as to why the second department was not included in the pilot. The first, Q Pulse was not available on all the computers within the study site as it was only available on PC's and laptops, whereas the majority of departments use thin clients. It was anticipated at the outset of the study that Q Pulse would be available hospital wide. A PC was specifically installed in the ward participating in the pilot study and a second PC was available in the medical library located in the department therefore facilitating the Q Pulse pilot. Q Pulse unavailability had a serious impact on the training of staff, the proposed project plan and the implementation of Q Pulse within the study site. It is anticipated that Q Pulse will be available hospital wide by the 1st September 2010. Secondly, strained industrial relations within the study site during the first six months of the year had an impact on the roll out and uptake of the new electronic system and placed a significant amount of stress on staff working within the organisation. Finally, limited resources in all departments and an increased workload, significantly impacted staff; especially on staff training and practice time as staff where unable to familiarise themselves with Q Pulse prior to going live with the pilot.

6.3 Dissemination of Findings

The results of the findings will be disseminated to the research participant and study site. The research participant will receive a summary of the recommendations from the study; improving the adverse event reporting process. The researcher will present the findings of the study to all relevant work colleagues; including the Chief Executive, Chief Operations Manager, Director of

Nursing, Director of Quality, Director of IT, the Quality Committee and other relevant stakeholders involved in the adverse event reporting process. The study was strongly supported by management and the results will be used by the Quality Department to improve the implementation of the electronic adverse event reporting process and other electronic systems hospital wide.

6.4 Implications for Management and the Quality Department

The aim of the study was to evaluate if an electronic adverse event reporting system will improve the time management and quality processes of a paper based system. The findings of the study will have implications for everyone involved in the adverse event reporting process and the hospital management team. The next section will discuss the implications of the findings for management and the Quality Department.

The culture of the organisation is directed by the Chief Executive and the Board of Directors. In order to create a culture which focuses on quality and safe patient care the organisation must promote, encourage and challenge the quality agenda. The Director of Quality and top level management are responsible for ensuring the adverse event reporting process is in line with what is recognised as best practice while facilitating compliance with mandatory accreditation standards. The hospital management team actively supports all processes that improve and address patient safety. The study focused on improving the current paper based process which is extremely time consuming and labour intensive by implementing an electronic adverse event reporting system. The results of the study are very promising and the recommendations are from the findings of the three month pilot study.

6.4.1 Implementation of Q Pulse Hospital Wide: The study strongly recommends the implementation of Q Pulse hospital wide. The study identified significant improvements in the time management of the adverse event reporting due to real time notification, access and resolution of the event. Q Pulse addresses many of the issues of the quality of information received; reducing the potential follow up required by the Quality Department. The electronic adverse event reporting process will facilitate closing the loop of care due to the formal resolution and close out of all electronically reported adverse events, therefore streamlining the current process.

6.4.2 Electronic System Upgrade and System Redesign: A number electronic reporting systems were reviewed by the Quality department over a number of years preceding the implementation of Q Pulse, which was initially purchased for its document control module. A decision was made to implement CA/PA on a pilot basis to assess if it would improve the current paper based adverse event process. CA/PA is easy to use when reporting a new event as the system is very similar to the QEF and there are a limited number of required or mandatory fields. Anecdotal comments from end users were positive stating that the system was easy to use and straight forward. The researcher identified a number of system design issues. Firstly, the system is restrictive as there is limited system redesign capabilities' therefore restricting the creation and the design of the electronic event form. There is inflexibility with parameter headings as they do not suit organisational requirements and can not be amended or altered. A limited number of drop down options are available. There is an inability to increase the number of required text boxes. The most urgent design flaw needing to be addressed by the administrator is the department selection hierarchical structure; the reported by and raised against drop down menu.

Restructuring of this drop down menu is required in an effort to improve compliance by the individual reporting the event and selecting the correct department. This is essential for triggering the correct email notification of a new event; informing the ward and departmental manager of the event and for the Quality Department when compiling the monthly reports. The researcher recommends the upgrade of Q Pulse to the latest version that includes the latest incidence and occurrence module. This new module facilitates organisations with flexibility in designing and creating an electronic form; assisting organisations with their own specific requirements.

6.4.3 Database Administrator and Trainer: The database administrator and trainer is a combined role, two days a week. The training role is to develop and continuously update training information, crib sheets and train all members of staff hospital wide; the general user, managers and super users "Train the Trainer". The database administrator's role is to ensure all managers and staff members have the correct access and user rights required to perform their tasks when using Q Pulse. The administrator manages all reported electronic events on a daily basis and acts a link between departmental managers and the Quality Department. The aim is to monitor compliance and adherence to the correct process whilst facilitating follow up with managers, their staff and other departments. The managers must be competent and confident users if this process is to succeed as they will educate and facilitate their own staff. This process will continue until all staff are familiar with Q Pulse and their responsibilities. Super user training was initiated in the department to assist the database administrator and trainer with the training of a number of existing staff and all new staff. There are a number of recommendations in relation to the training requirements as a number of issues were encounted during the pilot. At times a number of staff were trained all at once and the limited time available for training resulted in some staff not

practicing on Q Pulse during the allocated training sessions. This was compounded by the demanding workload in the department and the limited availability of Q Pulse resulting in most staff not familiarising themselves with Q Pulse before going live. This was especially significant for managers and super users. The recommendations of this study would be to increase the time required to train the general user, especially the managers and super users "Train the Trainer". This would assist in facilitating each staff member with sufficient time to practice and familiarise themselves with Q Pulse during the allocated training session. IT skill of varying levels also impacts on the time required for training. The second recommendation is to increase the database administrator and trainer's role to at least a minimum of three full days a week until the training is complete and staff are familiar with the system and its requirements. Once training is complete then this role will principally be a database administrator and facilitator role.

6.4.4 Reporting Capabilities: The main role of the participant is to analyse, categorise, grade and trend all adverse events and compile a monthly, quarterly, six monthly and annual reports. The Quality Department is dependant on the reporting capability and flexibility of Q Pulse to produce these reports. A recommendation from this study would be to have crystal reporting availability thereby facilitating the Quality Department in creating their own specifically designed reports; departmental specific. Therefore the Quality Department will not be required to use the standardised reporting functionality available on Q Pulse which is limiting and restrictive. An alternative to this recommendation would be a date warehouse.

6.4.5 Data Warehouse: The study site is exploring the possibility of implementing a data warehouse. This will facilitate the storage of large volumes of data from a number of different departments or databases thereby facilitating staff in modifying reports by either adding,

removing or adjusting the way data is displayed. The Quality Department could quickly and easily create their own report. The results of this study would recommend the availability of a data warehouse. The data warehouse would facilitate the next recommendation which is the integration of Q Pulse with the hospitals Patient Administration System (PAS).

6.4.6 Integration of Q Pulse with PAS: The integration of Q Pulse with PAS is recommended by the researcher. This functionality would assist with merging the patient demographic fields from PAS with the Q Pulse electronic event. This would reduce the amount of time required to repeatedly enter the already available demographic information and would increase the accuracy of the information available in Q Pulse.

6.4.7 Computer Access: Q Pulse is anticipated to be available on citrix by the beginning of September; therefore available hospital wide. This will significantly facilitate the training and implementation of Q Pulse in the study site. Many wards or departments have a limited number of computers, an average of 3 per ward. The researcher recommends a review of all IT requirements and the number on computer terminals availability in each area due to the increasing IT demands. A concern in relation to computer access has been highlighted by staff during Q Pulse training.

6.5 Recommendations of Future Research

The study site is continuously reviewing and addressing the quality process. The implementation of the electronic reporting system considerably improved and addressed the time management of the adverse event reporting process. Further research will be required to ascertain if the electronic

reporting system improves the actual quality of information received, the accuracy of the information received such as demographic details as well as the impact that the electronic reporting process has on closing the loop of care in a timely manner.

6.6 Reflections of the Study

The researcher would have preferred a larger sample size of electronic events and the pilot to run concurrently in two different departments. This would have allowed for more meaningful comparison between the paper based and electronic reporting results.

6.7 Conclusion

In summary, many recommendations were drawn up as result of the findings of the study which aim to improve the hospital wide implementation of Q Pulse. The hospital management team are required to review and consider the recommendations in line with promoting safe quality care and the implementation of the Quality Strategy objectives and accreditation requirements. Increased reporting may be associated with a more encouraging culture of safety and reporting (Hutchinson, et al., 2009). Adverse event reporting must be a culturally acknowledged requirement within healthcare and must be promoted by management. Reporting must be relaxed and non punitive. If the user has a high level of confidence in relation to using the adverse event reporting system then a higher level of acceptance can be expected (Wu, et al., 2008).

As described by Farley, et al. (2008) a hospitals adverse event reporting system should be one component of an organised patient safety strategy which includes the identification of adverse events through reporting and establishing organisational processes for a culture of patient safety.

ICT is essential in improving and addressing quality processes and patient safety within all healthcare organisations. The electronic adverse event reporting system appears to have improved some aspects of the current paper based reporting process due to real time reporting, immediate email notification and access of the electronic event. The electronic reporting system will assist in addressing the onerous workload, the time management, analysis, identification of trends and patterns, timely feedback, resolution and corrective action implementation of the current QEF process. The system has optimistically addressed the quality of information received by the Quality Department. Illegibility has all but been resolved. Mandatory fields and a structured format will facilitate a reduction in the potential follow up required by the Quality Department due to the missing or incomplete data. The system has addressed the many concerns discussed during this study in relation to paper based reporting. Overall the system appears to streamline and improve the burdensome and unmanageable paper based process. The electronic system will facilitate the Quality Department in meeting the Quality Strategy's objectives, accreditation requirements and most importantly improving patient outcomes and care.

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Chapter 9 Appendices

Appendix 9.1: Quality Event Form (QEF)

Research Site

Quality Event Form

This form is designed to enable you to report any incident, event or occurrence, which the hospital should be aware of in order to maintain it's sharp focus on quality. If you are not sure about reporting something the simple rule is – "IF IN DOUBT, FILL IT OUT"

Type of event:
Accident/Incident ☐   Near Miss ☐   Complaint ☐
Involving:
Patient ☐   Employee ☐   Visitor ☐   Other ☐ (please specify) _____

Name: _____

Address: _____

If patient please give patient number, if employees please give job title: _____

Date of event: _____   Time of event: _____

Please describe the event fully and use additional paper if necessary: _____

Please give details of any injuries sustained: _____

If injured part was an employee please state if any absence from work resulted and likely duration of such absence: _____

Please provide further information in relation to any action taken following the incident: _____

Signed: _____   Date: _____

Counter-signed Supervisor/Manager: _____   Date: _____

Appendix 9.2: Paper Based Adverse Event Reporting Process

Adverse event occurs (occurrence)	
↓	
Reported on QEF	
↓	
QEF's collected or posted to the QD	Manual
↓	
QEF stamped as received	Manual
↓	
QEF's assigned a unique identification number	Manual
↓	
QEF's punched and filed in chronological order	Manual
↓	
Additional documentation received are attached to the original QEF and filed	Manual
↓	
QEF event read	
↓	
QEF categorised	
↓	
QEF graded according to severity	
↓	
QEF Photocopied or scanned	Manual
Corrective action forms posted or scanned to departments if additional information is required	Manual
↓	
QEF posted or scanned to relevant individuals informing them of the event	Manual
↓	
Selected QEF's reviewed by the Director of Quality	Manual
↓	
Basic demographics and details of the event entered onto the database for analysis	Manual in
↓	
Number of incidents, the categories and grading analysed	
↓	
Monthly report compiled for the Quality Committee meeting	
↓	
All additional information entered onto database.	
↓	
QEF closed	

Appendix 9.3: Incident Reporting Management Policy

RESEARCH SITE	
Owner / Date:	Document No.:
Reviewed by / Date: 08/05/08	Date of issue: 08/05/08
Authorised by: Quality Dept. 08/05/08	Edition No.: 003(Review Date: 08/05/2011)
THE ABOVE IS FOR COMPLETION BY THE QUALITY DEPT.	

INCIDENT REPORTING AND MANAGEMENT POLICY

1.0   POLICY STATEMENT

1.1   Mater Private Healthcare is strongly committed to creating as safe an environment as possible for all patients, visitors and staff. A critical element of the approach to this task is the accurate recording and subsequent investigation of all adverse events that actually or potentially cause injury to people or damage to property.

1.2   It is the policy of Mater Private Healthcare that all staff members, consultants and contractors report adverse events. Staff will not be disciplined in any way arising out of adverse incidents which occur when they are carrying out their normal duties with due regard to the scope of their professional qualification and/or in line with their contract of employment in keeping with our fair and just culture.

2.0   AIM OF POLICY

2.1   The aim of the policy is to ensure that Mater Private staff and Consultants are aware of the procedures for incident reporting and investigation in the organisation.

3.0   SCOPE OF POLICY

3.1   This policy applies to all staff, consultants and contractors working in the Mater Private.

4.0   RESPONSIBILITIES

4.1   It is the responsibility of hospital consultants and their employees to be familiar with and to adhere to this policy.

4.2   It is the responsibility of non-consultant hospital doctors to be familiar with and to adhere to this policy.

4.3   It is the responsibility of department heads/ clinical nurse managers to:
   • ensure that staff are familiar with and adhere to this policy.
   • treat staff fairly and equitably during any investigation.

- support staff in an incident with internal / external support if considered appropriate.
- provide feedback to staff regarding outcomes and to promote an open and honest culture of reporting.
- identify and notify the Quality Department of incident reporting training requirements for staff working in their area.
- implement recommendations/ changes in practice resulting from an investigation.

4.4 It is the responsibility of all staff to:
- be familiar with and to adhere to this policy.
- to complete the relevant form as soon as possible after becoming aware of an adverse event and to discuss possible solutions to prevent incident reoccurring.

4.5 It is the responsibility of relevant designated staff to report incidents required by law and regulation to the relevant external bodies as required.

5.0   DEFINITIONS

5.1   Adverse Event
An adverse event is described an unanticipated, undesirable, or potentially dangerous occurrence which may have resulted in a person being exposed to injury or risk of injury.

5.2   Near Miss
A near miss is described as any adverse event which did not affect an outcome but for which a recurrence carries a significant chance of a serious adverse outcome.

5.3   Medication Near Miss
A medication near miss is described as any event/occurrence involving the prescribing, dispensing or administering of medication which, for good fortune, would have resulted in a person being exposed to risk.

5.4   Sentinel Event
A sentinel event is an event affecting any patient, member of staff, visitor or third party which may include the following:
a) Any unanticipated death unrelated to the natural patient's illness or underlying condition.
b) Major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition.
c) Wrong site, wrong procedure, and wrong patient surgery.

5.5   Verbal Complaint
A verbal complaint is described as any significant negative comment made by a patient, relative or staff member in relation to any aspect of the hospital service.

5.6   RCA   Root Cause Analysis
Root Cause Analysis is a systematic objective and logical process for identifying the root causes of an adverse event. A Root Cause is defined by the hospital as the most fundamental reason for the adverse incident occurring and which, if removed, would eliminate or greatly reduced the likelihood of a recurrence.

5.6 **Local Investigation**
Local Investigation in ward / department

5.7 **CNM** Clinical Nurse Manager

6.0 **PROCEDURE FOR REPORTING OF AN ADVERSE EVENT (Appendix 2)**

6.1   Notify Department Manager or nominee immediately after an adverse event has been discovered.
6.2   Where appropriate local resolution must take place
6.3   All adverse events, actual, potential or verbal complaint, must be documented on the appropriate form. (See appendix 1)
6.4   If an injury renders a person unable to fill a report form, then the department manager / CNM must complete the form on the injured parties behalf.
6.5   All forms must be fully completed, providing a factual and detailed description of the event e.g. how it happened and outcome
6.6   The original and completed form must be submitted to the Quality Department through internal post, or placed in the relevant Risk Management Box within 24-48 hours.
6.7   The following information must be completed on all forms:
- Date and time of event
- A patient label must be applied to all forms if available
- The exact location of the event should be recorded, i.e. ward, department, area etc.
- All sections of the form must be completed and written legibly
- Details of medical findings documented, if available
- The Department Manager / Clinical Nurse Manager must review the form before submission to the Quality Department
6.8   The facts of an incident should be documented in the patients notes were appropriate.
6.9   A copy of all forms must be kept at department level for discussion and follow up
6.10   All information relating to adverse events must be handled with confidentiality.

6.1 **Sentinel Events**

6.1.1   Staff should secure the safety of the patient / individual involved and / or environment. Secure any evidence related to the occurrence.
6.1.2   In the event of direct bodily harm, the patient must be attended to by a member of the medical team and if a staff member is injured they must be referred to the emergency department / occupational health department in Mater Misericordiae Hospital.
6.1.3   All sentinel events should be immediately, verbally reported to the Department Manager / CNM / Senior Nurse on Duty. In the event that this occurs outside of hours the Nursing Manager on-call and the HET On-Call Manager must be informed immediately.

7.0   SPECIFIC PROCEDURE FOR REPORTING HEALTH AND SAFETY INCIDENTS

7.1   The Department Manager / CNM must notify the Health and Safety Department immediately if:
- a serious work related incident occurs.
- if an employee is absent due to work related injury/illness.
- If an employee remains out of work for longer than three days as a direct consequence of a work related injury

7.2   The employee on return to work must notify human resources and complete a return to Work Form

7.4   Co-operation is required with the Health and Safety department while investigating any incident/event in your area.

7.5   The Department Manager / CNM must implement remedial action recommended by the Health & Safety Officer where necessary

8.0   SPECIFIC PROCEDURE FOR REPORTING BLOOD TRANSFUSION / MEDICATION EVENTS

8.1   All transfusion events (actual and near miss) must be reported to the haemovigilance nurse

8.2   The medication safety report form must be completed by the person who discovers the event. All completed medication event forms must be signed by the person reporting the event and countersigned by the Department Manager / CNM.

9.0   PROCESS IN QUALITY DEPT

9.1   The Quality Department will ensure each form is:
- allocated a unique identity number
- Categorised (Appendix 3)
- Graded using the grading system outlined in 10.1.
- Copied to relevant parties and to the staff responsible for management of the incident, i.e. Health & Safety Department, Director of Nursing, Drug Safety Committee etc.
- Entered onto the incident reporting database
- Copied to the hospital indemnifier

9.2   If further information is required a Follow up / Corrective Action Form will be sent to the relevant department / area for completion. This form should be returned to the Quality Department as soon as possible.

9.3   All adverse events will be reviewed monthly.

9.4   The aggregated data from adverse events will be discussed further at Heads of Department Meeting and by the Quest Committee. The Quest Committee oversees quality and patient safety issues in the hospital. Data will be used for continuous improvement/ practice development plans within individual departments and hospital wide. Issues highlighted or

raised will be discussed and any appropriate recommendations will be made and feedback given to the appropriate departments.

9.5   Staff education sessions will be provided for all staff on the incident reporting procedure.

10.0   EVENT GRADING AND INVESTIGATION CRITERIA

10.1   It is hospital policy that all reported adverse events will be analyzed by the Quality Department and will be given an appropriate risk grading of: Very High, High, Medium or Low. This grading is calculated by reference to the following matrix:

10.1   Very High Risk Events / Sentinel Events
10.1.1 Sentinel Events and other events graded as "Very High" are outlined in 5.3.
10.1.2 The hospital defines events that are graded as Very High Risk as highly significant. All

Likelihood of Recurrence	Outcome and Scope				
	Critical 5	Major 4	Moderate 3	Minor 2	Trivial 1
Certain 5	5x5	5x4	5x3	5x2	5x1
Very Likely 4	4x5	4x4	4x3	4x2	4x1
Possible 3	3x5	3x4	3x3	3x2	3x1
Unlikely 2	2x5	2x4	2x3	2x2	1x2
Highly Unlikely 1	1x5	1x4	1x3	1x2	1x1

■ Very High Risk	■ High Risk	■ Medium Risk	■ Low Risk
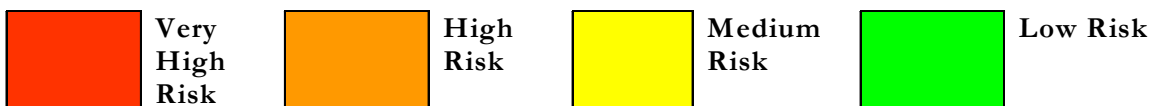
highly significant events lead to the initiation of the Root Cause Analysis (RCA) process. A RCA is initiated by the Chief Executive or nominee within 24 hours of being made aware of the event. This involves the establishment of an appropriate team to analyse the event. The membership
of the team will include external expertise if required. The team will always
include a minimum of 2 members trained in RCA techniques. The Chief

Executive or nominee is responsible for informing all other relevant groups and individuals in the hospital of the event and the initiation of the RCA.

10.1.3 All RCAs must be completed and the outcomes reported to the Chief Executive within one month of initiation.

10.1.4 The RCA team will conduct a root cause analysis of the event using an appropriate recognized method of determining the root cause/s of the event.

10.2 High Risk Events

10.2.1 Some incidents that are graded as High Risk are also investigated by a Root Cause Analysis process. The Chief Executive determines which High Risk Events require a RCA. All High Risk events that require a RCA will have same commenced within 5 working days of the decision taken by the Chief Executive. The timeframes and process for completion and reporting of the investigation is as for Very High Risk events.

10.3 Medium Risk Events

10.3.1 High risk events, which do not require a RCA and specific medium risk events, as determined by the Quality Manager, are investigated by a Local Investigation. Local Investigations are initiated by the quality department/area manager within three weeks of becoming aware of the event and the outcome of the investigation will be completed in a further 6 weeks. The quality department will report the outcome by routine reports. Local Investigation involves an investigation by an individual or a small team of appropriate members. The individual or at least one member of the team will be trained in Root Cause Analysis techniques.

10.3.2 A monthly report is issued to the Board, Quest Committee, Hospital Executive Team and Heads of Department detailing all medium risk incidents.

10.4 Low Risk Events

10.4.1 Low risk events are not routinely investigated on an individual basis. All low risk events are recorded on the incident reporting database and form the basis for trending and analysis. Where a similar event recurs within a reasonable timescale a local investigation will be initiated. The determination as to when a local investigation is initiated on the basis of the recurrence of a low risk event will be at the discretion of the Quality Department following reasonable discussion with relevant personnel. The timeframe and process for completion and reporting of the investigation outcome is the same as for all RCAs.

11.0 COMMUNICATION WITH PATIENTS/RELATIVES AND STAFF

11.1 Where an incident results in harm to a patient, then information pertaining to the incident should be disclosed to the patient and / or relative by the patients consultant and/ or CNM in consultation with the relevant healthcare professionals and in keeping with the patients physical and psychological condition

11.2 A prompt, truthful and compassionate explanation about the incident should be provided based on clinical facts only

11.3 Any decision not to inform a patient should be clearly documented in the patient's healthcare record along with the rationale for such a decision

11.4 All communication with the patient and /or relative should be appropriately documented and include information of all those present and details of discussion.

11.5 Further to an investigation and at the discretion of the Chief Executive written feedback may be made available to patients, relatives and / or staff.

12.0 CRITICAL INCIDENT DEBRIEFING PROGRAMME

12.1 Staff involved in adverse events are offered access to the Critical Incident Debriefing programme.

APPENDIX 1

FORM	WHAT TO REPORT	COLOUR
Quality Event Report Form	All other incident / verbal complaints	PINK
Medication Safety Report form	Medication / Blood (anything prescribed)	GREEN
Patient Fall Report Form	Patient Fall	PEACH
Follow up / Corrective Action	Follow up / Corrective Action	BLUE

All forms are available on the Intranet under the Forms Section.

APPENDIX 2

INCIDENT REPORTING FLOW CHART

INCIDENT OCCURS AT DEPARTMENT LEVEL
- Appropriate **Local Resolution** taken
- Relevant **Form** is filled in at department level.
- **Copy** of Form kept at Department level for discussion and follow up
- **Original Form** is Placed in **Risk Mgmt Box / Internal Post** to Quality Department

QUALITY DEPARTMENT
- Form reviewed, classified, graded and input onto incident reporting database.

Follow up Action Form sent back to department for further clarification of information

- Root Cause Analysis carried out if required
- Form copied to relevant Department / Committee for further management of the incident

- Unresolved issues taken to QUEST Committee for advice, discussion and action

- All relevant actions / issues completed

- Reports on Incident Trends and Analysis feedback to relevant areas

APPENDIX 3

CATEGORY OF INCIDENTS

CLINICAL CATEGORY	SUB CATETORY
Aggression	
	Confused/Disturbed Patient/Self Harm
	Pt refusing Advise/Procedure
	Disruptive/Aggressive/Violent Behaviour by Patient
	Verbal Abuse of Patient
Clinical Management	
	Allergy
	Bloods not taken
	Clinical Assessment (diagnosis, scans, tests, assessments)
	Consent
	Confidentiality
	CPR
	Foreign Body
	Implementation of Care
	Ongoing monitoring/review
	Pain Management
	Pre Op/Procedure Problem
	Intra Op/Procedure Problem
	Post Op/Procedure Problem
	Radiation
	Registrar Issue
	Test Not Done
	Test Result Problem
	Test Repeated
	Treatment/procedure
	Unexpected Death
Documentation	
	Documentation - general
	Documentation - Incomplete
	Documentation - Misfiled
	Charts
	Patient Identification
	Booking Errors
	Wrong Site Surgery (WSS)
	Mislabelled Specimens
	Missing Charts
	Missing Test Results
	Missing X-rays
Falls	
	Fall
Hospital Acquired Infection	
	Infection Risk
	Pressure Ulcers

Medical Devices / Equipment / Property	
	Equipment
Medication / IV Fluids	
	Blood Transfusion Management
	Medication
Patient Accident	
	Chemical Spill
	Hot Substance
	Sharp
	Other
Other - Clinical	
	Other
NON-CLINICAL CATEGORY	**SUB CATEGORY**
Staff Accidents	
	Assault
	Blood Exposure
	Chemical Spill
	Falling Object
	Hot Substance/Surface
	Manual Handling
	Radiation
	Sharps
	Slip/Trip
	Verbal Abuse/Aggression
	Waste Handling
Buildings / Fittings / Fixtures / Surrounds	
	Environmental Issues e.g. layout, space
	Water/Electricity/Gas
Organisational Management / Services	
	Admission Post Day Case
	Admission
	Beds Unavailable
	Cancelled Procedures
	Communication / Information for Patients
	Delay in Consultation/Diagnosis
	Discharge
	Inadequate Staffing
	Inadequate Facilities/Services
	Missing Patient/Self Discharge
	Operation/Procedure Cancelled/Postponed
	Smoking/Fire
	Transfer
	Wait/Delay
Security	
	Loss of Personal Property
	Security
Other - Non Clinical	
	Other / Visitors Accident

Appendix 9.4: Q Pulse Electronic Reporting System

Mandatory fields

An electronic event

Every new electronic event will be assigned a unique identification *Number*

Status will be changed to closed when the event is closed out by the Quality Department

Immediate Action: Completed By and *Closed Date* will be completed by the departmental manager once the follow up and corrective actions have been implemented and the event is resolved.

Appendix 9.5: Electronic Reporting Process

Adverse event occurs (occurrence)	
↓	
Reported on electronic adverse event reporting system	
↓	
Immediate e-mail notification sent to: The Quality Department, Departmental Manager Head of Department	Automated
↓	
Electronic event read	
↓	
Electronic event graded according to Severity	
↓	
Electronic event categorised	
↓	
The category triggers an e-mail notification to the Relevant individual / committee & Director of Quality	Automated
↓	
Email notification sent manager if follow up action required	Automated
↓	
Immediate action stage closed by the Departmental Manager	
↓	
Electronic event closed by the Quality Department	
↓	
Number of incidents, categories and grading analysed	
↓	
Monthly report compiled for the Quality Committee meeting	

The departmental manager is responsible for closing out the manager's stage of the event once the event is resolved. The event will remain an outstanding action for the departmental manager until the *Immediate Action Stage* is closed.

Once the *Immediate Action* stage is closed and the Quality Department has all the required information then the Quality Department close out the event.

Appendix 9.6: Quality Committee Structure

A diagram showing the Quality Committee at the center, connected to the following committees and manager:
- Chief Operations Manager
- Falls Committee
- Blood Transfusion Committee
- Equipment Committee
- Pain Committee
- Tissue Viability Committee
- Ionising Radiation Committee
- Radiation Audit Committee
- Drug Safety Committee
- CPR Committee
- Infection Control Committee
- Health & Safety Committee

Appendix 9.7: Terms of Reference of the Quality Committee

Research Site

Quality Committee: Terms of Reference

1. Mission: It is the mission of the Quality Committee to enhance patient and staff safety by overseeing the hospital quality and risk management programme.

2. Reporting relationship: The Quality Committee reports directly to the Hospital Board.

3. Membership

3.1Term of Office: is 3 years; members may serve consecutive terms on the committee
3.2 Committee Members:
- Chief Operations Manager (Chair)
- External Risk Management Consultant
- Director of Nursing
- Director of Quality
- Medical Representative
- Medical Representative
- Representative from Ionizing Radiation Committee
- Representative from Infection Control/
- Representative from Transfusion Committee
- Representative from Drug Safety Committee
- Representative from Health and Safety Committee
- Representative from Equipment Committee
- Representative from Radiation Audit Committee
- Representative from Pain Management Committee
- Nursing Representative/ CPR Committee
- Nursing Representative
- Representative Quality Department
- Representative Quality Department

3.3 Nomination to Committee: Members are nominated to the committee by the following means - nomination to represent a hospital committee or nomination by chairperson

4. **Quality Committee Meetings**

 4.1 Meeting Frequency: The committee meets once per month.
 4.2 Meeting Quorum: The meeting quorum is 50% of membership

4.3 Attendance Requirements: a member who is absent from 3 meetings in a row is considered to have resigned from the committee except in exceptional circumstances.

5. Role of Committee

5.1 Oversight of the hospital quality and risk management programme

5.2 Review of all quality data including incident reporting and quality indicators

5.3 Initiating and monitoring quality improvement programmes in hospital

5.4 Review of relevant hospital policies

5.5 Coordination of all other major hospital committees that report to the Quality Committee.

5.6 Participation in the hospital accreditation programme.

Appendix 9.8: Quality Processes under the remit of the Quality Department

Adverse Event Reporting

Patient Perception Survey

Key Performance Indicators

Quality Department

Patient Focus Groups

Document Control

Verbal and Formal Complaints

Comment Cards

Appendix 9.9: Pre Recorded Spread Sheet for the Data Collection of the Steps Involved in the QEF Process

Date collected																Total No	Total Min
Collect forms from the ward	No	Min	No	Min	No	Min	No	Min	No	Min	No	Min	No	Min	Total No	Total Min
Collect forms from ward																0	0
Internal post																0	0
Scanned																0	0
Total Number of Forms																0	0
Minutes																	
Processing Forms	No	Min	No	Min	No	Min	No	Min	No	Min	No	Min	No	Min	Total No	Total Mins
Date Stamp																0	0
Read, categorise, grade																0	0
Number incident forms																0	0
Sort / File																0	0
Input Name																0	0
Input Details																0	0
Incident review with AF																0	0
FU via scanning																	
Outgoing	No	Min	No	Min	No	Min	No	Min	No	Min	No	Min	No	Min	Total No	Total Mins
Photocopy all forms																0	0
Time to put into Envelopes																0	0
Scanned copies																	0
																Total No	Total Mins
Total																	

Appendix 9.10: Ethics Approval Letter

Director of Quality
Quality Department

Dublin 7

07th May 2010   Our Ref: 1/378/1307

RE: **How will an electronic adverse event reporting management system improve the time management and the quality processes of the adverse event reporting process in the healthcare organisation?**
Research Protocol
Participant Letter
Study Informati9on Leaflet, (Paper Based Adverse Event Reporting Leaflet V1)
Consent (Consent Form Paper Based Adverse Event Reporting V1)
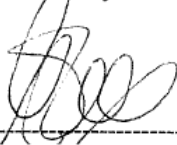
Dear

I acknowledge receipt of your correspondence dated 05th May 2010 clarifying as requested by the   Hospital and   I   Hospital Research Ethics Committee for the above research study to be carried out at the   Hospital   that study data will be encrypted.

This research study may proceed at the   this approval is valid until 24th March 2012.

It is your responsibility to adhere to the approved study protocol and ensure that all investigators involved with the research only use the approved documents without deviation (unless they have been approved by the Research Ethics Committee), to submit annual reports setting out the progress of the research (giving details of the number of participants who have been recruited, the number who have completed the study and details of any adverse events etc.) and to notify the Research Ethics Committee when the research is concluded.

Yours sincerely

Chairman Research Ethics Committee

Appendix 9.11: Letter of Permission to Study from the Director of Nursing

<div align="right">
Director of Nursing
Address 1
Address 2
Address 3
</div>

Ms
Administrator
Research Ethics Committee
Address 1
Address 2
Address 3

1 February 2010

Dear Ms

I herby give the researcher permission to carry out her proposed research in the Study site in accordance with the Masters in Health Informatics requirements.

The title of her proposed research is: How will an Electronic Adverse Event Reporting Management system improve the time management and the quality processes of the adverse event reporting process in the healthcare organisation?

Thanking you for your assistance

Yours sincerely

Director of Nursing

Tel:

Appendix 9.12: Letter of Permission to Study from the Director of Quality

<div align="right">

Director of Quality
Quality Department
Address 1
Address 2
Address 3

</div>

Ms
Administrator
Research Ethics Committee
Address 1
Address 2
Address 3

1 February 2010

Dear Ms

I herby give researcher permission to carry out her proposed research in the Study site in accordance with the Masters in Health Informatics requirements.

The title of her proposed research is: How will an Electronic Adverse Event Reporting Management system improve the time management and the quality processes of the adverse event reporting process in the healthcare organisation?

Thanking you for your assistance

Yours sincerely

Director of Quality

Tel:

Appendix 9.13: Letter Inviting the Participant to Participate in the Research Study

<div align="right">

(Name of Participant)
Address 1
Address 2
Address 3

</div>

Study site
Quality Department
Address 1
Address 2
Address 3

(Date)

Dear Participant,

I am currently undertaking a Masters in Healthcare and Informatics at Trinity College Dublin. As part of my requirements I am conducting a research study with the aim of evaluating how will an Electronic Adverse Event Reporting Management system will improve the time management and the quality processes of the adverse event reporting process in the healthcare organisation.

I would like to take this opportunity to thank you for assisting in the monitoring of the time taken to complete the steps involved in the paper based adverse event reporting process.

I realise this will place a demand on your time and increase your already heavy workload, but your participation in this study will be invaluable and will allow for a meaningful comparison between the paper based and electronic adverse event reporting processes. If you would like to receive a summary of the recommendations and findings I can forward these to you at the end of the study.

Please find attached:
- A study information leaflet outlining the study and your involvement
- A consent form which you are required to sign and return to the investigator

I would like to take this opportunity to thank you for your assistance in this research study. If you have any further queries please do not hesitate to contact me at the above address.

Many thanks for your help.

Yours sincerely,
The Researcher

Appendix 9.14: Research Study Information Leaflet for the Participant

Research Site

Study Information Leaflet

Paper Based Adverse Event Reporting in the Study Site

Please read carefully

Dear Participant

You are invited to take part in a study to monitor whether an Electronic Adverse Event Reporting Management System will improve the time management and quality processes of the adverse event reporting process in the Study Site?

The purpose of the Research Study is to:

- To show how an electronic adverse reporting system will improve the time management of the adverse event reporting process.
- To evaluate if an electronic adverse event reporting management system will improve the quality of information received in relation to the reported adverse event and will this reduce follow up required by the Quality Department.
- To identify gaps and weaknesses in the paper based system that may be improved with the implementation of an electronic adverse event reporting system.

Why have you been chosen?

As an employee working in the Quality Department with direct involvement in the adverse event reporting management process within the organisation your input and expertise would be invaluable to this research study. Part of this study is to monitor the time taken to perform the steps involved in the paper based adverse event reporting process which would require you to monitor the time taken to complete each task involved in this process. Your support, co-operation and assistance with this study would be greatly appreciated in order to provide a meaningful comparison between the paper based and electronic reporting system.

You would be the only participant involved in this research study as all other data collected in relation to the adverse event reporting process would be collected and collated by the investigator.

Who is organising the research study?

The investigator involved in the research study is the researcher and will be supervised by the Director of Quality in the Study Site.

The research study will be conducted in the Study Site for partial fulfilment of the requirements for the MSc in Health Informatics at Trinity College Dublin.

Permission has been obtained from the Chief Operations Manager, the Director of Quality and the Director of Nursing.

What will happen if I take part?

The participant participating in the research study is responsible for the adverse event reporting management process within the Study Site. The participant is required to monitor and record the time taken to complete each step involved in the paper based adverse event reporting process i.e. the time taken from when the paper based adverse event is received by the Quality Department until all the required details of the adverse event are entered onto the database. The time taken to complete each step of the process will be recorded on a pre designed spreadsheet, therefore ensuring the time taken for each step of the process is recorded. Non-participant observation will be used by the investigator to review this process and collate the data as the participant will be monitoring the time taken to complete each task during her regular working hours.
This process will continue over a period of time until the participant has completed monitoring the predetermined number of adverse events required. A sample size of approximately 10% of 2009 adverse events will be used for this review.

The researcher aims to evaluate the time management, the benefits and the quality of the information received of a paper based versus an electronic adverse event reporting management system. A quantitative approach using numerical data will be used to present the data.

What are the benefits?

The current adverse event reporting system in the research site is a manual paper based system which is extremely time consuming and labour intensive. The number of adverse events reported has increased by 142% since this process was first introduced in 2002. The electronic adverse event reporting management system is the first of many proposed changes that will hopefully improve patient safety processes within the organisation. Due to the large volumes of adverse events reported monthly, the slow and time consuming paper based system, an increased workload and a lack of required or legible information many incidents may not always have the mandatory follow up or close out.
The benefits of this proposed research is to try to improve patient safety within the organisation with aid of an electronic reporting management system. The primary aim is to improve the timeliness of adverse event reporting, to improve follow up of immediate and corrective actions taken and the quality of the information received by the Quality Department all of which are fundamental to any organisations quality and patient safety strategy. The electronic adverse event reporting management system is anticipated to address many of the above mentioned issues thereby improving patient safety outcomes.

Confidentiality

All data in relation to the paper based adverse events will be kept within the Quality Department at all times and will be destroyed on completion of the research. All electronic data will be encryption password protected.

Hospital Research Ethics Approval

Approval for this research study will be obtained from the Study Site's Research Ethics Committee.

What will happen to the results of the study?

The researcher will present the findings of the study to the following employees of the Study Site
- The Chief Operations Officer
- The Director of Quality
- The Director of Nursing
- The IT Steering Committee and the Quality and Patient Safety Committee.

This study is strongly supported by the Study Site as the findings of this study may be used to improve patient safety, quality and hospital processes with the assistance of electronic reporting management systems.

The author does not intend to publish the findings of this study.

Procedure to use if assistance or advice is required
Please contact the researcher
Email:
Tel:

Your participation in this research study is completely voluntary.

Thank you for considering taking part in this research study

Appendix 9.15: Consent Form for the Participant

Research Site

Consent

Paper Based Adverse Event Reporting in the Study Site

I confirm that I have discussed the research study with the researcher. The nature and purpose of the study has been explained to me and I confirm that I understand it and what my involvement in the study will be. I have been given an opportunity to ask questions and clarify concerns.

I have been given adequate time to consider the study and my involvement in it. I understand that participation in the study is voluntary and that I can withdraw from the study at any point for any reason which I deem fit.

I understand that all information will be treated confidentially.

I agree to participate in this study to monitor the time taken for me to perform the tasks involved in the paper based adverse event reporting process.

_____   _____

Name of Participant   **Date**

_____   _____

Name of Researcher   **Date**