Promoting patient safety using Failure Mode and Effect Analysis (FMEA)

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June 2010

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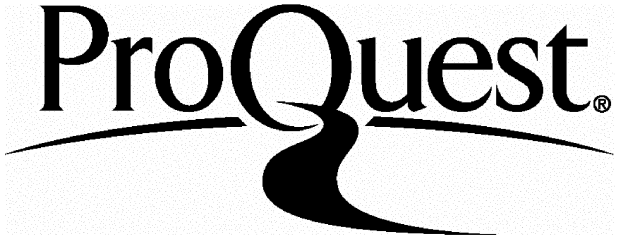

This thesis describes research conducted in The School of Pharmacy, University of London between October 2005 and December 2009 under the supervision of Professor Nick Barber and Professor Bryony Dean Franklin. I certify that the research described is original and that any parts of the work that have been conducted by collaboration are clearly indicated. I also certify that I have written all the text herein and have clearly indicated by suitable citation any part of this dissertation that has already appeared in publication.

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Acknowledgments

First and foremost I am thankful and grateful to God for giving me the strength and will power to complete my research and for surrounding me with the most amazing people during the last few years.

Firstly I am most grateful to my supervisors Professors Nick Barber and Bryony Dean Franklin for their invaluable guidance, support and encouragement throughout this thesis. I thank them for their enthusiasm for my research, for helping me clarify my ideas and reasoning and for enabling and facilitating my development and confidence as a researcher. Above all I thank them for believing in me and supporting me throughout all my little 'interruptions'. My sincerest thanks and appreciation.

Thanks to Ms Ann Jacklin, Service Lead for Pharmacy and Therapies at Imperial College Healthcare NHS Trust for her guidance and support especially when I was preparing for the hospital meetings.

Thanks to the infectious diseases pharmacists at Hammersmith and Charing Cross Hospital and for all the healthcare professionals who kindly agreed to participate in the research. Thanks are also due to everyone at the hospital for willingly allowing me to collect data on their wards and laboratory.

I am grateful to the Safer Patients Initiative Research Team at Imperial College Healthcare NHS Trust for giving me the opportunity to work with them and allowing me to analyse parts of their interviews and use the data for my thesis.

I am also grateful for the Overseas Research Student Award Scheme (ORS) for partly funding this research.

Enormous thanks to all my friends at the Department of Practice and Policy, especially Eman Al-Saeed (very special thanks to Eman for her help when my word document changed all my tables' formats!), Fatemah Alsaleh, Maisoon Ghaleb and

Yogini Jani. Thank you for your friendship- which means the world to me-, your support during the past few years and for all the good times (and of course for lending me Kleenex and your shoulders to cry on during the not-so-good times). May our friendship last forever and ever.

My greatest thanks must go to the two incredibly special people without whom I simply could not have got this far; my dad- Atef Shibl and mom- Omaima Ashry. Mom and dad I can never thank you enough for all your love, help, support and prayers. I am the person I am because of you and I hope I have made you proud.

Thank you to all my lovely family members for their moral support day in and day out and especially my lovely grandmother for her daily prayers and blessings.

My dearest husband, Ashraf: thank you so much for helping me chase my dream and turning it into a reality. Thank you for being there for me every step of the way, for your support and patience 24/7. For all the kind and comforting words when I doubted my abilities and you never did. Thank you for lovingly accepting that parts of our lives were on hold while I completed this thesis. You have been my prince in shining armour.

Finally to the most amazing gift God has sent me during my PhD, my son Yousef. Your smile has never failed to brighten my whole world. To all the times you have managed to cheer me up when things got tough- I love you with all my heart. Looking forward to hearing your comments when you read my thesis in 16 years time.

For my parents:
For loving me unconditionally and so much more...

For Ashraf:
For helping me chase my dream.

Abstract

During the last few years various important new initiatives have helped enhance the attention paid to patient safety. Healthcare organisations have been increasingly turning to human reliability techniques, such as Failure Mode and Effect Analysis (FMEA), to help them understand how and why errors or failures occur.

The aim of the thesis was to explore the use of FMEA within healthcare, in particular its validity and reliability. An extensive literature review regarding the application of FMEA within the healthcare system was first conducted. Following the literature review it was decided to test the reliability of FMEA by recruiting two multidisciplinary teams to conduct the same FMEA, in parallel, in order to compare their results. To explore the validity of FMEA, the team's FMEA results were compared to data collected from observational work, the hospital's incident report database, audits and additional data collected from the laboratory. In addition to this, a series of interviews conducted with healthcare professionals who have used FMEA around the UK were qualitatively analysed to identify their perceptions and experiences with FMEA. Finally, the use of clinical decision support systems (CDSS) for antibiotics was reviewed to determine whether or not some of the team's recommendations were feasible.

The literature review revealed that FMEA is relatively new in healthcare but its use has been supported by a number of patient safety organisations, particularly in the United States. Using a multidisciplinary team to map the process of care resulted in valid and reliable results. However, identifying failures within this process and scoring them accordingly indicated that FMEA's methodology is unreliable and not valid. FMEA results are very subjective and depend upon the specific multidisciplinary team involved. In addition to this, the interviews revealed that while participants thought FMEA was useful to identify potential failures, it was very subjective and lacked evidence for its validity and reliability. Finally the literature review conducted for the use of CDSS and antibiotics revealed that CDSS presents a promising future for optimising antibiotic use, however, it is difficult to generalise its success as most studies were conducted in the United States. In addition to this, the development and implementation of CDSS would require a lot of work, time and costs with no guarantee that its use will be supported by healthcare professionals

In conclusion, FMEA is a useful tool to aid multidisciplinary groups in mapping and understanding a process of care. However, it is not a valid or reliable tool for identifying the failures that can occur or scoring their severity, probability and detectability. Healthcare organisations should not solely depend on their FMEA results to ensure patient safety.

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Abbreviations

ASHRM: American Society for Health Risk Management

CDSS: Clinical Decision Support System

C&S: Cultures and Sensitivities

DOH: Department of Health

FMEA: Failure Mode and Effect Analysis

GP: General Practitioner

HACCP: Hazard Analysis and Critical Control Points

HAZOP: Hazard and Operability Study

HEART: Human Error Assessment and Reduction Technique

HFMEA: Healthcare Failure Mode and Effects Analysis

HRA: Human Reliability Analysis

HTA: Hierarchical Task Analysis

ICU: Intensive Care Unit

IHI: Institute for Healthcare Improvement

IOM: Institute of Medicine

ISMP: Institute for Safe Medication Practices

IV: Intravenous

JC: Joint Commission

JCAHO: Joint Commission on Accreditation of Healthcare Organizations

Kg: Kilogram

LDS: Latter Day Saints

µg: Microgram

mg: Milligram

MRSA: Methicillin Resistant *Staphylococcus aureus*

NHS: National Health Service

NPSA: National Patient Safety Agency

NPSF: National Patient Safety Foundation

PRODIGY: Prescribing Rationally with Decision Support In General Practice Study

RCA: Root Cause Analysis

RPN: Risk Priority Number

SHERPA: Systematic Human Error Reduction and Predication Approach.

SPI: Safer Patients Initiative

SPSS: Statistical Package for the Social Sciences

THERP: Technique for Human Error Rate Prediction

UK: United Kingdom

US/USA: United States of America

VA NCPS: Veterans Affairs National Center for Patient Safety

WHO: World Health Organization

Summary

Patient harm due to errors in healthcare is now a well-recognised and publicised phenomenon. During the past few years, research into patient safety has expanded beyond identifying error rates and reporting the kinds of errors that occur to exploring why these errors occur in the first place and how to prevent them. The use of human reliability analysis (HRA) techniques in different industries has been used to explain why errors or failures occur. HRA has been defined as the application of relevant information about human characteristics and behaviour to the design of objects, facilities and environments that people use. Over the past 40 years, a number of industries have embraced HRA as a solution to their safety problems. The nuclear industry was the first to develop and apply HRA, with other high risk industries such as aviation and aerospace, rail and automobile following (Lyons *et al,* 2004). In recent years, the healthcare sectors have been looking at HRA methods and other techniques widely adopted in industry, trying to transfer them into the medical domain. One such technique is Failure Mode and Effect Analysis (FMEA).

FMEA is a prospective risk assessment tool that helps promote patient safety by mapping out the process of care and then identifying the failures that may occur in this process in order to understand how and why errors or failures occur. FMEA has been widely used within the aerospace and automotive industry and has been gradually introduced within healthcare system since the early 1990s and is currently widely used in the United States. Following a literature search, it was concluded that the use of FMEA is relatively new and unexplored in the UK. Furthermore, there is no published data regarding the validity and reliability of the FMEA within healthcare.

The aim of this thesis is to explore the current use of FMEA within healthcare and to evaluate its validity and reliability within the healthcare setting. The thesis comprises six chapters.

Chapter 1 is an introduction to the research area, giving an overview of the definition of FMEA, its history and use in healthcare, and presents the literature review of the use of FMEA in healthcare. The aims and objectives of the thesis are stated at the end of chapter 1.

Chapter 2 focuses on testing the reliability of FMEA. In this chapter two multidisciplinary teams were recruited to conduct the same FMEA, in parallel, for the use of vancomycin and gentamicin within the hospital in order to compare their results and explore its reliability. Both groups described the process with five major steps: 1) starting vancomycin or gentamicin, 2) prescribing the antibiotics, 3) administering the antibiotics, 4) monitoring the antibiotics and 5) finally stopping or continuing the treatment. Although each group identified 50 failures, only 17 (17%) of them were common to both. Furthermore, the severity, detectability and risk priority number scores for both groups differed markedly resulting in their failures being prioritised differently.

Chapter 3 focuses on testing the validity of FMEA. This chapter is divided into four main sections including a) face validity, b) content validity, c) criterion validity and d) construct validity. The first section describes face validity of FMEA which was positive as both groups including the main steps identified by the researcher through

observations. Testing content validity of the FMEA was conducted by presenting the FMEA findings from the FMEA meetings conducted to other healthcare professionals. These healthcare professionals identified other potential failures within the process of vancomycin and gentamicin use. Furthermore, the FMEA groups failed to include failures related to omitted doses; yet these were the failures most commonly reported in the Trust's incidents database. Testing criterion validity of the FMEA was conducted by comparing the FMEA findings with data reported on the trust's incident report database and data collected from the laboratory. The results showed a negative correlation between the scores reported by the FMEA team and those reported on the hospital's incidents database as the FMEA team scored their severity and probability scores much higher than those reported using the database. There were also discrepancies between the probability of failures actually occurring within the laboratory and the probability of the monitoring failures as scored by the FMEA team. Finally the fourth section is about construct validity which was assessed by exploring the relevant mathematical theories involved in calculating the risk priority number (RPN). Each section includes its own methods and a brief discussion. The chapter concludes with an overall discussion of the results.

In chapter 4 healthcare professionals who have used or conducted an FMEA, within the UK, as part of the Safer Patients Initiative (SPI) programme, were interviewed. This chapter reports the participants' experiences and perception of FMEA. Themes were identified from 21 interviewees and included the perceptions and experiences of participants with the FMEA, validity and reliability issues and FMEA's use in practice. Both positive and negative opinions were expressed with the majority of the interviewees expressing constructive views towards FMEA in terms of it being a useful

tool particularly for mapping and identifying problems within a process of care. Other participants criticised FMEA for being subjective and lacking validity. In addition to this, the opinions of the multidisciplinary teams who participated in this study's FMEA (from chapter 2) are also reported.

Following the results of the previous three chapters and the recommendations of the FMEA team, a literature review was conducted for the use of clinical decision support systems (CDSS) and antibiotic use. This is presented in chapter 5. In this chapter randomised controlled trials as well as before and after trials of the use of CDSS and antibiotics were reviewed and critically appraised. The literature review showed that CDSS present a promising future for optimising antibiotic use and improving patient care, however more studies need to be conducted within different settings, since the majority of studies have been conducted in the United States. In addition to this, it is essential to clarify that CDSS have been proven to be useful and successful; however their development and implementation would require a lot of work, time and costs with no guarantee that its use will be supported by healthcare professionals and that specific failures or errors would be eliminated.

Each individual chapter includes a brief discussion of the findings. However chapter 6, as the final chapter, presents a discussion of the overall results, reports the relationship between reliability and validity and comments on the overall use of HRA techniques within healthcare. Suggestions for using FMEA in healthcare are also reported as well as areas for future research in this field. The thesis ends with a summary of the conclusions.

Chapter 1 Introduction

History of medicine:

2000 B.C.-Here, eat this root

1000 A.D.-That root is heathen. Here, say this prayer.

1850 A.D.-That prayer is superstition. Here, drink this potion.

1920 A.D.-That potion is snake oil. Here, swallow this pill.

1945 A.D.-That pill is ineffective. Here, take this penicillin.

1955 A.D.-Oops...bugs mutated. Here, take this tetracycline.

1960-1999 A.D. - More "oops".... Here, take this more powerful antibiotic.

2000 A.D.-The bugs have won! Here, eat this root.

Anonymous (WHO, 2002)

1.1 Background

Assuring patient safety, before any injury occurs, is the concern of all professionals involved in patient care. Patient safety is a cause of immense concern to the public because the traditional healthcare system's reliance on competent people to do the right thing has not fulfilled the intended purpose. Unfortunately, patients continue to experience adverse events and medical mishaps (Chiozza and Ponzetti, 2009).

Studies of medication errors and adverse events have been carried out for many years. The World Health Organisation (WHO) (2003) reports that as far back as 1850 a Hungarian physician linked transmission of infection to poor hand hygiene but failed to persuade his colleagues to alter their behaviour. However, not until the 1970s was any attempt made to provide an overview of the scale of harm or adverse outcomes. The rising scale of litigation in the 1970s and 1980s was an important stimulus to raising awareness of the problem of patient safety. This led to the development of risk management programmes in the United States (USA). Initially these programmes focused on legal and financial aspects but gradually evolved to address clinical issues. The first study to reveal the scale of harm to patients from healthcare was The Harvard Medical Practice study (Leape *et al*, 1991), which was initially commissioned to assess the potential for no-fault compensation in New York State (WHO, 2003). This study revealed that preventable adverse events occurred in 3.7% of inpatients and 7% of these suffered permanent disability and 14% of these patients died. Similar finding were reported from Colorado and Utah (Thomas *et al*, 2000); while an Australian study (Wilson *et al*, 1995) reported a 16.6% adverse event rate, where about half the cases were judged preventable. In the United Kingdom (UK), a review of patient records indicated a 10.8% adverse

event rate, with about half being preventable (Vincent *et al*, 2001). Emerging studies in Denmark (Schioler *et al*, 2001) and New Zealand (Davis *et al*, 2002) also report a relatively high rate of adverse events: around 10%.

During the last few years, several important initiatives have been set up to help enhance the attention paid to patient safety. Since the Institute of Medicine (IOM) in the USA released the report entitled 'To Err is Human: Building a safer healthcare system' in 1999, research in the field of patient safety, risk assessment and human errors has increased and became well established (Stelfox *et al*, 2006). Organisations such as the National Patient Safety Foundation (NPSF) in the USA, have also been promoting patient safety by drawing on research and practice from a number of different industries.

In the England, the Department of Health (DOH) commissioned a major report entitled 'An organisation with a memory' (2000), a report covering similar ground to the IOM report, but in a British context. This was followed by a second report titled 'Building a Safer NHS' (DOH, 2001). As well as other types of medical errors, this report explored the causes and frequency of medication errors, highlighted drugs and clinical settings that carry particular risks, and identified models of good practice to reduce risks. It included good practice recommendations in areas which were known to be error prone in order to help National Healthcare Service (NHS) organisations and professionals examine current practice to make medication safer for patients. The launch of the UK's National Patient Safety Agency (NPSA) in 2001 also brought an additional focus on safety, particularly the recording and learning from clinical incidents. Further examples of similar

initiatives have been set up in Canada, and several countries in Europe and Asia, in order to increase interest in research on patient safety and establish practical approaches to risk management (Woloshynowych *et al*, 2005). In 2002, the WHO also passed a resolution to establish a worldwide patient safety programme.

These landmark publications have made healthcare professionals realise that the risks associated with the administration of drugs are considerable and costs due to errors are high.

In the sixth report of the House of Commons Health Committee (2008-2009, p.22) it is stated that:

> *'The evidence, particularly from case note reviews, both in England and the internationally, indicates that the extent of medical harm is substantial, even on a conservative estimate and that much is avoidable. International studies suggest that about 10% of all patients who are admitted to hospital suffer some form of harm.'*

It has been estimated that 44,000-98,000 people die each year in hospitals in the USA as a result of medical errors. More people in the USA die in a given year as a result of medical errors than from motor vehicle accidents, breast cancer or AIDS (IOM, 1999). The IOM (1999) further reports that preventable medical errors cost between $17 billion and $29 billion per year. A substantial proportion of these medical errors, probably between 10% and 20%, are due to medication errors (Leape *et al,* 1991; Brennan *et al,* 1991) and are estimated to account for more than 7000 deaths in the USA annually (Guchelaar *et al*, 2005).

In the UK, it is estimated that 850, 000 patient safety incidents per year occur (DOH, 2000) with about as high as 25,000 resulting deaths (Report of The Bristol Royal Infirmary Enquiry, 2001). The cost per year of medication errors within the NHS in 2001 was estimated at £500 million, while adverse events due to medication errors were estimated by the NPSA in 2007 at £774 million per year.

Although many studies have highlighted the problems related to medication safety and reported incidents of error and harm; less focus has been accessible on solutions to enhance patient safety. The IOM report (1999) suggests that healthcare lags a decade or so behind other high risk industries in its approach to ensuring basic safety. Much of that which needs to be done in order to improve patient safety is already being done in other industries. However, the transfer of this type of knowledge is not automatic because health can not be considered as a mere 'product'. In addition to this, human factors, which encompass all those factors that can influence people and their behaviour, in the provision of healthcare may be responsible for some of the safety problems since practitioners are not computers, their ability to process multiple pieces of often contradictory information is limited, and of course human errors are often the result of processes beyond the conscious control of the professionals who make errors. Therefore, in order to prevent errors in healthcare we must understand the factors causing them (Marx and Slonim, 2003; Reason, 2000; Chiozza and Ponzetti, 2009).

In the next sections, the reasons why errors occur will be first discussed, followed by the introduction of techniques which have been used to identify errors and their causes. Two common techniques used in improving safety in healthcare will then be

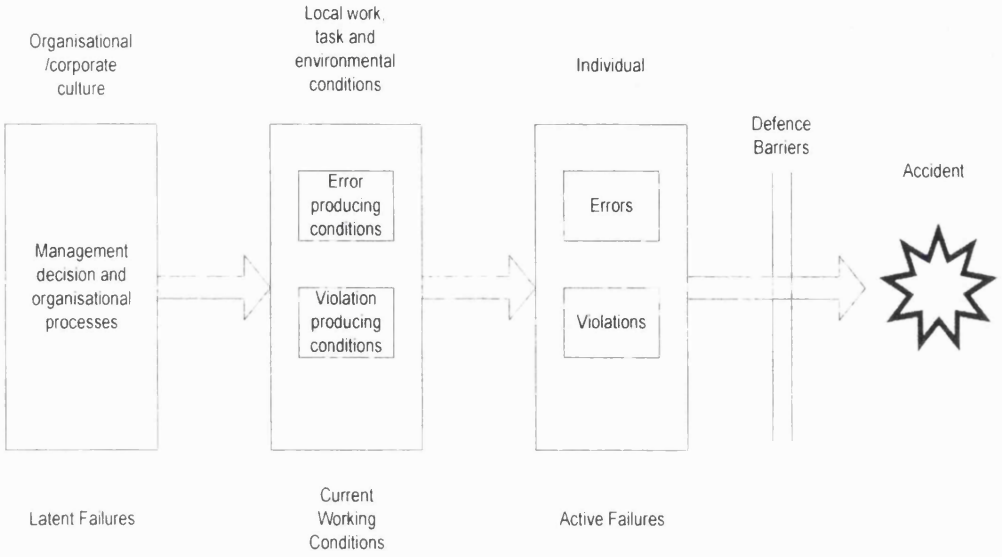
introduced. A brief discussion will be presented about retrospective techniques such as Root Cause Analysis (RCA); while the rest of the chapter will focus on a prospective technique, Failure Mode and Effect Analysis (FMEA).

1.2 Why do errors occur?

Taxis and Barber (2004) state that investigating the causes of errors is the first step towards error prevention, and Reason's Accident Causation Model (1990) has increasingly been used as a theoretical base to identify factors contributing to errors in medicine. Furthermore, one of the benefits of applying human error theory in medicine was that it led to the development of techniques like critical incident analysis and event reporting programmes (Vincent *et al,* 1993).

According to Reason (1990), humans contribute to accidents in two ways: through active failures or latent failures. Active failures are unsafe acts committed by those at the 'sharp end' of the systems (e.g. pilots, train drivers, surgeons, nurses). Active failures include both action slips and cognitive failures such as memory lapses and mistakes due to ignorance or mis-reading situations. Latent failures arise from frail decisions, usually taken within the higher sector of the organisation or within society at large. Their damaging consequences may lie dormant for a long time, becoming only evident when they combine with local triggers to breach the system's defenses (Reason, 1993). Figure 1 provides a schematic of the model.

Figure 1: Reason's (1993) Organisational Accident Causation Model (adapted from Taylor-Adams *et al*, 1999)



Historically, efforts of error prevention in healthcare have focused on training and motivating nurses and physicians so that they will not make any mistakes, as culture has used blame in an attempt to achieve an error-free performance (Leape, 1994). However, more recently, error has been viewed as being caused by an individual or as the result of ineffective systems. Reason (2000) makes this distinction between the person approach, which attributes errors to individuals, in contrast to the systems approach, which focuses on the conditions under which individuals work. Furthermore, Janofsky (2009) notes that improving systems, rather than focusing on individual provider mistakes, is the most effective way to reduce errors.

The use of human reliability analysis (HRA) techniques in different industries has been used to explain why errors or failures occur. HRA has been defined as the application of relevant information about human characteristics and behaviour to the design of objects, facilities and environments that people use (Lyons *et al*, 2004). HRA may be used retrospectively, in the analysis of incidents that have

already occurred, or prospectively, for potential incidents or failures in a system. Over the past 40 years, a number of industries have embraced HRA as a solution to their human factor and safety problems or have been required to apply them due to public or government pressure. The nuclear industry was the first to develop and apply HRA, with other high risk industries such as aviation and aerospace, rail and automobile following (Lyons *et al,* 2004).

1.2.1 Analysis of accidents

Analysis of accidents in different industries including medicine have led to a better understanding of accident causation, with less focus on the individual who makes an error and more focus on the pre-existing organisational factors that provide the conditions in which errors occur (Reason, 1990). This led to the human factor approach which is defined as the study of the interrelationships among humans, the tools they use and the environment in which they live and work (Schneider, 2002). These human factors may appear as components of the active or latent failures (Hambleton, 2005).

Industry has operationalised the safety culture and attitudes in a number of widely used models, tools and HRA techniques which can be subdivided into prospective, retrospective and organisational learning techniques. Prospective approaches are relatively new in healthcare, while retrospective approaches are used to describe and analyse actual incidents and their root causes and have been around much longer. Finally, the IOM report (1999) and the UK's 'Organisation with a memory' report (DOH, 2000) underscored the essential mechanisms for organisational

learning and the value of event and 'near miss' reporting mechanisms. These tools allow large databases to be created quickly but are also instruments to change the medical culture by involving and relying upon all levels of staff to provide input by voluntary sharing of experiences (van der Schaaf, 2002).

However, although HRA falls within the field of human factors and the techniques have been used for decades to assess the effect of human behavior on critical systems such as aerospace, defense systems, and nuclear power applications, the use of these techniques in medicine has received competitively less attention in the literature. Because human error has been identified as a major contributing cause to patient injury and death, HRA techniques have seen increased attention (Israelski and Muto, 2004).

In recent years, the healthcare sectors have been looking at HRA methods and other techniques widely adopted in industry, trying to transfer them into the medical domain (Trucci and Cavallin, 2006). Efforts to improve patient safety have incorporated the usage of retrospective techniques, such as Root Cause Analysis (RCA), and prospective techniques, such as Failure Mode and Effects Analysis (FMEA), in order to identify failures or errors within healthcare processes and either avoid their recurrence or to prevent potential errors from occurring in the first place.

In the next section, retrospective techniques such as the RCA will be briefly introduced before focusing the rest of the chapter on the prospective technique,

FMEA, and its use in healthcare. The chapter will conclude with the implications for this thesis and its aims and objectives.

1.3 Retrospective and prospective techniques

During the last few years, retrospective techniques have been increasingly used in healthcare (Lyons, 2009). These are techniques used to describe and analyse actual incidents after they have already occurred. In the USA the most familiar retrospective technique is the RCA (Vincent, 2004).

RCA is a systematic investigation approach that makes use of information collected during an assessment of an accident to determine underlying factors or deficiencies that led to the accident (Latino, 2000). It is a structured analytic method used primarily to examine the underlying contributors to an adverse event or condition (LaPietra *et al*, 2005). The RCA involves bringing a team together to recreate a detailed chronology of the steps that gave rise to an adverse event or incident. The contributory factors that led to the incident are charted, followed by identifying the deeper root causes that led to an incident. For every event there will be likely to be a number of contributory factors and for each contributory factor a number of root causes. Finally the team is expected to generate recommendations for corrective actions (Dhillon, 2003; Hambleton, 2005).

RCA allows healthcare professionals to attain an understanding of the factors that led to an undesirable incident and acts as a learning tool for others. However, RCA is only applicable to single events and only provides a retrospective analysis of the factors that lay behind the consequent event. RCA's main limitation is that it is

conducted for a single specific incident or cause of harm instead of a more general approach across an organisation and as a result it can be blind to events that intervene across organisational boundaries (Wreathall and Nemeth, 2003). Furthermore, some criticise RCA's use because it represents uncontrolled case studies, and it is often impossible to show a statistical correlation between cause and outcome (Wald and Shojania, 2001; Dhillon, 2003).

RCA is common in medicine because of the number of adverse events that must be explained (Senders, 2004). However, recently, there has been growing awareness that more proactive or prospective analysis methods, such as those that have been used in other high hazard industries like nuclear power and aerospace, provide additional benefits for improving quality and safety in healthcare (Battles *et al*, 2006). Prospective analyses of systems have been increasingly explored in healthcare on the reasonable argument that it is better to examine safety proactively and to prevent incidents before they happen (Vincent, 2004).

Proactive methods are more readily accepted by clinicians because they call for hope and exploit professional competences through a positive approach to problems by focusing on the examination of the entire process, thus anticipating major adverse events and implementing changes to prevent them from occurring (Chiozza and Ponzetti, 2009). For correct risk management, an organisation must promote the awareness that the human factor can not be completely prevented from causing adverse events and that operators must minimise the chances of making errors (Morelli *et al*, 2007).

While healthcare has increased its awareness of the retrospective safety assessment techniques, such as RCA, adoption of the corresponding prospective safety assessment techniques has been slow and sporadic (Lyons, 2009). Despite many decades of acceptance of the HRA techniques in other industries, Lyons *et al* (2004) found only seven techniques had been published as being used for healthcare application, with FMEA being the most commonly applied.

FMEA is stated to be the most widely known tool that incorporates prospective methods for identifying potential failure and their causes (McDermott *et al*, 1996).

1.4 Failure Mode and Effect Analysis (FMEA)

In this section the definition of FMEA, its history and its use in healthcare are described. This is followed by a description of Healthcare FMEA (HFMEA) and a brief summary of the differences and similarities between traditional FMEA and HFMEA.

1.4.1 What is FMEA?

FMEA is defined as a team-based, systematic, proactive technique that is used to prevent process and product problems before they occur (VA NCPS, 2005). It assumes that no matter how knowledgeable or careful people are, failures may still occur in some situations. The focus is on *what* could allow the failure to occur rather than *whom*. Ideally, FMEA should help prevent failures from occurring but if a particular failure cannot be prevented, then it focuses on defences that can be put in place to prevent the failure from reaching the patient, or, in the worst case, lessen

its effects. It addresses problems people have actually seen happen or errors they have almost made and it is claimed to be useful for capturing incidents that can occur and that generally may not captured any other way (JCAHO, 2005).

Reiling *et al* (2003) states that FMEA is a systemic group of activities intended to do three things:

1. Recognise and evaluate the potential failures of a product or process and the effects of those failures.
2. Identify actions that could eliminate or reduce the chance of the potential failures occurring.
3. Document the entire process.

The NPSA (2004), in the UK, explains that FMEA identifies the following factors:

- **Process:** how is care expected to be delivered?
- **Failures that may occur:** what could go wrong?
- **Contributory factors or causes:** why would the failure happen?
- **Effect:** what are the consequences of the failure?

1.4.2 History of FMEA

The history of FMEA dates back more than 40 years. The first formal FMEAs were conducted within the aerospace industry in the 1960s. In contrast to other failure prevention methods, FMEA was reported to use universally understandable terms that were free of industry- specific jargon (McDermott *et al*, 1996). Also, individuals who had limited technical or systems training could participate productively in multi-disciplinary FMEA teams. As these attributes of FMEA became known, leaders in the chemical and mechanical engineering industries also began to adopt this approach (Duwe *et al*, 2005).

The automotive industry then brought FMEA into the mainstream. A task force developed jointly by Chrysler, Ford, and General Motors required the application of FMEA to identify and address failure modes for the manufacture of automobiles (McDermott *et al*, 1996). However, it was only introduced into healthcare since the early 1990s.

1.4.3 Introducing FMEA into healthcare

In the mid-1990s, the use of FMEA was recommended by the US Institute for Safe Medication Practices (ISMP)[1] to ensure a proactive posture in planning medication use processes, so that fatalities or debilitating situations due to medication errors could be prevented (Cohen *et al*, 1994; Duwe *et al*, 2005). In 2001, the USA's Veteran's Administration (VA) National Centre for Patient Safety (NCPS)[2] specifically designed the Healthcare FMEA (HFMEA) tool for risk assessment in the healthcare field and deployed the techniques and tools in all of its 163 healthcare centres (Esmail *et al*, 2005).

[1] The Institute for Safe Medication Practices (ISMP), based in the USA, is a nonprofit organisation devoted to medication error prevention and safe medication use. ISMP represents over 30 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. The organisation is known and respected worldwide as the premier resource for impartial, timely, and accurate medication safety information (http://www.ismp.org/).

[2] The Department of Veterans Affairs (VA) in the US was established on March 15, 1989, succeeding the Veterans Administration. It is responsible for providing federal benefits to veterans and their families. The NCPS was established in 1999 to develop and nurture a culture of safety throughout the Veterans Health Administration (http://www.va.gov/about_va/).

Implementations of HFMEA by the VA NCPS caught the attention of The Joint Commission on Accreditation of Healthcare Organisations (JCAHO)[3] and in 2001 the JCAHO revised its accreditation standards to include a requirement that healthcare organisations perform, annually, at least one proactive risk assessment on a high-risk process (Duwe *et al*, 2005). Completion of one proactive risk assessment project annually, using FMEA or a similar process, is also now a required organisational practice for accreditation by the Canadian Council on Health Services Accreditation.

While initially the JCAHO and the Canadian Council on Health Services Accreditation did not mandate that a specific proactive risk assessment methodology, such as the traditional FMEA, be used, they did outline a generic process for identifying and addressing failure in healthcare processes using the same basic steps as the industrial FMEA.

The FMEA tool has also been subsequently recognised by the American Society for Healthcare Risk Management (ASHRM). In an effort to globally share the perceived merits of this process, a video, instructional compact discs and worksheets on the use and application of HFMEA has been sent to every hospital

[3] At the time of the study the Joint Commission on Accreditation of Healthcare Organisations was known as the JACHO. In 2008, the JCAHO was changed to Joint Commission (JC). In this thesis the Joint Commission will be referred to as the JCAHO, as the FMEA guidelines were published in 2005 under the name of the JCAHO. The Joint Commission was founded in 1951and seeks to continuously improve health care, in the USA, for the public, in collaboration with other stakeholders, by evaluating health care organisations and inspiring them to excel in providing safe and effective care of the highest quality and value. In response to increasing public attention to the problem of medical errors and patient injuries, JC strengthened its commitment to patient safety and by the beginning of 1996 JC introduced several new standards that were intended to support continuous improvement in the safety of care provided to the public.

chief executive officer in the USA to be shared with individuals and risk managers responsible for patient safety (ASHRM, 2002; Esmail *et al*, 2005). Furthermore, the USA's influential Institute for Healthcare Improvement (IHI)[4] and ISMP have also supported FMEA's use. The IHI provides a tool to aid FMEA development and allows others to share their FMEA analyses online.

In the UK, FMEA's application in healthcare is not as popular as in the USA. It became more widely known, only in 2004, when the Health Foundation, an independent charity that aims to improve health and the quality of health care for the people of the UK, in collaboration with the IHI, launched the Safer Patients Initiative (SPI). The SPI was a programme launched in 24 acute trusts in the UK aimed to improve patient safety in hospitals. During the SPI, participants were expected to complete an FMEA on a core process in medicines management and report its outcome (Health Foundation, 2009). This is described in more detail in chapter 5.

In addition to this, in 2004, the UK's NPSA published a report titled 'Seven steps to patient safety for primary care'. The third step in the report was to integrate risk management activities and FMEA was identified as a useful risk assessment for primary care organisations. In spite of its inclusion in the SPI and the NPSA's recommendations, FMEA's use in healthcare is not considered to be widely publicised in the UK and its use is not incorporated into the health system as it is in the USA.

[4] The IHI is an independent not-for-profit organisation helping to lead the improvement of health care throughout the world. Founded in 1991 and based in the United States, IHI works to accelerate improvement by building the will for change, cultivating promising concepts for improving patient care, and helping health care systems put those ideas into action (http://www.ihi.org/ihi).

1.4.4 FMEA steps

Traditional FMEA is composed of five main steps (JCAHO, 2005; VA NCPS, 2005; Wetterneck *et al*, 2006):

STEP 1: ***Defining the FMEA topic:*** The FMEA topic is usually a high-risk process. However the scope of an FMEA project should be limited and clearly defined so that participants have a clear idea of what is being studied and so that the FMEA can be completed in a reasonable amount of time.

STEP 2: ***Assemble the team:*** An FMEA team should be multidisciplinary. This ensures that different perspectives or viewpoints are taken into consideration. The team should include individuals with fundamental knowledge of the particular process involved.

STEP 3: ***Graphically describe the process and identify the failures that may occur***: Flowcharts are the most commonly used tool for helping teams understand the steps in a process. Once the process is mapped out, the failures that could occur in each step of the process are identified and causes and effects of these failures are listed.

STEP 4: ***Calculate the risk priority number (RPN):*** After each failure is identified, a severity, probability and detectability score for the failure is obtained. This is done using a predefined scoring scale provided for the multidisciplinary team.

- Severity relates to the seriousness of the injury or impact that could ultimately result if a failure occurs.

- The probability of occurrence is the likelihood that something will happen, i.e. what is the likelihood that this failure will occur?
- Detectability is the degree to which something can be discovered or noticed, i.e. if this failure occurs, how likely is it to be detected before an injury occurs?

Scores are usually ranked either on a 1 to 5 scale (appendix 1) or a 1 to 10 scale (appendix 2)

The risk priority number (RPN) is then calculated for each failure by multiplying the severity, probability and detectability scores. The severity, probability and detectability scores may be subjective from the participants' experience and knowledge or based on data from audits and research studies.

STEP 5: ***Actions and Outcome Measures:*** The team then makes recommendations to decrease or eliminate the failure modes. These recommendations should be then implemented and the FMEA process may be repeated.

The above three FMEA steps are recorded on an FMEA worksheet such as that shown in figure 2

Figure 2: Example of an FMEA worksheet

Process step	Sub process	Failures	Causes	Effects	Severity scores	Probability scores	Detectability scores	RPN (SxPxD)	Recommended actions

1.4.5 Healthcare Failure Mode and Effects Analysis (HFMEA)

HFMEA was developed in the summer of 2001 by the VA NCPS after they examined existing proactive HRA models from other industries. The VA NCPS reviewed two proactive techniques that have been successfully used in other industries; these were the FMEA and the HACCP (Hazard Analysis and Critical Control Points)[5] (Food and Agriculture Organization of the United Nations, 2006). The VA NCPS included concepts from the FMEA model as well as the HACCP model to form HFMEA. In particular, the use of the decision tree was adapted from the HACCP, while the bulk of the HFMEA was adapted from the traditional FMEA. The HFMEA involves five basic steps in which the first three steps are exactly the same as with the traditional FMEA and include identifying a topic, recruiting a multidisciplinary team, graphically describing the process and identifying the failures. The main difference between the two lies in the fourth step which involves identifying scores for the failures. HFMEA only includes severity and probability scores. Theses scores are described using a 4-point descriptive scale (appendix 3). Once the severity and probability are determined, the hazard score is obtained from a Hazard Scoring Matrix developed by the VA NCPS (appendix 4). After the hazard score is determined the HFMEA Decision Tree (appendix 5), adapted from HACCP, is used to determine whether the failure identified warrants further action on the basis of a lack of detectability, criticality and absence of effective control measures. This decision tree serves as a triaging function to identify areas where the team needs to mitigate vulnerabilities and areas not

[5] The HACCP is a systematic approach to the identification, assessment and control of hazards. It was developed by the National Advisory Committee on Microbiological Criteria for Foods for the US Department of Agriculture. It involves 7 steps which include: 1-conducting a hazard analysis, 2-Identifying critical control points, 3-establishing critical limits, 4-establishing monitoring procedures, 5-establishing corrective actions, 6-establishing verification procedures and finally 7-recored keeping and documentation.

needing attention because they are not critical, they are highly detectable or they already have effective control measures. Finally, as with the traditional FMEA, the final step includes setting an action plan for those failures that need attention. The last three steps of HFMEA are recorded on the HFMEA worksheet (appendix 6). The VA NCPS claims that HFMEA is conceptually easier to apply than the traditional FMEA because of its definitions and algorithms (DeRosier *et al*, 2002). Tables 1 and 2 present the main similarities and differences between FMEA and HFMEA.

Table 1: The five basic steps of FMEA/HFMEA

(NPSA, 2007; VA NCPS, 2005; Wetterneck *et al,* 2006). The main difference between the two is highlighted in step 4

STEP 1: Defining the topic: The topic is usually a high-risk process.
STEP 2: Assembling the team: An FMEA/HFMEA team should be multidisciplinary.
STEP 3: Graphically describing the process using flowcharts and identifying the failures that occur along with their causes and effects.
STEP 4: Calculating the risk priority number (RPN) for FMEA (by multiplying the severity, probability and detectability scores) or hazard analysis for HFMEA (by multiplying severity and probability using the Hazard scoring matrix and then using the HFMEA decision tree).
STEP 5: Actions and outcome measures: The team makes recommendations to decrease or eliminate the failure modes.

Table 2: Summary of similarities and differences between FMEA and HFMEA*

Concepts	FMEA	HFMEA
Team membership	YES	
Diagramming process	Flowcharts	
Brainstorming and identifying failures	YES	
Causes of failures	YES	
Effects of failures	YES	NO
Worksheet	FMEA worksheet (figure 2)	HFMEA worksheet (appendix 6)
Scoring failures	Severity, probability and detectability scores (appendix 2)	Hazard Scoring Matrix including severity and probability scores only (appendix 4)
Prioritising failures	Risk Priority Number (RPN)	Decision Tree (appendix 5)
Actions and outcomes	YES	

*** Adapted from: Trucco and Cavallin, 2006; DeRosier *et al*, 2002**

FMEA/HFMEA appears to be a popular HRA tool and its use has been promoted within healthcare by a number of patient safety organisations following the example of other high risk industries. A literature review, described below, was conducted to investigate the use of FMEA/HFMEA within healthcare.

1.5 Literature review

This section now reviews the literature on the use of FMEA/HFMEA in healthcare. The method of the literature review conducted will first be described. This will be followed by the results and a brief discussion which will include the study settings,

the topics studied and the steps followed. Finally the implications for the present research will be reported.

1.5.1 Methods

A systematic search of studies related to the use of FMEA in healthcare was performed using the following databases:

- Medline including Medical Subject Heading (MeSH) terms (1966-July 2009)
- EMBASE (Excerpta Medica, 1980-July 2009)
- International Pharmaceutical Abstracts (IPA, 1970-July 2009)
- British Nursing Index (BNI, 1985- July 2009)
- Cumulative Index to Nursing and Allied Health Literature (CINAHL, 1981-July 2009)
- Websites www.sciencedirect.com and www.proquest.com containing full text journals were also searched.

The following keywords were used: (Failure mode and effect(s) analysis), (Healthcare failure mode and effect(s) analysis), (HFMEA), (FMEA), (human reliability techniques) (human reliability analysis) and (risk assessment techniques).

These keywords were combined with the following terms:
(health), (healthcare), (hospital(s)), (patient(s)) or (reliability), (validity) and (patient safety).

Any research paper relating to the use of FMEA/HFMEA within the healthcare setting was retrieved and the reference sections of all retrieved articles were

searched for any further relevant articles. Any articles not in the English language were excluded.

In addition to this, several websites were searched including:

- The JC http://www.jointcommission.org/PatientSafety/ including their journals' websites: Joint Commission Journal on Quality (http://www.jcrinc.com/Periodicals/THE-JOINT-COMMISSION-JOURNAL-ON-QUALITY-AND-PATIENT-SAFETY/903/) and Safety and Joint Commission Perspectives on Patient Safety (http://www.jcrinc.com/The-Joint-Commission-Perspectives-on-Patient-Safety/)
- NPSA (www.npsa.nhs.uk)
- VA NCPS (www.patientsafety.gov/)
- NPSF (www.npsf.org/)
- FMEA Info Centre Home page (www.fmeainfocentre.com/)
- IHI (www.ihi.org)
- ISMP (www.ismp.org/)

1.5.2 Results

After the removal of duplicates, the keywords produced 638 hits. Only studies that have used FMEA/HFMEA in relation to healthcare and patients were included. All hits were scanned for relevance and irrelevant studies reporting the use of FMEA in other industries such as engineering, automotive, food manufacturing, marketing and other industries were excluded. Abstracts and articles not in English language were also excluded. In total, 121 articles were relevant to the use of

FMEA/HFMEA in healthcare, of which 56 were research papers and 65 were reviews.

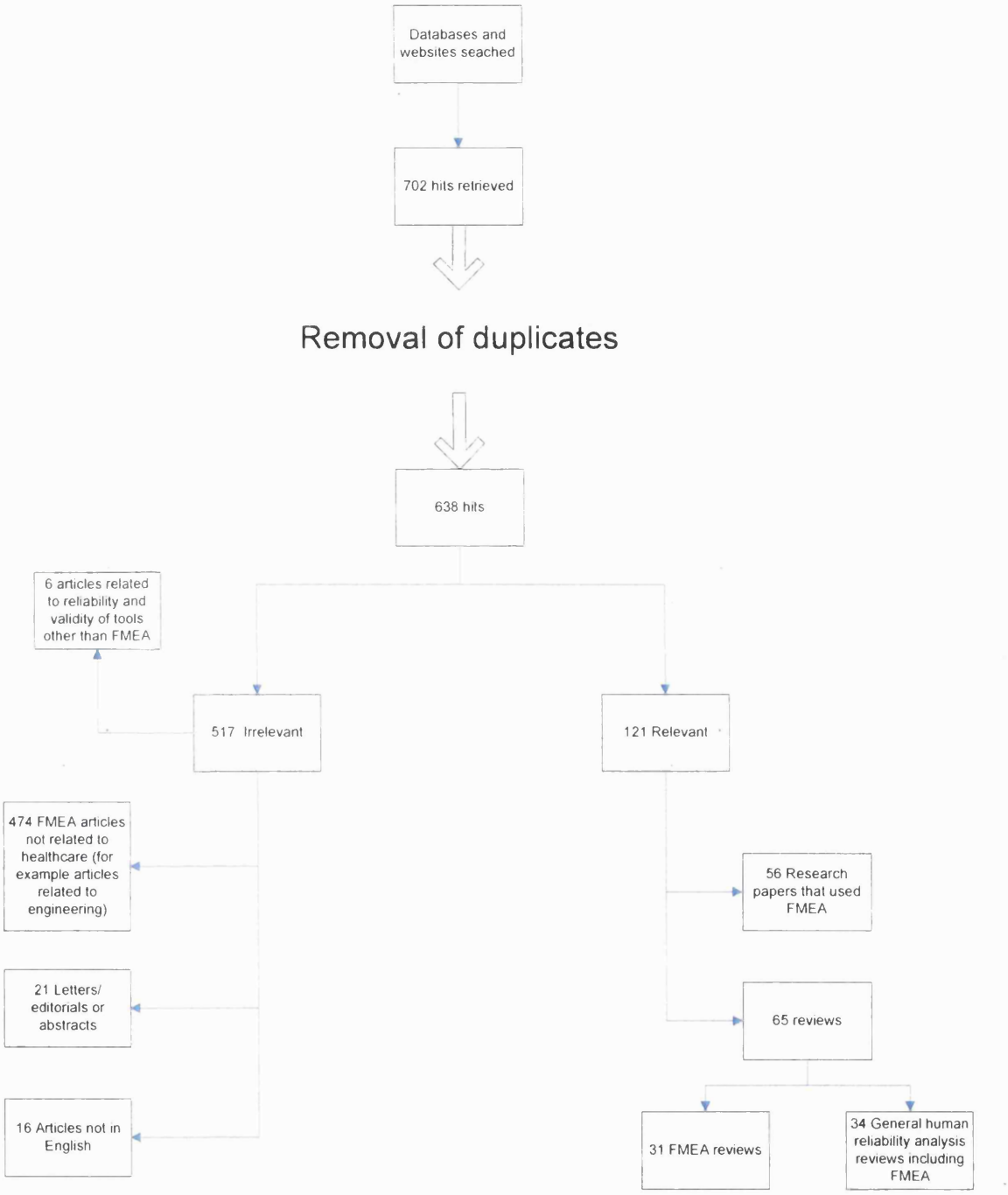
The reference lists of all 121 articles were reviewed to identify other relevant studies; no additional papers were identified but three books were retrieved as a general guidance and reference for FMEA, one of which was relevant to the use of FMEA in healthcare. They were:

1. The Basics of FMEA by McDermott *et al* (1996)
2. Failure Mode and Effect Analysis: FMEA from theory to execution by Stamatis (2003)
3. Failure Mode and Effects Analysis in Healthcare by the JCAHO (2005)

Searching the relevant websites did not reveal any further articles but only guidelines and recommendations for the use of FMEA/HFMEA. Figure 3 summarises the results of the search.

The keywords 'reliability' and 'validity' did not yield any studies or reviews related to the use of FMEA/HFMEA in healthcare.

Figure 3: Summary of literature search results



The next section summarises the 56 research studies retrieved. The settings and objectives for the use of FMEA/HFMEA in these papers will be first described. The choice of FMEA approach will then be reported along with details about how the FMEAs/HFMEAs were conducted. Each section will be followed by a brief discussion. Finally the outcomes of the FMEA/HFMEA and reported advantages and disadvantages from the authors' perspectives will be reported. A summary of all the research papers included in the literature review can be found in appendix 7.

1.5.2.1 Studies' settings

The majority of the studies were conducted in the USA (36 studies, 64%). This is not surprising or unexpected since the use of FMEA/HFMEA in healthcare has been promoted by American bodies and in particular the JCAHO. Table 3 presents the countries which have reported the use of FMEA/HFMEA.

Table 3: Countries reporting the use of FMEA/HFMEA

Countries	Number of studies (percentage)
United States	36 (64%)
United Kingdom	3 (5%)
Canada	3 (5%)
Switzerland	3 (5%)
The Netherlands	3 (5%)
Italy	2 (4%)
Australia	2 (4%)
Brazil	1 (2%)
Germany	1 (2%)
France	1 (2%)
New Zealand	1 (2%)
Total	56 (100%)

The majority of studies were conducted only in secondary care (35, 63%). Only one study was based in primary care (Singh *et al*, 2004) and one in a care home (Kovner *et al*, 2005). One study was conducted between both the primary care and secondary

care setting (Habraken *et al*, 2009). Three studies were conducted in tertiary specialist hospitals (Wetterneck *et al*, 2004; Wetterneck *et al*, 2006; Stanton *et al*, 2007) while two others were conducted in laboratories (Capunzo *et al*, 2004; Van Leeuwen *et al*, 2009). Finally three studies did not specify where the FMEA was used (Wehrli-Veit *et al*, 2004; Uslan *et al*, 2004; Jeon *et al*, 2007).

There are no restrictions or limitations to where FMEA can be applied and used. It is promoted as a process that is widely applicable in a variety of settings especially since it is tool that is free from industry-specific jargon (McDermott *et al*, 1996). Its use in secondary care is more common than primary care, perhaps due to the steps comprising the FMEA. Hospitals may have more data regarding adverse incidents and errors from audits or incident report systems, and identifying high risk topics is usually based on available data or incidents occurring. Furthermore, FMEA has been used to identify risks in new processes or before the implementation of new technologies which are usually piloted in hospitals. In addition to this, FMEA's second step involves recruiting a multidisciplinary team and patient care in hospitals is based on interdisciplinary team work rather than primary care where the patient is usually only seen by the general practitioner (GP) or family doctor or nurse.

1.5.2.2 FMEA or HFMEA

Both FMEA and HFMEA have been used in healthcare. The literature review identified eight studies (14%) that used the HFMEA. Since the literature review did not identify any studies testing or exploring the validity or reliability of either method, it was not possible to determine which method produced more valid or

reliable results. Arguments for the use of HFMEA include that it is conceptually easier to apply because its definitions and algorithms were specifically developed for use in healthcare (DeRosier *et al,* 2002). However, it has been criticised for using a limited hazard matrix scoring (Wetterneck *et al*, 2006; Jeon *et al*, 2007). Furthermore, HFMEA team members have stated that the HFMEA scoring method does not allow for adequate differentiation of probability, severity and detectability scores and therefore made the prioritisation of failures and the ability to follow the hazard score over time for improvement difficult (Wetterneck *et al*, 2004). On the other hand, arguments for the use of FMEA in the literature include that is has been previously used successfully in other industries (Spath, 2003; JCAHO, 2005; Reid, 2005; Paparella, 2007) and it includes the detectability scores, which means that the quantitative analysis combines three complementary factors (Bonnabry *et al*, 2005; Bonnabry *et al*, 2008).

Since there is no evidence for the use of either FMEA approaches, some studies have combined elements from FMEA as well as HFMEA (Gering *et al,* 2005; Wetterneck *et al*, 2006; Day *et al*, 2006; Day *et al*, 2007; Redfern *et al*, 2009). Others have modified the steps for FMEA or HFMEA to meet their requirements and needs (Singh *et al*, 2004; Lenz *et al*, 2005; Kovner *et al*, 2005; Coles *et al*, 2005; Kimchi-Woods and Shultz, 2006). From an organisational point of view, this flexibility in its use is advantageous as the FMEA tool can be tailored to meet a given organisation's needs. However, this clearly violates the concept of reliability in relation to its use. If it is modified according to each hospital's needs then there is no guarantee that the results obtained are accurate or consistent. In spite of the VA NCPS's attempt to create a modified FMEA specifically for healthcare, its use has

not been widespread. This perhaps may be an indicator that neither technique is perceived to be ideal for use in healthcare.

In this thesis the traditional/industrial FMEA will be referred to as FMEA only as the majority of the guidelines retrieved were relevant to the traditional/industrial FMEA and not HFMEA. Where relevant, HFMEA will be specified.

1.5.2.3 FMEA topics and types of studies

Of the 56 studies, only three studies (5%) were qualitative, reporting the participants' opinions as well as challenges faced conducting an FMEA/HFMEA (Wetterneck *et al*, 2004; Wetterneck *et al*, 2009; Habraken *et al*, 2009). The remaining studies reported the use of FMEA/HFMEA for different topics and purposes. JCAHO (2005) states that, in theory, almost any healthcare process or sub processes could benefit from FMEA but organisations should aim to focus on high-risk patient care processes first. According to JCAHO (2005), high risk topics have one or more of the following characteristics: variable input, complexity, lack of standardisation, dependence on human intervention and time constraints. However, besides choosing a high risk topic it is essential to make sure the FMEA is manageable. It is important to select a process that people are interested in fixing and at the same time to make sure the scope of the project is limited and clearly defined so participants have a clear idea what's being studied and so that meetings are not overly long (JCAHO, 2005). Table 4 summarises the topics for which FMEA/HFMEA has been used in healthcare.

Table 4: Uses of FMEA/HFMEA in healthcare studies

Topics (n: total number of studies)	Sub topics	Studies[6]
1. Medication- related topics and blood (n: 20)	1.1 Intravenous drugs (IV) (n: 6) • Potassium chloride • Other medication • Labeling of IV drugs	• Esmail *et al.* 2005; Fletcher, 1997 • Adachi & Lodolce, 2005; Bonnabry *et al.* 2005 • Jeon *et al.* 2007; Kimchi-Woods and Shultz, 2006
	1.2 Blood- related topics (n:5) • Transfusion • Donation • Blood & haemodynamics supply	• Stanton *et al.* 2007; Coles *et al.* 2005; Burgmeier, 2002 • Lenz *et al.* 2005 • Morelli *et al.* 2007
	1.3 Use of chemotherapy (n: 4)	Robinson *et al.* 2006; Van Tilburg *et al.* 2006; Kozakiewicz *et al.* 2005; Kunac and Reith, 2005
	1.4 Other medication-related processes (e.g. prescribing, administering of drugs) (n: 3)	Nickerson *et al.* 2008; Kovner *et al.* 2005; Williams and Talley, 1994
	1.5 Delivery of drugs (n:2)	Apkon *et al.* 2004; Coles *et al.* 2005
2 Use or implementation of new technology/ service (n: 8)	2.1 Computerised prescriber order entry (n:2)	Bonnabry *et al.* 2008; Kim *et al.* 2006
	2.2 Outpatient antibiotic therapy (n:1)	Gilchrist *et al.* 2008
	2.3 Bar coding (n:1)	Koppel *et al.* 2008
	2.4 Using dosing windows for drug administration (n:1)	Riehle *et al.* 2008
	2.5 Electronic medical records (n:1)	Singh *et al.* 2004
	2.6 Point-of-care testing (n:1)	Nichols *et al.* 2004
	2.7 Health informatics (n:1)	Win *et al.* 2004

[6]Some studies have conducted more than one FMEA/HFMEA on different topics; these studies have been mentioned more than once depending on the topic.

Table 4: Continued

Topics (n: total number of studies)	Sub topics	Studies[7]
3 Use of medical devices (n:7)	3.1 Cardiac related devices (n:2)	Florence and Calil, 2006; Wehrli-Veit *et al*, 2004
	3.2 IV pumps (n:2)	Wetterneck et al, 2006; Fechter & Barba, 2004
	3.3 Others (n:3)	Van Leeuwen *et al*, 2009; Ford *et al*, 2009; ; Uslan *et al*, 2004
4 Processes of patient care (n:10)	4.1 Prevention of patient falls (n:3)	Coles *et al*, 2005; Weeks *et al*, 2004; Gowdy &Godfrey, 2003
	4.2 Others (psychiatric observations, registration of trauma patients, management of sepsis, administration of contrast media, contamination of corneas, care of the obese, dialysis) (n:7)	Janofsky, 2009; Day *et al*, 2007; Marwick *et al*, 2007; Ouellett-Piazzo *et al*, 2007; Builles *et al*, 2006; Cheung *et al*, 2006; Day *et al*, 2006
5 Hospital design or integration (n:3)		Nickerson *et al*, 2008; Gering, 2005; Reiling *et al*, 2003
6 Laboratory-related processes (n:2)		Saxena *et al*, 2005; Capunzo *et al*, 2004
7 Comparing new and old systems (n:2)	7.1 Centralisation or decentralisation of pharmacy (n:1)	• Bonnabry *et al*, 2006
	7.2 Drug distribution systems (n:1)	• McNally *et al*, 1997
8 Topics related to healthcare professionals (n:4)	8.1 Use of equipment (n:1)	Linkin *et al*, 2005
	8.2 Use of guidelines (n:1)	Dawson *et al*, 2005
	8.3 Communication between healthcare professionals (n:1)	Redfern *et al*, 2009
	8.4 Nurses' response to alarms (n:1)	Semple and Dalessio, 2004

[7] Some studies have conducted more than one FMEA/HFMEA on different topics; these studies have been mentioned more than once depending on the topic.

However, not all the published studies included in table 4 focused on reporting the use of FMEA alone, but instead some described the use of FMEA in addition to other research methods or risk analysis (McNally *et al,* 1997; Gowdy &Godfrey, 2003; Nichols *et al*, 2004; Lenz *et al*, 2005; Builles *et al,* 2006; Marwick *et al*, 2007; Koppel *et al,* 2008). These seven (13%) studies used FMEA as an additional method to contribute to their findings or to support them.

1.5.2.4 FMEA participants

After selecting a high risk topic, the second key step in FMEA is recruiting a multidisciplinary team. The purpose of the FMEA team is to bring a variety of perspectives and experiences to the project (McDermott *et al*, 1996). There is no consensus on the ideal number of team members who should be included. The JCAHO (2005) reports that teams limited in size to fewer than 10 individuals tend to perform with greater efficiency and four to eight people may be the ideal size depending on the process being analysed. McDermott *et al* (1996) recommends a team of four to six people but the minimum number of people will be dictated by the number of areas affected by the FMEA. Woodhouse (2005) recommends a team limited to fewer than 10 individuals to enhance efficient performance. Irrespective of the team size, the main aim of the multidisciplinary team is to bring a diverse mix of knowledge related to the process studied, and thus the team should include individuals with fundamental knowledge of the process studied as well as representatives from areas that may be directly affected by changes in the process (JCAHO, 2005). Bonnabry *et al* (2005; 2008) states that from experience the team involved should be large and multidisciplinary to buffer any subjectivity bias.

The team should include process experts and representatives of specific healthcare disciplines. A team leader should also be appointed to chair the FMEA meetings. This team leader should be knowledgeable and skilled at both using FMEA and leading a team to task completion (McDermott *et al*, 1996; JCAHO, 2005). It is essential however, that the team leader does not dominate the team's decisions. A team facilitator may also be appointed alongside the team leader to document the FMEA records and ensure team members complete each step. If a facilitator is not present, then a scribe or recorder should be nominated to document the FMEA results and take notes. It has been recommended that the scribe's role is rotated among team members except the team leader so that no one person has to take notes all the time (McDermott *et al,* 1996; JCAHO, 2005).

Training the team on how to conduct an FMEA has also been debated. McDermott *et al* (1996) states that extensive training is not necessary and that a team leader or facilitator who is well versed in the FMEA process can guide the rest of the team. McDermott *et al* (1996) further states that what is important is that team members know the basics of working in a team, and have knowledge of consensus-building techniques, project documentation and idea-generating techniques such as brainstorming. The JCAHO (2005) supports this and states that team members don't have to be familiar with FMEA prior to starting the process as along as a knowledgeable facilitator is able to guide them. However, team members should be familiar with techniques such as brainstorming, flowcharts and how to contribute to and participate in an improvement team.

The literature review identified 26 (46%) studies that reported the exact number of participants in the FMEA team along with their discipline. Numbers of participants ranged from two to 22 members in one team, with an average number of eight participants. Fourteen studies (25%) did not report any details related to the participants, while thirteen (23%) only reported the disciplines represented within the team without providing further details. The remaining three studies were qualitative. The first qualitative study, conducted by Wetterneck *et al* in 2004, included interviewing 14 FMEA team members. The multidisciplinary nature of the FMEA team was identified as a key strength by nine of the 14 FMEA team members interviewed, while seven of the 14 indicated that an experienced facilitator was necessary to guide them and to strength of the process. Another more detailed study conducted by the same authors in 2009 evaluated FMEA team members' perceptions of team performance. There was wide variation in responses but questions related to team composition and knowledge generally yielded positive comments associated with the diversity of team membership, while negative comments included lack of participation of key team members and lack of knowledge of the FMEA method itself.

Guidelines for FMEA success from Wetterneck *et al* (2009) included:

- Obtain a skilled and effective leader and facilitator for the team
- Ensure the team is multidisciplinary
- Assess baseline knowledge of the FMEA and train team members to assure adequate knowledge before starting the process mapping.

Finally the study by Habraken *et al* (2009) stated that although the multidisciplinary nature of the team was perceived to be beneficial, 13% (8) of respondents faced problems within the team such as planning problems and absence of certain members. The facilitator's role was also perceived to be crucial and that the analysis would not have been possible without a facilitator.

The majority of the studies did not provide details regarding the team leader or facilitator. However Nickerson *et al* (2008) reported that among the lessons learned during the FMEA was that the team leader and facilitator played a crucial role in maximising the efficiency of the team. Having a defined scribe was also helpful for dealing with questions that arose later in the analysis. Riehle *et al* (2008) stated that their experience confirmed that successful FMEA use required a trained designated facilitator, with a neutral and objective approach, to guarantee consistent use of terminology, ranking scales and application and ensure unbiased outcomes. Gilchrist *et al* (2008) reported that the researcher facilitated the HFMEA meetings without participating in the HFMEA itself and an independent observer also attended the meetings to ensure the participants' views were accurately recorded. The team leader and facilitator in the study of Kimchi-Woods and Shultz (2006) shared the responsibility of instructing the team about HFMEA and leading the discussions. The team leader in Van Tilburg's *et al* study (2006) had no previous experience with HFMEA but learnt it using the VA NCPS's HFMEA toolkit and had a student assist him. Wetterneck *et al* (2006) also concluded that the team facilitator, who had an understanding of the process and the FMEA, was critical for the team to remain on task and function effectively. Weeks *et al* (2004) stated that from their experience, the FMEA team requires a team leader, facilitator and safety

expert who can teach the FMEA tool along side the process experts. Also team members should be educated in the FMEA concept, terminology and tools because without such knowledge they would fall behind the discussion, interrupt for clarification of terms and inhibit the team's progress which may result in frustrating waste of time and energy.

Only one negative experience with the facilitator has been reported (Semple and Dalessio, 2004). The facilitator in this case only had basic skills associated with the FMEA process and felt uncomfortable providing direction to the team.

Only three studies (5%) stated that training was provided for the FMEA team members before the start of the FMEA meetings. Van Leeuwen *et al* (2009) reported that the participants of the team attended a one-day course on FMEA; Stanton *et al* (2007) reported that prior to the first meeting, an educational packet introducing the tool to the members was distributed to all team members and finally Wetterneck *et al* (2006) reported that the team underwent training in the use of HFMEA before the meetings. However the qualitative study by Wetteneck *et al* (2004) reported that six of the 14 members interviewed felt that in spite of having training for FMEA through a half-day seminar, they still did not have a good understanding of FMEA at the beginning of the meetings.

1.5.2.5 The FMEA steps followed

Following choice of topic and identifying the FMEA participants, the third FMEA step is mapping out the process and identifying the failures. All the studies reviewed mapped out a high risk process in order to identify the failures.

Flowcharts are the most common used form of graphical visualisation of the processes and brainstorming the most common method for identifying failures (JCAHO, 2005). McDermott *et al* (1996) suggests that the best way to create a flowchart is to walk through the process as if you were the thing being processed; while Woodhouse (2005) states that success of the FMEA depends on a detailed and accurate flow chart of the current process.

Another type of flowchart that is also commonly used is called an event line. The event line is linear and consists of boxes that contain each step involved in a process with arrows that connect them. Studies by Janofsky (2009), Redfern *et al* (2009), Ford *et al* (2009), Nickerson *et al* (2008), Ouellett-Piazoo *et al* (2007) Day *et al,* 2006 ; Dawson *et al* (2005), Burgmeier (2002), and Fletcher (1997) all used flowcharts with traditional symbols; while studies by Gilchrist *et al* (2008) , Jeon *et al* (2007), Florence and Calil, (2006), Kimchi-Woods and Shultz (2006), Wetterneck *et al* (2006) , Esmail *et al* (2005), Kovner *et al* (2005), Linkin *et al* (2005) , Saxena *et al* (2005), Semple and Dalessio (2004), and Win *et al* (2004) used simple event lines.

Irrespective of the flowchart design used, the JCAHO (2005) presents brief guidelines on the steps to follow when creating a flowchart. These include: establishing starting and ending points of the process, brainstorming activities, determining the sequence of activities, use of information to create the flowchart and finally analysing the flowchart before proceeding.

Brainstorming potential failures is a structured but creative process that a group of people uses to generate as many ideas as possible in a minimal amount of time. According to JCAHO (2005), brainstorming can be accomplished in five basic steps comprising: first defining the subject, then thinking briefly about the issue, then setting a time limit, this is followed by generating ideas by having team members take turns or by allowing group members to voice ideas as they come and finally clarifying the ideas, this ensures that the ideas are recorded and understood by the group. Brainstorming is not the necessarily the only method used to generate ideas. Stalhandske *et al* (2003) states that besides brainstorming, there are several techniques that should be used to develop reasonable and concrete failures once the process diagrams are complete and the focus areas are chosen. These techniques may include reviewing databases, literature surveys, audits and participating in patient safety rounds.

Besides brainstorming, some studies have reported using observations of the process mapped (Janofsky, 2009; Koppel *et al*, 2008; Day *et al*, 2007; Day *et al,* 2006; Wetterneck *et al*, 2006), data from the literature (Day *et al,* 2007; Jeon *et al*, 2007, Wetterneck *et al,* 2006; Linkin *et al*, 2005, Apkon *et al*, 2004), interviewing healthcare professionals (Redfern *et al,* 2009; Ford *et al*, 2009; Koppel *et al*, 2008; Jeon *et al*, 2007; Day *et al*, 2006, Lenz *et al*, 2005, Linkin *et al*, 2005) and even using the incident report system within the hospital (Day *et al*, 2007; Robinson *et al*, 2006; Wetterneck *et al*, 2006).

In this third step identifying the effects of the failures is a characteristic of the traditional FMEA but not HFMEA. Effects of failures describe what could happen

if the failure actually occurs. Failures may have more than one effect but team members are encouraged to consider the specific effects of the failure on the patient (JCAHO, 2005). Only 14 (25%) studies reported the effects of the failures identified in their study (Van Leeuwen *et al* , 2009, Redfern *et al*, 2009; Riehle *et al* , 2008; Day *et al*, 2007; Jeon *et al*, 2007, Cheung *et al*, 2006), Kimchi-Woods and Shultz, 2006, Kozakiewicz *et al,* 2005; Kunac and Reith, 2005; Saxena *et al*, 2005, Semple and Dalessio, 2004, Wehrli-Veit *et al* , 2004 Win *et al*, 2004, Burgmeier, 2002).

Identifying the causes of the failures is also suggested by the JCAHO (2005) using the RCA technique. RCA is used retrospectively to identify the basic casual factors that underlie variation in performance. Characteristics of an effective RCA include: focusing on the system processes and not individual performance, progresses from special causes in clinical processes to common causes in organisational processes, digs deep by asking 'why' then when answered asks 'why' again and so on and finally identifies changes that would reduce the likelihood of failures occurring (JCAHO, 2005). Conducting a RCA for all failures is very time consuming. Some studies chose not to identify causes for the failures, while some identified basic causes through brainstorming or interviews without conducting RCA (Janofsky, 2009; Van Leeuwen *et al*, 2009; Redfern *et al*, 2009; Ford *et al*, 2009; Riehle *et al*, 2008; Day *et al*, 2007; Jeon *et al*, 2007; Morelli *et al*, 2007; Kimchi-Woods and Shultz, 2006, Van Tilburg *et al*, 2006,;Wetterneck *et al*, 2006; Wehrli-Veit *et al,* 2004; Burgmeier, 2002) . Only five studies (9%) reported the use of RCA to explore causes of failures (Cheung *et al,* 2006; Robinson *et al*, 2006; Bonnabry *et al,* 2005; Kozakiewicz *et al*, 2005; Kunac and Reith, 2005).

The fourth step is to rank the failures and calculate the RPN. This is discussed in detail in the next two sections (section 1.5.2.6 and section 1.5.2.7) and finally, the last step is to make recommendations and implement them. This is discussed in more detail in section 1.5.2.8.

1.5.2.6 Scoring scales and RPN values

The most heterogeneous FMEA step is the fourth step, which involves scoring the failures according to their severity, probability and detectability and finally calculating the RPN. The goal of this step is to help prioritise the failures with the highest risks that should be addressed. In FMEA, failures are scored according to their:

- Severity: severity relates to the seriousness of injury as a result of the failure.
- Probability: the likelihood that the failure will happen
- Detectability: the degree to which something can be discovered or noticed.

The RPN value is calculated as follows:

- RPN: Severity score X probability score X detectability score OR simplified as
- RPN: S x P x D

The JCAHO (2005) does not specify a particular scale or method for calculating RPN. Healthcare professionals are free to choose the scale they believe is most effective, as long as that scale is used consistently even if they used simple ratings such as high, medium and low. The JCAHO however, emphasises that no matter what rating method and rating scale is used, team members must reach consensus on the ratings assigned. McDermott *et al* (1996) promotes the use of a 10-point scale with 1 being the lowest rating and 10 being the highest and the RPN is

calculated by multiplying the severity, probability and detectability scores. Stamatis (2003) reports that the two most common rankings used in industries today are the 1 to 5 scale or the 1 to 10 scale. He further explains that the ranking 1 to 5 is limited in nature but offers expediency and ease of interpretation; however, it does not provide sensitivity or specific quantification. The ranking of 1 to 10 (appendix 2), on the other hand, is used widely and is highly recommended because it provides ease of interpretation, accuracy and precision in the quantification of the ranking. It is generally agreed that FMEA is a team based tool and that irrespective of the ranking scale or method used, reaching consensus is essential (McDermott *et al*, 1996; Stamatis, 2003; JCAHO, 2005). Consensus is defined as a collective decision reached through active participation by all members and under no circumstances should any FMEA be done with a single individual as there would be built-in biases based on the single perspective of the individual conducting that FMEA (Stamatis, 2003).

Recommendations by McDermott *et al* (1996) to help reach consensus include:

- The team should agree in advance how disagreements will be handled.
- Voting and ranking is a vehicle to help the team reach consensus. When there is disagreement, team members who feel strongly about their ratings should present their rationale for the rating to the rest of the team. If necessary a time limit can be put on these presentations. When the presentations are complete, team members should cast their votes what they feel the rating should be. The mean rating should then be calculated and used as a reference point for the team to arrive at a consensus score.

- It is important not to take the mean score as the score without any additional discussion.
- If consensus is still not reached, then inviting a process expert who is currently not the team might add additional information.
- The team could assign one member of the team to make the final decision if there is a person on the team with a lot of expertise on the process.
- Another method could be to put the failures in order (from highest to lowest) according to the scale in question. Once the failures are in order, indicate the ratings for any of the failures that the team has been able to agree upon. By thinking of the failures relative to each other, rather than in terms of an absolute scale, the team may be able to agree on the ratings for the failure in dispute.
- Avoid assigning a rating arbitrarily because this could result in a decision not to focus on the failure. Talk about sticky issues until they are resolved.
- If consensus still can not be reached, the team might agree to bias the decision towards the safe side by assigning the higher rating.

Studies identified in the literature using HFMEA used the Hazard Scoring Matrix along with the Decision Tree Analysis, with the exception of the study by Kimchi-Woods and Shultz (2006); they used the HFMEA scoring matrix but modified it to include detectability scores.

Studies using FMEA have reported the use of 1 to 5 scales and 1 to 10 scales as well as other variations. Fifteen studies (27%) used a ranking scale of 1 to 10 but only three (5%) studies (Van Leeuwen *et al*, 2009; Ford *et al*, 2009; Adachi and

Lodolce, 2005) explicitly state that the scores were derived by consensus. Four (7%) other studies states that the participants scored the failures individually then the average or mean scores were derived (Dawson *et al*, 2005; Apkon *et al,* 2004; Burgmeier, 2002; Fletcher, 1997) and one study by Kunac and Reith (2005) had the team members independently rate each failure then the median scores used for the RPN. The remaining seven studies did not specify how the scores were derived.

Studies by Bonnabry *et al* (2008, 2006, and 2005) used a scale of 1 to 9 for severity and detectability but a scale of 1 to 10 for detectability and the scores were obtained by consensus.

Stanton *et al* (2007) and Uslan *et al* (2004) used a scale of 1 to 5 without mentioning how the scores were derived. Win *et al* (2004) used a scale of 1 to 3, while Fechter and Barba (2004) and Singh *et al* (2004) used modified scales with ranking 1 to 4; however Fechter and Barba (2004) used consensus to derive the scores and Singh *et al* (2004) calculated the average scores for the failures.

Two studies (Jeon *et al*, 2007; Semple and Dalessio, 2004) used a combination of a 1 to 4 scale as well as a 1 to 5 scale for their scores, however, one study calculated the median values of rating across the participants (Jeon *et al*, 2007), while the other used consensus (Semple and Dalessio, 2004).

The studies by Wetterneck *et al* (2006) and Coles *et al* (2005) were the only two studies that used a descriptive scale without assigning any numerical values to rate their failures.

1.5.2.7 Prioritising the failures

The theory behind calculating an RPN value is to guide the team to decide which failures should be addressed first. Failures with the highest RPN are presumed to be the highest risk failures that require immediate attention. However, since hospitals do not have infinite resources, they usually choose which high-RPN failures they need to address rather than addressing all the failures identified. How to decide which failures need addressing is entirely up to the organisation and healthcare participants, according to their judgments and in some cases according to the costs.

From the literature reviewed, four main methods of choosing the failures that need to be addressed have been used:

1. For HFMEA, according to the Hazard Score Matrix used, failures with a score >8 should be addressed (Day *et al*, 2007; Ouellett-Piazzo *et al*, 2007; Day *et al*, 2006; Florence and Calil, 2006; Van Tilburg *et al,* 2006; Esmail *et al,* 2005 and Linkin *et al,* 2005).

2. For FMEA, some studies have specified a cut off point for RPN at which any failures with a RPN higher than the cutoff point would be addressed (Bonnabry *et al,* 2008; Ford *et al* 2009; Bonnabry *et al*, 2006; Builles *et al*, 2006; Saxena *et al,* 2005; Apkon *et al*, 2005; Fechter and Barba, 2004; Burgmeier, 2002).

3. Others have chosen to address failures with:
    - The highest two RPN (Robinson *et al*, 2006),

- The highest three RPN (Capunzo *et al*, 2004; Semple and Dalessio, 2004),
- The highest five RPN (Kimchi-Woods and Shultz, 2006; Dawson *et al*, 2005; Adachi and Lodolce, 2005; Singh *et al*, 2004; Williams and Talley, 1994;)
- The highest six RPN (Van Leeuwen *et al*, 2009; Cheung *et al*, 2006), the highest 10 RPN (Stanton *et al*, 2007)
- Or even their highest 30 RPN scores (Kunac and Reith, 2005).

4. Finally some studies addressed failures with an RPN greater than the mean (Kozakiewicz *et al*, 2005, Fletcher, 1997).

Stamatis (2003) recommends that if there are more than two failures with the same RPN, then first address the failures with high severity, and then detectability. Severity is approached first because it deals with the effects of the failure and detection is used over the probability because it is more important than just the frequencies of the failure.

1.5.2.8 Recommendations and recalculating the RPN

The final FMEA step is to make recommendations and implement them.

Recommendations can involve redesigning the whole process to:

1. Prevent failures from happening (decrease the likelihood of occurrence)
2. Prevent failures from reaching the individuals (increase probability of detection)

3. Protect individuals if a failure occurs (decrease the severity of effects)

Recommendations made to eliminate or decrease failures may include strategies to standardise the process or simplify it, decrease variability in the process, use technology, improve documentation, develop backups, provide comprehensive education and establish a culture of teamwork (JCAHO, 2005).

Following implementing the new recommendations, it is expected that the team analyses and tests the new process. Conducting a new FMEA for the modified process involves the team completing steps three (graphically describe the process and brainstorm failures) and step four (recalculating the RPN or calculating new RPNs).

Finally the team should aim to monitor the improvement's ongoing effectiveness by maintaining documentation, training, retraining and competence assessment and finally ongoing monitoring. The JCAHO (2005) concludes that the essential ingredient for the team's success with an FMEA is the leadership support.

Only 10 (18%) studies recalculated their RPN values following the implementation of new recommendations or modification of the current process. However 21 (38%) studies adopted solutions and implemented them without recalculating the RPN. Ten (18%) studies included recommendations but did not publish any information about the adoption of these recommendations and three (5%) did not make any recommendations (Redfern *et al*, 2009; Jeon *et al*, 2007; Win *et al*, 2004).

1.5.2.9 Duration of FMEA

There are no guidelines or limitations for the amount of time taken to complete the FMEA. From the literature review, 22 studies (39%) provided some information about how long the team members met for, or how long the FMEA took to complete. Some studies reported only the total duration of the FMEA, for example, the study by Gowdy and Godfrey (2003) stated that the FMEA took one year to complete, Ford *et al* (2009) reported that their FMEA took five months, Stanton *et al* (2007) reported that their FMEA took three months, while Esmail *et al* (2005) reported that it only took two months. Dawson *et al* (2005) states that the FMEA took them 11 weeks and the team in Coles *et al* (2005) study met for 12-16 hours to complete the FMEA. Ten studies (18%) reported the exact number of meetings required to finish the FMEA. The greatest number of meetings reported to complete a single FMEA was nineteen meetings (Linkin *et al*, 2005), while Riehle *et al* (2008) met only twice but the duration of these two meetings was not reported. An average of eight meetings was required to finish the FMEA. Only seven (13%) stated the duration of each meeting; the average duration was an hour and a half. One study reported that the FMEA participants met for two consecutive all day sessions followed by an additional two days two weeks later (Burgmeier, 2002). Finally another study reported that their FMEA took more than 30 hours over an average of seven to eight months (Nickerson *et al*, 2008) and another that it took them 46 hours over four and a half months (Wetterneck *et al*, 2006).

The time intervals between each meeting were reported in only six (11%) studies (Semple and Dalessio, 2004; Saxena *et al*, 2005; Esmail *et al*, 2005; Dawson *et al*,

2005; Kimchi-Woods and Shultz, 2006; Gilchrist *et al*, 2008). The typical time interval between successive FMEA meetings was either one or two weeks.

1.5.2.10 Advantages and disadvantages

In the literature reviewed, a number of studies reported their experiences with FMEA. Positive experiences and advantages of FMEA included:

- Good tool to identify potential risks in high risk processes (Redfern *et al*, 2009)
- Prospective tool- Allows one to consider vulnerabilities before failures occur (Ford *et al*, 2009)
- Valuable educational tool (Ford *et al*, 2009)
- Powerful tool to capture the collective knowledge of the team and improve quality of care (Riehle *et al*, 2008; Nickerson *et al*, 2008)
- Provides a common language and technique for a group to develop systems for process change and empowers the team to make decisions based on its own assignment of scores, thus the overall score had the ability to motivate change (Riehle *et al*, 2008; Cheung *et al*, 2006)
- Concerns over confidentiality make it impossible for the Joint Commission to share root cause analysis event-level data with interested healthcare institutions or professionals outside the Joint Commission. In contrast, FMEA risk reduction strategies and actions can be shared in detail across institutions without such concerns (Janofsky, 2009).

The limitations or disadvantages reported included:

- Its unavoidable subjectivity (Van Leeuwen *et al* 2009; Bonnarby *et al*, 2008; Cheung *et al*, 2006).
- Time consuming (Cheung *et al*, 2006; Nickerson *et al*, 2008; Kunac and Reith, 2005).

- Individuals or groups can be slightly biased (Ford *et al*, 2009).
- Semiquantitiative nature of the scoring system (Ford *et al*, 2009).
- No generic definition for failures or effects of failures in FMEA (Jeon *et al*, 2007).
- Difficult to rate failures without a specific scenario (Jeon *et al*, 2007).
- Competing priorities among healthcare professionals may lead to disagreements (Stanton *et al*, 2007).
- It does not take into account the cost or ease of implementing improvements (Cheung *et al*, 2006; Van Tilburg *et al*, 2006).
- User attendance at the meetings may be inconsistent due to work schedules and time commitments (Wetterneck *et al*, 2006).

1.6 Discussion and implications for this thesis

The literature review in the previous section (section 1.5.2) illustrated that FMEA is an up and coming prospective risk analysis tool that is gaining popularity within healthcare. It is however considered relatively new; the oldest study in healthcare dates back to 1994 and 64% (36) of the studies retrieved were conducted in the USA. Furthermore, there were no published literature reviews about the use of FMEA/HFMEA in healthcare as the one conducted in the previous section.

Two main limitations regarding its use were identified:

- First, there is inconsistent use of the FMEA tool and its components.
- Second, there are no reports of its validity and reliability for use in healthcare.

One might assume that FMEA is a standard tool, especially since it is publicised as a relatively simple tool with standard steps; however the literature review has highlighted wide variations at every one of its many steps. The lack of consensus on 'how FMEA should be conducted' already raises questions about the validity and reliability of its outcomes and limits its generalisability.

In addition to this, FMEA's use in the UK was only identified in three published studies and all three studies conducted FMEA/HFMEA differently. In the first study by Marwick *et al* (2007), an FMEA was conducted but used as a complementary method for improving sepsis management and only the highest and lowest RPN for the failures was reported. In the second study (Gilchrist *et al*, 2008) an HFMEA was conducted, however only the first three steps of HFMEA were completed and published. Finally, Redfern *et al* (2009) reports that they did not follow the traditional FMEA steps, but instead conducted individual interviews with healthcare professionals to identify failures and combined the use the scoring matrix of HFMEA and FMEA.

Since this literature review is the first of its kind to review the use of FMEA/HFMEA in healthcare and has drawn attention to the discrepancy for its use; evidence for -or lack of -its validity or reliability was explored.

Although a number of articles reporting the reliability and validity of HRA techniques other than FMEA/HFMEA were retrieved, the search did not reveal any further evidence related to FMEA's validity or reliability. In view of the lack of

evidence for FMEA's validity and reliability, it was concluded that this dearth needed to be addressed.

1.7 Aims and Objectives

The overall aim of this thesis was to explore whether FMEA is a suitable HRA technique for use in healthcare. The objectives were to explore the reliability and validity of the FMEA process and report users' experiences with FMEA.

Specific objectives related to the work conducted are presented in the relevant chapters.

The next chapter (chapter 2) describes testing the reliability of FMEA.

Chapter 2 Reliability of FMEA

"The definition of insanity is doing the same thing over and over and expecting different results."

Attributed to Albert Einstein (1879-1955)

2.1 Introduction

Following a literature review about FMEA in healthcare (chapter 1), it was concluded that the validity and reliability of FMEA have not yet been assessed in any setting. This chapter describes how the reliability of FMEA was tested in a healthcare setting.

2.2 Reliability

Reliability can be defined as a characteristic of a particular measurement or technique indicating that this measurement or technique can be used again and again, i.e. not merely by one subject or team, and that each subject or team will use the technique in the same way. This ensures consistency of results and of the application of the method (Kirwan, 1997a). Carmines and Zeller (1979) define reliability of a research instrument as the extent to which the instrument yields the same results on repeated trials. This tendency towards consistency found in repeated measurements is referred to as reliability.

In scientific research, accuracy and consistency in measurement is of great importance and reliability testing is a method of ensuring this accuracy and consistency especially since research entails a lot of time, effort and resources. Without reliability, the results of a study would be considered meaningless and readers would lack confidence that the results could be obtained again and thus there would be no assurance that the results are free from errors and that they reflect reality.

Reliability in quantitative studies usually refers to a scale or measurement that consistently reflects the construct it is measuring (Bowling and Ebrahim, 2006). Different types of reliability tests include:

- Test-retest: A test of the stability (reproducibility) of the measure over short periods of time in which it is not expected to change.
- Inter-rater: The extent to which the results obtained by two or more raters or interviewers agree, using the same measurement for the same population.
- Internal consistency: This involves testing for homogeneity and is the extent to which questions relating to a particular dimension in a scale tap only this dimension and no other.
- Split half: If the instrument is divided into two parts, the correlations between the two are computed.
- Item-item and item-total: These are the extent to which each of the items within a multi-item domain are correlated and the extent to which each item within a domain correlates with the total score for that domain.
- Cronbach's alpha: Produces an estimate of reliability based on all possible correlations between all the items within a multi-item scale.

In most cases the reliability tests mentioned above, and particularly the last four, are applied to multi-item questionnaires using scoring scales and their reliability is tested using statistical tests. Since FMEA is not based on multi-item scales but instead it is an instrument or tool comprised of several steps, many of which are not numerical, and even the numerical step is based on group consensus rather than individual scoring, the majority of the above reliability tests were not feasible to use. In this chapter reliability of FMEA does not only refer to the consistent use of the tool since the FMEA is comprised of five basic steps that can be easily followed over and over again, but instead the reliability of FMEA refers to the consistency and accuracy of the FMEA results when the same steps are followed for the same

process but by different people or during a different time. Therefore, although the same steps will be used for a certain process, will the same results be generated when different groups use it or when FMEA is repeated at a different time?

FMEA is comprised of five basic FMEA steps (as described in the introduction in chapter 1, section 1.4.4,). The first two steps are choosing a topic and recruiting a multidisciplinary team, while the last three steps involve describing the process using flowcharts, identifying the failures in this process and calculating RPN values for these failures and finally making recommendations to decrease or eliminate these failures. In this chapter the inter-rater reliability of FMEA was tested by recruiting two different groups to conduct the same FMEA about the same topic, in parallel, in order to compare their results. The results compared were those for the last three steps of FMEA.

2.3 Aim and Objectives

2.3.1 Aim

The aim of this study was to test the reliability of FMEA by comparing the FMEA outcomes of two multidisciplinary teams.

2.3.2 Objectives

The objectives were:

- To recruit two multidisciplinary teams to conduct the same FMEA in parallel for a high-risk process of care within the same UK hospital.

- To compare the two multidisciplinary teams' FMEA results including:

- The processes mapped
- The failures identified
- Their causes and effects
- The scoring scales and RPN values
- And finally the recommendations proposed to decrease the failures.

2.4 Methods

First the choice of FMEA approach rather than HFMEA will be discussed. This will be following by identifying the FMEA topic and recruiting the team members. Information about the how the FMEA meetings were conducted are then presented. Finally, how the two FMEAs were compared is explained.

2.4.1 Choice of FMEA approach

Industrial/traditional FMEA, rather than HFMEA, was chosen for this study as it is the original process from which HFMEA was adapted. FMEA has been used in healthcare since the early 1990s, before HFMEA was introduced in 2001, and is still used by many healthcare organisations, as 75% of the studies retrieved in the literature search (chapter 1) used the traditional FMEA approach. In addition to this, the main guidelines describing how to conduct an FMEA were all based on the traditional FMEA approach rather than HFMEA.

Both processes have similarities at their core, but deal with detectability differently, and HFMEA uses four- point scales while FMEA uses ten-point scales. Although they both involve the same five basic steps, the main difference between them lies in the scoring step. HFMEA detectability scores are only determined if the failure

identified warrants further action, as determined by a decision tree (VA NCPS, 2005).

For the present study, the decision to use industrial FMEA was due to the fact that it had a longer period of use, was used widely in healthcare, and would still be likely to reveal information relevant to HFMEA. Furthermore, the IHI (2009) and NPSA(2004) in the UK all promote the use of the industrial FMEA. In addition to this, during the Safer Patients Initiative (SPI) programme (described in chapter 5) the industrial FMEA was used rather than HFMEA (IHI, 2009; Health Foundation, 2009).

2.4.2 Study Setting

The study was conducted in two large teaching hospitals in the same NHS Trust in London. Participants were recruited from the two main hospitals within the Trust. Ethical approval was granted by the local Research Ethics Committee (appendix 8).

2.4.3 Step one: Choosing the FMEA topic

The first step of FMEA is to choose a high risk topic. The use of antibiotics was a topic of interest because it was an extensive topic involving several drugs and different infectious diseases, thus there was a broad spectrum for choice for an FMEA topic. In addition to this, the two participating teaching hospitals shared the same antibiotic guidelines and policies and thus theoretically speaking, the use of antibiotics would be the same. Finally, nearly all healthcare professionals working in a hospital have been involved with a patient taking an antibiotic and there were a number of experts in the field and thus we were able to recruit two separate

multidisciplinary teams without worrying about the contamination of information between the two teams.

In order to narrow the broad topic of antibiotics further down, three steps were undertaken to choose a high risk topic. First, the researcher conducted a literature search in several infectious diseases and microbiology journals to identify common topics related to patient safety and antibiotic use. Second, two infectious diseases pharmacists from the relevant NHS Trust provided information regarding the most common antibiotic-related risks that they come upon during their daily clinical practice. Finally the Medication Incidents Steering Group and Antibiotic Steering Group within the Trust were consulted to recommend a topic for FMEA related to antibiotic use. The Medication Incidents Steering Group provided a list of the high risk topics encountered, during 2005, related to medicines use; while access to Antibiotic Steering Group meetings allowed the researcher to contact the group members and involve them in the project from the start.

A list of high risk topics and a number of questions was then compiled to form a questionnaire (appendix 9) to help choose the FMEA topic and meet the study's aims and objectives. The questionnaire included six antibiotic-related topics. For each topic the participants were asked to answer the same set of questions for each topic with 'yes, no or not sure' answers. There were also two questions related to the severity and probability of failures that may occur in the process of care for each topic provided. The Antibiotic Steering Group members were asked to complete the questionnaire either immediately after one of the group's meeting or return it to the researcher by the freepost address provided. The remaining members, who were not

present at the meetings, were contacted by E-mail (appendix 10). Reminder E-mails were also sent to all the group members for three consecutive weeks.

2.4.4 Step Two: Choosing the group members

After the topic was chosen, it was then presented to the members of the Antibiotic Steering Group during one of their meetings. They were invited to participate and asked to recommend other healthcare professionals who may be interested in participating. The study details, including information explaining what FMEA is and how it is conducted, were subsequently sent to 70 healthcare professionals including senior doctors, junior doctors, pharmacists, nurses, laboratory personnel, service managers and risk managers (appendix 11). An invitation letter, addressed to doctors and nurses, was also distributed on six medical and surgical wards within the hospital (appendix 12). Respondents were then allocated into one of two groups to conduct the same FMEA simultaneously. The participants were divided depending on the groups' meeting schedules that best suited their work commitments, while ensuring that each group had at least one senior doctor, nurse and pharmacist. Members of both groups were familiar with the same policies and guidelines within the Trust.

2.4.5 Steps three-five: Conducting the FMEA

The next step after choosing the topic and recruiting the participants was to conduct the FMEA meetings and complete the remaining three traditional FMEA steps. Before facilitating the FMEA meetings, the facilitators (Professor Nick Barber and myself) familiarised themselves with the FMEA process using the toolkits provided by JACHO (2005) and VA NCPS (2005) and ran a practice session with pharmacists at another site. Relevant reviews and guidelines retrieved following the

literature search also served as guidance for FMEA. In addition to this, before facilitating the FMEA meetings, the facilitators met with a group of researchers from the Healthcare group of the Engineering Design centre at Cambridge University to discuss their experiences with FMEA as they had facilitated FMEA meetings with doctors. The lead facilitator (NB) facilitated FMEA meetings for the first time but had previous extensive experience in leading group discussions and meetings and thus facilitated five meetings. The second facilitator (NS) received further training on facilitating group meetings and facilitated to completion two pilot FMEAs with pharmacists before the start of the study. The second facilitator was present at all eight meetings and facilitated three of them. None of the group members had previously participated in FMEA meetings. Consent was obtained from all participating group members (appendix 13).

Meetings for both groups were conducted in parallel on an alternating basis and the facilitators aimed to ensure that both groups were provided with the same information and that facilitators did not influence the group discussions. During the first meetings for both groups, a brief presentation was conducted explaining what FMEA was and its use (appendix 14). The groups were also given a simple example about how to use the FMEA for their daily commute to work. The teams were shown two different examples of flowcharts, one flowchart including the 'yes' and 'no' choices and the other was an 'event line design' (appendix 15). This helped the participants clarify what exactly they were expected to do during the meetings. The start and end steps of the process were provided to help ensure that both groups had a unified first and last step and to ensure that the FMEA was completed within a suitable time frame. Common ground rules were set for both groups (table 5) and

both groups agreed that renal patients and patients in the intensive care (ICU) setting would be excluded from the FMEA study since they require specific dosing regimens for antibiotics. The team leader led the teams' discussions while taking notes, and at the same time the facilitator took notes of what was being said during the meetings. At the end of the meetings the team leader and facilitator compared notes in order to ensure that everything said during the meetings was recorded.

During the first meeting, participants were asked to map the process of care related to the topic and identify sub processes. Participants then brainstormed potential failures in the sub processes mapped. They were then expected to score the potential failures identified. Ten-point scales for severity, probability and detectability of each failure were used (Department of Defense Patient Safety Center, 2003; McDermott *et al*, 1996) and each scale was accompanied by written descriptions (appendix 2). The group members were asked to score each failure with respect to the effect on the patient. The scores were obtained by consensus in each group. The RPN of each failure was then calculated by the facilitator by multiplying the severity, probability and detectability scores (lowest possible RPN value: one, highest possible RPN value: 1,000). After determining the scores for each failure, participants were asked to identify the causes and effects of these failures as well as make recommendations to help improve the process of care and eliminate the failures. During the meetings participants in both groups indicted that for some failures there were a number of predicted effects on the patients. Due to the participants' time constraints it was recommended to both groups that they list only the most common expected effect and score the failure accordingly.

Table 5: Ground rules for both FMEA groups

- The start and end step for the FMEA were provided for both groups.
- The objective of the FMEA was to address issues related to patient safety including prescribing, administering and monitoring of the relevant drugs.
- The groups were asked to list the failures that they encountered during their daily practice.
- Members were requested to score each failure with respect to the effect on the patient. The final scores were obtained by consensus.

Before every meeting both groups were reminded what was achieved in the previous meeting. For example, during the second meeting, the group members were given a copy of the process they mapped out during the first meeting in order to verify the flow chart and ensure consensus.

During the second meeting the participants were given a choice to either complete the scoring scales during the next meeting or to complete the scores individually and send them back to the investigator to compile the scores and discuss them in the following meeting to save time. Group one chose to complete the scores individually, while group two chose to score the failures together during the meeting. However, only two participants of seven (29%) in group one actually scored the failures and sent them back, while the remaining participants said that they had underestimated their work commitments and thus did not have time outside the meetings to complete the scores. In the end, both groups scored their failures during the third and fourth meetings.

All participants attended all the meetings, with the exception of one pharmacist, in group two, who missed one meeting due to work commitments. Occasionally, some participants joined the group later than the scheduled meeting time or left slightly early due to their work commitments. In such situations, these participants were

briefed about what they had missed when they later joined the group or at the start of the following meeting,

2.4.6 Comparing the two FMEAs

After all the FMEA meetings for both groups had finished, the results were compiled and the FMEA sheets completed. The mapped processes presented as flowcharts were first compared to determine whether both groups outlined the same steps in the process of care (FMEA step 3). Next, a list of all the failures, their severities, probabilities, detectabilities and RPN values were compiled in descending order for both groups in order to help identify the top five failures and identify the common failures between both groups (FMEA step 4). The total RPN values for both groups were added. The scoring scales and RPN values for the common failures were then statistically compared using the two-sample Kolmogorov-Smirnov Z test. This is a statistical test similar to Mann-Whitney test, which is a non parametric test that tests for differences between two independent samples. However Kolmogorov-Smirnov Z tends to have a better power than the Mann-Whitney test when sample sizes are less than about 25 per group (Field, 2005). An a priori level of significance of $p<0.05$ was adopted.

The top five failures identified by each group were also identified and focused on in more detail. Finally, the causes and effects of the failures, as well as the recommendations (FMEA step 5) from both groups were also listed and compared.

2.5 Results

In this section the results are divided into three main parts. The first part describes the high risk topic chosen for the FMEA process. The second part describes the FMEA participants and meeting details. Finally the results of steps 3, 4 and 5 of the two FMEAs are compared. The complete FMEA worksheet for group 1 is presented in appendix 16 and for group 2 in appendix 17.

2.5.1 Topic chosen for the FMEA

A shortlist of six topics identified by the researcher was compiled to form the questionnaire. In total 21 members of the Antibiotic Steering Group were contacted to help prioritise the FMEA topic and 13 responded (62%). All respondents indicated that they did not answer the questions related to topics they were unfamiliar with. The topic with the most 'yes' answers as well as the highest risk and highest probability was the topic chosen for the FMEA (table 6).

Table 6: Results from the antibiotic steering group in relation to choosing the FMEA topic*

	Is there risk of patient harm in this process? Yes/ No/ Not sure	Do failures in this process affect patients' outcomes? Yes/ No/ Not sure	Can the steps of the process be graphically mapped out in a flow chart? Yes/ No/ Not sure	Are there enough experts within the trust to be able to map out the process? Yes/ No/ Not sure	Is there potential for improvements to decrease failures? Yes/ No/ Not sure	Average percentage of 'yes' answers	Is the risk associated with failures in the process Catastrophic or Major or Moderate or Minor?	Is the risk associated to patients Frequent or Occasional or Uncommon or Remote?
Prescribing antibiotics in renal failure (especially vancomycin and gentamicin)	100% (n=13)	92% (n=12)	77% (n=10)	77% (n=10)	85% (n=11)	86%	Major (n=7)	Frequent (n=7)
Monitoring vancomycin or gentamicin (process of monitoring levels and changing the dose)	85% (n=11)	92% (n= 12)	85% (n=11)	69% (n=9)	85% (n=11)	83%	Major (n=8)	Frequent (n=8)
Prophylactic use of antibiotics (preoperative)	77% (n=10)	77% (n=10)	62% (n=8)	62% (n=8)	85% (n=11)	73%	Moderate (n=6)	Frequent (n=7)
Process of changing IV antibiotics to oral	77% (n=10)	54% (n=7)	69% (n=9)	69% (n=9)	77% (n=10)	69%	Minor (n=8)	Frequent (n=6)
Antibiotic use in the accident and emergency department	46% (n=6)	46% (n=6)	15% (n=2)	38% (n=5)	46% (n=6)	38%	Major (n=3)/ Minor (n=3)	Not sure (n=5)
Management of MRSA or *C.difficile* patients	92% (n=12)	92% (n=12)	77% (n=10)	69% (n=9)	77% (n=10)	81%	Major (n=6)	Frequent (n=5)/ Ocassional (n=5)

*The two topics with the highest percentage of 'yes' answers are highlighted in blue.

Based on these results, the topic chosen for the FMEA was the use of intravenous (IV) vancomycin and gentamicin in adult inpatients as this topic had the highest percentage of 'yes' answers and the majority of respondents considered the risk associated with failures in this process to be major and frequent as highlighted in table 6. At the time of the study, the gentamicin dosing regimen used for the majority of clinical conditions in the hospital was either 5mg/kg or 7mg/kg once daily, depending on the patient's clinical condition. IV vancomycin was dosed according to a dosing table, depending on the patient's weight and renal function. Continuous vancomycin infusions were used in the adult intensive care unit, but were not included in the FMEA.

2.5.2 Participants and meeting details

Fourteen healthcare professionals agreed to participate in the FMEA meetings (table 7). The participants were divided depending on the groups' meeting schedules that best suited their work commitments. Each group comprised seven participants including at least one senior doctor, one pharmacist and a nurse. Each group also included senior healthcare professionals with managerial positions. Group one also included a laboratory manager. Four meetings were conducted, each lasting 90 minutes (table 8).

Table 7: Demographic details of the 14 healthcare professionals who agreed to take part in the study.

Profession	Specialty and Grade
Group 1	
Doctor	Microbiology Consultant
Doctor	Microbiology Consultant
Pharmacist	Principal Patient Services
Pharmacist	Medicine Information Manager
Nurse	Clinical Practice Educator Specialist Medicine
Risk Manager	Clinical Risk Manager
Laboratory Manager	Clinical Chemistry
Group 2	
Doctor	Respiratory Consultant
Pharmacist	Lead infectious disease
Pharmacist	Senior Research Pharmacist
Pharmacist	Principal Patient Services
Pharmacist	Pharmacy Clinical Services Manager
Nurse	Senior Orthopaedics Nurse
Nurse	Senior Infection Prevention and Control Nurse

Table 8: The FMEA meetings with the healthcare professionals

First meeting: FMEA process was explained, ground rules set and an example given. Group members started to map out the process of vancomycin and gentamicin use using the predefined start point 'The decision to start vancomycin or gentamicin' and ending the process with 'The decision to stop or to continue the treatment'.
Second meeting: Continued mapping the process and sub processes and started identifying the potential failures
Third meeting: Finished identifying the potential failures. Started scoring the severity, probability and detectability of each failure along with their causes and effects as well as making recommendations
Fourth meeting: Completed scoring the failures, listing the causes and effects and making recommendations.

2.5.3 Comparing the two FMEAs:

In the next section the two FMEA's will be compared by first comparing the mapped flowcharts. The RPN values will be then be compared along with the identified common failures. This is followed by comparing the causes and effects of failures listed by both groups and finally their recommendations to decrease the failures.

2.5.3.1 The mapped process

The start step provided for both groups was 'The decision to start vancomycin or gentamicin'. The end step was 'The decision to stop or to continue the treatment'. Group one identified eight main steps for the use of vancomycin or gentamicin, including the predefined start and end steps provided, and 23 sub processes (figure 4). Group two identified 10 main steps and 29 sub processes (figure 5).

The flowcharts complied by both groups including prescribing, administering and monitoring processes. However, group two derived a more detailed flow chart for

the use of vancomycin or gentamicin. They divided the monitoring stages into more detailed steps and included 'pharmacy review' twice; this may be due to the fact that four pharmacists, including an infectious diseases pharmacist, were present in this group. Group one, on the other hand, included laboratory analysis as a separate process step; this may be due to a laboratory representative being included that group.

The sub processes listed by both groups were relatively similar with minor differences. For example group two included checking culture and sensitivities and Methicillin Resistant *Staphylococcus aureus* (MRSA) more than once while group one mentioned checking cultures and sensitivities only in the first step and did not mention MRSA at all.

2.5.3.2 The Risk Priority Numbers (RPN)

Each group identified 50 potential failures along with their causes and effects (appendix 16 & 17). However, from the combined total of 100 potential failures, only 17 were common to both groups and none of these common failures had the same RPN (table 9). When comparing the two groups it was sometimes difficult to make direct comparisons between the failures identified by each group, due to differences in the level of detail presented. In such cases we matched one failure from one group with two or more from the other group where necessary (table 9).

Table 9: Common failures identified by both groups in each sub process

Group 1	Group 2
Deciding to start vancomycin or gentamicin	
Not checking culture and sensitivities (if available) before starting treatment (RPN:63)	Not sending sample for culture & sensitivities or screening for MRSA (RPN: 320).
Prescribing failures	
Not finding the doctor to write prescription (RPN: 96)	Failure to write prescription especially junior or locum doctors empirically (RPN: 80).
	Failure to write prescription especially junior or locum doctors according to specific treatment protocol (RPN: 80).
	Failure to write prescription especially junior or locum doctors according to culture & sensitivity (RPN: 80).
Prescribing wrong dose (RPN: 80)	Wrong dose prescribed (RPN: 160)
Administration Failures	
Nurse not informed of new prescription order written (RPN: 14)	Drug order written but nurse is not informed (especially during out-of-hours) (RPN: 210)
Drug out of stock (RPN: 16).	Drug not in stock (RPN: 210).
Using wrong diluent for reconstitution (RPN: 90)	Using wrong diluent for reconstitution (RPN: 288)
Wrong patient identified (RPN: 12)	Wrong patient gets drug (RPN: 168).
Patient not cannulated (RPN: 16).	Patient not cannulated (RPN: 240).
Dose given at the wrong time (RPN: 100).	Failure to administer drug at correct time (RPN: 576).
Dose given at the wrong rate (RPN: 100)	Failure to give drug correctly (wrong rate for example) (RPN: 576).
Wrong route of administration (RPN: 100)	
Monitoring Failures	
Filling in wrong form (RPN: 16)	Wrong form filled (RPN: 160)
Incorrect sample and form labeling (RPN: 84).	Incorrect labeling (RPN: 160).
Samples analysed in batches at specific times, therefore failure to send sample at appropriate analysis time resulting in delays (RPN: 24)	Delay in analysis because samples are run in batches at specified times (RPN: 210).
Failure to understand/interpret reported results (RPN: 84)	Not acting upon results because unable to interpret results (RPN: 280).
Doctor does not receive results via phone nor does he/she check results on the computer system (RPN: 168)	Results not checked (RPN: 280)
Stopping or continuing the treatment	
Failure to stop treatment when it should be stopped (RPN: 54)	Continuing treatment inappropriately (RPN: 200).
Failure to continue treatment (RPN:48)	Stopping treatment inappropriately (RPN: 240)
Total RPN for common failures: 1,165	Total RPN for common failures: 4,518

RPN: Risk Priority Number
MRSA: Methicillin Resistant *Staphylococcus aureus*

Figure 4: FMEA group one's mapped process and sub processes

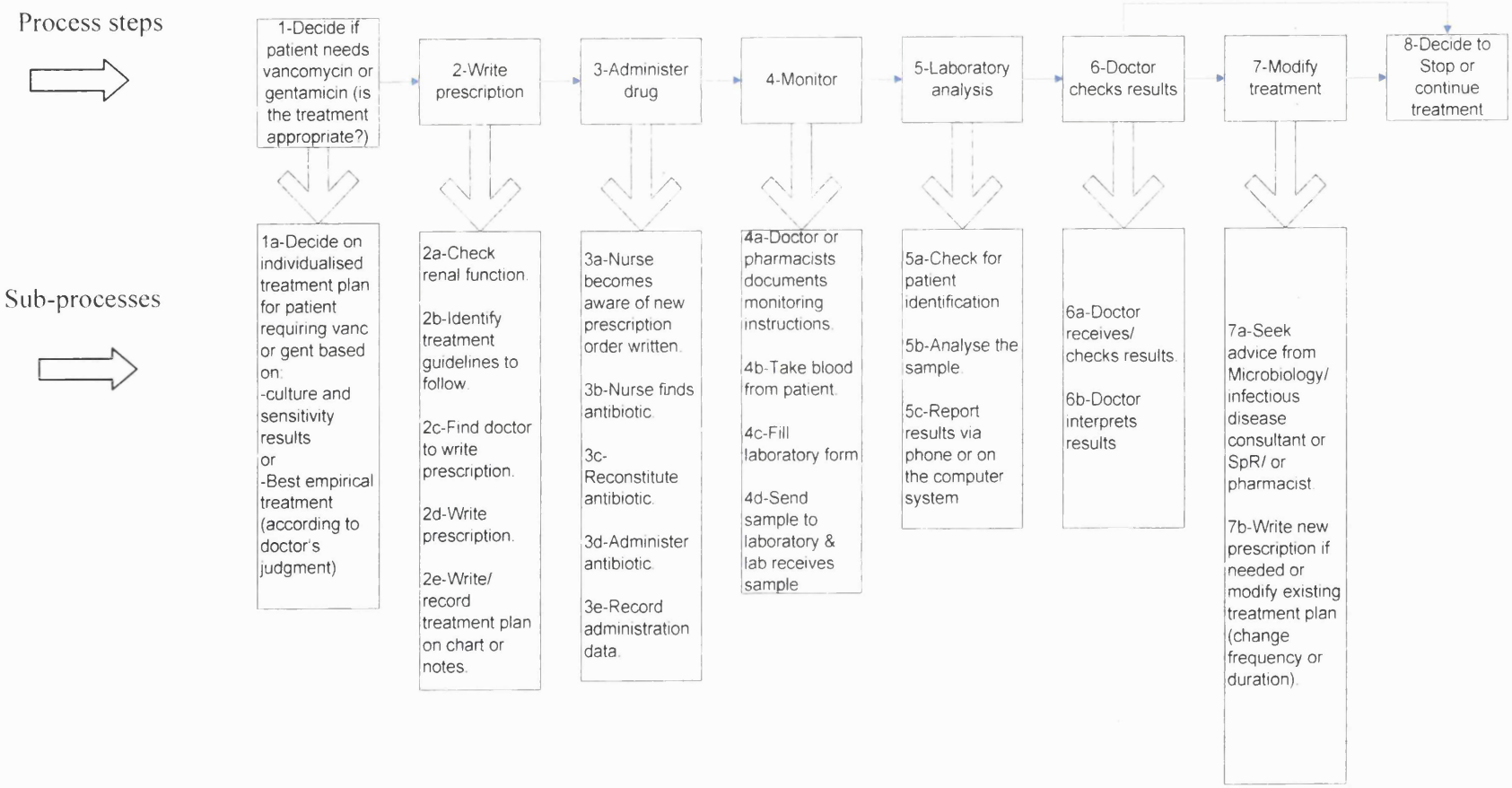
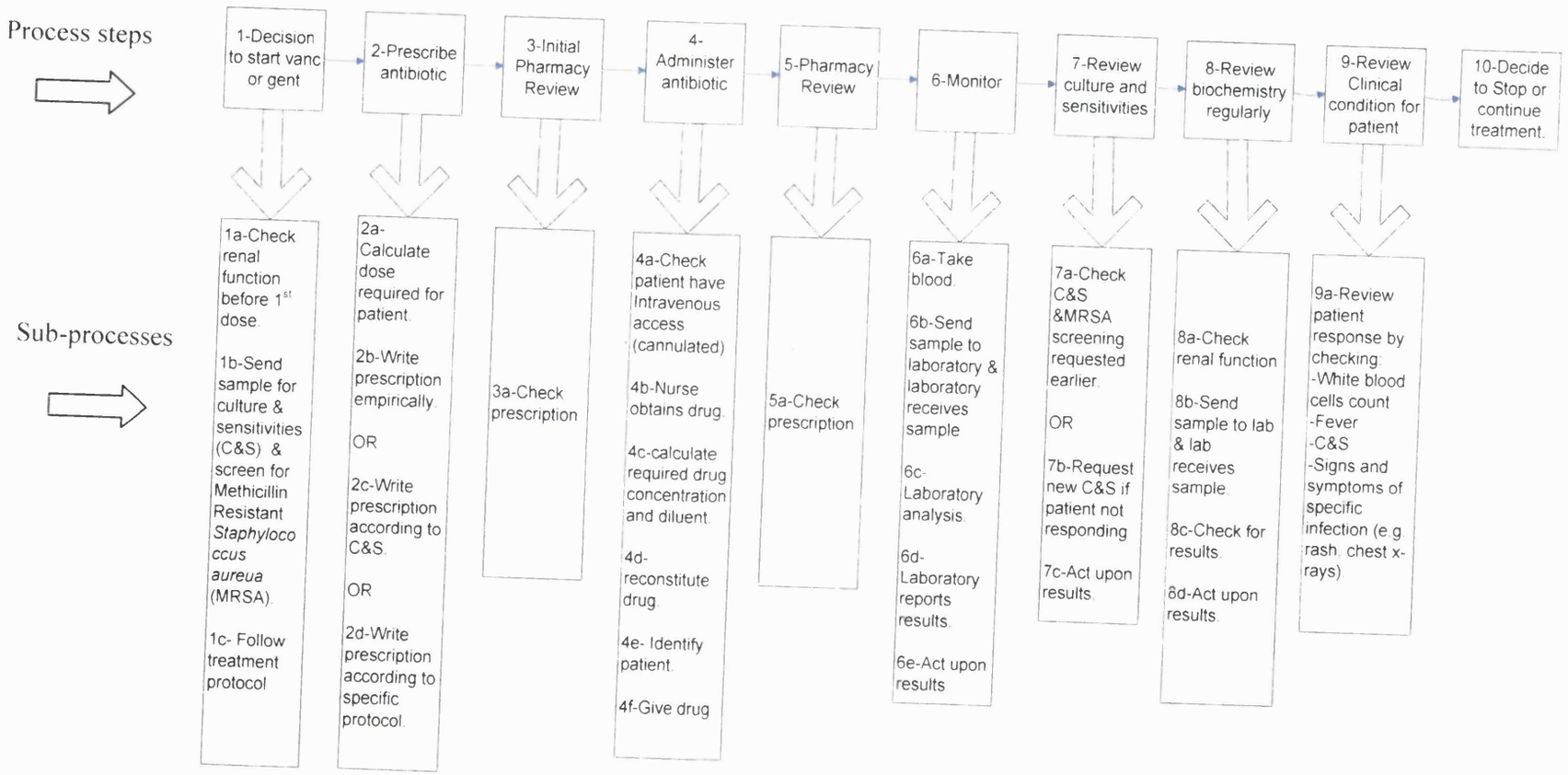


Figure 5: FMEA group two's mapped process and sub processes



Overall, group one scored their failures with markedly lower RPNs than group two. The RPNs calculated for group one ranged from 12 to 168 and for group two from 32 to 576 (appendix 18). The total RPN for group one was 3,589 and for group two was 11,585. The total RPN values for the common failures for group one was 1,165 and for group two was 4, 518, further indicating that group two scored their failures nearly four times higher than group one.

For the common failures, the results of the Kolmogorov-Smirnov Z test showed that there was a significant difference between the groups' common severity scores (p: 0.028) (figure 6), detectability scores (p: 0.010) (figure 7) and RPN scores (p: 0.001) (figure 8) but the difference between the groups' probability scores failed to meet statistical significance (p: 0.069) (figure 9).

Figure 6: Severity scores for the common failures for both groups

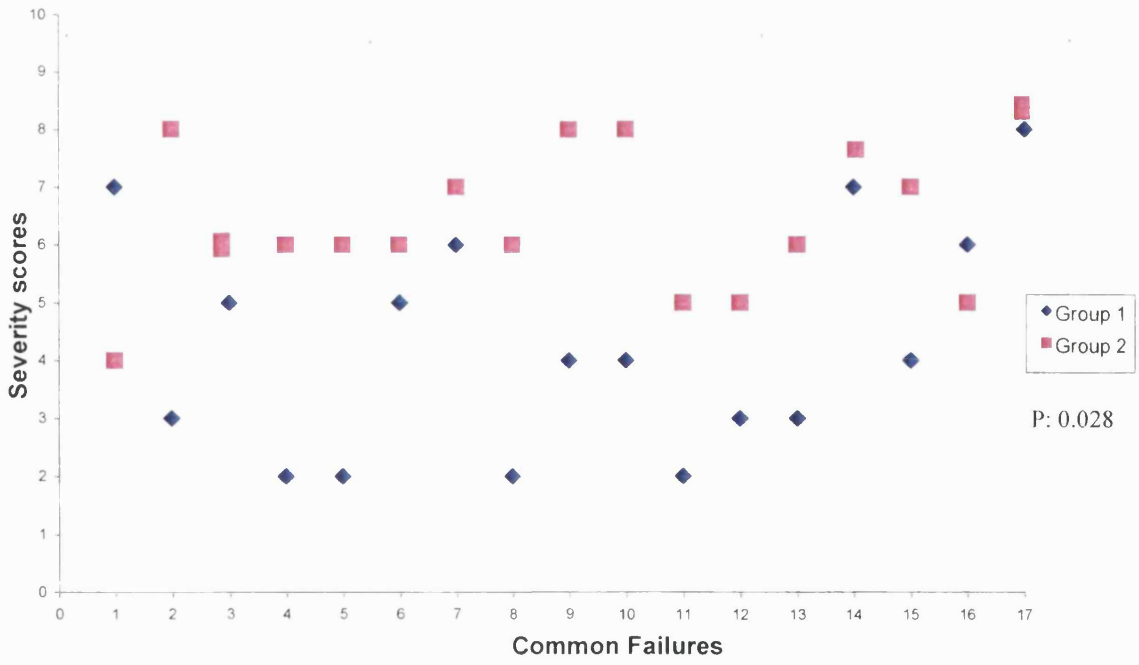


Figure 7: Detectability scores for the common failures for both groups

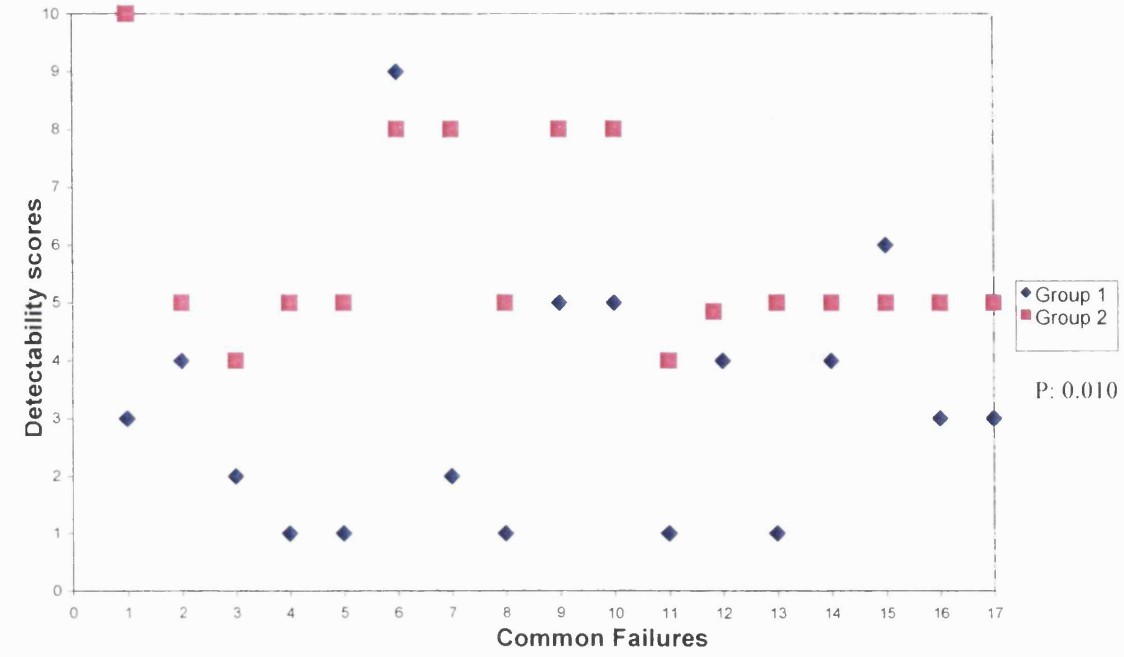


Figure 8: Risk Priority Number (RPN) scores for the common failures for both groups

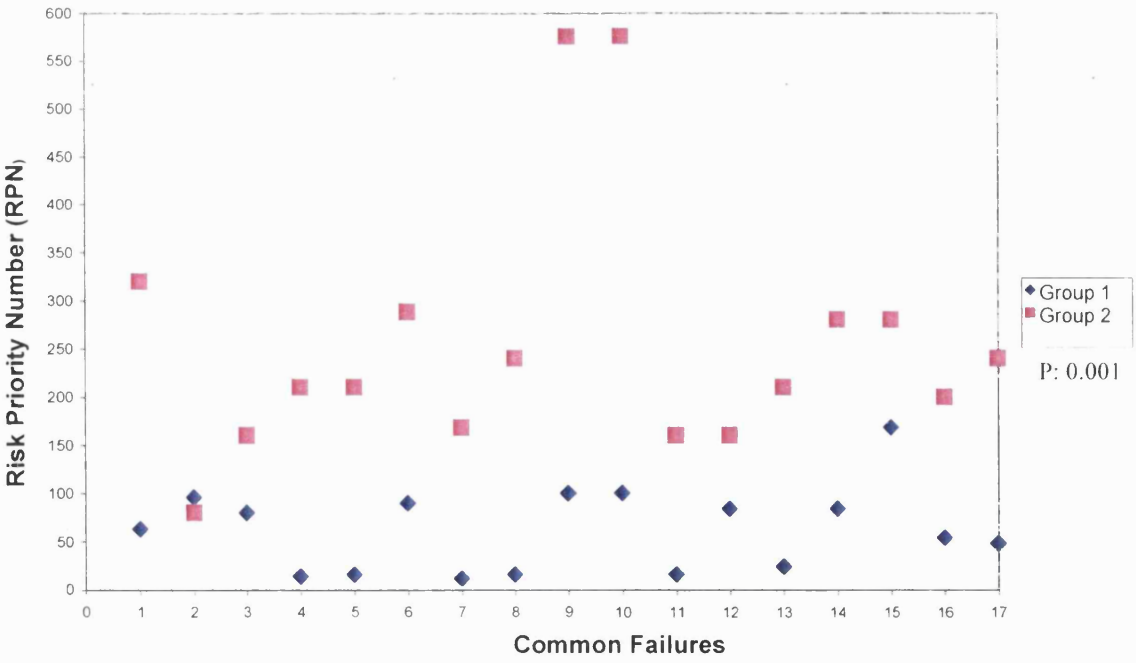
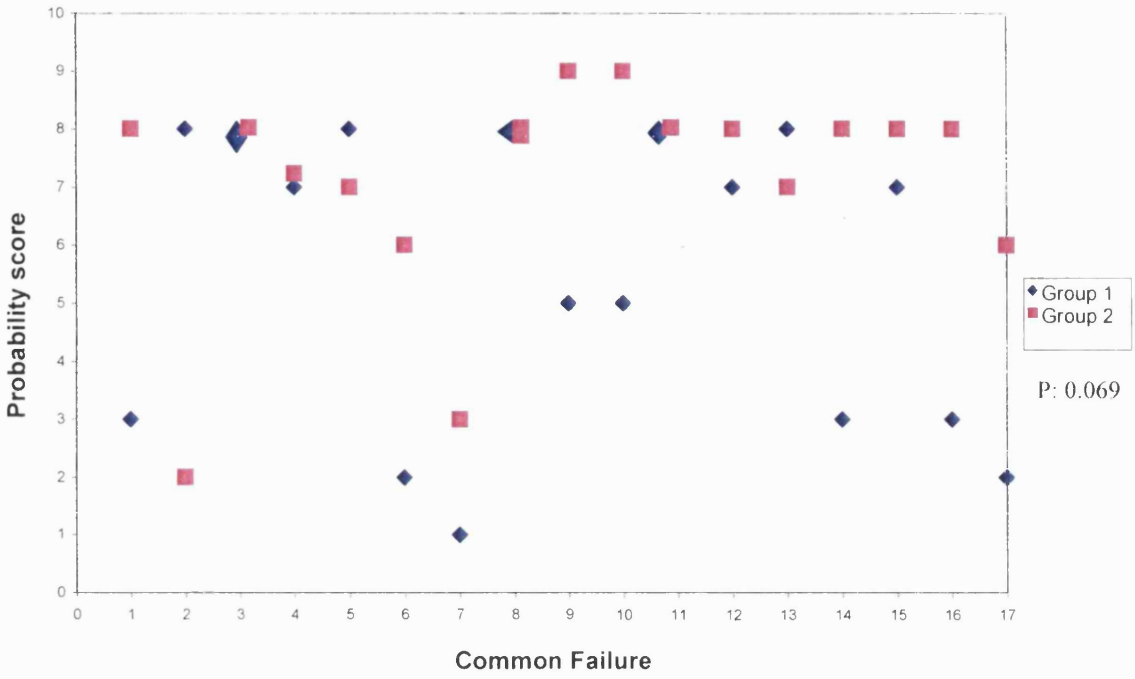


Figure 9: Probability scores for the common failures for both groups



The top five failures identified by each group were also compared. For group one, they consisted of three monitoring failures and two prescribing failures, while the top five failures for group two consisted of three administration failures and two different monitoring failures. There was no overlap between the top five failures identified in each group (table 10)

Table 10: Top five failures identified by each group

Group one								Group two							
Potential failure	**Causes**	**Effects**	**Severity**	**Probability**	**Detectabilit**	**Priority Number**	**Recommendations**	**Potential failure**	**Causes**	**Effects**	**Severity**	**Probability**	**Detectabilit**	**Priority Number**	**Recommendations**
1-Unclear changes, e.g. not crossing out wrong dose, not writing correct changes clearly	-Doctor in a rush not seeing that the previous drug needs crossing off	-Can cause confusion on the ward resulting in double doses given or no dose given at all. -Patient treatment not modified.	7	8	3	168	*Nurse giving medication should be aware of this occurrence and query doctor or pharmacist. *Have a specific section in the drug chart for vancomycin and gentamicin prescribing to accommodate the variable doses and drug levels.	1-Failure to administer drug at correct time	-Very busy wards-understaffed -Lack of knowledge and nurses not knowing the drug's properties and effects.	-Adverse drug reactions-if wrong rate. -Inaccurate monitoring levels if the drugs are given at the wrong time.	8	9	8	576	*Use intravenous (IV) pumps. *Educate nurses.
2-Failure to monitor treatment changes			7	8	3	168		2-Failure to give drug correctly (wrong rate for example).			8	9	8	576	
3-Doctor does not receive results via phone nor does he/she check results on the computer system	-Person receiving results via phone does not inform doctor. -Doctor fails to check computer system for results.	Patient treatment not modified	4	7	6	168	*Text results to doctor's pager if abnormal results. *Results could be recorded next to the record of the specimen when it was first sent. *Encourage ward clerk or nurses to record results in notes if results were received by phone.	3-Delays in giving following doses while waiting for drug levels.			8	9	8	576	
4-Not checking renal function (before prescribing)	-No bloods available. Lack of knowledge, not knowing that renal function needs to be checked.	Giving patient a higher dose, may lead to renal failure or worsening of renal function or ototoxicity.	7	3	3	147	*All prescriptions to be supervised by pharmacy. *Education of medical staff.	4-Results (for drug levels) not accurate	-Not recording the time sample was taken on the request form.	-Results may not be reliable or accurate.	6	10	6	360	*Educating who takes blood about the importance of recording the time the blood was taken.
5-Not considering renal function (when prescribing)			7	3	3	147		5- Time lag between sending sample & receiving the results.	-Laboratory not onsite.	-Delays in receiving results.	6	10	6	360	

2.5.3.3 The Causes and Effects of the failures:

Group one identified 21 causes for their failures, while group two identified 32 causes for their failures. Only 10 causes of failures (19%) were common to both groups; these were:

1. Staff's lack of knowledge
2. Differences in staff experiences
3. Time constraints
4. Protocols or guidelines not being easily accessible
5. Lack of communication between members of the multidisciplinary team
6. No defined roles within the team for basic tasks such as checking the level results
7. Nurses not checking patients' identity before administering the drug
8. Phlebotomist not available to obtain blood sample
9. Nurses not trained to withdraw blood from patients
10. And finally, confusion because of different laboratory order forms available.

For the top five failures in each group, only two causes of failures were common to both groups: time constraints and lack of knowledge (table 10).

No key differences were identified in the effects of failures identified by each group. The overall three main effects of the failures described by each group included adverse effects, therapeutic failure and delays in treatment or monitoring. Adverse effects described by both groups included deterioration of renal function, renal failure or ototoxicity, while therapeutic failure referred to treatment failure which may ultimately lead to the deterioration of the patients' condition. Both groups also agreed that delays in treatment or monitoring may or may not lead to adverse effects or treatment failure. Group two also mentioned 'increased costs' as a consequence if IV antibiotics were continued to be used inappropriately.

2.5.3.4 Recommendations

Collectively, the groups identified 65 recommendations to help decrease or eliminate the failures. Group one listed 26 recommendations, while group two listed 39. Only nine recommendations (14%) were common to both groups (table 11) and educating healthcare professionals was the only common recommendation relating to the top five failures identified by each group (table 10). The majority of the remaining recommendations were related to improving the clinical practice of healthcare professionals. For example, nurses to organise and store IV medication bags in a manner that would be minimise confusion or errors, pharmacists to supervise all prescription orders and to ensure that the ward stock is constantly updated and clearly labeled or organised, and doctors to improve their handwriting and record all relevant information in the patients' notes.

Table 11: Nine common recommendations for the failures identified

1-Educate and train healthcare professionals (include basic prescribing information, the correct prescribing, administration and monitoring of vancomycin and gentamicin as well as raising awareness of available protocols and how to access them).
2-Introduce electronic prescribing if possible.
3-Ensure guidelines are more easily accessible.
4-Introduce a computer program that informs staff that the laboratory has received the sample and as well as alarms the staff in the ward that the results have been reported.
5-Encourage communication between nurses and doctors.
6-Increase numbers of medical staff covering the wards.
7-Introduce bar coding for patients as well as drugs if possible.
8-Use intravenous (IV) pumps if feasible.
9-Train nurses to cannulate patients.

2.5.3.5 Summary of finding

Table 12 summarises the differences and similarities between the two groups for the FMEA steps three-five.

Table 12: Summary of the differences and similarities between the two FMEA groups

FMEA steps	Summary of results
Step 3: Flow charts	Group1 mapped eight main steps and 23 sub processes, while group 2 mapped 10 main steps and 29 sub processes. However the same basic steps & sub processes were identified including prescribing, administering and monitoring the antibiotics.
Step 3: Failures identified	Each group identified 50 different failures in the process of care, however, only 17 (17%) of the failures were common.
Step 3: Causes and Effects	Group 1 listed 21 different causes for the failures, while group 2 listed 32. Only 10 (19%) were common to both groups.
Step 4: Scores and RPNs	Over all group 1 scored their failures with markedly lower RPNs than group two. The RPN for group 1 ranged from 12 to 168 and for group 2 from 32 to 576. There was also a statistically significant difference between the severity, detectability and RPN scores for the 17 common failures listed.
Step 5: Recommendations	Group 1 listed 26 recommendations, while group 2 listed 39. Only nine (14%) were common to both groups.

2.6 Discussion

In this study the reliability of FMEA was explored by conducting two parallel FMEAs for the use of vancomycin and gentamicin in hospital inpatients. This is the first time that two different groups have conducted the same FMEA in parallel in order to compare their results. Previously published papers have only conducted one FMEA, implemented recommendations and then repeated the same FMEA, with the same group of participants, after the new recommendations have been implemented (Bonnabry *et al*, 2005; Bonnabry *et al*, 2006; Robinson *et al*, 2006). In the present study, both groups identified similar sub processes and identified the same number of failures, however, there were marked differences in the failures identified, as well as in the RPN scores. These findings bring into question the reliability and hence the value of FMEA when it is used as a tool to prioritise hazard reduction.

It is difficult to identify conclusively why the FMEA results from the two groups differed. Before conducting the meetings, the researcher tried to ensure consistency between the teams when using FMEA in order to attempt to ensure that any discrepancies between the team's results would indeed be due to inherit limitations of the FMEA technique rather than error or inconsistency with team leadership or facilitation. First, the team leader and facilitator conducted an extensive background search regarding the use of FMEA to ensure that the FMEA technique was conducted accordingly. General guidelines for the use of FMEA, as well as previous researchers' experience about the use of FMEA were carefully studied and considered. For example, JCAHO (2005) suggest that the start and end point of the FMEA may be provided for the team to make sure the team knows the scope of the

project, and this approach was therefore adopted. The team leader and facilitator did not participate in the group's discussion or influence their decisions in any way but simply led the team through the FMEA steps and recorded the results. Consensus was achieved at every step of the FMEA, including identifying the failures, determining their causes and effects, scoring them and proposing recommendations and the same ground rules were set and followed for both groups. In addition to this, the team leader and facilitator met with the Healthcare Group of the Engineering Design Centre at Cambridge University who were studying HRA techniques and had previously conducted an FMEA with GPs, in order gain insight from their experience and to avoid any mistakes. A practice session was also run with postgraduate pharmacists and their feedback was taken into consideration for the hospital's FMEA.

The main differences between the results of both groups lay in the different failures identified along with their RPN scores. Surprisingly, although both groups had similar sub processes and identified the same number of failures, only 17% of all failures identified were common to both groups, and even these had very different RPN scores. Overall, group two scored their failures with much higher RPN scores than group one. This was also the case for the common failures. This suggests that the same FMEA might generate different results depending on the group conducting the FMEA and whether they tend to subjectively score high or low for the failures identified.

The group composition may have been one influence on the types of failures identified and their RPNs although it was ensured that at least one representative

from each discipline was present during the meetings. Group one included laboratory analysis as a separate process step; this may be have been because a laboratory manager was in the group. Group two, on the other hand, developed a more detailed flow chart for the use of vancomycin or gentamicin. They divided the monitoring stages into more detailed steps and included two 'pharmacy reviews'; this may be because four pharmacists, including an infectious diseases pharmacist, were present in this group, while group one included only two pharmacists.

The wide differences between the scores may also be partly attributed to the fact that the industrial FMEA ten-point scale was used and detectability scores were included, both of which allow for greater discrepancies than when using a shorter scale and fewer categories. As with prioritising the failures, there are no set rules for the scoring scales used to describe severity, probability and detectability. Some studies have used four- point scales (Day *et al*, 2007; Van Tilburg *et al*, 2006), others five- point scales (Wehrli-Veit *et al,* 2004) and some ten-point scales (Bonnabry *et al*, 2006; Apkon *et al*, 2004). Furthermore, not all studies include the detectability scores when calculating the RPN. HFMEA only includes the severity and probability scores initially; the detectability scores are determined only if the failure identified warrants further action as determined by a decision tree. To test whether removal of detectability would alter the conclusions, the total RPN values for the failures *without* the detectability scores were compared. The total RPN, without the detectability scores, for group one was 1,238 and 2,056 for group two, indicating that there was still a significant difference between the groups' total RPNs (p: 0.000) using the Kolmogorov-Smirnov Z test.

The effects of the failures identified by both groups reflect the FMEA's objective, which was to focus on patient safety in relation to the use of these two antibiotics. From a total of 53 causes of failures identified by both groups, only 10 (19%) were similar. Furthermore, the common causes identified, such as lack of knowledge, time constraints, protocols not being accessible and lack of communication, are causes that are common to many areas, both within and outside of healthcare. For example, Reason's Organisational Accident Model recognises these common causes as 'error-producing conditions' that result from managerial decisions and organisational processes (Reason, 1995; Dennison, 2005). These causes have also been reported in previous studies of medication error (Taxis and Barber, 2003; Dean *et al,* 2002). While some causes were identified by both groups, the failures and more importantly their seriousness, frequency and detectability were noticeably different. This indicates that although one aspect of the whole process was similar, the overall outcomes differed dramatically between the two groups and there would be no guarantee that addressing the similar causes would ultimately address the failures or decrease their RPN to the same extent.

The decision to closely compare the top five failures was based partly on the literature and partly on a pragmatic judgment that in practice only a small number of changes would be focused on. In the published literature, there are no standard rules regarding the number of failures that should be focused on. Previous studies have chosen to address failures with the highest five RPN (Williams and Talley, 1994; Adachi and Lodolce, 2005), the highest six RPN (Cheung *et al*, 2006) or even their highest 30 RPN scores (Kunac and Reith, 2005). Other studies have addressed failures with an RPN greater than the mean (Kozakiewicz *et al*, 2005). If we chose

to address the failures with a RPN greater than the mean, then the first 26 failures in group one would need to be addressed and the first 24 failures in group two. Furthermore other studies have specified a cut off point for RPN at which any failures with a RPN higher than the cutoff point would be addressed (Burgmeier, 2002; Apkon *et al*, 2004). The difference between the two groups in the present study is particularly dramatic if this last method is used. The highest RPN for group one was 168 (for three failures). However, in group two, 34 failures were given an RPN of 168 or more. This means that if we had chosen a cut-off of 168, we would have only addressed three failures in group one, and 34 in group two. If a higher cut off point is chosen, for example 200, then group one would have no failures addressed at all.

In addition to concluding that the same FMEA conducted by two different groups generates different results, it is important to highlight that there is no real consistency for the use of the FMEA technique itself and that different sources of references may provide different guidelines (McDermott *et al* 1996; Stamatis, 2003; JCAHO, 2005) about the ideal ways for its use as highlighted in the introduction in chapter 1. Although the same steps are followed, the literature review in chapter 1 has shown discrepancies within these basic steps. These discrepancies include:

- Using different scoring scales: Some studies use a 10-point scale (Bonnabry *et al,* 2005, 2006, 2007), while others use a five or four point scale (Uslan *et al*, 2004; Singh *et al*, 2004; Stanton *et al*, 2007). Furthermore, some studies choose to use a descriptive scale without even assigning numerical values (Coles *et al*, 2005; Wetterneck *et al*, 2006).

- Even if two hospitals used a 10-point scoring scale, the description and interpretation of the numerical values differs from one place to another as each hospital modifies the scale it uses.
- The decision to include or exclude the detectability scores in the RPNs.
- How the scores are derived: Some studies report that the RPNs are obtained by consensus (Bonnabry *et al,* 2006; Bonnabry *et al,* 2005; Van Tilburg *et al,* 2006) while others used the average scores (Apkon *et al,* 2004; Burgmeier, 2002).
- Which failures are addressed? The top five or ten or specifying a cut off point for RPN at which any failures with a RPN higher than the cutoff point would be addressed?
- What is done with the recommendations or outcomes? Some studies have simply implemented recommendations without recalculating the FMEA (Day *et al,* 2007; Cheung *et al,* 2006; Ford *et al,* 2009; Riehle *et al,* 2008) while others repeat the FMEA after changes are implemented to determine whether the RPN values have decreased (Apkon *et al,* 2004; Saxena *et al,* 2005; Bonnarby *et al,* 2008; Van Leeuwen *et al,* 2009).
- Finally, the purpose of conducting an FMEA. As mentioned before, in countries like the USA, it is mandatory to conduct an FMEA in the hospital setting. Does this sense of obligation add bias to the results?

The above discrepancies in the tool's usage thus further support the claim of FMEA's unreliability because published studies have shown that there is no consistency for its use by different healthcare institutions.

The main limitation of this study and of FMEA in practice was that it was difficult to recruit healthcare professionals with matched levels of experience and knowledge in each group. However, it was ensured that at least one senior doctor, senior nurse and senior pharmacist participated in each group as the key disciplines involved in this process. Also, unlike in the USA where hospitals are required and expected to conduct FMEAs, we relied on participants volunteering to participate. Although hospitals in the USA are expected to conduct at least one FMEA, most published papers indicate that the main disadvantage encountered was how much time consuming FMEA was (Cheung *et al*, 2006; Nickerson *et al*, 2008; Kunac and Reith, 2005). In this study the main difficulty we also experienced was the difficulty in recruiting participants who could take the time to attend the FMEA meetings.

Initially it was intended to also test the 'test-retest' reliability by asking both groups to determine the severity, probability and detectability scores again on a different occasion in order to assess whether their responses had changed or not. However, this was not feasible as it was not possible for the same healthcare professionals to attend another meeting due to time constraints, increased workload and a merger between the trust and another large teaching hospital in London. Furthermore, as hospital guidelines and policies are periodically updated, it would have also been impossible to rule out that any 'test-retest' differences were not due to other confounding factors such as updated guidelines, new policies or reported incidents or even due to the participants' learning following their first experience with FMEA. As the hospital environment, including guidelines and policies, is constantly re-evaluated and updated, the 'test-retest' may not have been meaningful.

Although the results cast doubt on the reliability of FMEA, it may still be an important and useful tool to help guide hospitals to potential failures. It allows healthcare professionals from different disciplines to get a shared understanding of the process of care and its inter-relationships as well as share the tangle of action and the drive to bring on change and improvement. In this study, all the participants said that this FMEA allowed them to examine a process thoroughly as part of a multidisciplinary team. However, considering the hours invested in FMEA, it would only be beneficial if it resulted in changes in patient care and helped avoid 'potential errors' from reaching the patients. Although recommendations at the end of the process were included by both groups, they were not implemented or tested in this study. It is therefore unknown whether or not the groups' recommendations would decrease the RPN of a potential failure or whether the RPN value would be lowered to the same extent in both groups or even make the process safer.

2.7 Conclusion

The results of this study call into question the reliability of the FMEA since its outcomes cannot be repeated; instead the results appear to depend on the individual groups' experience, knowledge and perceptions. The fact that different groups identify different high risk failures makes it impossible to tell which failures should be addressed and thus where money, time and effort should be allocated to avoid these failures.

In the next chapter (chapter 3) the validity of FMEA will be explored.

Chapter 3 Validity of FMEA

'It is hard to know what you are talking about in mathematics, yet no one questions the validity of what you say. There is no other realm of discourse half so queer.'

James R. Newman, 1989

3.1 Introduction

In chapter 2 the reliability of the FMEA was called into question since its outcomes depend on the participating team and cannot be repeated.

In this chapter the validity of the FMEA process related to the use of vancomycin and gentamicin is tested. The chapter is divided into six main sections. In the first section the general types of validity will be explained with an emphasis on the validity tests that were used in the present study. Sections two to five each describe a different validity test for FMEA. Each section includes methods, results and a brief discussion. The sixth and final section is an overall discussion and presents the conclusions.

3.2 Validity

Validity is concerned with the accuracy of data (Smith, 2002). It is an assessment of whether an instrument measures what it aims to measure (Bowling, 2002). In science, validity is essential to a research proposal's theoretical framework, design and methodology, including how well specific tools or instruments measure what they are intended to measure (Higgins and Straub, 2006). While the definition of validity seems relatively simple and straightforward, there are several different types of validity. Each of these types takes a somewhat different approach in assessing the extent to which a measure measures what it purports to (Carmines and Zeller, 1979).

3.2.1 Types of Validity

- **Face validity**: This is the first test of validity (Smith, 2002). It refers to the investigators' or an expert panel's subjective assessment of the presentation and relevance of the instrument: do the questions appear relevant, reasonable and clear? (Bowling, 2002).
- **Content validity**: This is concerned with the extent to which an instrument covers all relevant issues (Smith, 2002). It is more systematic than face validity and involves the judgments, usually made by a panel, about the extent to which the contents of the instrument appears to examine and include the domains it is intended to measure (Bowling, 2002).
- **Criterion validity**: This refers to the extent to which the instrument correlates with other measures of the same variable (Bowling and Ebrahim, 2006). To demonstrate criterion validity, the results are compared with established standard methods of collecting the same information.
- **Construct validity**: For questionnaires, construct validity is concerned with whether or not a question or a group of questions corresponds to what is understood by a construct or concept. To achieve construct validity, the researcher must include questions that easily be answered and which provide a classification that reflects the components and complexities of a theoretical construct (Smith, 2002). It is confirmation that the instrument is measuring the underlying concept it purports to measure (Bowling, 2002). Carmines and Zeller (1979) report that construct validity is concerned with the extent to which a particular measure relates to other measures consistent with theoretically derived hypotheses concerning the concepts that are being

measured, i.e. the validity seeks agreement between a theoretical concept and a specific measuring procedure or device.

In most cases the validity tests mentioned above are applied to questionnaires or surveys. Since the FMEA process comprises of several steps, the above approaches to assessing validity were adapted in order to test FMEA's validity. Therefore the above validity tests were applied to this study as follows:

- **Face validity:** In the present study, this was taken to refer to the researcher's and supervisors' subjective assessment of the process mapped out by the FMEA teams.
- **Content validity:** Here we included the judgement of healthcare professionals who did not participate in the FMEA teams to determine the extent to which the contents of the FMEA appeared to include all the domains judged to be required.
- **Criterion validity:** This involved assessing the extent to which parts of the FMEA correlated with other similar objective measures.
- **Construct validity:** Carmines and Zeller (1979) state that construct validity is by necessity theory-laden, therefore it is impossible to 'validate' a measure of a concept in this sense unless there exists a theoretical network that surrounds the concept. The main theory behind FMEA is to prioritise failures and this is achieved by calculating the RPN value. The mathematical properties of the scoring scales used were therefore assessed and their use in FMEA was evaluated.

3.3 Aim and objectives:

3.3.1 Aim

The aim of this part of the study was to explore the validity of the FMEA process.

3.3.2 Objectives

The objectives were:

- To assess the face validity of FMEA through observation of the process being studied.
- To test content validity of the FMEA by presenting the FMEA findings presented in chapter 2 to other healthcare professionals.
- To test criterion validity of the FMEA by comparing the FMEA findings with audit data available at the study hospitals, data reported on the trust's incident report database and data collected from the laboratory.
- To assess construct validity by exploring the relevant mathematical theories involved in calculating the RPN.

In the following section, each validity test along with its results and discussion are described separately. The chapter will conclude with an overall discussion of the findings.

3.4 Face validity

3.4.1 Methods

To explore the face validity of the FMEA, observational work was carried out. All observations focused on the use of vancomycin and gentamicin. The researcher shadowed a number of pharmacists on their daily clinical pharmacy visits to

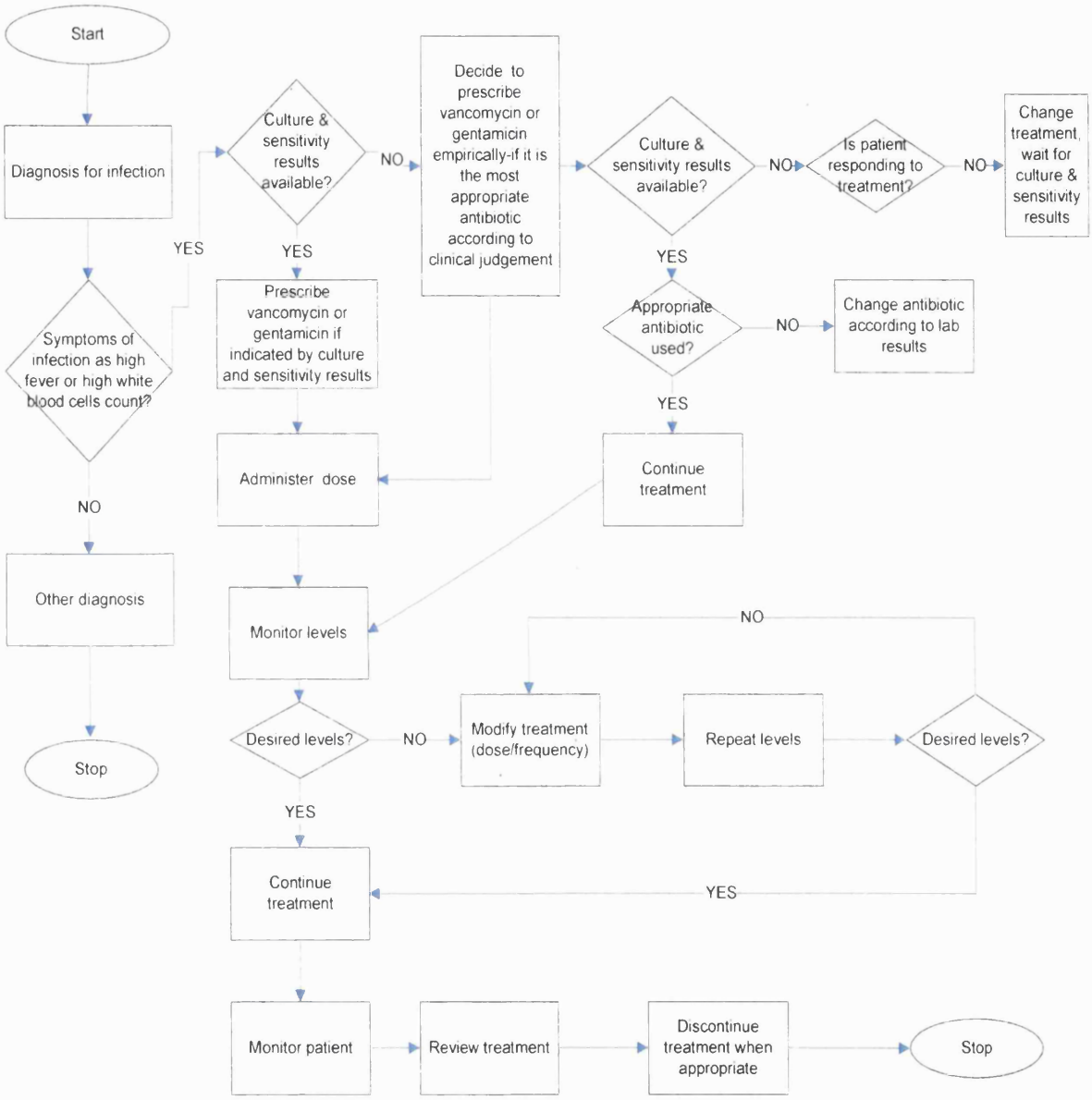
medical and surgical wards for a period of two weeks. Two days were also spent in the microbiology and chemistry laboratories. Permission was obtained from consultants to attend a number of ward rounds and from nurses to observe the process of administering vancomycin and gentamicin to patients.

Other aspects of the process such as blood sampling from patients, nurses receiving laboratory results on the phone or doctors checking the computer systems for the levels were not directly observed as they occur at unpredictable times during the day. Instead, information about these steps was obtained indirectly through conversations with the ward nurses and pharmacists. Before the FMEA meetings were conducted, the researcher created a flowchart mapping the use of vancomycin and gentamicin as observed. This flowchart was further revised by the supervisors who have a strong clinical background. This flowchart had not been seen by the FMEA team members in order not to influence them and to avoid bias. The researcher's flowchart was subsequently compared with those developed by the two FMEA teams.

3.4.2 Results and Discussion

Figure 10 presents the flowchart developed by the researcher following the observations of the relevant processes.

Figure 10: Flow chart for the use of vancomycin and gentamicin as developed by the researcher.



To assess the face validity of FMEA, the flowchart in figure one was compared to the mapped processes prepared by the FMEA teams (chapter 2, pages 89 & 90). The first main difference was that the flowchart style developed by the FMEA team did not include the 'yes' and 'no' choices. Instead the team developed a simple event line and included the sub processes under each main step identified. In spite

of the differences in the flowchart design, the main steps identified by both teams were the same as those identified by the researcher through observations on the ward. These steps included prescribing, administering and monitoring the use of vancomycin or gentamicin. The start and end steps of the FMEA processes mapped by the groups were more concise than that presented in figure 10 because both groups were provided with these start and end steps. Key issues such as cultures and sensitivities, empirical treatment and modifying treatment after levels are reported were also acknowledged by both groups and by the researcher. The second main difference between the FMEA flowcharts mapped by the FMEA teams and that developed by the researcher is the level of details presented in the FMEA flowchart. The teams identified more detailed sub processes to help them list the failures more easily. Thus, the first validity test of FMEA proved to be positive.

3.5 Content validity

The second validity test, known as content validity, ensures that the process covers all relevant issues related to the use of vancomycin and gentamicin. For this, healthcare professionals not involved in the FMEA itself but involved in the use of vancomycin and gentamicin in the same NHS Trust were contacted and asked to comment on the complete FMEA sheets (appendix 16 &17).

3.5.1 Methods

Initially 70 healthcare professionals including senior doctors, junior doctors, pharmacists, nurses, laboratory personnel, service managers and risk managers had been contacted to participate in the FMEA meetings. Only 14 actually participated in the meetings (chapter 2 page 84). The remaining 56 were contacted again after the FMEA was completed and shown the FMEA flow chart and the potential

failures identified. They were invited to comment as to whether or not they agreed with the mapped process and the potential failures identified. E-mail reminders were sent once a week for three weeks.

3.5.2 Results and Discussion

Only four (7.5%) of the 56 healthcare professionals agreed to comment about the FMEA, and only three (5.4%) actually replied after three weeks of E-mail reminders. All three respondents were medical consultants (15 of the 56 healthcare professionals contacted were medical consultants). Two were sent group one's FMEA and one was sent group two's FMEA.

Their comments were as follows:

Group one

Consultant one:

> *"I can see the value of identifying every step in the process of prescribing, administering and monitoring the use of these drugs. I think my main query is about the use of the severity/likelihood/detectability scores, and what scales you use, and how you derive them. In risk analysis this is a frequent cause of confusion."*
>
> *"I agree with the methodology, and with the attempt to break down the process of giving these drugs into the many different steps or components. I have had a look at these and I am unable to identify any glaring omissions, or find any changes in the proposals for remedial action."*
>
> *"I would still query some of the severity/probability scores you have adopted, and ask what assumptions you have made in choosing them."*

Consultant two:

> *"Sub process 1a: Not taking proper history of penicillin allergy – if patient is not really allergic, then vancomycin not really the best option.*
>
> *Sub process 2a: Does weight not need to be checked and age to work out dose?*
>
> *Sub process 2c: I disagree with need to find doctor to write prescription. It is the doctor who decides to write it, so by definition the doctor is there."*

"There is a whole very important tranche of result interpretation that doesn't seem to be covered in existing documents this is the recording of the timing of the level and the timing of the dose.
And then IF these are recorded (and they are often not or the timing of the blood being drawn is but this information is not transposed onto the computer result),

that the doctor checks the relative timings of level and dose before trying to interpret the level.
This is in my experience THE commonest failing and far more important than the nurse finding the drug or the prescription being legible etc.
One of the ways in which this failing can be addressed is to insist that all regular vancomycin prescriptions are for 10am (and again at 10pm if twice daily) so that the routine phlebotomy service will take the blood at the right time."

Group two

Consultant one:

"Looks excellent - very comprehensive. I can't think of any processes/risks that have not been addressed."

The consultants who revised group one's FMEA had a number of comments and additions to the completed FMEA sheet. The first consultant did not have comments regarding the FMEA data but instead questioned the evidence behind the use of the scoring scales. This highlights two important issues; first the queries mentioned about the scoring scales suggested that the consultant was not familiar with fact that the FMEA process involves using scoring scales that have been previously developed and used in different industries including healthcare. Second, these comments highlight difficulties of using such scales particularly since subjective assumptions play a large role when choosing a score. These comments are similar to those that will be presented by the SPI participants in chapter 5. The second consultant commented on the sub processes and failure identified, indicating that there were still failures that the groups did not identify such as checking for

allergies and recording the patients' weight and age. Furthermore, from this consultant's experience, some failures deserved a much higher priority than others. This clearly emphasises the subjective nature of the FMEA data. More importantly, from the consultant's point of view, the RPN values of some failures may have differed if she/he had participated in the FMEA meetings. As for group two's FMEA, the consultant seemed content with the FMEA data provided and did not make any further comments.

Though few, these results bring into question the content validity of FMEA. However, there are two important arguments here. First, the response rate from the healthcare professionals was very low and from the three consultants who revised the FMEA outcomes only one had specific comments about the FMEA data provided, while the remaining two said they were content with the data. Thus it is not entirely fair to claim that the content validity test for FMEA was not successful. The second argument is that content validity refers to extent to which an instrument or tool covers all relevant issues. Does this mean that if 90% of the instrument or tool covers all relevant issues is it valid? Or does it become invalid since 10% of the issues were not covered? In order to be able to exclusively determine whether the content validity test of FMEA has a positive or negative outcome, the FMEA data would need to be reviewed by more healthcare professionals. What this test suggests is the confirmation that the FMEA results will depend on the participants' experiences and views and that a multidisciplinary team may still not be able to identify and cover 'all' the potential failures within a process.

3.6 Criterion validity

To test the criterion validity of FMEA, the extent to which the FMEA data correlated with other measures of the same variable was explored. Three different approaches were used, two of which involved comparing the FMEA data to existing data from the trust's incident report database and the trust's audits; while the third method involved collecting new data from the laboratory. Each method will be described in turn along with its results and discussion.

3.6.1 Ethics approval

Before the start of this study, an ethics application was submitted to the Riverside Research Ethics Committee. Initially a notice of substantial amendment was submitted to the first ethics application submitted for the FMEA meetings in May 2007 (chapter 2, page 76) in order to collect data from the hospital to compare it to the results obtained from the FMEA meetings. However the ethics committee requested a new application form to be sent rather than a substantial amendment. A new ethics application form was compiled and sent in October 2007. The committee requested clarifications to the application in November and final approval was granted in January 2008. Research and Development approval was then sought from the trust and approval was granted by March 2008 (appendix 19).

3.6.2 Comparing FMEA to existing data

In the following section data collected from the hospital's incident report database and from previously conducted audits related to the use of vancomycin and gentamicin will be compared to the FMEA data generated by the teams in chapter 2.

3.6.2.1 Trust's incident report database

The trust uses an incident reporting database, called Datix (introduced in 2006), to record clinical and non-clinical incidents and keep track of their progress as the causes are investigated and reviewed.

The medication incident report form is available on the trust's intranet and includes mandatory and non-mandatory fields with some fields chosen from the drop down menu. The severity of the incident is a mandatory field to complete while probability of the incident occurring is not mandatory.

The severity index is selected from the following options:

- None: No harm
- Minor: Minimal harm, extra observation or minor treatment required.
- Moderate: Short term harm. Further treatment or procedure required.
- Major: Permanent or long-term harm-major incapacity.
- Extreme: Death

The probability of the incident occurring again is rated as:

- Rare: Not expected to occur for years.
- Unlikely: Expected to occur at least annually.
- Possibly: Expected to occur at least monthly.
- Likely: Expected to occur at least weekly.
- Certainly: Expected to occur at least daily.

Since the FMEA failures include severity and probability scores, they were compared to the severity and probability scores recorded in the reported incident forms on Datix.

3.6.2.2 Methods

Incidents involving the use of IV gentamicin or vancomycin were retrieved from Datix between January 2006 (when Datix was introduced) and January 2009. Incidents that did not specifically mention vancomycin or gentamicin or were related to the use of theses antibiotics in children and patients on dialysis were excluded. Incidents involving the continuous infusion of vancomycin, for example in the intensive care unit, were also excluded because they were excluded from the FMEA discussions.

A list of all the reported incidents related to the use of vancomycin and gentamicin along with their severity and probability scores were collected and complied in a table. For each incident reported, a list of corresponding FMEA failures identified by the FMEA teams was then compiled by the researcher. When comparing the incidents reported to the FMEA failures identified, it was sometimes difficult to make direct comparisons because some reported incidents included a number of errors or failures, while other incidents did not provide enough information. In such cases, the researcher matched one reported incident with two or more FMEA failures where necessary and this was then reviewed by one of the supervisors. Any discrepancies or disagreements were resolved after discussion and an agreed list of corresponding FMEA failures to the reported incidents was compiled (appendix 20).

After the list of reported incidents and their corresponding FMEA failures were compiled, the severity of the incidents reported on Datix and its probability of occurrence and the severities of their corresponding failures and their probabilities

were tested for correlation. However, for some reported incidents the probability of the error occurring again was not reported because it was not a mandatory field to complete on the incidents report form.

There are three common correlation tests: Pearson's correlation, Kendall's rank correlation and Spearman's correlation.

- **Pearson's r correlation:** Pearson r correlation is widely used in statistics to measure the degree of the relationship between two sets of interval/ratio data. For the Pearson r correlation, both variables should be normally distributed.
- **Spearman's correlation:** Spearman rank correlation is a non parametric test that is used to measure the degree of association between two variables. It is used when the data is not normally distributed or when ordinal data are being compared.
- **Kendall's tau correlation:** Kendall's rank correlation is also a non-parametric test that is used when the data is not normally distributed or for ordinal data. It should be used rather than Spearman's coefficient when a small data set as small as 9 is used (Siegel, 1956).

Since the data set was non parametric, the correlation between the FMEA severity and probability scores and the Datix severity and probability scores was calculated using Spearman's correlation.

Since the probability scores were not completed for all incidents reported on Datix, it was decided to compare the FMEA probability scores with the Datix incidents using another method. However, comparing the FMEA probability scores with other sources of data is complex because the FMEA probability scores are presented by two ways (appendix 2):

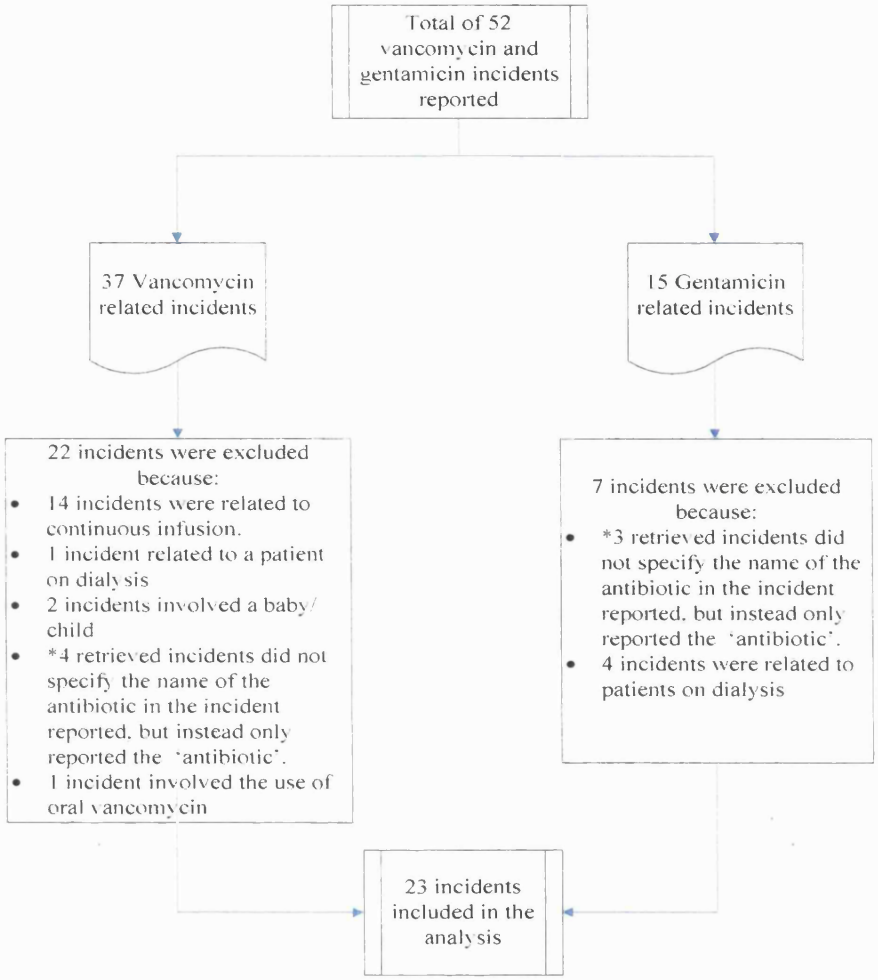
- One method related to reporting the probability per event, for example 'a probability of 1 in 20 events'. However, the term 'event' used in the scoring scale (appendix 2) is not defined and it is not clear whether '1 in 20 events' refers to '1 in 20 patients', or '1 in 20 prescriptions written' or even '1 in 20 antibiotic doses administered'. Since the denominator was not clear, it was decided not to use this method for comparing the probability scores.
- The other method relates to reporting the probability of the failure occurring during a specific time period, for example 'a probability of one occurrence per month' and this may be described as the frequency. This was the method chosen to compare the FMEA probability failures with the frequency of similar incidents reported on Datix.

The FMEA failures were first listed together with the probability of occurrence estimated by the FMEA team. The corresponding incidents reported on Datix similar to the failures identified by the FMEA team were then listed. The frequency of reported incidents on Datix similar to the FMEA failures was then calculated over a three year period.

3.6.2.3 Results and Discussion

In total, 52 incidents were retrieved for the period January 2006 to January 2009 but only 23 were included in the analysis (figure 11).

Figure 11: Incidents reported for the use of vancomycin and gentamicin included in the analysis.



* These incidents were probably picked up in the search if the antibiotic was specified in other fields on the report form. These incidents were excluded because the field in which the antibiotic was specified was not found during the search.

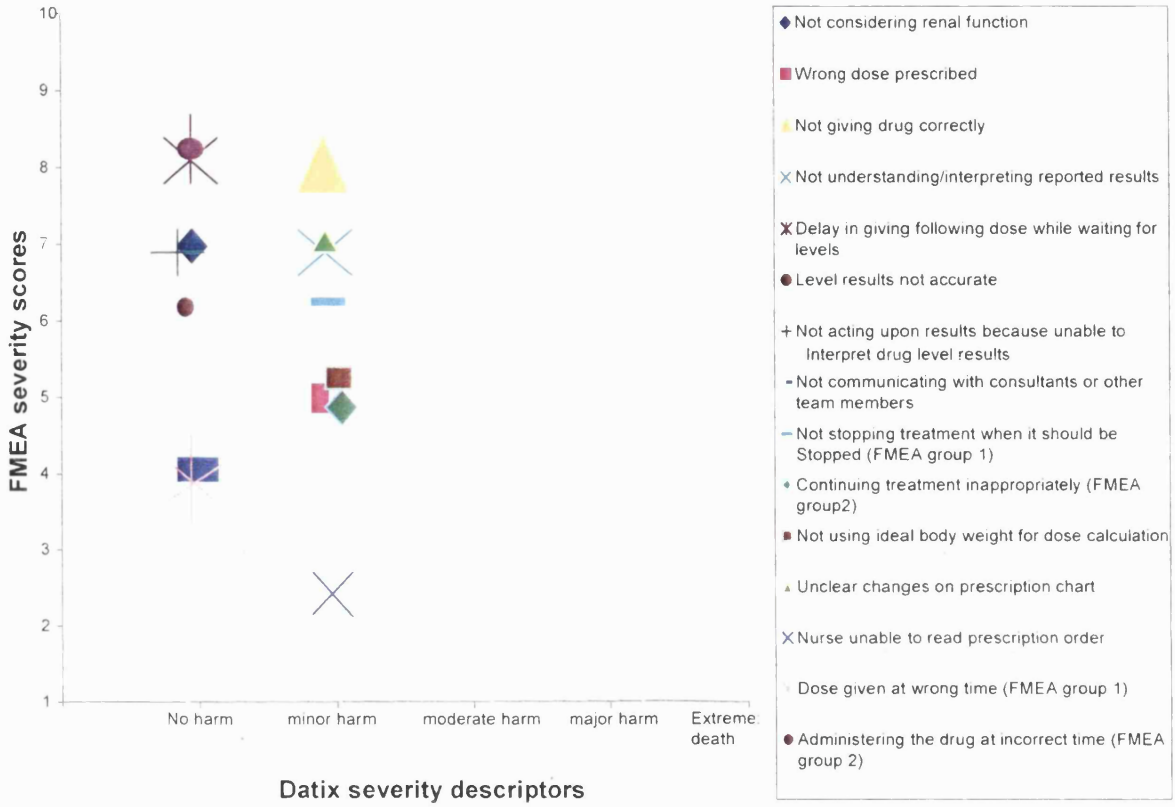
A total of 14 reported incidents from 23 (60.9%) were compared to the FMEA failures. The remaining nine reported incidents (39.1%) were not compared to any FMEA failures because the FMEA teams did not identify these incidents as failures during the meetings. Of the nine incidents, seven (78%) were related to omitted doses and two incidents (22%) reported that the wrong route for the medication had been prescribed on the drug chart. This again suggests that both groups did not

identify all the potential failures as previously reported when content validity was assessed.

3.6.2.3.1 Comparing the severity scores

Figure 12 shows that the severity scores on Datix were either 'no harm' or 'minor harm', while for the FMEA failures, the lowest severity score was 2 for only one failure and the highest score was an 8 (major injury), with the majority of scores ranging between 5 and 7. This highlights the extensive difference between the perceived severities of similar failure scenarios. This great difference can probably be attributed to the fact that with Datix, the error or failure is reported retrospectively, i.e. the person reporting the incident has witnessed the effect of the error-if any- on the patient and thus the reported severity score is based on the actual effect of the error on the patient. While with the FMEA, the failures indentified by the groups were identified as prospective failures, i.e. potential failures. This perhaps made it difficult for the FMEA team members to determine the true effect of this failure and thus in some cases the groups were perhaps presuming the worst effects of certain failures on the patients. Furthermore, figure 12 highlights the differences between the severity scores assigned for the same failure by each FMEA team.

Figure 12: Severity descriptors for incidents reported on Datix and the equivalent FMEA failures and their severity scores (n:15).



The correlation between the FMEA severity scores and Datix severity scores was also calculated using Spearman's correlation (table 13).

Table 13: Correlation coefficient and significance value for FMEA and Datix severity scores

FMEA severity scores	Datix severity scores	
	Correlation coefficient	-0.174
	Sig (2-tailed)	0.417

A negative correlation coefficient (-0.174) indicates that there is no agreement between the severity scores identified by the FMEA team members and the severity scores for the similar reported incidents on Datix.

3.6.2.3.2 Comparing the probability scores:

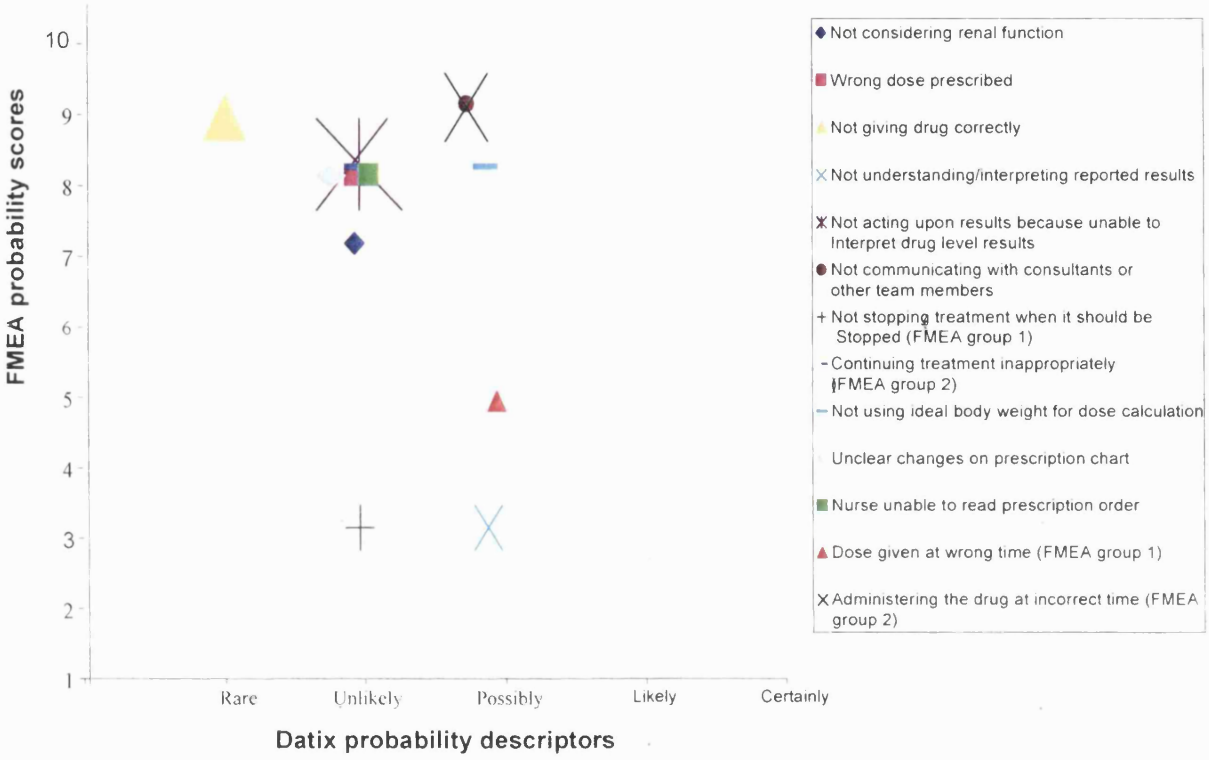
The reported probability scores on Datix, where the probability field was completed, were compared to the FMEA scores by the same method the severity scores were compared. The Spearman's correlation is presented in table 14 and figure 13 summarises the results.

Table 14: Correlation coefficient and significance value for FMEA and Datix probability scores

FMEA probability scores	Datix probability scores	
	Correlation coefficient	-0.092
	Sig (2-tailed)	0.766

A negative correlation coefficient (-0.092) indicates that there is no agreement between the probability scores identified by the FMEA team members and the probability scores for the reported incidents.

Figure 13: Probability descriptors for incidents reported on Datix and the equivalent FMEA failures and their probability scores (n:13).



From figure 13, the lowest probability score for the FMEA failures was 3 for two failures. All the remaining scores ranged between 5 (one occurrence every six months) and 9 (one occurrence every three to four days); and the only failure given a probability of 9 by the FMEA team had an equivalent probability of 'rare' reported on Datix. Over all the FMEA participants anticipated that the probability of the majority of failures will occur again at least once a month (probability score of 8), while the majority of similar incidents reported on Datix were unlikely to occur, i.e expected to occur again annually. This indicates that the probability scores based on subjective assumptions and experiences are neither reliable nor valid since they are neither consistent nor accurate, as shown by the discrepancies of the scores shown in figure 13.

Since not all the probability scores for the Datix incidents were reported by the healthcare professionals reporting the incident, it was decided to attempt to compare the probability scores by comparing the frequency of incidents reported over a three year period with the probability scores estimated by the FMEA teams as presented in table 15 and figure 14.

Table 15: FMEA failures and probability scores and the number of incidents reported and their calculated probabilities.

Failures identified by FMEA	Probability score of FMEA failure	Number of incidents reported on Datix similar to the FMEA failure	Mean frequency of incidents being reported on Datix	Comment
Failure to understand/interpret reported level results (group 1) or not acting upon results because unable to interpret drug level results (group2)	Group 1: probability score 3: a probability of 1 in 15,000 (0.0067%) or one occurrence every one or two years. ---------- Group 2: probability score: 8-a probability of 1 in 8 (12.5%) or 1 occurrence per week	3 incidents reported in 3 years[8]	**Frequency:** An average of 1 incident per year.	Group 1 scored this failure/incident with a low probability score reflecting that they did not think it occurred more than once a year which was similar to the frequency of reported incidents on Datix. Group two on the other hand recorded that this failure/incident occurs on weekly basis. This highlights the discrepancy between the groups' scores.

[8] Data collection period between January 2006 and January 2009.

Table 15: Continued

Failures identified by FMEA	Probability score of FMEA failure	Number of incidents reported on Datix similar to the FMEA failure	Mean frequency of incidents being reported on Datix	Comment
Failure to understand/interpret reported level results (group 1) or not acting upon results because unable to interpret drug level results (group2)	Group 1: probability score 3: a probability of 1 in 15,000 (0.0067%) or one occurrence every one or two years. ---------- Group 2: probability score: 8-a probability of 1 in 8 (12.5%) or 1 occurrence per week	3 incidents reported in 3 years[9]	**Frequency:** An average of 1 incident per year.	Group 1 scored this failure/incident with a low probability score reflecting that they did not think it occurred more than once a year which was similar to the frequency of reported incidents on Datix. Group two on the other hand recorded that this failure/incident occurs on weekly basis. This highlights the discrepancy between the groups' scores.

[9] Data collection period between January 2006 and January 2009.

Table 15: continued

Failures identified by FMEA	Probability score of FMEA failure	Number of incidents reported on Datix similar to the FMEA failure	Mean frequency of incidents being reported on Datix	Comment
Wrong dose prescribed (group 1 &2)	Group 1& 2: probability score 8- a probability of 1 in 8 events (12.5%) or one occurrence per week.	2 incidents reported	**Frequency:** 2 incidents reported during the 3 year period.	Both groups gave the FMEA failure a probability score of 8 while only 2 incidents were reported.
Level results not accurate (group 2)	Group 2: probability score: 10- a probability of 1 occurrence in every 2 events (50%) or more than one occurrence per day.	1 incident reported	**Frequency:** 1 incident during the 3 year period, therefore the incident does not occur on daily basis or even annually.	Group two have given this failure the highest probability score. However, only 1 similar incident was reported over a 3 year period.

Table 15: continued

Failures identified by FMEA	Probability score of FMEA failure	Number of incidents reported on Datix similar to the FMEA failure	Mean frequency of incidents being reported on Datix	Comment
Not considering renal function before prescribing (group 1)	Group 1: probability score : 7- a probability of 1 in 20 (5%) or 1 occurrence per month	2 incidents reported	**Frequency:** 2 incidents during the 3 year study period.	Only 2 similar incidents were reported during the last 3 years.
Delays in giving following doses while waiting for drug levels (group 2)	Group 2: probability score : 9- a probability of 1 in 3 (33.3%) or 1 occurrence every three to four days	2 incidents reported	**Frequency:** 2 incidents during the 3 year period.	Only 2 similar incidents were reported during the last 3 years.

Table 15: Continued

Failures identified by FMEA	Probability score of FMEA failure	Number of incidents reported on Datix similar to the FMEA failure	Mean frequency of incidents being reported on Datix	Comment
Not communicating with consultant or other team members (group 1)	Group 1: probability score: 9- a probability of 1 in 3 (33.3%) or 1 occurrence every three to four days	1 incident reported	**Frequency:** 1 incident reported during the 3 year period.	Only 1 similar incident were reported during the last 3 years, while the FMEA group 1 estimated that this incident is likely to occur every few days.
Failure to give drug correctly for example wrong rate (group 2)	Group 2: probability score: 9- a probability of 1 in 3 (33.3%) or 1 occurrence every three to four days	1 incident reported	**Frequency:** 1 incident reported during the 3 year period.	Only 1 similar incident was reported during the last 3 years while the FMEA group 2 estimated that this incident is likely to occur every few days.

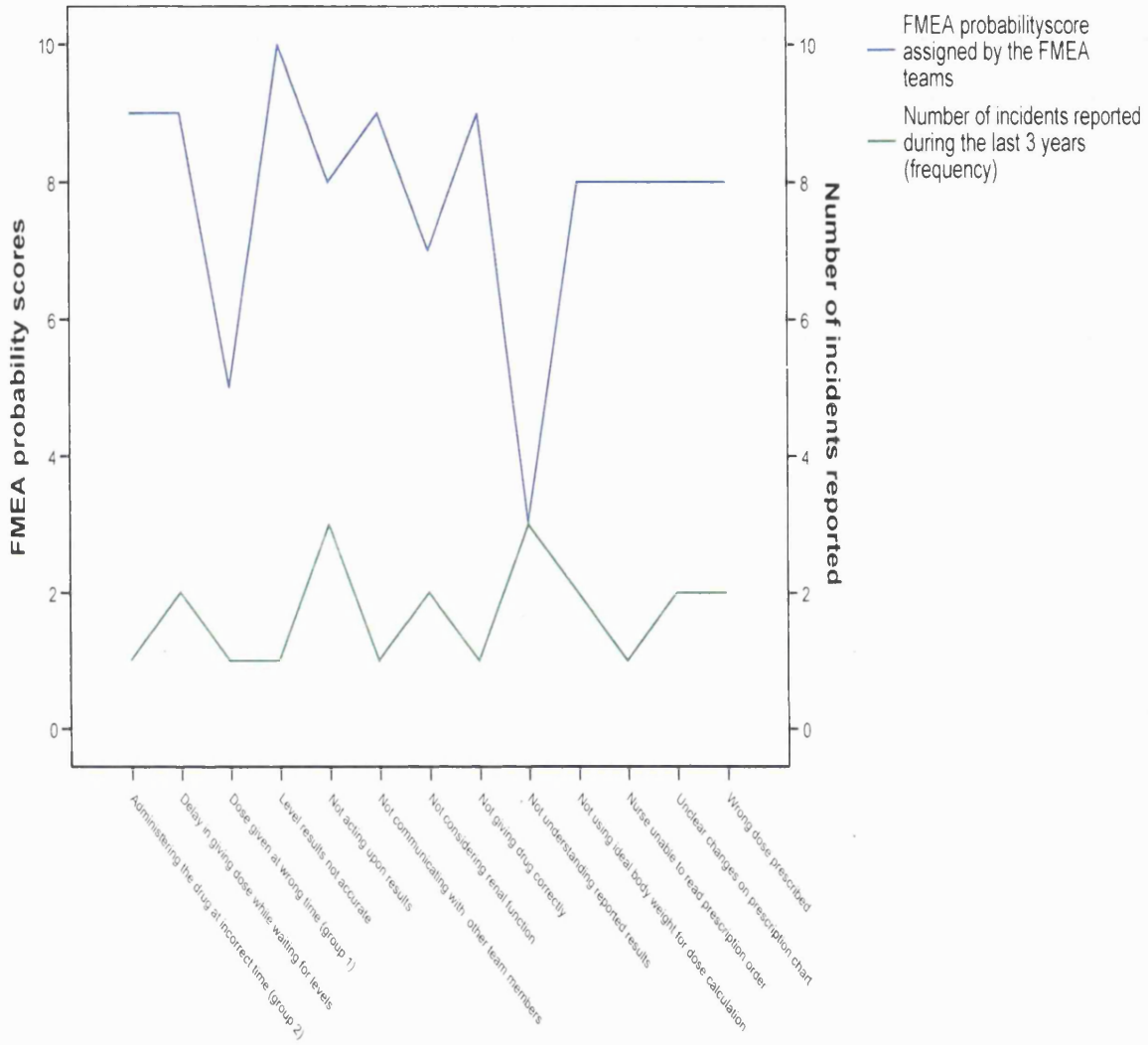
Table 15: Continued

Failures identified by FMEA	Probability score of FMEA failure	Number of incidents reported on Datix similar to the FMEA failure	Mean frequency of incidents being reported on Datix	Comment
Not using ideal body weight in dose calculation (therefore wrong dose) (group 1)	Group 1: probability score: 8- a probability of 1 in 8 (12.5%) or 1 occurrence per week.	2 incidents reported	**Frequency:** 2 incidents during the 3 year study period time.	Only 2 similar incidents were reported during the last 3 years; however group 1 estimated that this incident/failure was likely to occur every week.
Unclear changes (for example not crossing out wrong dose, or not writing correct changes clearly) (group1)	Group 1: probability score: 8-a probability of 1 in 8 (12.5%) or 1 occurrence per week.	2 incidents reported	**Frequency:** 2 incidents during the 3 year study period time.	Only 2 similar incidents were reported during the last 3 years; however group 1 estimated that this incident/failure was likely to occur every week.

Table 15: Continued

Failures identified by FMEA	Probability score of FMEA failure	Number of incidents reported on Datix similar to the FMEA failure	Mean frequency of incidents being reported on Datix	Comment
Nurse unable to read prescription order (group 1)	Group 1: probability score : 8-a probability of 1 in 8 (12.5%) or 1 occurrence per week	1 incident reported	**Frequency:** 1 incident reported during the 3 year period.	Only 1 similar incident was reported during the last 3 years.
Dose given at wrong time (group 1) or failure to administer drug at correct time (group 2)	Group 1: probability score 5: a probability of 1 in 400 (0.25%) or one occurrence every six months to one year. ---------- Group 2: probability score: 9- a probability of 1 in 3 (33.3%) or 1 occurrence every three to four days	1 incident reported	**Frequency:** 1 incident reported during the 3 year period.	Again this failure highlights the great discrepancy between the groups' predications. Group one estimated that the failure would occur once every 6 months to a year while group 2 estimated its occurrence every few days. Only 1 similar incident was reported.

Figure 14: Comparing FMEA probability scores



Common failures identified by the FMEA and incidents reported on the incident database

Comparing the FMEA failures with incidents reported on the trust's reporting database proved to be a challenge. Only a small number of incidents were retrieved perhaps partly because Datix was only introduced in 2006. Furthermore, reporting databases are known to be unreliable because of underreporting. The IOM (1999) states that underreporting is believed to be the 'plague' of all incident reporting programs especially in their early years of operation. It is stated that underreporting of adverse events is estimated to range from 50%-96% of the adverse effects

actually occurring annually (Leape, 1994; Cullen *et al*, 1995; IOM, 1999). In a recent comparison between reporting systems and systematic review of records, the reporting systems detected only about 6% of the adverse events found by systematic review of records (Sari *et al*, 2007). Vincent and colleagues (2008) further state that reporting systems do not effectively detect adverse events and that although they are valuable they cannot and never will act as a measurement system for safety. Although the reporting systems can detect a broad range of adverse events, these systems miss the vast majority of events and cannot provide stable estimates of the true underlying defect rates, which has resulted in the development and evaluation of other detection methods that do not rely on spontaneous reporting (Murff *et al*, 2003). Medication errors have also suffered from underreporting although it is one of the most common methods to report medication errors (Chiang et al, 2006). Nurses estimate that only between 25% and 63% of medication errors are actually reported (Chiang *et al*, 2006; Wakefiled *et al,* 2005); while a study by Franklin *et al* (2009) compared four methods of detecting prescribing errors. Spontaneous reporting identified only 1% of all prescribing errors while prospective data collection identified 36% of all prescribing errors and retrospective reviews identified 69%. Another study by Franklin *et al* in 2007 stated that pharmacists perceived an incident report form to be merited for 4% of the errors identified (total of 474 errors were identified), but forms were actually completed for only about 0.2%.

Comparing the FMEA failures to Datix incidents proved to be a difficult task for a number of reasons which included:

1. Differences in the level of details provided. The majority of the reported incidents were more detailed, while the FMEA failures were more succinct (appendix 16&17).
2. In spite of the level of detail provided for the reported incidents, it was sometimes difficult to identify a specific error or failure especially if the incident was composed in 'story like' form.
3. On several occasions, single reported incidents included more than one failure identified by the teams.

Although comparing incident reports to the FMEA data is not an ideal method for comparison, mainly because of the problems of underreporting, it is still recommended by the JCAHO (2005) to use incident report databases when conducting an FMEA. However, from this comparison several important conclusions can be derived: First, the severity scores reported on Datix and those estimated by the FMEA teams differed greatly and there was a negative correlation between the scores (table 13). This indicates that the FMEA participants had the tendency to over estimate the severity of the effect of the failure for the patients. Second, although no detectability scores are reported on Datix, the proportion of incidents reported indicate that they were indeed detectable failures; yet, none of the failures compared to the incidents in Datix was given an FMEA detectability score of '1', i.e. that the failure was almost certainly detectable. On the contrary two failures were given a detectability score of 8 (remote chance of detecting the failure) although similar incidents were in fact detected and reported. The majority of detectability scores for the FMEA failures ranged between 2 (very highly detectable) and 6 (low chance of detecting the failure). Third, when comparing the FMEA probability scores to those reported on Datix there was also a discrepancy between the two, as the majority of the FMEA failures were perceived to occur at

least once a month while the similar failures reported on Datix were reported to occur annually and there was also negative correlation between the scores (table 14).

Due to the problem of underreporting it was expected that when using the frequency to compare the probability scores, the probability of the FMEA failures anticipated by the team would be overall higher than those reported on Datix. However new limitations in the FMEA scoring scale was identified; were the two methods of describing the probability of FMEA failures equivalent? Is it the same to say a probability score of 10 implies that there will be 1 occurrence in every 2 events AND that more than one occurrence will take place per day? In addition to this the lack of clear definition for the term 'event' made it difficult to compare the probability scores using the '1 occurrence in every 2 event' descriptor.

3.6.2.4 Audits

The second method used to test the criterion validity of the FMEA data was to compare the groups' results with relevant audits conducted in the trust.

3.6.2.4.1 Methods

The antibiotic pharmacists and clinical services managers were asked to identify the previous audits relevant to the use of vancomycin or gentamicin.

The audits' outcomes were compared to the FMEA failures identified by the two groups. Depending on the audits' findings, the severity or probability scores were to be compared with any equivalent failures identified by the groups.

3.6.2.4.2 Results and Discussion

Five audits about the use of vancomycin and gentamicin, conducted between 2002 and 2006, were retrieved. Three related to the use of vancomycin and two to once daily gentamicin. However, of the three vancomycin audits, one was conducted in the ICU for the continuous vancomycin infusion and the other tested the introduction of a new vancomycin prescription chart; therefore only one vancomycin audit was relevant.

The vancomycin audit, conducted in 2002, showed that from a total of 34 patients only 10 patients (29%) had an appropriate initial dose prescribed. The first gentamicin audit, conducted in 2003, on the other hand, reported that from a total of 17 patients, over a period of one month, 9 (53%) patients were prescribed an initial appropriate dose with an appropriate dosing interval achieved in 16 patients (94%). The second gentamicin audit, in 2006, also reported that from a total of 19 patients, over a four week period, 10 patients (53%) had a correct initial dose prescribed and the correct initial intervals prescribed in 18 (94%).

It was not possible to compare the results reported in the above audits to the FMEA data for the following reasons:

1. There are several equivalent failures identified by both groups that may be related to prescribing the initial dose as described by the audits. Both groups identified several failures that may eventually contribute an incorrect initial dose, for example not using ideal body weight for calculation of the dose or not considering the patient's renal function. Thus no one specific failure would be comparable to the audits' results.

2. The audits report their result from a number of patients included in the study over a specified time period, while the probability scores of the FMEA failures, as explained in the previous section, are described by two different methods, none of which are suitable for comparison to the audits.

In the next section, the new data collected will be described along with the methods, results and discussion.

3.6.3 Additional new data collected for comparison with FMEA results

The third method used to test criterion validity was to collect new data and compare it to the FMEA's results. The three main processes identified by both FMEA teams were prescribing, administering and monitoring the antibiotics. It was decided to only collect data related to the monitoring failures identified by the FMEA teams. This was based on three main reasons; first, vancomycin was usually prescribed and administered once or twice a day while gentamicin was prescribed and administered once daily in the trust. The prescribing and administration of these antibiotics may therefore occur at any time during a 24-hour period, depending on when judged to be required for the patient, making it difficult to observe and assess prescribing and administration failures. Secondly, in order to identify and follow all patients within the hospital being given IV vancomycin or gentamicin, ward pharmacists and perhaps nurses would have had to have been recruited to help collect the data and this was not practical and might have resulted in variation of the data collected. The third reason was that there is a dearth of literature on the safety and quality of the monitoring processes for such drugs and collection of data on this topic was seen as an opportunity to explore this under- researched topic.

3.6.3.1 Study Setting

Laboratory data was collected from the Hammersmith Hospital chemistry laboratory only, because at the time of this study, samples from Charing Cross Hospital were being sent and analysed at another hospital at a different trust.

In the next sections the data collection will be described in two main parts. Part A describes the data that was initially intended to be collected from the laboratory at the start of this part of the study, while part B describes the data that was actually collected following various changes in the laboratory setting.

3.6.3.2 Data collection-Part A

Before any monitoring data was collected, all the monitoring failures related to vancomycin and gentamicin identified by both FMEA groups were compiled in a table (table 16). This was to help identify those failures for which it was feasible to collect comparable data from the laboratory or wards. The severity and detectability scores for the actual failures occurring in the laboratory were not determined, therefore, it was decided that the probability scores for the FMEA monitoring failures would be compared to the frequencies that these failures actually occurred in the laboratory or on the wards. Table 16 presents the FMEA failures identified by both groups along with their probability scores and the proposed methods for collecting equivalent data from the laboratory or wards.

Table 16: Monitoring Failures identified by both FMEA groups and the proposed methods for collecting equivalent data

Group 1		Group 2	
Failures	**Method for data collection**	**Failures**	**Method for data collection**
Not finding a phlebotomist (Probability score: 8) (RPN: 24)	No data was collected due to the unpredictable timings of doctors putting in a request and the phlebotomists' timings.	Results not reported via telephone if toxic levels (Probability score: 10) (RPN: 360).	Not standard procedure unless in neonates. Scientific clinician was the one responsible to report any abnormal results and not the laboratory personnel. All telephoned results were kept in a record that was reviewed.
Difficulty in withdrawing blood from patient (Probability score: 8) (RPN: 24)	No data was collected due to the unpredictable timings of doctors putting in a request and the phlebotomists' timings.	Time lag between sending sample and receiving results (Probability score: 10) (RPN: 360)	The time the sample arrived to the laboratory was recorded as well as the time the level results were recorded on the computer system and the time gap was calculated.
Samples analysed in batches at specific times, therefore failure to send sample at appropriate analysis time resulting in delays (Probability score: 8) (RPN: 24)	The time the sample arrives to the laboratory was recorded as well as the time the level results were recorded on the computer system and the time gap was calculated.	Results not accurate (failure to record time sample was taken on the request form & therefore can generate inaccurate results (Probability score: 10) (RPN: 360).	All request forms for the antibiotic levels were checked as they come to the laboratory and any missing information such as the time the sample was taken was recorded.
Results not reported (via phone or on the IT system (Probability score: 8) (RPN: 24)	At the end of the day, the total number of samples that the laboratory received and the total number of level results reported was counted. Any discrepancy between the two was noted.	Wrong form filled (Probability score: 8) (RPN: 160)	All request forms for the antibiotic levels were checked and any incorrect forms sent were recorded.

Table 16: continued

Group 1		Group 2	
Failures	**Method for data collection**	**Failures**	**Method for data collection**
Wrong labeling on sample and/or form (when checking for the patient's identification) (Probability score: 8) (RPN: 24)	All request forms for the antibiotic levels as well as the samples were checked as they come to the laboratory and any missing or incorrect information was recorded.	Laboratory not onsite so delay in laboratory receiving sample (Probability score: 8) (RPN: 160)	No data was collected because this failure only applies to Charing Cross hospital where samples are sent off-site for analysis.
Filling in the wrong form to request the analysis of the sample (Probability score: 8) (RPN: 16).	All request forms for the antibiotic levels were checked as they come to the laboratory.	Delay in taking blood by phlebotomist (Probability score: 8) (RPN: 280)	No data was collected due to the unpredictable timings of doctors putting in a request and the phlebotomists' timings.
Doctor does not receive results via phone nor does he/she check results on the IT system (Probability score: 7) (RPN: 168).	Drug charts were checked to see if the results were recorded or not.	Blood taken at incorrect time (the time of the last dose not stated) (Probability score: 8) (RPN: 280)	All request forms for the antibiotic levels were checked as they come to the laboratory and any missing information such as the time the last dose was given was recorded.
Sample sent down wrong pneumatic tube (Probability score: 7) (RPN: 84)	No data was collected because it was difficult to determine if samples were sent through the wrong pneumatic tube.	Results not checked (Probability score: 8) (RPN: 280)	Drug charts were checked to see if the results were recorded or not.
Incorrect sample and form labelling (Probability score: 7) (RPN: 84)	All request forms for the antibiotic levels as well as the samples were checked as they come to the laboratory and any missing or incorrect information was recorded.	Not acting upon results because unable to interpret results (Probability score: 8) (RPN: 280)	This will be interpreted by checking if any changes in treatment regimen occurred after abnormal results were reported.

Table 16: continued

Group 1		Group 2	
Failures	**Method for data collection**	**Failures**	**Method for data collection**
Failure to understand/interpret reported results (Probability score: 3) (RPN: 84)	This was interpreted by checking if any changes in treatment regimen occurred after abnormal results were reported.	Delay in analysis because samples are run in batches at specified times (Probability score: 7) (RPN: 210).	The time the sample arrived to the laboratory was recorded as well as the time the level results were recorded on the computer system and the time gap was calculated.
No documentation of monitoring guidelines on chart (Probability score: 3) (RPN: 81).	Data was collected from chart or notes. Patient details as weight, creatinine clearance and monitoring information as when to take levels were checked from the drug chart.		

Initially two forms were prepared for data collection, one for the laboratory data and the other for the data from the wards. Both forms were piloted before data was collected during the first week of September 2008. This led to incorporation and adjustment of the forms into a single form to ensure ease of recording the data (appendix 21).

3.6.3.3 Changes in the laboratory setting

The data collection was planned after the FMEA meetings were completed and the FMEA teams' results compiled at the end of 2007 but actual data collection commenced in September 2008.

Between 2007 and 2008, several changes occurred in the laboratories across the trust. At the time of the FMEA meetings in mid 2007, vancomycin and gentamicin assays were conducted in the clinical chemistry laboratory (figure 15). The laboratory samples were analysed twice a day in batches using a dedicated analysis machine. Reference ranges for vancomycin and gentamicin during this time were 10-15mg/L (trough levels) and <1.0mg/L (trough levels) respectively and trough levels >20mg/L for vancomycin and >5mg/L for gentamicin were telephoned to the ward. Request forms were handwritten on blue forms (appendix 22) and the results recorded manually on the computer system. The blue handwritten forms required that the healthcare professional complete the patient's details as well as record the following information before it was sent to the laboratory (appendix 22):

1. Name of antibiotic
2. Dose and interval
3. Date and time of last dose
4. Blood collection time

By the beginning of 2008, new computerised request forms had been introduced in the trust. The nurses or doctors on the ward were able to request pathology tests via the computer system (figure 16). A printed copy of the electronic request form was then sent to the laboratory with the sample (appendix 23). On the electronic form healthcare professionals were only expected to handwrite the following information:

1. Date sample was taken
2. Time sample was taken
3. Signature of the healthcare professional

Each electronic request form also had a barcode that the laboratory staff were able to scan rather than manually type in the patient details and the test requested in the laboratory computer. At the same time, the chemistry laboratory installed two new analysis machines that allowed vancomycin and gentamicin to be analysed together with other samples throughout the whole day. The results were then automatically reported on the laboratory computer system and checked by the clinical scientist before being reported back to the wards via the computer system. New reference ranges for vancomycin and gentamicin were also introduced (table 17).

Table 17: Reference ranges for gentamicin and vancomycin from 2008 onwards

Drug	Reference Range	High levels that must be telephoned[10]	Low levels that must be telephoned
Gentamicin			
Pre dose gentamicin level	Pre <1mg/L	>5mg/L	<0.3mg/L
Post dose gentamicin level	Post 5-10mg/L	>15mg/L	
Vancomycin			
Pre dose vancomycin level	Pre 10-15mg/L	>20mg/L	<1.0mg/L
Post dose vancomycin level	Post 20-40mg/L	>45mg/L	

Figure 17 shows a timeline of the changes that occurred in the laboratory between 2007 during the FMEA, and 2008 when the laboratory data was collected.

[10] Before the level results are sent to the wards via the computer system, the clinical scientist reviews them and is responsible for reporting the high or low levels above to the wards by telephone.

Figure 15: Sample pathway from ward to laboratory for analysis in 2007

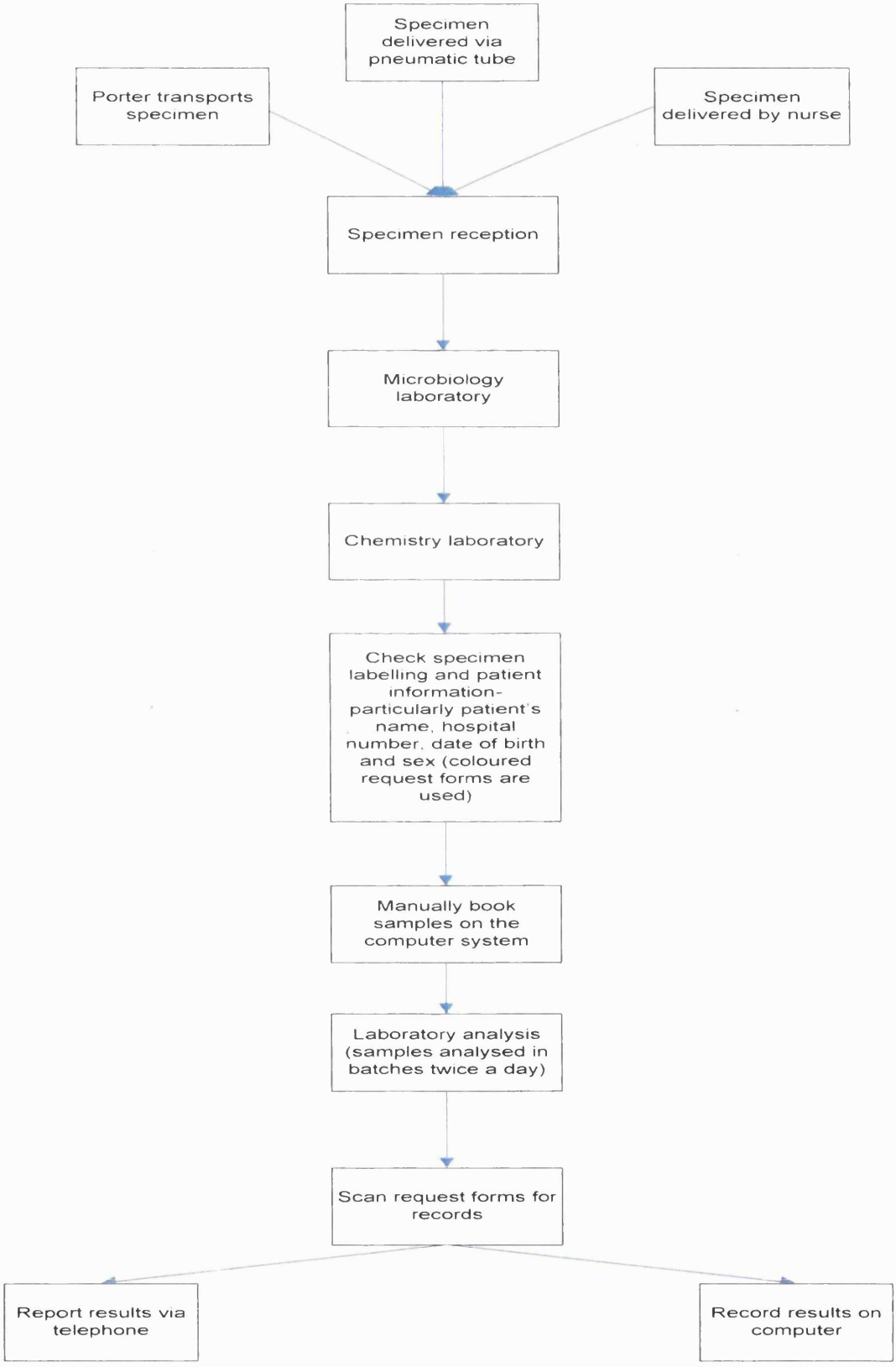
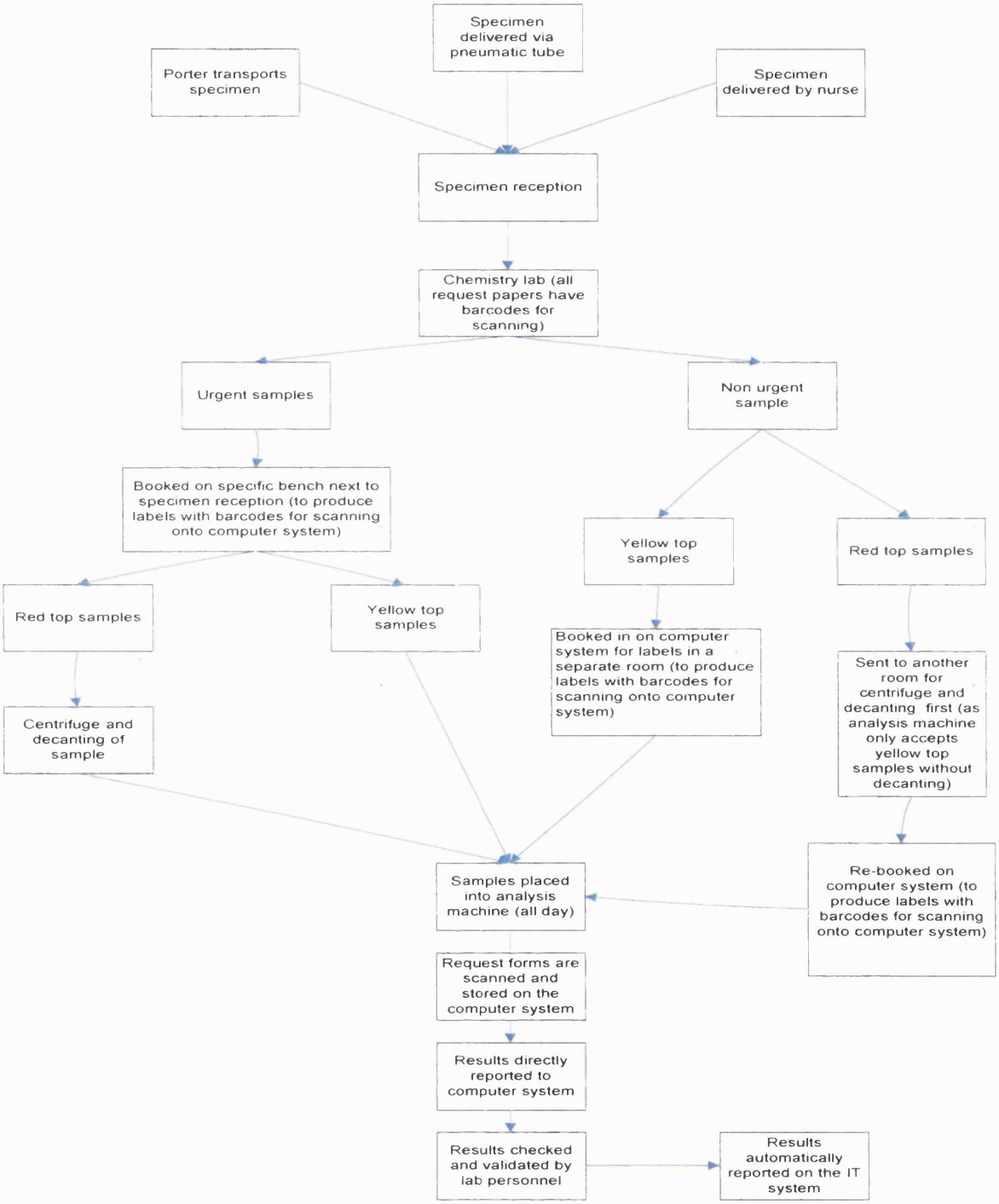
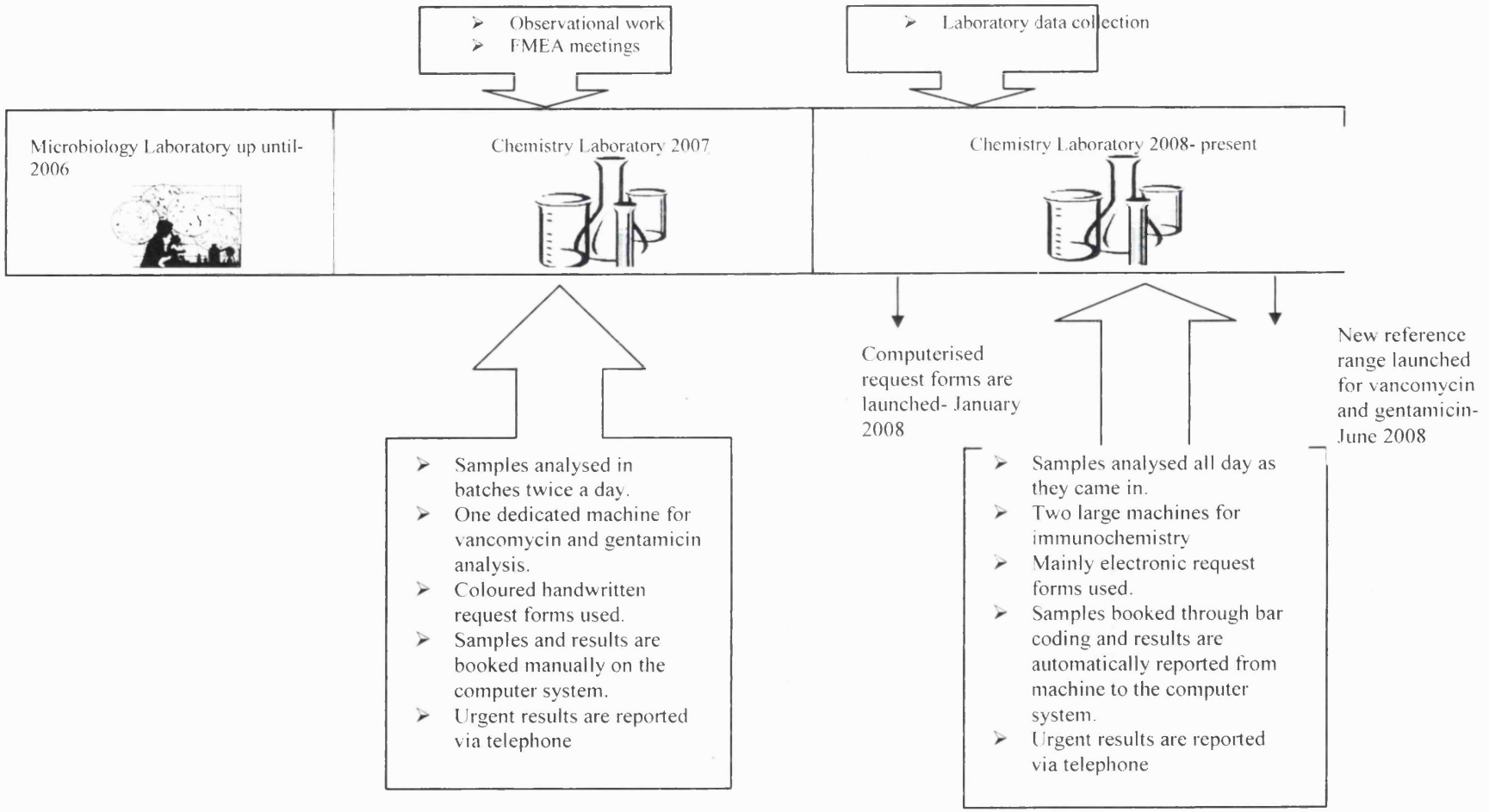


Figure 16: Sample pathway from ward to laboratory for analysis in 2008 onwards[11]



[11] The new analysis machine used in 2008 only accepts yellow-top test tubes. These yellow-top test tubes contain a gel layer that separates blood cells from serum and serum is then analysed. Red-top tubes do not contain this gel layer and therefore the sample must be centrifuged first to separate the cells from the serum. The separated serum is then analysed.

Figure 17: Time line for changes in vancomycin and gentamicin analysis



3.6.3.4 Data collection-Part B

As a result of these changes, a number of failures identified by the FMEA groups were no longer valid or had been minimised by the new practices established within the laboratory. For example since the antibiotic levels were no longer analysed in batches, the potential failure relating to this was no longer relevant, while since electronic requesting was introduced; the number of hand written forms decreased significantly decreasing the probability of filling in the wrong request forms. Table 18 shows the failures for which equivalent data was therefore collected following the laboratory changes.

3.6.3.4.1 Study duration

Data collection took place between 15 September and 10 October 2008, including weekends.

3.6.3.4.2 Inclusion criteria

All adult patients on IV vancomycin or gentamicin with reported 'out of reference range' levels from the laboratory at Hammersmith Hospital only.

3.6.3.4.3 Exclusion criteria

- Renal patients
- General intensive care unit patients
- Children and neonates.
- Patients on once only ('stat') doses

These patients were excluded because they were also excluded during the FMEA meetings.

Table 18: Monitoring Failures identified by both groups and methods for collecting equivalent data following changes in the laboratory

Group 1			Group 2		
FMEA Failures*	**Method for data collection**	**Data Collected**	**FMEA Failures**	**Method for data collection**	**Data Collected**
Samples analyzed in batches at specific times, therefore failure to send sample at appropriate analysis time resulting in delays (Probability score: 8) (RPN: 24)	This failure has been eliminated since the new arrangement within the laboratory.	No data was collected for this failure.	Results not reported via telephone if toxic levels (Probability score: 10) (RPN: 360).	Not standard procedure unless in neonates. Scientific clinician is the one responsible to report any abnormal results and not the laboratory personnel. All telephoned results are kept in a record that was checked during the study period.	Any result on the laboratory computer programme that was tagged to indicate that it has been telephoned was recorded. Also the scientific clinicians' record books were checked to record which antibiotic results were telephoned during the study period.
Results not reported (via phone or on the IT system (Probability score: 8) (RPN: 24)	Computer programme points out any pending results until they reported.	No pending results existed during the study period; therefore no data was collected for this failure.	Time lag between sending sample and receiving results (Probability score: 10) (RPN: 360)	The new computer programme reported the time the sample was sent to the laboratory, received by the laboratory and the time the results were reported	The time the sample was sent to the laboratory, received by the laboratory and the time the results were all recorded for all the samples during the study period

*** Failures presented in italics are the failures that have been eliminated or minimised following the laboratory changes.**

Table 18: Continued

Group 1			Group 2		
FMEA Failures	**Method for data collection**	**Data Collected**	**FMEA Failures**	**Method for data collection**	**Data Collected**
Wrong labeling on sample and/or form (when checking for the patient's identification) (Probability score: 8) (RPN: 24)	This failure has been minimised since the introduction of electronic request forms. However, data from any handwritten forms sent to the laboratory during the study period was collected.	Handwritten forms were checked and any incorrect or inconsistent information was recorded.	*Results not accurate (failure to record time sample was taken on the request form & therefore can generate inaccurate results (Probability score: 10) (RPN: 360).*	This failure has been minimised since the introduction of electronic request forms. However, data from any handwritten forms sent to the laboratory during the study period was collected.	Handwritten forms were checked and any missing information relevant to the level's request was recorded.
Filling in the wrong form to request the analysis of the sample (Probability score: 8) (RPN: 16).	This failure has been minimised since the introduction of electronic request forms. However, data from any handwritten forms sent to the laboratory during the study period was collected.	Any antibiotic requests not requested on the specified blue handwritten forms were recorded.	*Wrong form filled (Probability score: 8) (RPN: 160)*	This failure has been minimised since the introduction of electronic request forms. However, data from any handwritten forms sent to the laboratory during the study period was collected.	Any antibiotic requests not requested on the specified blue handwritten forms were recorded; however no incidents were recorded during the study period.

Table 18: Continued

FMEA Failures	Method for data collection	Data Collected	FMEA Failures	Method for data collection	Data Collected
Doctor does not receive results via phone nor does he/she check results on the IT system (Probability score: 7) (RPN: 168).	Drug charts were checked to see if the results were recorded or not.	Out of range[12] levels were traced back to the wards to record if they have been reported on the patient's drug chart or in the notes.	Blood taken at incorrect time (the time of the last dose not stated) (Probability score: 8) (RPN: 280)	Now the computer programme requests that you specify if the sample is Pre, Post or a random sample. However, data from any handwritten forms sent to the laboratory during the study period was collected.	Handwritten forms were checked and any missing information relevant to the level's request was recorded.
Incorrect sample and form labelling (Probability score: 7) (RPN: 84)	This failure has been minimised since the introduction of electronic request forms. However, data from any handwritten forms sent to the laboratory during the study period was collected.	Handwritten forms were checked and any incorrect or inconsistent information was recorded.	Results not checked (Probability score: 8) (RPN: 280)	Drug charts were checked to see if the results were recorded or not.	Out of range levels were traced back to the wards to record if they have been reported on the patient's drug chart or in the notes.

[12] 'Out of range' levels refer to the antibiotic levels that are not within the recommended reference ranges provided by the laboratory in table 17.

Table 18: continued

Group 1			Group 2		
FMEA Failures	**Method for data collection**	**Data Collected**	**FMEA Failures**	**Method for data collection**	**Data Collected**
Failure to understand/interpret reported results (Probability score: 3) (RPN: 84)	This was interpreted by checking if any changes in treatment regimen occurred after out of range results are reported.	Any changes in the treatment after out of range levels were reported were recorded.	Not acting upon results because unable to interpret results (Probability score: 8) (RPN: 280)	This was interpreted by checking if any changes in treatment regimen occurred after out of range results are reported.	Any changes in the treatment after out of range levels were reported were recorded.
No documentation of monitoring guidelines on chart (Probability score: 3) (RPN: 81).	Data was collected from chart or notes. Patient details as weight, creatinine clearance and monitoring information as when to take levels were checked from the drug chart.	The drug charts for patients with out of range levels were checked to determine if monitoring guidelines were recorded.	*Delay in analysis because samples are run in batches at specified times (Probability score: 7) (RPN: 210).*	This failure has been eliminated since the new arrangement within the laboratory.	No data was collected for this failure.

During the study period, the researcher printed a record of all the vancomycin and gentamicin samples that were analysed on a daily basis from the two analysis machines in the laboratory. Records for samples analysed on the weekend were obtained the following Monday. These records listed the patients' names and results. Once this list was obtained, patients with levels outside the reference range identified by the laboratory were traced using ICE, the hospital's requesting and reporting system for laboratory investigations, to determine which wards they were staying on. Patients were located on the ward using their hospital numbers and dates of birth. Patients' names were kept anonymous and their hospital number and date of birth were used to identify them on the ward. Once the patient's ward was identified, the researcher went to the ward and identified whether the patient's weight and creatinine clearance had been recorded on the chart as well as the pharmacists' monitoring instructions for the antibiotics and reported levels.

The laboratory kept a record of all request forms for the previous six months. These request forms were then scanned and saved on the laboratory computers for future reference. In order to collect data from the request forms sent by the wards to the laboratory, the researcher initially stayed in the laboratory to observe the request forms as they came to the laboratory. However this was not efficient as there were times when no vancomycin and gentamicin request forms came to the laboratory for hours. Furthermore, request forms arriving to the laboratory between 5 pm and 9 am the following morning would have been missed. Therefore it was decided to spend time in the archives at the end of the study period to collect data retrospectively from the request forms for patients with levels outside the reference range. If

patients were discharged or deceased before completion of data collection, their notes and drug charts were retrieved through the Medical Records Department.

3.6.3.4.4 Data analysis

Data collected was entered and analysed using the SPSS (Statistics Package for the Social Sciences version 15.0). The following were summarised for the data collected:

1. The number of included and excluded patients
2. Patients' demographics
3. Number of levels requested during the study period
4. Types of forms used for the antibiotic level requests
5. Information provided on the request forms
6. The time gap between the laboratory receiving a sample and reporting the results
7. Number of patients with 'out of range'[13] levels
8. For the 'out of range' levels, the number of levels reported on the drug charts
9. For the 'out of range' levels, the number of charts with documented creatinine clearance
10. For the 'out of range' levels, the number of charts with documented monitoring guidelines for these antibiotics

Next, the data collected was compared to the FMEA data. This was achieved by comparing the frequencies of data such as the number of levels reported on charts and the presence of information on the request forms to the probability scores of the FMEA failures. Probability scores are reported as 'occurrence per day' or 'occurrence per event' (appendix 2). Because this is the first time that these

[13] 'Out of range' levels refer to the antibiotic levels that are not within the recommended reference ranges provided by the laboratory in table 17

probability values were compared to actual data, an approach of using 'occurrence per event' was used to compare our data. The definition of 'event' was dependant on the FMEA failure. For example, if out of 50 request forms, five had missing information, this was then defined as a probability of 1 occurrence in every 10 events and this probability was compared to that of the equivalent FMEA failure. After comparing the probabilities, it was possible to determine whether the FMEA teams' scores were pessimistic or optimistic and to identify any correlation between the estimates of the FMEA teams and the data collected. Since the data set was small (<9 failures) and non parametric, the correlation between the FMEA probability scores and the probability scores for the collected laboratory data was calculated using Kendall's tau correlation.

3.6.3.4.5 Results

The results are divided into four main sections. The first section describes in detail the number of patients who were included and excluded from the study as well as the number and types of requested antibiotic levels. The second section reports the types of forms used as well as any missing information. The delay in reporting results is also described. In the third section, out of range levels are analysed in more detail. This includes reporting whether or not the levels, monitoring guidelines, the creatinine clearance and weight were recorded on the drug charts. Changes to treatment for out of range levels will also be reported. Finally, in the fourth section, the FMEA data reported in chapter 2 will be compared to the relevant data collected from the laboratory.

3.6.3.4.6 Patients' details and requested levels

During the 26 day data collection period, 286 patients had requests for either vancomycin or gentamicin levels. Of these only 109 (38%) patients met the inclusion criteria specified and figure 18 clarifies the reasons for the exclusions. The demographics of the included patients are presented in table 19 .The 109 patients had a total of 221 levels requested during the study period (figure 19).

Figure 18: Included and excluded patients (n: 286).

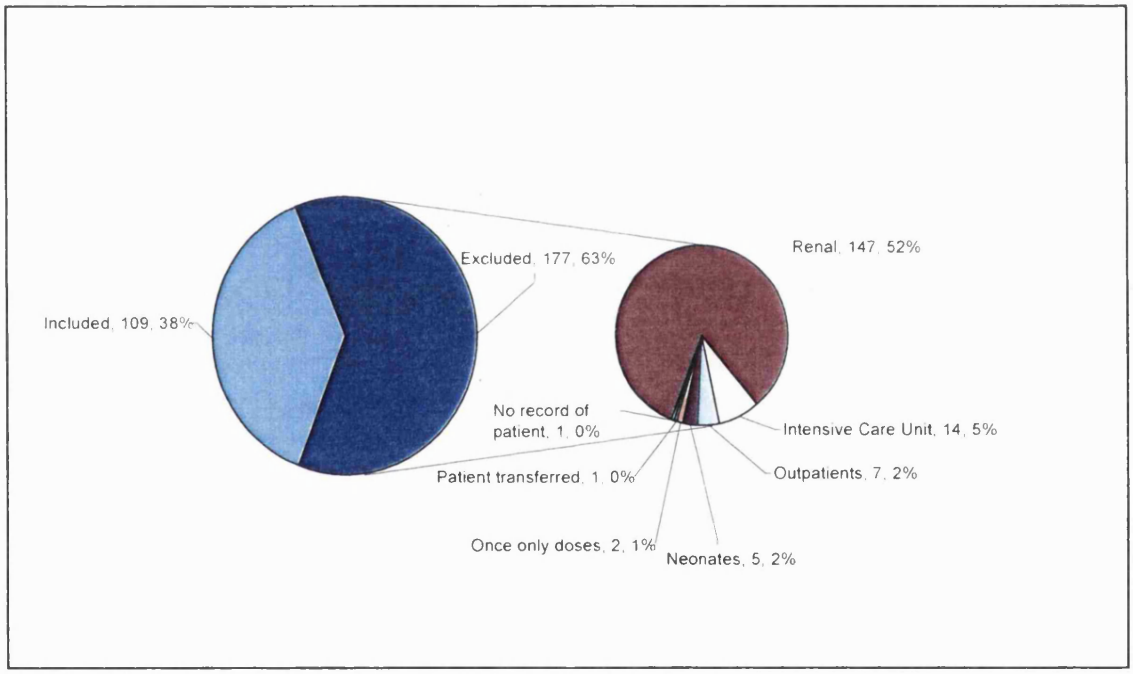
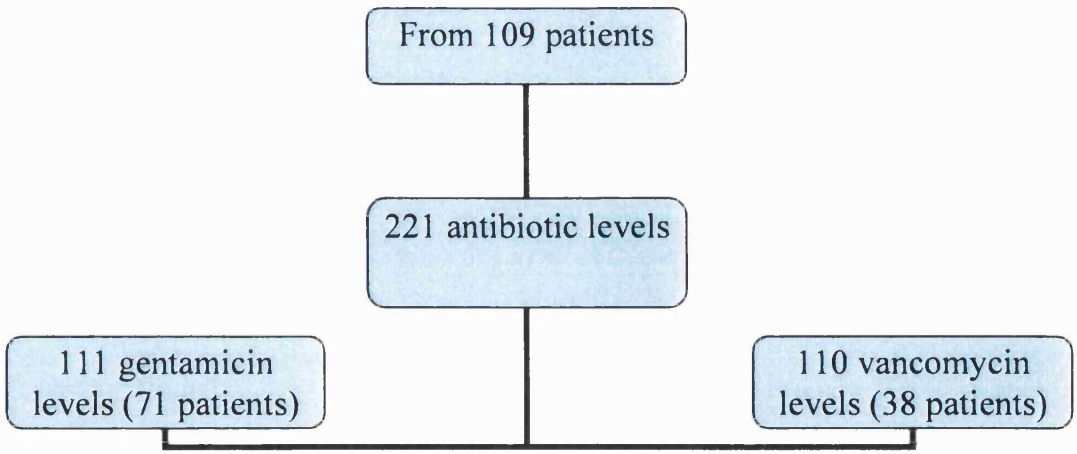


Table 19: Patients' demographics:

Number of patients	109
Gender **Male** **Female**	 66 (61%) 43 (39)
Median age-years (range)	64 (17-85)
Antibiotic **Gentamicin** **Vancomycin**	 71 (65%) 38 (35%)
Wards **Cardiology** **Medical** **Admissions** **Oncology** **Private** **Gynaecology**	 58 (53.2%) 10 (9.2%) 6 (5.5%) 28 (25.7%) 6 (5.5%) 1 (0.90)

Figure 19: Levels requested for the patients



3.6.3.4.7 Request forms and the time taken to report results:

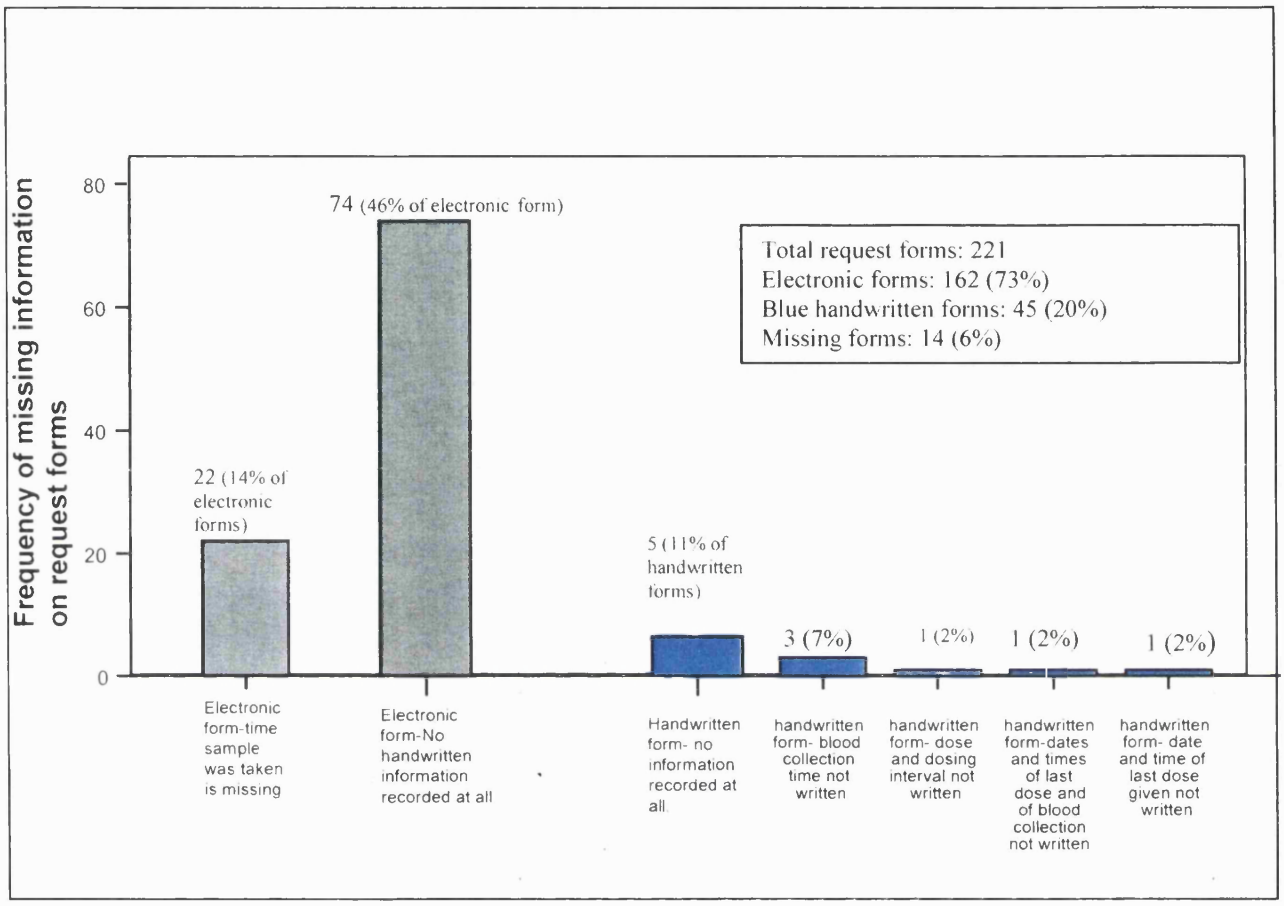
The majority of the request forms received were the new electronic forms, (162, 73%), while the handwritten forms comprised 45 (20%) of the forms received by the laboratory during the study period. The remaining 14 (6%) forms were not retrieved. Information provided on the request forms varied. For the handwritten forms, health care professionals had to complete the following information:

1. Name of antibiotic:
2. Dose and interval
3. Date and time of last dose
4. Blood collection time

Only thirty-five (16%) handwritten forms include all the above information. As for the electronic forms, health care professionals were only requested to document date and time the sample was taken. Sixty-five (29%) of the electronic forms were complete.

Figure 20 summarises the missing information on the remaining electronic (97 forms) and handwritten forms (10 forms).

Figure 20: Missing Information on the request forms.

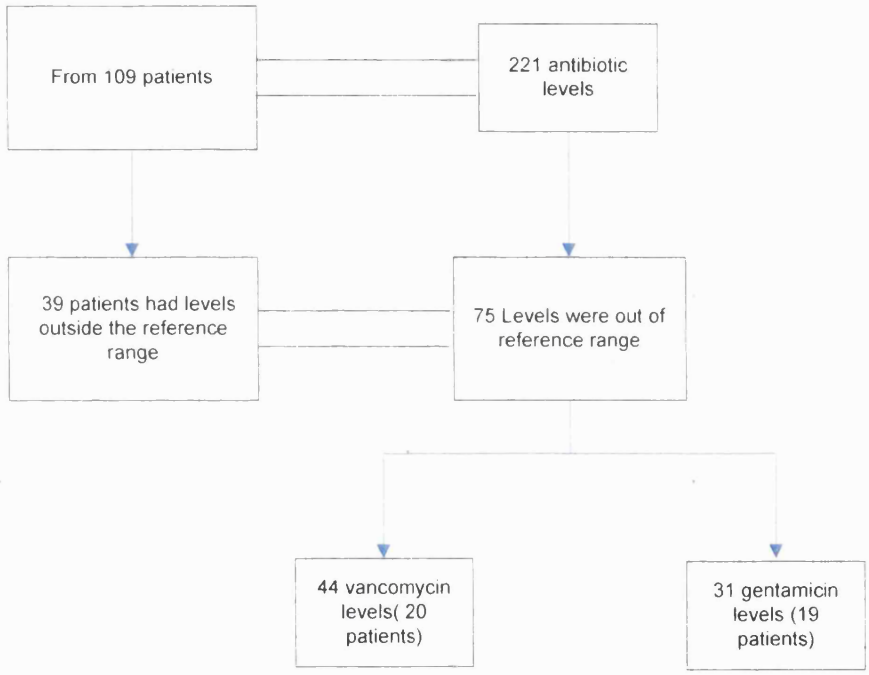


The overall mean time elapsed between collecting the sample from the ward and reporting levels on the computer system was 3.67 hours (range: 0-33 hours; median: 3 hours), while the mean time taken to send the laboratory the sample from the ward was 1.54 hours (range: 0-29 hours, median: 1 hour). The mean elapsed time between the laboratory receiving the sample and reporting the results on the computer system was about 1.70 hours (range: 0-9hours; median: 1 hour).

3.6.3.4.8 Out of range levels

From the 221 levels requested during the study period, 75 (34%) antibiotic levels were not within the recommended reference ranges provided by the laboratory (figure 21).

Figure 21: Number of patients and levels followed up



The 39 patients with out of range levels were then located on the wards. These patients' drug charts and notes were checked to identify if the levels were reported on the chart (figure 22), if the monitoring instructions for the use of these antibiotics were recorded on the drug chart (figure 23) and if the creatinine clearance and weight were reported on the drug chart (figure 24). There were seven drug charts that were not retrieved during the study period. Of the seven missing drug charts, three were for deceased patients and their files were kept with their consultants, while two patients were transferred to another hospital. The remaining two patients

were hospitalised but their drug chart that included the relevant data was missing. The missing data was reported as such in the analysis.

Figure 22: Documentation of drug levels on the drug chart for the 75 out of range levels

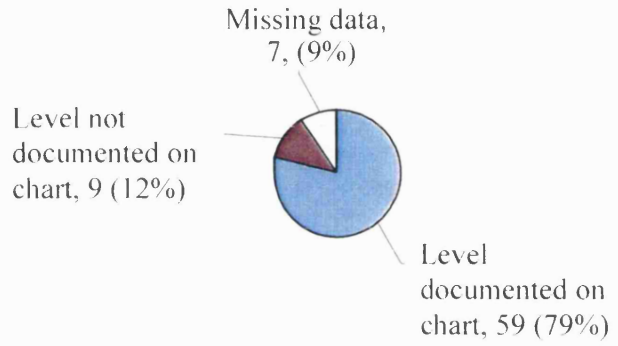


Figure 23: Documentation of monitoring instructions on drug chart for the 75 out of range levels

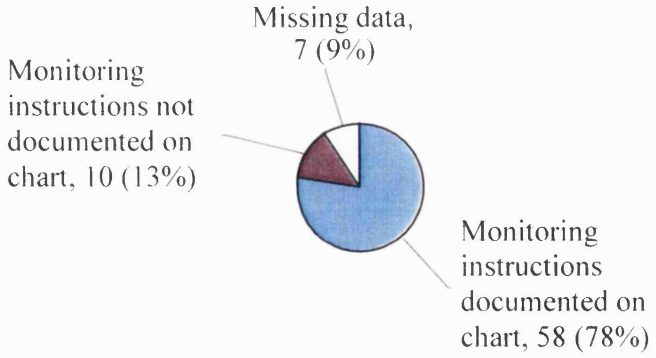
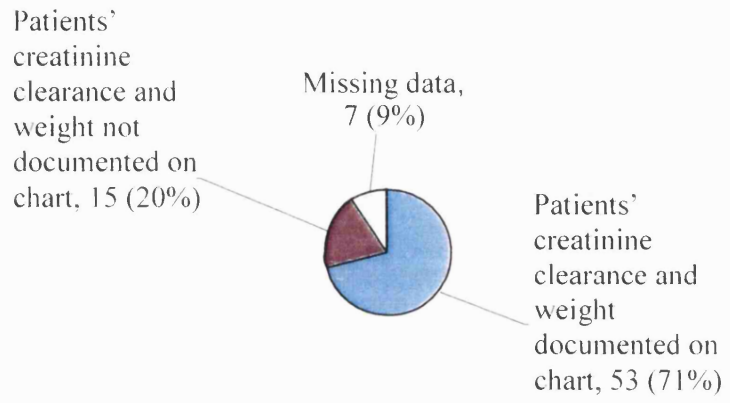


Figure 24: Documentation of patient's creatinine clearance and weight on drug chart on drug chart for the 75 out of range levels



From a total of 221 levels, 75 (34%) were out of range according to the reference range used by the laboratory. Although there are no rigid rules regarding recording monitoring guidelines or creatinine clearance on the drug charts, according to the trust's guidance and procedures for pharmacy practice, the creatinine clearance should be written on the top front of the chart. Furthermore, pharmacists are asked to prompt requests for drug blood levels and interpret the results as well as provide any additional instructions especially for IV infusions. However, recording drug levels is not specifically specified as the pharmacist's duty and this was debated during the FMEA meetings. It is not clear who is responsible for reporting levels on the drug charts, but undoubtedly having the levels written on the drug charts helps the prescriber, who is usually the doctor, the nurses who administer the drug, and the pharmacist, who reviews the drug chart and tailors the treatment according to the patients' needs. The majority of the drug charts included the reported levels (59,

79%), monitoring guidelines (58, 78%) and the creatinine clearance and weight needed to calculate the appropriate dose (53, 71%).

Changes in the treatment were then documented for those patients with out of range levels. Of 75 out of range levels, 45 (60%) did not result in changes to the treatment regimen. There were 17 gentamicin levels out of range for 14 patients. Four of these levels were pre levels of 1.0 μg/ml exactly (reference range for pre levels of gentamicin <1 μg/ml) and therefore the dose was not adjusted. Ten reported out of range levels were levels taken after the first dose was administered. It was observed that in most cases the doctors did not change the dosing regimen after the first gentamicin level was reported back and they tended instead to wait for a second level before deciding to modify the treatment. For eight of these levels the correct decision was taken as the following levels were within the desired range. In one patient, one dose was omitted after the second level was also out of range. When the nurse was asked whether that omitted dose was a mistake or a deliberate action, she said that the drug wasn't given because the previous day the level was high. This was not appropriate, as omitting one dose does not necessarily imply that the subsequent level will decrease if the patient remains on the same dose especially if the patient has an underlying renal problem. Instead the dose should be adjusted accordingly or the level repeated if the doctor thought that the level result was inaccurate because the sample was taken at the wrong time. The remaining three levels were out of range levels among previous normal levels. These levels were perhaps taken at the wrong time or the wrong information on the request forms was recorded. None of the out or range levels reported for gentamicin were high or low

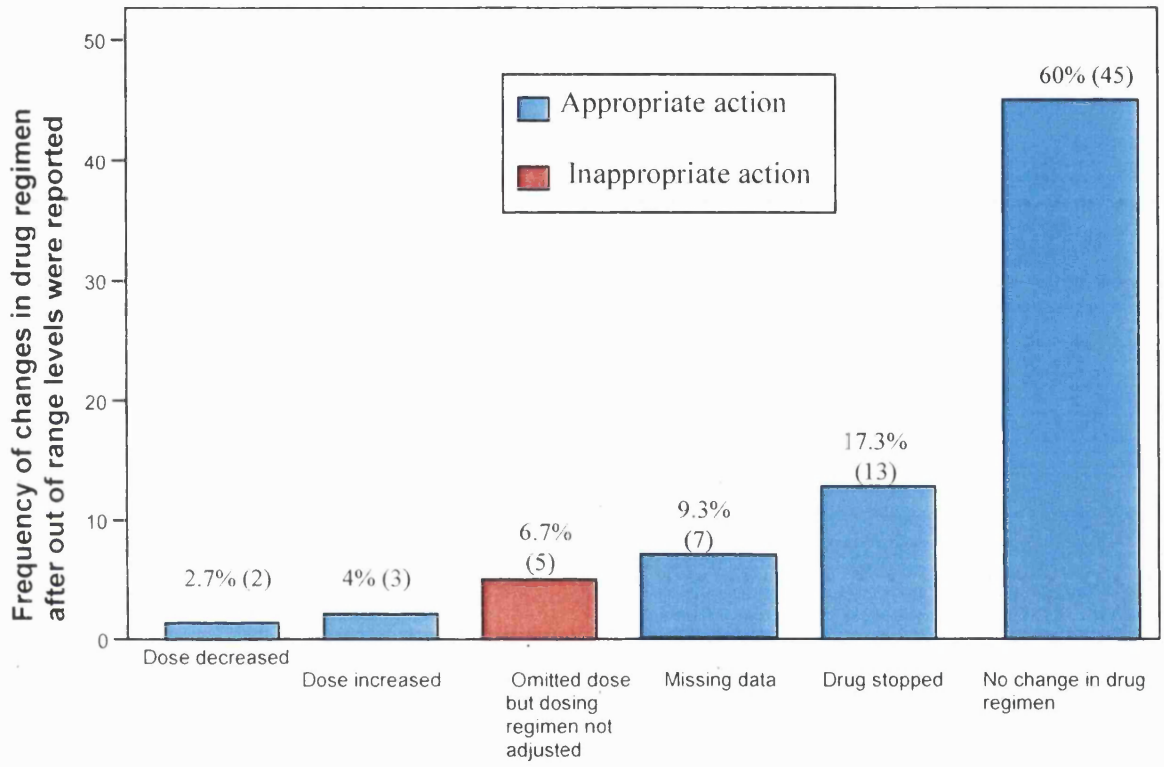
levels that were required to be telephoned according the laboratory's reference range (table 17).

For the vancomycin levels, there were 28 out of range levels from 14 patients. Nine reported out of range levels were levels taken after the first dose was administered. This action does not comply with the hospital guidelines (appendix 24) that state that for vancomycin monitoring, the levels should be taken before the third or fourth dose and not after the first dose to allow the drug to reach steady state. In seven of these levels taken after the first dose no change was observed to the treatment regimen and the subsequent levels were within the required range. In one patient the dose was increased after the second level was also out of range, which was an appropriate course of action. Finally, for one patient, three consecutive levels were very high and the laboratory had telephoned the ward to inform them. This patient was diagnosed with renal failure, the antibiotic was stopped and dialysis was commenced.

Eight vancomycin levels were out of range among previous normal levels. One patient in particular had two out of range levels which the infectious disease consultant recorded in the patient's medical notes that perhaps the sample was taken at the wrong time. One patient was on vancomycin during the entire 26-day study period. Overall the patient had 19 levels reported. Six levels were borderline out of range, for example a pre level of 15.2 μg/ml or 15.3 μg/ml (reference range for pre levels of vancomycin 10-15 μg/ml). No treatment modification was required for this patient.

Changes in the dosing regimen were required for ten out of range vancomycin and gentamicin levels. The dose was decreased twice for one patient taking gentamicin because the pre levels were 1.3 μg/ml and 1.9 μg/ml respectively (reference range for pre levels of gentamicin <1 μg/ml). Three patients had their vancomycin dose increased because the pre levels were 7.9μg/ml, 6.6μg/ml and 3.4μg/ml respectively (reference range for pre levels of vancomycin 10-15μg/ml). Thirteen patients with out or range levels had their antibiotics stopped. Nine patients (69%) had completed the antibiotic course and therefore the out of range levels were the last levels requested and no changes in the treatment was required. However, four patients (31%) only received two doses of the antibiotics and then the antibiotics were stopped abruptly. All four patients had started the antibiotic empirically and had their antibiotics adjusted according to the diagnosis and/or cultures and sensitivities. Figure 25 summarises the actions taken after out of range levels were reported.

Figure 25: Action taken after the out of range levels were reported



3.6.3.4.9 Comparing the FMEA data with the data collected

Following the analysis of the laboratory results, the data collected was then compared to the FMEA monitoring failures identified by the group. The probability of failures occurring in the laboratory or on the ward were determined for the study period and compared to the probability scores of the FMEA failures. Table 20 summarises the findings.

Table 20: Comparing the monitoring FMEA probability scores with the data collected from the laboratory and wards.

FMEA monitoring failure	FMEA Probability score (percentage)	Equivalent laboratory data collected	Calculated Probability (percentage) for collected data	Comment
Results not reported via telephone if toxic levels	10- A probability of more than 1 occurrence in every 2 events (50%)	Six levels were high levels that should have been telephoned according to the laboratory's new reference range. Only three levels were reported by phone according to the record book kept by the clinical scientist.	3 toxic levels not reported by phone from a total of 6, therefore 1 occurrence in every 2 (50%)	The estimated probability score determined by the FMEA group is the same as that calculated during the study period.
Time lag between sending samples and receiving results	10- A probability of more than 1 occurrence in every 2 events (50%)	The new computer programme reported the time the sample was sent to the laboratory, received by the laboratory and the time the results were reported.	A probability score was not calculated but the time taken for the laboratory to receive a sample and report the results is around 3.7 hours.	This is difficult to compare because the team did not specify how long they consider a delay from the time the sample is sent to the laboratory, but from the results above in section 3.6.3.4.7, it takes on average 4 hours for results to be reported back to the ward.

Table 20: continued

FMEA monitoring failure	FMEA Probability score (percentage)	Equivalent laboratory data collected	Calculated Probability (percentage) for collected data	Comment
Results (of levels) are not accurate (due to failure to record the time the sample was taken on the request form and the time of last dose to determine pre, post or random level)	Group one: 10- A probability of more than 1 occurrence in every 2 events (50%) Group two: 8-A probability of 1 in 8 (12.5%).	This is a particular problem when the handwritten forms are used because this kind of information must be hand written, unlike the electronic forms that must indicate the type of level.	Ten of the 45 blue handwritten forms did not include the relevant information. This is the equivalent to 1 occurrence in every 4.5 events (22.2%).	In this case, the FMEA group one predicted a worse probability for such a failure to occur, while group two was more optimistic. Calculated probability was between the groups' scores.
Doctor does not receive results via phone nor does he/she check results on the computer system.	Group one: 7-a probability of 1 in 20 (5%). Group two: 8-a probability of 1 in 8 (12.5%).	This failure was interpreted by checking if the drug level is recorded on the drug chart or not. Nine levels out of 68 were not recorded on the patients' drug chart.	A probability of 1 in 7.5 (13.3%).	In this case, both groups were optimistic rather than pessimistic; however, group two gave a closer score than group one.

Table 20: Continued

FMEA monitoring failure	FMEA Probability score (percentage)	Equivalent laboratory data collected	Calculated Probability (percentage) for collected data	Comment
Not acting upon results because unable to interpret results.	Group one: 3-a probability of 1 in 15,000 (0.007%). Group two: 8- a probability of 1 in 8 (12.5%)	This failure was interpreted by checking if any changes in the treatment occurred after high or low levels were reported.	From 68 abnormal levels reported, 45 levels had no action taken to adjust these levels. Following the analysis, it seems that the appropriate decision was taken. However for one patient 3 reported levels were very high and were telephoned to the ward. This patient continued to take the vancomycin for 5 days before she was diagnosed with renal failure and the vancomycin was finally stopped. Therefore only 3 levels required a dose modification, a probability of 1 in 15 (6.7%)	In this case, the FMEA group one was more optimistic, while group two predicted a worse probability for such a failure to occur. Calculated probability was between the groups' scores.
No documentation of monitoring guidelines on charts.	3- A probability of 1 in 15,000 (0.007%)	From 68 drug charts, 10 did not have any monitoring guidelines	A probability of 1 in 6.8 (14.7%).	The FMEA team was very optimistic.

Following the analysis of the data, the correlation between the FMEA probability scores and the laboratory probability scores was calculated using Kendall's tau correlation (table 21).

Table 21: Correlation coefficient and significance value for FMEA and laboratory probabilities.

FMEA probability scores	Laboratory probability scores	
	Correlation coefficient	0.500
	Sig (2-tailed)	0.113

A positive correlation coefficient (0.500) indicates that there is an agreement between the probabilities in spite it not being a perfect relation. However the significance value for this correlation coefficient is more than 0.05, therefore, it can be concluded that there is a non significant relationship between the FMEA probabilities and the laboratory probabilities calculated.

3.6.3.5 Discussion

Laboratory testing is an essential component of the diagnosis and monitoring of patients. Forsman (1996) reports that around two-thirds of important clinical decisions about admission and discharge of patients from hospital and the prescription of medicines are based on laboratory test results. Therefore, precise timely results are the basis of effective diagnosis and treatment of patients.

A total of 109 patients and 221 levels were followed up during the 26 day study period. The results indicated that the use of electronic request forms is overtaking the use of the handwritten forms. The use of electronic forms helped the laboratory produce more informative results since it is mandatory to report whether the

requested levels is a pre, post or random level, unlike the handwritten forms where the laboratory personnel had to determine the kind of level requested from the information provided.

Overall, the time taken for the laboratory to receive a sample and report the results was over three hours. However during informal discussions, the laboratory manager indicated that reported timings may not be accurate because the laboratory personnel are theoretically able to change the time reported on the computer screens. When probed to provide further information, the manager replied that he was unaware of such incidents but just wanted to highlight the weaknesses of any calculated time gaps. This information potentially affected the validity of the data collected. In addition to this, the FMEA groups did not specify the definition of a time 'delay' so the comparison of the FMEA's results with the actual time delays was not feasible.

After receiving the out of range levels, only 40% (n: 30) of the levels resulted in treatment modification. The majority of the changes were appropriate. However, on five occasions, after high levels were reported, the subsequent dose was omitted without changing the ongoing dose regimen. There is no evidence that this is clinically appropriate and instead the ongoing dosing regimens should have been adjusted. Another observation was that doctors tend to request levels for vancomycin after the first dose, while the levels are not meaningful until before the third or fourth dose. The remaining drug regimens (45, 60%) were not modified and this seemed to be the appropriate clinical decision except for one patient who continued to receive vancomycin in spite the very high levels reported.

After the previous results were compiled (section 3.6.3.4.5) they were compared with the FMEA failures (table 20). From a total of six types of failures, the probabilities of five FMEA failures were compared to the data collected from the laboratory after their probabilities were calculated. The only failure that was not compared was 'the time lag between sending the samples to the laboratory and receiving the results.' Both teams did not specify how long they defined a 'time lag' and although the time taken between sending the samples and receiving the results was about four hours, it was not possible to determine an appropriate probability score for this. Only one FMEA failure and one laboratory failure had the similar probability score, while two calculated probabilities for laboratory data were between the probabilities calculated by both groups for the same failure. Group one predicted a lower probability of occurrence for one failure than that calculated from the laboratory data thus the FMEA group was more optimistic and for another failure a higher probability of occurrence was calculated indicating that the group was being more pessimistic.

Finally the correlation between the FMEA failure's probability scores and the probability scores calculated for the laboratory data was positive indicating that there is some agreement between the variables, however the significance value of 0.113 illustrates that the agreement is not statistically significant.

Following the analysis of the results and the comparison with the FMEA data, can the criterion validity of FMEA be described as valid? Although a novel approach was used to compare the FMEA data, the probability scores were the only scores compared because of the lack of severity and detectability scores for the laboratory

data, furthermore only a small part of the process, the monitoring failures, was assessed. These limitations make it difficult to draw a confident conclusion. There is no doubt that the failures identified by the groups were indeed failures that tend to occur in the laboratory but the probability of the failures identified by the groups and the failures collected were not significantly correlated. In addition to this, the results further highlighted the differences between the two FMEA groups and their RPN predications. These findings cast doubts on the criterion validity of FMEA as the subjective probabilities assessed by the groups differed from the actual probabilities of the failures occurring in the laboratory and ward. In addition the content validity is also called into question as the majority of vancomycin and gentamicin incidents reported in the trust were related to omitted doses and yet neither group identified this as a potential failure.

3.7 Construct validity

The final type of validity to be assessed was construct validity. This kind of validity involves seeking an agreement between a theoretical concept and the measure being studied. The main theory related to the use of FMEA is that the failures identified are prioritised according to the RPN values, i.e. the potential failures with higher RPN values are assumed to have a higher risk than those having lower numbers and thus should be addressed first. The RPN is calculated by multiplying three ordinal scales: severity scores, probability scores and the detectability scores. The main characteristic of the ordinal scale is that the categories have an ordered or ranking relationship to each other. This type of scale describes the order in which things are placed but not the specific amount of difference between them. Siegel (1956) stated

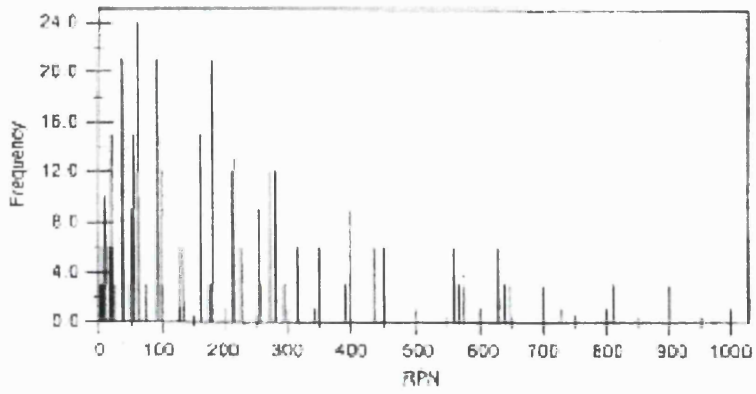
that ordinal scales incorporate the relation of equivalence (=) but also the relation 'greater than (>)' or 'less than (<)'. For example, a doctor might use a scale of 1-10 to indicate degree of improvement in some condition, from 1 (no improvement) to 10 (disappearance of the condition). While you know that a score of 4 is better than a score of 2, there is no implication that a 4 is 'twice as good' as a 2. Nor is the improvement from 2 to 4 necessarily the same "amount" of improvement as the improvement from 6 to 8. All we know is that there are 10 categories, with 2 being better than 1 and 3 being better than 2 etc. Bowles (2003) states that the arithmetic operations of multiplication and division are not meaningful on ordinal numbers, while Siegel (1956) further explains that the properties of an ordinal scale are not isomorphic to the numerical system known as arithmetic. Therefore parametric statistical tests which require the operations of arithmetic on the original scores should not be used with data in an ordinal scale.

In FMEA however, the ordinal scales of severity, probability and detectability are multiplied to produce the RPN, which breaches the mathematical properties of the ordinal scales. Bowles (2003) highlights four main limitations of using the RPN in the way that it is currently used in FMEA:

1. Holes in the scale: Many of the numbers in the range of 1 to 1000 cannot be formed from the product of severity, probability and detectability. While it is true that the numbers cover a range from 1 to 1000, 88% of that range is empty, as only 120 of the 1000 numbers generated are unique. No number having a prime factor greater than 10 can be formed. Thus the numbers 11, 22, 33 or even 990, which are all multiplies of 11 cannot be formed and are excluded. 1000 is the largest number, but 900 is the second largest followed by 810, 800, 729 and 720. In this case, can you say that the difference

between 900 and 901 is the same or less than the difference between 900 and 1000? Figure 26 shows the numbers formed by the RPN and the 'holes' in the scale between the numbers graphically.

Figure 26: RPN scale showing the number of occurrences of each number (Sankar and Prabhu, 2000, p.873; Bowles, 2003, p.5; Seyed-Hosseini *et al*, 2005, p.326).



2. Duplicate RPN values: Since 1000 numbers are produced from the product of severity, probability and detectability but only 120 of them are unique, thus the majority of the RPN values can be formed by several ways. For example, the RPN values of 60, 72 and 120 can each be formed from 24 different combinations of severity, probability and detectability scores. Although the RPN values maybe identical, their risk implication may be different.

3. Sensitivity to small changes: Small variations in one ranking can lead to very different effects on RPN, depending on the values of other factors. For example:

Severity	Probability	Detectability	RPN
3	8	8	192
8	3	8	192

However a 1 point change in the severity in the first example causes a 64 point change in the RPN, whereas in the second a 1 point change in severity causes only a 24 point change.

Severity	Probability	Detectability	RPN
4	8	8	256
9	3	8	216

The significant differences between the two FMEA group scores described in chapter 2 can perhaps be attributed to the fact that the RPN values are sensitive to small changes. Thus if one team was more 'pessimistic' than the other, an increase by just 1 score for the severity, probability and detectability scores will completely alter the order of the RPN values and thus the prioritised failures. For example:

Group 1

Severity	Probability	Detectability	**RPN**
1	5	5	**25**
3	3	3	**27**

Increasing each score by just 1 value for the same failure alters the RPN and thus the list of prioritised failures.

Group 2

Severity	Probability	Detectability	**RPN**
2	6	6	**72**
4	4	4	**64**

4. Comparing the RPNs: Bowles (2003) also argues that comparing the PRN values is generally not possible without some cost function that quantifies how reductions along one dimension relate to changes along another dimension. He further states that calculation of RPN implies that trade-offs can be made between the severity, probability and detectability factors. For

example, doubling the severity from 4 to 8 while halving the probability from 4 to 2 and keeping the detection the same has no net effect on the RPN.

It could be argued that the RPN values are used to guide the team conducting the FMEA and that quantifying the failures and prioritising them helps 'visualise' the improvement in a system.

> *"When you measure what you are speaking about and express it in numbers, you know something about it, but when you cannot express it in numbers your knowledge about it is of a meager and unsatisfactory kind."*
> Sir William Thomson, Lord Kelvin, 1883[14]

> *"If you cannot measure it, you cannot improve it."*
> Sir William Thomson, Lord Kelvin, 1894[14]

As seen from the quotes above, the idea of using numbers to measure and quantify improvement dates back from the 19th century. It is no surprise that the FMEA method and a large number of risk assessment tools use numbers to help 'quantify risk' and measure improvement. However, with FMEA in particular, multiplying the ordinal scales is technically flawed from a mathematical point of view.

In the last few years a number of approaches have been suggested to overcome the drawbacks of calculating and using the RPN values, however, these suggestions have not been widely implemented. The majority of these suggestions integrate further mathematical conditions or incorporating further steps to calculate the RPN for example by including costs or using 'if-then' rules (Ravishankar and Prabhu, 2001; Rhee and Ishii, 2003; Arunachalam and Jegadheesan, 2006; Dong, 2007). Perhaps these new 'improved' methods have not been widely publicised particularly in healthcare because they demolish the appeal of FMEA as being a straight forward and easy tool to use. Furthermore, other high risk industries such as

[14] http://www.top-biography.com/9103-William%20Thomson/quotations.htm. (Taken from Bowles, 2003)

aviation or automotive industry have not used these methods. Although in the future, these new proposed methods or modifications may help decrease the current RPN limitations, they will still require to be validated and their reliability assessed before promoting them extensively.

In this case, the construct validity of FMEA was low. The theory behind the use of calculating RPN and using it to prioritise failures is based on invalid mathematical assumptions. Thus if the main theory behind FMEA is based on incorrect assumptions about the mathematical properties of the scales used, then the FMEA outcomes cannot be described as valid.

3.8 Discussion

In this study the validity of FMEA was explored by assessing the different types of validity for the FMEA process. No previous work has formally explored the validity of the FMEA process. Since this is the first time that the validity of FMEA was explored, all approaches to assess the validity was based on pragmatic judgments. Four different types of validity were assessed: face, content, criterion and construct validity.

The first type of validity tested was face validity and the outcome was positive as both groups including the main steps identified by the researcher in their FMEA flow chart.

Following the FMEA meetings and the discussions that took place, the aim of the content validity was to ensure that the process mapped and the failures identified by the two teams indeed did cover all relevant issues related to the use of vancomycin

and gentamicin. So can the content of FMEA be described as valid? Unfortunately a definitive answer would not be possible for a number of reasons. First, one of the revealed limitations of FMEA is that no brainstorming session will cover all the potential failures and even if the majority is covered it is likely that some will be missed (Bramstedt, 2002; Croteau and Schyve, 2000; JCAHO, 2005). This was true for the groups' FMEA because:

1) The groups identified only 17 (17%) common failures out of a total of 100.
2) One of the consultants who revised the FMEA identified a number of failures not recorded by the group.
3) The incident reporting system identified two more types of failure that both groups failed to include.

On the other hand, two other consultants said they could not think of any missing failures and the monitoring failures discussed by the groups were all failures identified during the data collection time in the laboratory and wards. Furthermore, some of these failures were eliminated when the laboratory changes were implemented. It is fair to claim that including a multidisciplinary team helped the groups identify a large number of failures across different disciplines; however we should acknowledge that no one group will be able to identify all the potential failures that can occur. Another important issue concluded as well is that FMEA is short-lived. Since its aim in healthcare is to avoid harm from reaching the patient and improve the quality of the service, the FMEA should be periodically updated. As seen in this study, after the FMEA meetings were conducted there were improvements occurring in the laboratory system in the trust, therefore some of the

failures identified by the groups were no longer valid while new potential failures may have risen.

The third type of validity tested was the criterion validity, in which existing and new data was collected, relevant to the failures identified, in order to compare them with the FMEA outcomes. Existing data included identifying incidents related to the use of vancomycin and gentamicin from the trust's incident reporting database and retrieving audits conducting for the use of these antibiotics. Comparing the FMEA to the existing data proved to be complicated and a number of limitations of using the incident report database were identified including:

1) Small number of incidents included were relevant to vancomycin and gentamicin, perhaps due to underreporting or because the electronic incident reporting system was relatively new.

2) There was no standard method of reporting the incident or the level of detail provided so some reported incidents were very detailed while others lacked important information.

3) The severity and probability scores of incidents reported were assessed as a 5-point descriptive scale, while the traditional FMEA uses numerical values accompanied with written descriptions. Also the probability scores were not always reported on the incident reporting system.

4) Another limitation highlighted during this study was the use of two different descriptions for the FMEA probability scores, one related to the number of incidents per event and the other related to the number of incidents during a specific time period. It is not possible to conclude that both methods are equal or valid especially as they have not been validated or tested.

5) The probability scores reported on the incident report database are also subjective; therefore even if the FMEA probability scoring scales used were similar to that of the database, the results would still be based on subjective measures rather than an objective approach.

Overall, the FMEA groups provided a more pessimistic approach when assessing the severity of the failures, whereas the severity of all the reported incidents included in this study caused no harm or minor harm to the patient. At the same time, the groups also over estimated the probability of failures occurring, i.e. the majority of the probabilities of failures occurring identified by the groups were higher than those reported on the incidents database. In addition to this, it could be concluded that the detectability scores estimated by the FMEA participants were also overestimated since there were similar incidents reported on the incident report database. Although incidents are underreported, the results highlight that the participants tended to overestimate all the scores and thus an over exaggerated RPNs might have been derived which indicates that this subjective method of scoring failures is not appropriate for prioritising failures or distributing costs and resources. Using audits in this study was not very rewarding because the audits included mainly focused on providing prescribing data, in particular the number of patients receiving the correct initial dose which was difficult to compare to the FMEA data.

In order to test the criterion validity of FMEA from an objective point of view, new data related to the monitoring failures was collected. First, it was confirmed that the failures identified by the groups were failures that were indeed happening in

practice. Then, it was decided for which failures it would be possible to collect sufficient meaningful data during the specified time period. Following this, comparing the data was the most challenging. Since the severity and detectability scores were unattainable for the data collected from the laboratory, the frequency of these failures was compared to the probabilities of the FMEA failures. The result was inconclusive because from a total of five types of failure compared to the data collected:

1) One FMEA failure and one laboratory failure had the same probability score
2) Two FMEA failures had a lower probability than the data collected
3) Two FMEA failures had two different probability scores by each group. The calculated probability of the data collected lay in between the two groups' estimates.

However in order to identify any relationship between the probabilities, their correlation was calculated. The results indicate that there was a trend towards a positive relation between the probabilities of the FMEA data and the data collected but not a statistically significant one.

Following these results, it can be concluded that the optimal method for testing the criterion validity of FMEA in the future is to collect relevant data. This is because the data collected will be objective rather than subjective. Furthermore, it helps relate FMEA to the actual daily practice and failures that occur. In addition to this, because FMEA data and outcomes are not standard, the data collected could be tailored for each specific FMEA. In this case, the validity of the outcomes will be tested rather than the FMEA process itself.

Finally the construct validity was assessed. This type of validity is based on testing or proving a theory. From the published literature and the guidelines about FMEA, FMEA aims to identify failures, determine their severity, probability and detectability scores and based on these scores the failures are prioritised and addressed. Therefore, assessing this type of validity was based on the assumption that the main and important theory behind the use of FMEA is prioritising the failures to address them. The construct validity of FMEA proved to be flawed because the RPN calculations are based on inappropriate mathematical calculations that breach the properties of the scales used. Although the RPN does help 'quantify' the risk and enables the team to 'see' an actual improvement in the FMEA (since the RPN values supposedly drop after change is implemented) technically the science or evidence behind it is not valid.

This is the first time that the validity of FMEA has been assessed. A published review by Kirwan in 1997 addressed the validity of human reliability techniques in general. Unfortunately FMEA was not included; however, Kirwan proposed criteria for validating these techniques in general. The criteria included:

1. Presence of a significance correlation between the estimates and the true or recorded values.

2. How accurate the techniques must be to be seen as valid or at least useful in risk assessment terms. Kirwan (1997) states that the ideal and realistic precision level to be aimed for is that estimates will lie within a factor of three of the true or recorded values.

3. A further aspect of precision is the degree to which the technique, when not accurate, is pessimistic rather than optimistic. If a technique is optimistic, then human error probabilities and ultimately risk predictions will be under-estimated and this is unacceptable.

4. There should be an inter-assessor agreement between usage of the technique by multiple subjects or teams.

5. Finally, there should be a measure of the consistency of usage of the technique by different assessors.

In the case of FMEA in this study, the correlation between the groups' estimates and the data collected from the laboratory was not significant and none of the FMEA failures had a precision factor of three or less in relation to the 'true' data collected. Both groups were more pessimistic than optimistic, scoring their severity and probability scores highly, however to what extend is it acceptable to depend on the 'pessimistic' approach especially when it involves investing money and resources to improve patient care. Inter-assessor agreement was addressed in chapter 2, where the two groups conducted the same FMEA using the same technique but concluded different outcomes. Finally measuring the consistency of usage of the technique by different assessors is not possible since the scoring scales are very subjective and thus the outcomes will depend on the group conducting the FMEA.

3.9 Conclusion

In conclusion, testing the validity of FMEA is not straightforward because the tool involves more than one step and each step should be validated. The results of this

chapter call into question the validity of the FMEA. The first step regarding mapping the process was valid; however identifying the failures and using scoring scales and RPN values cannot be conclusively described as valid. The teams missed a number of failures, the scores were very subjective, the scoring scale itself was not validated and the concept of multiplying ordinal scales to achieve an RPN value was proven to be flawed. Furthermore, using Kirwan's (1997) criteria as a guide, FMEA failed to fulfill most of the criteria's requirement further confirming the doubts about FMEA's validity.

In the next chapter the perceptions and experiences of healthcare professionals who have used FMEA in the UK will be described.

Chapter 4 Perceptions & Experiences with FMEA

"Good judgment comes from experience, and often experience comes from bad judgment."

Rita Mae Brown, 1983

4.1 Introduction

During the literature review presented in chapter 1, only three qualitative studies related to the use of FMEA in healthcare were retrieved. During the time course of this thesis an opportunity arose to work with another research team studying FMEA as part of an evaluation of the Safer Patients Initiative (SPI) programme launched in 2004 by the Health Foundation in the UK in collaboration with the IHI in the USA.

This study is part of a large ongoing study being conducted at Imperial College London supported by the Health Foundation and the National Institute for Health Research, exploring the process and experiences of the trusts that participated in SPI programme. During the SPI programme, participants were expected to do an FMEA on a core process in medicines management. The chapter describes the analysis by the researcher of a series of qualitative interviews relating to FMEA conducted by the Imperial College SPI Research Team[15].

This chapter will focus on exploring the perceptions, attitudes and experiences of the SPI participants who have used FMEA as part of their medicines management initiative as well as reporting the opinions of the FMEA participants who conducted the FMEA in chapter 2, regarding their experience with FMEA. The chapter is divided into two main sections: First, the IHI and SPI programme will be briefly described; highlighting the use of FMEA in SPI. This will be followed by a summary of the methods used by Imperial College SPI Research Team to explore the process and experiences of the trusts that participated in the SPI programme.

[15] Department of Bio-Surgery & Surgical Technology, Imperial College, London.

The analysis, results and discussion conducted by the researcher (Nada Shebl) will then focus on the participants' experiences with the use of FMEA. Secondly, the perceptions and views of the FMEA team members described in chapter 2 regarding the use of FMEA will also be presented.

4.2 Safer Patients Initiative (SPI) Programme

The Health Foundation is an independent charity that aims to improve health and the quality of health care for the people of the United Kingdom. It has been around in various guises since 1983, when it was first launched as the Private Patients Plan Medical Trust. In 2003, the Foundation re-launched with a new name 'The Health Foundation' with a focus on improving health and the quality of healthcare (Health Foundation, 2009).

The IHI is an independent not-for-profit organisation helping to lead the improvement of health care throughout the world. Founded in 1991 and based in the USA, IHI works to accelerate improvement by building the will for change, cultivating promising concepts for improving patient care, and helping health care systems put those ideas into action (IHI, 2009a).

With the support of The Health Foundation and IHI, the SPI was launched in April 2004. SPI is a quality and performance improvement programme that encompasses all four nations of the UK. The Health Foundation selected the IHI to design, promote and implement the SPI, one of the Health Foundation's quality and performance improvement programmes (IHI, 2009b). Acute care trusts from across

the UK were encouraged to apply for participation in the initiative via a competitive bidding process.

The Safer Patients Initiative has been run in two phases – the first started in 2004 and following a competitive bidding process four acute trusts were chosen to take part and act as exemplars from which other hospitals can learn. The second phase started in 2006 and the SPI expanded from the initial four hospitals to another 20, spread across the UK (Health Foundation, 2009).

4.2.1 Phase one – 2004 to present:

Since 2004, The Health Foundation has supported four hospitals in a £4.3 million four-year initiative to test ways of improving safety on an organisation-wide basis. The four hospitals: Luton and Dunstable Hospital NHS Trust, Conwy and Denbighshire NHS Trust, Down Lisburn Health and Social Services Trust (now South Eastern Health and Social Care Trust), and NHS Tayside, were working with international experts from the IHI to develop their expertise in patient safety.

All four sites were following a programme designed by IHI which worked on three levels:

- Addressing five clinical areas, each including multiple interventions that have an established and accepted evidence base in the UK (such as better management of patients in intensive care, infection control, preventative antibiotics for surgery and medicines safety)
- Teaching methods for quality and safety improvement
- Establishing a specific role for the chief executives and senior executive team.

4.2.2 Phase Two – 2006 to present:

To meet their vision of transforming patient safety in UK, in 2006, the SPI was expanded from the initial four hospitals to another twenty, spread across the UK. Each of the additional twenty hospitals received £165,000 plus a tailored support package of similar value. The hospitals worked in pairs on the safety improvement work and worked with international patient safety experts from the IHI.

The 20 hospitals involved in the second phase aimed to reduce their mortality rate by at least 15% and to reduce adverse events by at least 30% over the two year period (2006 to 2008)(IHI, 2009b).

In general, SPI phase one and two focused on key elements of safety work including Critical Care, Perioperative, General Ward, Medicines Management and Culture and Leadership.

The tasks specifically set by the IHI for the medicines management team for all participating trusts included:

- **Coordination of care :** Medication Reconciliation (Medicines at the Interface)
- **Anticoagulation Management:** Use of protocols and standardised processes to manage anticoagulation patients
- **Identification of High Risk Areas:** Conduct an FMEA on a high risk medication process (such as chemotherapy, insulin)

All participating Trusts in phase one and two were therefore expected to conduct an FMEA and feed back their outcomes and results to IHI.

4.3 Aims and Objectives

4.3.1 Aims

The aims were to explore users' experiences with FMEA, from two sets of data:

- The SPI participants
- The FMEA team members regarding the use of FMEA described in chapter 2.

4.3.2. Objectives

The objectives were:

- To develop a suitable framework for the FMEA-related interview data in order to:
  - To determine where and how FMEA was conducted in the Trust
  - To determine the views of participants about the use of FMEA
  - To identify the changes and outcomes that resulted from the use of FMEA

- At the end of the FMEA meetings described in chapter 2, participants were asked to report information about their opinion of FMEA and its strengths and weaknesses both in general and in relation to vancomycin and gentamicin.

4.4 SPI participants

4.4.1 Methods

Methods used by the Imperial College SPI Research Team to explore the process and experiences of the trusts that participated in SPI programme were employed in two parts: A and B, where A focuses on the first phase -SPI 1 and B which focuses on the second phase- SPI 2. The aim of their research overall was to assess the organisational readiness for SPI, to explore the variability in responses to SPI and to determine SPI's impact. In order to achieve these aims, a mixed method approach was used which included interviews, surveys, qualitative analysis of varied sources and analysis of time series data related to the care processes.

In this chapter only the methods used to generate FMEA-related data will be reported in detail (table 22).

Table 22: Details of methods used by the Imperial College SPI Research Team to collect interview data relating to SPI

	Part A- SPI 1	Part B-SPI 2
Time period of the study	The study took place between August and December 2007.	The study took place during 2008.
Number of sites involved	4 hospitals	18 hospitals
Participants	One operational lead in the Medicines Management team was interviewed from each site (4 interviews)	One lead in the medicines management team was interviewed from each site (18 interviews)
Methods of data collection	Semi-structured interviews	
Interviews	• A team of 5 researchers conducted the interviews. Each pharmacist or nurse was interviewed by one or two people from the research team. • Participants were interviewed during a site visit and interviews lasted on average between 45 minutes to an hour. • All interviews were recorded on audiotape and all information collected was treated as confidential.	
Transcribing	Interviews were transcribed by a professional transcription agency.	
Topics discussed during the interview	• Medication reconciliation • Plan, Do, Study, Act (PDSA cycles) • Failure Mode and Effect Analysis (FMEA)	

All trusts participating in part A and B of the study received the same information about FMEA.

4.4.2 Ethics approval

Ethics approval had previously been granted to the Imperial College Study by the Leicestershire, Northamptonshire & Rutland Research Ethics Committee. In order for the FMEA data to be specifically analysed and included in this thesis, a substantial amendment was submitted to the Committee to request the addition of a student researcher (Nada Shebl) to the ethics application in November 2008. Approval was granted in January 2009.

4.4.3 Data analysis and validation

Before the interviews were analysed they were assessed to ensure that this data had been collected in a robust manner using valid and reliable methods. Scott (p.6, 1990) suggests four criteria which can be used for deciding whether or not to employ specific data for the research. They include:

- Authenticity: Is the evidence genuine and of unquestionable origin?
- Credibility: Is the evidence free from error and distortion?
- Representativeness: Is the evidence typical of its kind, and, if not, is the extent of its untypicality known?
- Meaning: Is the evidence clear and comprehensible?

The first criterion, authenticity, addresses the question of whether the document is a primary or secondary document and in this study all the interviews were primary documents. They were all genuine and conducted by a team of researchers at Imperial College NHS Trust. Credibility refers to the accuracy of the documentation, the reliability of the producer of the document and freedom from error. The over all aims and objectives of the SPI interviews were to understand the process of improvement, organisational readiness, variability, impact and

sustainability of benefits associated with complex systems level interventions such as the SPI, rather than focus on FMEA only. Thus the interviews were scheduled to meet these broad aims and objectives and not focus on FMEA per se. Although details about FMEA were sometimes not fully explored; these interviews provided a rare and rich opportunity to explore the use of FMEA in the UK on a wide scale. Research approval was required for all the interviews and this helped ensure that all the data was accurate and reliable. The data was also clear and comprehensible but the extent of its untypicality is unknown as this was the first SPI study as well as the first time participants of FMEA within the UK have expressed their thoughts and opinions about it. In addition to this it is important to acknowledge that the SPI research was conducted by a highly reputable research team at Imperial College NHS trust and has resulted in a number of publications in peer-reviewed journals (Benn *et al*, 2009; Burnett, 2009; Burnett *et al*, in press) as well as conference presentations (Benn, 2008; Benn, 2009; Burnett, 2009; Parand, 2009; Pinto, 2009).

All the interviews were first read thoroughly to gain an overview of the data and to become familiar with the range and diversity of the information. All interviews were anonymised and printed out. Any FMEA-related data was then identified from the interview transcripts. A thematic framework analysis approach (which classifies and organises data according to key themes, concepts and emergent categories) was applied and content analysis was conducted. During this stage the key ideas and recurrent themes related to FMEA were identified and listed manually. An initial coding frame was then constructed for a sample of four interviews by the researcher and revised by one of the supervisors. Differences in the coding were discussed and the revised final coding frame was used to develop additional themes. Another five

interviews were further coded using the modified coding frame and again verified by the supervisor. The remaining interviews were coded and analysed by the student alone. Finally, after the results were analysed, the Imperial College SPI Research Team reviewed the analysis; no further modifications were required.

4.4.4 Results and Discussion:

Twenty pharmacists and two nurses were interviewed. Of a total of 22 interviews; four were from SPI 1 and 18 from SPI 2. One interview, with a senior nurse, was not included in the analysis because she did not discuss FMEA at all in the interview.

Themes from the 21 interviews were analysed as two main clusters. The first cluster comprised the perceptions and experiences with the five basic FMEA steps (chapter 1, section: 1.4.4). The second cluster comprised emerging themes from the interviews which included interviewees' opinions of FMEA, how participants described it, validity and reliability issues, how FMEA compares to other risk assessment techniques and FMEA's use in practice. The thematic framework used for the interview analysis is displayed in table 23.

Table 23: Thematic framework used for the interview analysis

Cluster	Themes	Sub-themes
Cluster one: Describes the perceptions of the participants of the five FMEA steps and how they were conducted	Step one: choosing a topic	Topic chosen and department
		How and why topic was chosen?
		Attitudes of participants towards chosen topic
	Step two: choosing a multidisciplinary team	Experience of use
		Who participated?
		Attitude of participants towards FMEA
	Step three: mapping the process and identifying failures	Mapping the FMEA process
		Identifying the failures
	Step four: calculating the RPN	How RPN was derived
		Scoring scale
		Significance of RPN
	Step five: actions and outcomes	Actions and outcomes focusing on the process of care
		Actions and outcomes focusing on the RPN value
Cluster two: Describes the perceptions and opinions of the interviewees towards FMEA	Describing FMEA	Expectations from FMEA
		Characteristics of FMEA
		Limitations of FMEA
	Opinion of FMEA	Positive opinions
		Negative opinions
	Training and teaching FMEA	Training for FMEA
		Teaching FMEA
	Comparing FMEA to other risk assessment tools	Other techniques used
		How FMEA compares to other tools
	FMEA's use in practice	How wide spread is its use?
		Its use and function in the Trust
		Will it be used again?
		Its use in other settings
	Validity of FMEA	Validity of FMEA
	Reliability of FMEA	Reliability of FMEA

FMEA: Failure Mode and Effect Analysis
RPN: Risk Priority Number

4.4.4.1 Cluster one: The five FMEA steps:

4.4.4.1.1 Theme one: Choosing the topic:

The first step of FMEA is to choose a high risk topic. During the SPI, IHI specifically identified tasks that participants had to do. These included reviewing medication reconciliation, anticoagulation management and conducting an FMEA on a high risk medication such as chemotherapy or insulin or on a core process such as prescribing, administering or monitoring medicines. Following the IHI recommendations, the majority of Trusts conducted an FMEA on anticoagulation (15 Trusts, 71%) signifying the influential role of IHI, while only six trusts conducted their FMEA on other high risk topics identified. Seven Trusts (33%) conducted more than one FMEA on different topics. This suggests that these seven had positive experiences and outcomes of FMEA because after conducting the 'obligatory' FMEA, they voluntarily conducted other FMEAs on topics of their choice.

One pharmacist expressed the complexity of the anticoagulant topic recommended as a first attempt for FMEA but nonetheless conducted the FMEA following the sense of eagerness from IHI.

> *"Well, we initially had other ideas about what we might to do for it but it became apparent that they (IHI) were keen for us to do an FMEA round anticoagulation so, hey, that's what we did ... so I would say that it[anticoagulation] was a priority and we were quite happy to do it, it's just that we knew that it was going to be tough for us to effect a change within anticoagulation so maybe, might have found it easier to go somewhere else to start with, is the only thing really ... No, this is again, why we weren't intending to do our first FMEA in this particular area [anticoagulants] because it just felt like it was going to be wading through fire with eye glasses."* Specialist Pharmacist, Trust 12.

4.4.4.1.2 Theme two: Choosing a multidisciplinary team

The second step of the FMEA is choosing a multidisciplinary team to conduct the FMEA. The first sub theme identified from the interviews related to the participants' experience with FMEA. A number of participants said that this was their first encounter with FMEA and only two pharmacists reported that they had previous experience with FMEA

> *"...: as I said, I thought I was a bit of an expert on FMEA, cos I did some of that..."*
>
> Principal pharmacist, Trust 4

> *"...the principal pharmacists for production and quality control said we know all about FMEA, we use it all the time."*
>
> Chief Pharmacist, Trust 17

A multidisciplinary team is a key component and an essential condition to try to ensure a valid FMEA. Furthermore, if the topic chosen involves mapping several steps that covers different areas of patient care then it is essential to include a team member from each area.

FMEA participants varied among the trusts and depended on the topics chosen. Since the use of FMEA was specific to the medicines management team, all the FMEAs were conducted within the pharmacy department and thus the majority of participants were pharmacists or pharmacy-based staff such as technicians or assistants. The majority of the trusts also recruited multidisciplinary team members to conduct the FMEA. Only two of the interviewees did not actually participate in the FMEA and therefore only reported what was fed back to them from the team.

> *"Talking to the staff who've used it I think it's very useful, but they both had to go back and recalculate their initial FMEA."*
>
> Pharmacist, Trust 9

> *"As I say I haven't been directly involved, it's been the dispensary manager leading it and then she's invited a junior, more of a junior member of the pharmacy department.."*
>
> Patient Services Pharmacist, Trust 15

Two pharmacists reported struggles when trying to choose a multidisciplinary team. The first pharmacist highlighted the complexity of the health care system and the hierarchy of the medical team members highlighting the deficiencies in every day practice and the lack of 'defined' roles for members of the multidisciplinary team.

> *"Within the FMEA's we used erm, we were actually trying to find clinicians or consultants that prescribe and very few of them were hands on prescribe, okay? The group that will are consultant anaesthetists. They will actually prescribe drugs, but if you look at most other areas of the Trust, a consultant may prescribe, i.e. he will decide the change of treatment, but he will instruct somebody else to actually do the prescription and again if you know on some ward rounds, the registrar is making those decisions, but the actual person who writes it, is a junior doc. So in terms of getting a consultant representative to the FMEA's for prescribing, we didn't tend to do that, we tended to go for the staff grades and the people that actually do hands on prescribing. So that's a bit of a deficiency..."*
>
> Principal pharmacist, Trust 4

The second pharmacist faced challenges related to the composition of the team. The lack of harmony and arising conflicts between the team members potentially affected the FMEA results.

> *"We started off by getting together different groups of staff, so some nurses off the wards, some junior doctors and some pharmacists. We would have liked to have included some of the, one of the consultant haematologists and the, one of the anticoagulant nurses but at the time we'd just started the whole thing and we felt that they would stop the other people from openly discussing what their concerns were because when we'd had, when the sister and matron had had the initial meeting with the consultant haematologist, there were various things that we were saying that we were concerned about which she was quite adamant weren't a problem ... there were certain things that, like the nurses who were there were quite, spoke quite strongly in terms of all the problems around anticoagulation being down to ... but no, there weren't any problems on the nursing side of the process. And they left the room first and the junior doctors afterwards were like, I didn't want to have an argument with them, but that isn't how I would perceive it to be and there are probably more problems. So for example, one of the risks could be that somebody's given the wrong dose or the dose*

isn't given when it's prescribed and they were absolutely adamant that that will never happen, but were quite critical, so it's very difficult"

Specialist Pharmacist, Trust 12.

Two main elements characteristic of the healthcare environment were raised by the above interviewees. First, there are certain roles within healthcare that are not clearly defined and vary from hospital to hospital. Whose responsibility is it, for example, to follow up reported drug levels? Is it the nurse? Is the pharmacist or is it the doctor? This lack of clearly defined roles for each member of the multidisciplinary team will without doubt raise conflicts within the team when they are discussed. The lack of defined roles was also discussed during the FMEA meetings described in chapter 2 and conflicts between the consultants and pharmacists, regarding their roles for drug monitoring, arose. The second important topic identified was the lack of communication within the FMEA team. Problems arising due to ineffective communication between healthcare professionals have been well documented in the literature (MacKay *et al*, 1991, BMA 2004, Astrom *et al* 2007, Nijjer *et al* 2008). In a report by the British Medical Association in 2004, it was reported that although most healthcare professionals have a firm understanding of their own role, they may not necessarily understand others' work or how their role fits in with the rest of the healthcare team. Furthermore good communication can deepen professionals' understanding of different working cultures and professional language. Another essential outcome of good communication is education of the junior doctors by the more senior members. From the experience of interviewee 12, nurses and doctors were reluctant to discuss the anticoagulant process openly. This may have been due to the lack of self-esteem from the nursing staff to challenge the doctors. The nurses may also have been avoiding confrontational discussions with doctors, whom may not necessarily accept

constructive criticism due to their perceived status from the hierarchical structure within the profession.

Poor communication between team members from other Trusts was perhaps not reported because the majority of the FMEA teams were pharmacists and pharmacy-based staff and it has been documented that healthcare professionals tend to interact with less difficulty with others in their own discipline than with those from other disciplines (Ker, 1986). The remaining participating interviewees did not report any conflict between the team members.

Another important issue brought up during the SPI interviews, in general, was the policy of junior doctors 'turnover' or rotations within different NHS Trusts. These doctors' rotations threaten the reliability of the FMEA results since the FMEA's outcomes differ depending on the participating team as shown in chapter 2 (reliability chapter). Furthermore, these junior doctors might be available to participate in the FMEA discussions but their rotations would mean that they may not be around to implement the new changes or teach them to others. One Trust acknowledged this problem when recruiting a multidisciplinary team and chose to include the junior doctors that would be staying in the Trust for a longer period of time.

> *"So we identified some F1s who we knew were going to stay on F2 year and some of us had worked with and that we knew would contribute to the discussion. In terms of getting nurses, again, we went through one of the nursing managers just to tell us who she could make available to us."*
>
> Specialist Pharmacist, Trust 12.

Following the subject of recruiting a multidisciplinary team, the attitudes of these team members towards FMEA were explored. Some were encouraging:

> *"More or less everybody has picked up the tool and is interested in it."*
> Clinical Pharmacy Coordinator, Trust 3

Others felt like it was a tool that helped pharmacists raise their profile and earn the attention they deserved when it came to patient safety and risk:

> *"...it's a good tool and this means that you're encouraged to not just become slavish and but it's this business about, it's a good tool for experience people to take and run with, are you with me? And it opens some doors as well because it gets senior management back up and you're no longer a, you're no longer a voice in the wilderness, you're not the pharmacist banging on about risk, it becomes, we do quite well with it, we're quite well accepted, I'm not saying we're marginalised but it just raises the whole thing up the agenda."*
> Director of Pharmacy, Trust 11

> *"There are now three trained [for FMEA] and everyone; it's an issue that's discussed on a weekly basis at other clinical meetings. So pharmacy staff are very much stitched into that process and patient safety is something that pharmacists love."*
> Chief Pharmacist, Trust 13

Other interviewees reported that the participants were negative and counterproductive, expressing their doubt towards FMEA as a valid tool:

> *"...people start challenging the evidence behind it when it's not about the evidence, it's we're saying we've already agreed that, now can we put it in place please?"*
> Head of Pharmacy, Trust 5

> *"I'm a bit, the jury's still out on the FMEA process because, and this is something that I had raised, has anybody evaluated FMEA as a tool for analysing risk? And it turns out there isn't. And I had raised it with xxx last week, and he doesn't know if anybody has, so I thought, well why are we doing this process?"*
> Medicines Governing Pharmacist, Trust 6

"I think there would've been better ways of implementing a changed policy around gentamicin than doing FMEA."

Director of Pharmacy, Trust 14

"...and they thought well, what they didn't like was the semi subjective, or semi objective nature of the scoring parameters. I said, just take it as it is. And there was a lot of argument as, it's not valid, it's not relevant, it's not this, it's not that..."

Chief Pharmacist, Trust 17

Responses from interviewees 5, 7 and 17 indicate that the participating team did not believe FMEA to be valid, whereas the interviewed lead pharmacists did not share the same opinion. On the contrary, they believed that the evidence behind FMEA was not of importance and that it was a useful tool in identifying the risks overall. The pharmacists interviewed in these three Trusts oversaw the medicines management aspects of the project and perhaps their main aim and focus was to complete the FMEA and decrease the scores rather than question the evidence behind FMEA.

4.4.4.1.3 Themes three and four: mapping the process and identifying the failures and calculating the RPN

Steps three and four describe how the participants actually conduct the FMEA. Little detail was provided in the interviews on how FMEA was actually conducted in terms of mapping the process and identifying the failures but the scores were calculated differently among the Trusts. Some did it through consensus, others did it separately and then combined the scores; while at one Trust the pharmacist calculated the scores single handedly.

"What we'd do is get them all to score on a piece of paper independently and then put it all together. At the end of it, we tended to have a bit of a

group consensus if there was some you know, if there was a wide variation..."

Principal pharmacist, Trust 4

"I did it initially, I drafted it and then another pharmacist overlooked it and scored it, so I drafted it and scored it, didn't give her my scoring, showed her to see if I was saying this right. One of the cardiology consultants also scored it and looked at the drafts and he said things, no that that doesn't occur. And then the sister, the cardiology sister as well."

Medicines Management Lead Pharmacist, Trust 7

"we set out initially what we thought the steps probably were in a table, so we had the document set up and we booked a room with, where we could take a laptop and projection, do it onto a screen so that we could put the information straight in and did just a short five minute explanation at the beginning to explain what we were doing. So we did that and then went through the process and then, so most of the information got typed into a ... at the beginning and we scored everything but then we didn't add up all the scores because again, it takes so much time. So after it we went back and added up all the scores ... I think it was clear on the sheet, and then sent it out to the people who were involved to, if they wanted to, to comment any further and we then looked at the scores of each bit of the process and ranked them in order of priority of what we wanted to do"

Specialist Pharmacist, Trust 12.

"I decided eventually once the group had decided what the process was, and where the flaws in the process were, I did the scoring."

Chief Pharmacist, Trust 17

How scores are calculated is a controversial component of FMEA. The JCAHO (2005) states that no matter what the rating method and scale used in the FMEA, team members must reach a consensus on the RPN. No specific methods to reach consensus are mandatory but McDermott *et al* (1996) recommends that team members can cast their votes for the rating and the average of these ratings is used. The majority of the participants that gave an account about how FMEA was conducted resorted to consensus, except for one trust. In trust 17 the pharmacist chose to score the FMEA single handedly. Perhaps this was due to the team

dissatisfaction with FMEA and their concerns about its validity and reliability. This however lessens the confidence in the FMEA's results as it did not take into account the multidisciplinary team input and thus its reliability and validity become questionable.

4.4.4.1.4 Theme five: actions and outcomes

The last theme from cluster one is step five of the FMEA; actions and outcomes. Participants described the outcomes of FMEA either by change in the process of care or by a reduction of RPN. More than half of the Trusts (13 Trusts, 62%) reported that a decrease in the RPN was the desired outcome of the FMEA and an indication for its successful use.

> *"So we had all those FMEAs done and then we were able to rescore the FMEA after we introduced the new charts and that brought down the scores."*
>
> Clinical Pharmacy Coordinator, Trust 3

> *"I think the worry is you have to try and get the score down so much by September and we can only keep trying what we are doing ... but we're still just working on it; our score's not come down (for dispensing process). It did go up for a time but we were told that was all right."*
>
> Principal Pharmacist, Trust 8

> *"We have our FMEA well down below the 50% now, so we've achieved our target for June. And on the other site they looked at warfarin prescribing, as I said, prescribing, administration, monitoring, etc, and they have just got their FMEA down to 48% of the original, so they've achieved the target as well."*
>
> Pharmacist & Medicines Management Lead, Trust 9

> *"And we've implemented quite a number of changes to practice and we've rescored our FMEA subsequent to that. And we've managed to hit the target in bringing it down ... So we used the tool to map us through the process and look at what happened at each step and look at what could be done to improve things at each step of the way."*
>
> Director of Pharmacy, Trust 10

"We're still doing it because we're having to improve our scores remember..."

Director of Pharmacy, Trust 11

"we scored that and identified the mean risk areas and very quickly changed processes, very simply and quickly changed processes, and we, our target is to halve the risk score. We haven't done that yet and we're probably down to about 60% of the score that we had. So we're already approaching the halving of the score and just recently reviewed that FMEA and we've got other actions to take forward which, if they're successful, should reduce that risk score quite, probably to the 50% mark."

Chief Pharmacist, Trust 13

"I think it's the, to be fair, I think from the scoring, we probably never, we might never achieve the 75% drop that the SPI ask for because of the way it's scored..."

Director of Pharmacy, Trust 14

"Yeah, we've done that with anticoagulation, and again we have, we felt we had our processes right but we've not been able to reduce our FMEA because we haven't been able to roll out across the whole of the Trust."

Senior Pharmacist, Trust 21

According to IHI, the target of FMEA is to reduce the RPN value when the scores are recalculated after changes have been implemented. According to McDermott *et al* (1996) there should be at least a 50% or greater reduction in the total RPN after an FMEA, However, if there is no target RPN for the FMEAs, then it is up to the team and company to decide how far the team should go with improvements. From the interviews it was unclear whether the target was 50% or 75% reduction in total RPN, but what was clear were the Trusts' pressure and worries about the scores rather than the actual actions and outcomes implemented.

4.4.4.2 Cluster two: Perceptions and opinions of FMEA:

Cluster two of the themes describes the opinions of the FMEA participants and use of FMEA in practice. Seven main themes were identified after coding the interviews.

4.4.4.2.1 Theme one: Describing FMEA:

The first theme is how participants describe FMEA from their perspective by outlining FMEA's characteristics, their expectations and limitations of its use from their experience. This helped reveal how participants define FMEA and its use in the clinical setting. Participants' descriptions of FMEA are outlined in table 24

Table 24: How participants describe FMEA

	Description
1. A tool that allows you to identify where the high risk areas are in the process of care	*"Gives you a clearer picture of which parts (of the process) are at the most dangerous"* Trust 1 *"It enables you to, um, come up with very bite sized pieces and to prioritise certain areas."* Trust 2 *"Its process mapping and risk assessing all in one ... More proactive."* Trust 3 *"The FMEA gives you a chance to actually sit down, and think well what actually, each step by step, what happens and what can go wrong?.... The FMEA has allowed us to sit and think which bits we need to really concentrate on."* Trust 5 *"All it is doing is bringing a few things to the surface."* Trust 6 *"I think you probably know in your head what the issues are, but it's actually quite good then to sit down, map it out and get score."* Trust 8 *" I think it's a tool that I can see can be applied in quite a lot of settings when you're looking at a whole process and you want to unpick it and look at what's going wrong or what the risks are in each bit of it."* Trust 10 *"Useful tool in identifying risk and scoring risk and helping you work towards reducing the risk in those particular areas."* Trust 14 *"Highlighted where the problems were, and then made you understand them."* Trust 16 *"I suppose it's good that it gets you sitting down, thinking of all the steps in the process, and your own gut instinct to what you know is wrong in the process. It's just reinforced that so it's put some science behind it."* Trust 18 *"It was useful as much as anything in actually identifying where things go wrong."* Trust 19 *"What it highlights is just where your greatest risk."* Trust 21

Table 24: Continued

2. Subjective	*"Slightly subjective."* Trust 8 *"It's such a simple process but I think it was the subjectiveness of the scoring that concerned me initially but it does seem to work in practice."* Trust 13 *"It's a subjective measure."* Trust 14 *"It is so subjective and depending on who does it makes it even more subjective really, how you look at it."* Trust 18 *"It's extremely subjective."* Trust 19
3. A tool that allows people to get together to talk	*"...but actually what it was, was just getting people to talk"* Trust 4 *"Gets quite big discussion going."* Trust 7 *"it opens some doors as well because it gets senior management back up and you're no longer a, you're no longer a voice in the wilderness, you're not the pharmacist banging on about risk, it becomes, we do quite well with it, we're quite well accepted, I'm not saying we're marginalised but it just raises the whole thing up the agenda."* Trust 11

Table 24: Continued

4. Systematic and Structured process	*"Systematic"* Trust 3 *"It's intuitive, it's an arbitrary scale but it's intuitive because it's like if, the things is that we're quite positive about this, you can tell, because it gives some structure to what we've been trying to do."* Trust 11 *"The thing that we love about it is that it takes all the finger wagging away. It's your fault, whoever you are, and it turns it into a structure where you can identify where the real flaws are and then discuss how you're going to put them right ... It's a very structured approach."* Trust 20
5. Other descriptions	*"The FMEA serves to ... cause analysis but it's done before anything happens so it's really gone through the steps of the process.....It's prospective."* Trust 7 *"A lot of it is brainstorming ... FMEA's are good for testing improvements."* Trust 11 *"It's a bit like capacity planning but with risk ... It's semi quantitative ... It's got good reliability."* Trust 17

The FMEA participants demonstrated a diverse understanding of FMEA. Overall, the majority concluded that it was a subjective but systematic tool that helps identify high risk areas by getting people together to discuss the problems. As the majority of the participants interviewed were those who received training for FMEA, it can be assumed that from the definitions provided, they have understood its overall purpose which is to identify high risk areas in a process of care. However, only two interviewees mentioned that it was proactive. Whether the teams focused on the current problems and used FMEA retrospectively rather than prospectively is unknown. Although FMEA's use can be flexible, it is important to remember that FMEA is publicised as proactive technique that is used to prevent process and product problems before they occur (VA NCPS, 2005) and thus it would be defying its purpose if the teams only focused on the current problems and overlooked its use as an innovative indicator of future problems.

Limitations of FMEA, according to the participants, were divided into two main concerns; limitations of the specific FMEA undertaken by the participants and limitations of FMEA in general. Limitations of the specific FMEAs undertaken by the participants included issues such as choosing a complex and long process for their first FMEA, not having a multidisciplinary team, or a lack of resources from the trust to support the use of FMEA. The general limitations of FMEA included issues such as the scoring scales, multidisciplinary team requirements and validity and reliability issues. General limitations of FMEA described by the participants are outlined in table 25.

Table 25: Limitations of FMEA according to the SPI participants' experience

Limitations	Participants' experience
1. Time consuming	*"FMEA is very time consuming ... It's a resource issue because dispensing FMEA and went on to prescribing and administering, somewhere round between 15 and 20 hours of staff time involved with it and a lot of that is sort of getting people used to the technique..."* Trust 4 *"Because it takes up so much time, we were going to do it over lunchtime."* Trust 12 *"Lengthy process."* Trust 16
2. Difficulty of FMEA itself as a process and the scoring scales in particular.	*"This is a more difficult concept, took a bit more time to get used to. Well we're still getting used to it in truth ....To get across the point about the scoring of it was possibly the biggest, just try and tell them what was really an arbitrary figure and it's really what they felt, it wasn't a ... was possibly the biggest but obviously none of the scores matched but we were able to come to a consensus..."* Trust 7 *"I think they [the staff who used FMEA] hadn't given themselves the correct marks, they had, in some cases they'd underestimated portions and others they'd overestimated, so their actual failures, their RPN was not 83RPN, it was more a tendency to underestimate rather than overestimate."* Trust 9 *"The score itself can be quite difficult in terms of looking at the number and looking at how the number drops. Doesn't really always, I think, in my personal opinion, doesn't always reflect on a risk reduction. I think it just changes the way you think the score, because it's subjective, you might just think initially, oh, I scored that a bit too high, or, actually I think maybe that should've been higher ... The scores are a hindrance rather than anything else, yeah."* Trust 14

Table 25 continued

3. Lack of validity and reliability and therefore acknowledging that only the same group of people can redo the FMEA	*"The jury's still out on the FMEA process because, and this is something that I had raised, has anybody evaluated FMEA as a tool for analysing risk? And it turns out there isn't...it's not a validated process."* Trust 6 *"I suppose really to score it again you need to get the same people back in a sense, to redo it."* Trust 8 *"The scoring in the FMEA teams need to be the same people, if you change half way through because of the highly subjective interpretation things change dramatically."* Trust 17 *"I'm unsure; I have to say, about how reliable. Unless you could get somebody absolutely objective to redo the FMEA. Maybe because of the way that we worked it, it was the same group of people who'd been involved with setting the process up we wanted, we all felt it was going to be reduced."* Trust 19

FMEA is very time consuming and this limitation for its use has been acknowledged in several published papers (Burgmeier, 2002; Capunzo *et al*, 2004; Duwe *et al*, 2005). In order to reduce this limitation, proper initial training as mentioned before is important for the team facilitator or team leader. In addition to this, having the managerial support and resources available may help minimise this limitation.

As for the scoring scales, there are no rules for choosing a specific scoring scale to rate the failures identified as described in the introduction in chapter 1. However the JCAHO (2005) advices that whatever scale is chosen it should be used consistently. According to the FMEA data on the IHI website, a 10-point scale is used for the failures. The above comments about the scoring scales indicate that the participants found the 'theory' of using numbers to access a risk as their main concern rather than the scoring scale itself. Furthermore, the level of subjectivness in interpreting these scores made it even more difficult to grasp.

The lack of validity and reliability again is a concern brought up on more than one instance as several participants acknowledged that the same people had to redo the FMEA in order to confirm valid and reliable results. Perhaps this concern with validity and reliability comes from an evidence-based approach and pharmacists' awareness of validity and reliability themes in research and practice.

4.4.4.2.2 Theme two: Opinions of FMEA:

The second theme reports the opinions of participants. Both positive and negative opinions were expressed. The majority of the interviewees expressed constructive

views towards FMEA, some more strongly than others, in terms of it being a useful tool particularly for mapping a process and identifying the problems within this process.

> *"It's [FMEA] one of the best techniques I've seen ... I think it's a fantastic technique."*
>
> Director of Pharmacy, Trust 4

> *"I think it's an excellent tool."*
>
> Pharmacist, Trust 9

> *"We've done an FMEA because we like that, we found that tool very helpful for some of the other work that we've been doing."*
>
> Director of Pharmacy, Trust 10

> *"We like FMEA and we like the process focus as well."*
>
> Director of Pharmacy, Trust 11

Two interviewees particularly mentioned that FMEA mostly suited and interested pharmacists.

> *"Well the FMEAs really, it was something that really interested pharmacists ... I think FMEA suits pharmacists because they are very, you know just by the nature they're very, um, fussy, you know ... It's a tool that definitely pharmacists love."*
>
> Clinical Pharmacy Coordinator, Trust 3

> *"Pharmacy staff are very much stitched into that process and patient safety is something that pharmacists love. It's our raison d'être."*
>
> Chief Pharmacist, Trust 13

Two additional purposes of FMEA have been mentioned; firstly, that it resolves the problem of blaming individuals. This is an accurate description of FMEA since its aim is to identify 'potential' failures that have not yet occurred.

> *"The thing that we love about it is that it takes all the finger wagging away. It's your fault, whoever you are, and it turns it into a structure where you can identify where the real flaws are and then discuss how you're going to put them right..."*
>
> Chief Pharmacist, Trust 20

Secondly, FMEA is seen as a means for pharmacists to be heard and their input about risk and safety to be taken into consideration. This again highlights the problems of poor communication between healthcare professionals and the barriers between a multidisciplinary team due to power disparities from the hierarchical structure within healthcare.

> *"It's a good tool for experience people to take and run with, are you with me? And it opens some doors as well because it gets senior management back up and you're no longer a voice in the wilderness, you're not the pharmacist banging on about risk, it becomes, we do quite well with it, we're quite well accepted, I'm not saying we're marginalised but it just raises the whole thing up the agenda."*
>
> Director of Pharmacy, Trust 11

On the contrary, other participants expressed how the subjectivness of FMEA and lack of validity deterred some pharmacists.

> *"When all it is doing is bringing a few things to the surface, which is no bad thing, but it's not a validated process ... .Is it any point in putting this [FMEA] data on to the SPI website if it's nonsense in a way? It's what you're doing with it isn't nonsense, but the values of it mightn't tell you very much."*
>
> Medicines Governing Pharmacist, Trust 6

> *"So, the score itself can be quite difficult in terms of looking at the number and looking at how the number drops. Doesn't really always, I think, in my personal opinion, doesn't always reflect on a risk reduction ... I don't think it works effectively ...*
> *I think there would've been better ways of implementing a changed policy around gentamicin than doing FMEA ...*
> *Forget FMEA. It doesn't really work effectively, I don't think, and the scores are a hindrance rather than anything else, yeah ...*
> *We wasted a lot of time on FMEA before we realised, this isn't actually working.*
> *Yeah, because I think you can get caught up on just the score, that's the thing...*
> *I just don't know why someone didn't stand up and say, this process doesn't work."*
>
> Director of Pharmacy, Trust 14

"I'm comfortable with it what they (the other participants) didn't like was the semi subjective, or semi objective nature of the scoring parameters. I said, just take it as it is. And there was a lot of argument as, it's not valid, it's not relevant, it's not this, it's not that. If said, if you're doing your pre-analysis, and you're doing your post analysis then you've introduced a degree of uniformity into the scoring process yourself unless of course you were scoring randomly in the first place, and you've forgotten what you were doing."

Chief Pharmacist, Trust 17

"A very useful exercise and a useful tool at the beginning of the process. I wonder about, because we've, the same group of people did the review to the FMEA and I'm unsure about whether we already decided almost what we thought we wanted it to be. Because we felt the process was successful. I'm unsure, I have to say, about how reliable. Unless you could get somebody absolutely objective to redo the FMEA. Maybe because of the way that we worked it, it was the same group of people who'd been involved with setting the process up we wanted, we all felt it was going to be reduced."

Clinical Pharmacy Manager, Trust 19

This conflicting report of attitude can perhaps be explained by the limitations of the interview itself. First, pharmacists in managerial positions were interviewed and most likely they were the ones who facilitated the meetings, thus the opinions of the rest of the participating pharmacists have been reported through the eyes of their managers. Second, the interviews were conducted by five different researcher and thus variation in the questions and how they were asked was inevitable and thereby may have led to reporting conflicting attitudes particularly if leading questions were used.

"Researcher/Interviewer: No, that's why I was asking you, because some of the other people we've interviewed have said they didn't like the subjectivity around it, and then found
Pharmacist/Interviewee: Pharmacists don't like subjectivity.
Researcher/Interviewer: Pharmacists didn't like, yeah that's why I was just asking.
Pharmacist/Interviewee: Don't like it, just said, well no, just get over it. If you've got something that works 95% of the time in your department that is not dispensing."

Chief Pharmacist, Trust 17

Some participants positively described FMEA but with associated reservations. Although they recognised the positive use of FMEA, they still managed to acknowledge its limitations and drawbacks.

> *"I think it's useful if you've already identified your high risk areas."*
>
> Head of Pharmacy, Trust 5

> *"It is a useful tool but it's we who have a difficult concept because I've had no training whatsoever in it, I haven't had any of that...It is a good tool once you get used to it."*
>
> Pharmacist, Trust 7

> *"But I think once you kind of understand it you feel it isn't actually as difficult as I think you think it's going to be."*
>
> Principal Pharmacist, Trust 8

> *"Overall yes (it's useful) but it is so subjective and depending on who does it makes it even more subjective really, how you look at it. But I suppose it's good that it gets you sitting down, thinking of all the steps in the process, and your own gut instinct to what you know is wrong in the process. It's just reinforced that so it's put some science behind it."*
>
> Principal Pharmacist, Trust 18

> *"It was useful as much as anything in actually identifying where things go wrong. Rather than necessarily the absolute number.... But I think, the process itself of picking the things apart was probably the most useful"*
>
> Clinical Pharmacy Manager, Trust 19

Negative opinions of FMEA were associated with the perceived limitations of its use as mentioned in section 4.4.4.2.1. However, two pharmacists reported that they had initial negative opinions about FMEA until they were more familiar with it and that their experience with FMEA improved as they became more experienced with its use.

> *"I found FMEA a complete nightmare in the beginning. I didn't know what I was doing with it at all. And I think a lot of people kind of went, what on earth is this? And it took us a while to get FMEA started because I don't think we were really quite sure what we were doing with it."*
>
> Principal Pharmacist, Trust 8

"FMEA, I have to say is something I was a little bit cynical about because it's, the scoring system is, I feel, relatively subjective and depends who's in the room. But in practice, I found that a really pleasing experience."

Chief Pharmacist, Trust 13

4.4.4.2.3 Theme three: Training and teaching FMEA

The third theme describes the training for FMEA. Since eight interviewees mentioned that this was their first time using FMEA, the issue of training for FMEA was brought up on several occasions. Training provided by the IHI and the Trusts included: attending learning sessions/ workshops, meetings and conferences, and information published on the extranet.

"..went through the process as per the guideline and we were assisted quite well with IHI and their conference calls for this.."

Principal pharmacist, Trust 4

"They do have quite a lot of resources like FMEA or the extranet. I use the extranet quite a bit, the private line from the extranet, partly the IHI part because they have FMEAs, they have a folder worth of FMEAs including references and things they've downloaded."

Pharmacist, Trust 7

Other participants resolved to find out information themselves from the internet or through communication with other Trusts.

"...because the other Trust did their FMEA before us, and so they kindly sent us the FMEA to work on our own, but we doctored the one that they were doing.."

Nurse, Trust 16

"I went on the net...You expect to do that surely on everything? We're all grown ups and most people have got three or four degrees under their belt.."

Chief Pharmacist, Trust 17

Finally some interviewees said they combined both the use of IHI resources and self teaching to understand FMEA, indicating that the SPI information provided was not sufficient.

> *"I've subsequently gone to different conferences out with SPI and I've got some more training and understanding of FMEA through that. I did actually go to a whole day of FMEA....But I have to say, I suppose to answer your question, I don't really feel that SPI did really give you enough training on it. I've probably had to find out a bit more about it myself."*
>
> Principal Pharmacist, Trust 8

> *Pharmacist: I think they showed us this FMEA light sheet, I think it was called, and so they did discuss it briefly but frankly I don't know why they did that because we didn't need to do an FMEA light, we needed to do an actual FMEA. So it wasn't really that helpful, so they discussed it but to actually go away and so something so*
> ***Interviewer: You had to learn it for yourself afterwards?***
> *Pharmacist: Yeah, so we looked at what was available on the extranet and looked just really in pharmacy journals to see if there were any reports of any, read up on it and then went for it.'*
>
> Specialist Pharmacist, Trust 12

Although team members don't have to be familiar with FMEA prior to starting the process, proper training for the FMEA facilitator to conduct FMEA is an important element for the FMEA's success (JCAHO, 2005). This helps ensure that the facilitator is capable of guiding his/ her team and that the correct information about FMEA is passed on. Not all participants were asked about the training provided for FMEA or how useful it was; however, the majority of the participants who spoke about FMEA training reported that they needed to seek more information. It was also unclear from the interviews whether the people that were trained for FMEA actually facilitated the meetings or not. Improper training and lack of information made some participants feel less confident about its use as they expressed how difficult and complicated they found FMEA.

> *"This is a more difficult concept, took a bit more time to get used to."*
>
> Pharmacist, Trust 7

> *"To be honest with you, I found FMEA a complete nightmare in the beginning. I didn't know what I was doing with it at all. And I think a lot of people kind of went, what on earth is this? And it took us a while to get FMEA started because I don't think we were really quite sure what we were doing with it."*
>
> Principal Pharmacist, Trust 8

Only one pharmacist brought up the issue of having to teach FMEA to other staff, while highlighting the difficulties that accompanied this task.

> *Pharmacist: The FMEA had to be taught to one of the other pharmacists and that was part, it was also taught to the doctor and the nurse, the principle behind the FMEA.*
> ***Interviewer: Did you teach the FMEA then?***
> *Pharmacist: Yeah, possibly how effectively I'm not sure but I did.*
> ***Interviewer: Was there any difficulty in these teachings?***
> *Pharmacist: To get across the point about the scoring of it was possibly the biggest, just try and tell them what was really an arbitrary figure and it's really what they felt, it wasn't a ... was possibly the biggest but obviously none of the scores matched but we were able to come to a consensus...*
>
> Pharmacist, Trust 7

The above comment indicates that FMEA was being 'passed on' by a non expert in FMEA. There is no published work studying whether the outcomes of FMEA differ when taught by an FMEA 'expert' compared to an FMEA taught to participants by a non expert. However, the general approach from the participating trusts in SPI was to allow one or two lead members of the Medicines Management team to attend the training sessions for the SPI methodologies, which included FMEA, and to then 'pass on' the information to the remaining team members. It was unclear how effectively the FMEA information was passed as the interviewee from trust 7 indicated. The extent to which this may have affected the FMEA results is unknown.

4.4.4.2.4 Theme Four: Comparing FMEA to other risk assessment tools:

Theme four relates to comparing FMEA to other risk assessment tools. Only two pharmacists made such a comparison and both compared FMEA to the root cause analysis technique. Both pharmacists were in favour of FMEA.

> *"we had all done training in root cause analysis and fishbone diagrams and all that kind of stuff but somehow the FMEA seemed a little bit more relevant, particularly to some of the pharmacy processes although it could be applied to anything, but I think because that it adds an extra element, this element of detection, which the other risk management tools don't take account of in pharmacy.."*
>
> Principal Clinical Pharmacist, Trust 1

> *"I mean we've put a bit of emphasis in route cause analysis, erm and I think we've got 50 members of staff in the Trust who have been trained up on route cause analysis. Frankly I'd just scrap that, go for FMEA, cos FMEA you're looking at a global system, where as with route cause analysis, you're homing in on one particular incident and looking at it and actually what, if you expand it into a whole FMEA of that whole process, you'll learn so much more than doing an individual route cause analysis."*
>
> Director of Pharmacy, Trust 4

The comparison between root cause analysis (RCA) and FMEA is difficult because they are different techniques that serve different purposes. RCA is a reactive technique because it is conducted after an incident actually occurs. Spath (2003) states that actual or theoretical blame that often occurs with RCA may result in fear and resistance by some participants, while because FMEA is supposedly proactive, no participants are being blamed for an incident. In addition, RCA focuses on one specific event, while FMEA tends to focus on an entire process, a point which was acknowledged by the interviewees who have used RCA.

4.4.4.2.5 Theme five: Use of FMEA in practice:

The fifth theme derived from the interviews was the use of FMEA in practice. Three subthemes emerged from the interviews:

1. How widespread is its use?

> *"It's beginning to spread out, it's not just being used for medicines, other people are beginning to look at using the tool as a way of helping them to decide..."*
>
> Principal Clinical Pharmacist, Trust 1

> *"We've not at the moment expanded enough, but that's a resource issue and I don't think we've insufficient spread of that...I really don't think that technique is spread sufficiently."*
>
> Director of Pharmacy, Trust 4

2. Is it transferable to other settings?

> *"It [FMEA] could be applied to anything."*
>
> Principal Clinical Pharmacist, Trust 1

> *"Yes certainly [we found FMEA transferable]."*
>
> Head of Pharmacy, Trust 5

3. Will they be using it again?

Seven Trusts voluntarily conducted more than one FMEA and four other interviewees expressed their desire to use it again.

> *"Yeah, I think, yeah, we could possibly could actually [use FMEA for other processes], and use it perhaps for something a bit smaller."*
>
> Principal Pharmacist, Trust 8

> *"We'd like to use it [FMEA] elsewhere."*
>
> Specialist Pharmacist, Trust 12

> *"I think we'll use things like the FMEA...If we wanted to look at, if we had another problem area, we thought that would be useful, that, might use that [FMEA]."*
>
> Nurse, Trust 16

"So yes, absolutely, we would do that [FMEA] again."
Clinical Pharmacy Manager Trust 19

This indicates that from the majority of the Trusts' experiences, the benefits of FMEA outweighed its limitations and drawbacks and that it is a useful transferable tool that still isn't sufficiently wide-spread.

4.4.4.2.6 Themes six and seven: Validity and Reliability of FMEA:

Finally, the sixth and seventh themes were validity and reliability of FMEA.

Seven interviewees brought up either the issue of perceived validity or reliability of FMEA, some more directly than others.

One participant clearly stated that FMEA was not a validated process:

"The jury's still out on the FMEA process because, and this is something that I had raised at Imperial, has anybody evaluated FMEA as a tool for analysing risk? And it turns out there isn't. And I had raised it with xxx last week, and he doesn't know if anybody has, so I thought, well why are we doing this process?...When all it is doing is bringing a few things to the surface, which is no bad thing, but it's not a validated process...We rescored it to say, I want to look at it outside of our FMEA group to see what sort of variations there are between our scores, because it's just, is it any point in putting this data on to the SPI website if it's nonsense in a way? It's what you're doing with it isn't nonsense, but the values of it mightn't tell you very much."
Medicines Governing Pharmacist, Trust 6

Another pharmacist simply expressed that FMEA does not work and was a waste of time:

> *"So, the score itself can be quite difficult in terms of looking at the number and looking at how the number drops. Doesn't really always, I think, in my personal opinion, doesn't always reflect on a risk reduction ... I don't think it works effectively ...*
> *I think there would've been better ways of implementing a changed policy around gentamicin than doing FMEA ...*
> *Forget FMEA. It doesn't really work effectively, I don't think, and the scores are a hindrance rather than anything else, yeah ...*
> *We wasted a lot of time on FMEA before we realised, this isn't actually working.*
> *Yeah, because I think you can get caught up on just the score, that's the thing ...*
> *I just don't know why someone didn't stand up and say, this process doesn't work."*
>
> Director of Pharmacy, Trust 14

Three interviewees highlighted the issue of reliability by recognising that the same group of people was needed to redo the FMEA in order to obtain reliable outcomes:

> *"I suppose really to score it again you need to get the same people back in a sense, to redo it."* Principal Pharmacist, Trust 8

> *"FMEA, I have to say is something I was a little bit cynical about because it's, the scoring system is, I feel, relatively subjective and depends who's in the room."* Chief Pharmacist, Trust 13

> *"The scoring in the FMEA teams need to be the same people, if you change half way through because of the highly subjective interpretation things change dramatically."*
>
> Chief Pharmacist, Trust 17

One pharmacist explained that perhaps the desire to want the RPN to decrease was the main influence and drive behind the FMEA thus questioning its reliability:

> *"Because we had, we already felt that that was a problem. Whether than influenced how we did the FMEA, I don't know. But it did confirm what we wanted, we thought it should show ... Whether it's a reliable measure, I think my feeling was that it was a very useful exercise and a useful tool at*

the beginning of the process. I wonder about, because we've, the same group of people did the review to the FMEA and I'm unsure about whether we already decided almost what we thought we wanted it to be. Because we felt the process was successful. I'm unsure, I have to say, about how reliable. Unless you could get somebody absolutely objective to redo the FMEA. Maybe because of the way that we worked it, it was the same group of people who'd been involved with setting the process up we wanted, we all felt it was going to be reduced."

Clinical Pharmacy Manager, Trust 19

In another trust, the FMEA team had to repeat the scores because they felt that their scores were not accurate.

"I think they [the staff who used FMEA] hadn't given themselves the correct marks, they had, in some cases they'd underestimated portions and others they'd overestimated, so their actual failures, their RPN was not 83RPN, it was more a tendency to underestimate rather than overestimate."

Pharmacist, Trust 9

In three trusts, the participating members of FMEA expressed their concern for the use of FMEA in terms of its validity and reliability. However, in these three trusts, the pharmacist managers overlooked these concerns and chose not to question FMEA but instead to focus on completing it.

"People start challenging the evidence behind it when it's not about the evidence, it's we're saying, we've already agreed that, now can we put it in place please?"

Head of Pharmacy, Trust 5

"To get across the point about the scoring of it was possibly the biggest, just try and tell them what was really an arbitrary figure and it's really what they felt, it wasn't a ... was possibly the biggest but obviously none of the scores matched but we were able to come to a consensus. I would say probably in, everybody, the pharmacists as well saying to me, well I don't really think that that's that, I do think it's ... get a quite big discussion going"

Pharmacist, Trust 7

> *"We're all grown ups, and most people have got three or four degrees under their belt, ... and they thought well, what they didn't like was the semi subjective, or semi objective nature of the scoring parameters. I said, just take it as it is. And there was a lot of argument as, it's not valid, it's not relevant, it's not this, it's not that. If said, if you're doing your pre-analysis, and you're doing your post analysis then you've introduced a degree of uniformity into the scoring process yourself unless of course you were scoring randomly in the first place, and you've forgotten what you were doing. So set out a few rules for yourself. And that's what I had to do, I decided eventually once the group had decided what the process was, and where the flaws in the process were, I did the scoring."*
>
> Chief Pharmacist, Trust 17

Only two pharmacists spoke positively about the reliability of FMEA, one directly

> *"It's based on can you detect it? How clinically significant is this thing when it goes wrong? And how frequently does it occur? So rather than on a one to ten scale, one being 10%, well in fact if you wanted it specifically that way you'd have to have an awful lot of data to show that in fact this error occurred 10% of the time. So 1, we say, well hardly ever, hardly ever happens, it's a reliable, it's got good reliability. We get to 3, say well it occurs occasionally, it's a bit irritating. If it occurs 5 or 6 we're saying, gosh could do better, and if it's 7, 8, 9, or 10, it says god it's happening all the time. And we never got any 10s because you wouldn't put up with that in a process."*
>
> Chief Pharmacist, Trust 17

And the other indirectly;

> *"At the end of it, we tended to have a bit of a group consensus if there was some you know, if there was a wide variation but erm it was quite fascinating to see how we all seemed to think down a similar sort of line, even though you'd got people with a vast amount, you know as a clinical pharmacist, I'd got 25 years experience and I've got an assistant, to somebody who'd been dispensing and got no qualifications. You know and when we came up with very sort of similar ideas, it was great."*
>
> Director of Pharmacy, Trust 4

The majority of the interviewees have acknowledged that FMEA lacks validity and reliability. It is perceived that the FMEA teams with good communication skills produced more reliable FMEA results than the FMEA teams that experienced problems between its members. Furthermore, the interviewed lead pharmacists did

not all agree with their participating team members when it came to questioning the evidence behind FMEA. Pharmacists' concern with validity and reliability aspects of processes perhaps is a result of their educational and professional training where they are encouraged to apply evidence-based medicine in their daily practice.

Perhaps the lead pharmacists' attitudes towards FMEA resulted from sense of pressure or high expectation to conduct an FMEA as part of SPI project requirements and to meet deadlines.

> *'there was an expectation that we had been privileged to be part of SPI so there was an expectation that something was going to happen, something good was going to happen and we were the ones that were going to have to make that something good happen."*
>
> Principal Clinical Pharmacist, Trust 1.

> *"Well, you want to achieve, don't you? At the end of the day, you want to achieve, you do, we don't want to let ourselves down, we don't want to let 'the other hospital' down, and we don't want to let the programme down..."*
>
> Nurse, Trust 16

At some trusts the IHI was not solely responsible for the sense of pressure or expectations described by the pharmacists. One pharmacist states that it was also to do with senior management within the trust.

> *"Well, it, it (the pressure) was very much from IHI, I mean it, er, you know their attitude was very much, there is, um...no excuses for not doing it. But because it also put pressure on senior management at the Trust to show that they were playing ball. Then if you like the pressure was from both sides but I think initially the pressure was from IHI, that was my feeling anyway."*
>
> Chief Pharmacist, Trust 2

Although these comments were relevant to SPI methodologies in general rather than FMEA specifically; FMEA was promoted as one of the SPI methodologies. The fact that issues of validity and reliability, brought up by the FMEA participants,

were discarded by the team leaders shows that the aim was perceived to be to reduce the RPN values irrespective of its validity, reliability or even sustainability. The comments of several interviewees regarding having the same team to redo the FMEA further support our reliability study results which report that the FMEA results will depend on the team conducting the FMEA.

The next section of this chapter describes the perceptions about FMEA of the two teams who conducted an FMEA as part of the reliability study in chapter 2.

4.5 FMEA participants in the reliability study (chapter 2)

In the next section the experiences of the multidisciplinary team who conducted the FMEA in chapter 2 will be reported. The methods and results will be first described. Then the facilitator's experience will be reported.

4.5.1 Methods

At the end of the FMEA meetings, each participant was asked to answer, in writing, four open-ended questions: two questions related to the general use of FMEA and the other two related to the use of FMEA for vancomycin and gentamicin:

- From this experience, do you think FMEA is a useful technique? Would you participate again in an FMEA mapping process?
- What, in your opinion, are the strengths and weakness of the FMEA technique in general?
- What do you think were the benefits and drawbacks of doing an FMEA related to the use of vancomycin and gentamicin?
- How do you think the FMEA conducted for vancomycin and gentamicin could be improved?

The answers were anonymous with regards to the healthcare professional but not with regard to the FMEA group.

4.5.2 Results

In total, eleven participants attended the final FMEA meetings; six participants from group one and five from group two attended their last FMEA meetings.

When asked if they thought FMEA was a useful technique, all except one participant thought it was a useful technique on the condition of implementing the recommended changes. Another participant said the process was "too lengthy" to participate again. The perceived strengths and weaknesses of FMEA are reported in table 26.

Table 26: The strengths and weaknesses of FMEA according to our FMEA team members

Strengths		Weaknesses	
Having a multidisciplinary team	*"Allows the input of several disciplines..."* Group 1 *"Produces a consensus, which is useful since people may interpret problems in different ways."* Group 1 *"Good to have multidisciplinary views of process."* Group 2	Time Consuming	*"Very time consuming"* Group 1 *"Time was required to explore but did take up quite a lot of time..."* Group 2
		Too subjective	*"Some of the scoring is very subjective"* Group 1 *"Too subjective"* Group 1 *"Our experiences are subjective and not necessarily accurate"* Group 2
Identifying the high risk areas	*"Enormity of the area covered, so many issues covering a variety of divisions of the hospital."* Group 1 *"The main strength of the system is that it provides you a systematic approach to the identification of risks within a process."* Group 1 *"I hope that it will reveal the steps that are important and highlight weaknesses in the system and ways the system could be improved. It has also revealed the enormous complexities involved in giving an antibiotic."* Group 2 *"Goes into lot of detail which reveals issues/areas may not otherwise be aware of."* Group 2	Scoring scale is difficult and not necessarily accurate	*"Trying to understand what you are trying to grade when it comes to severity, i.e. the over scope or worse case. Just trying to keep things logical in your brain!"* Group 1 *"Scoring system is difficult without having hard data to base it on"* Group 2 *"The scoring system as with others is an estimate that may change if you discussed it again as scores are influenced by the discussion and opinions of the groups"* Group 2 *"No way of knowing how realistic are people's estimations of risk"* Group 2
		Strong team participants influencing the discussion and scoring scales	*"Although multidisciplinary input is essential, strong individuals might map the process according to their experiences.."* Group 1 *"The scoring system as with others is an estimate that may change if you discussed it again as scores are influenced by the discussion and opinions of the groups"* Group 2
		Inflexible	*"Even though it allows for lots of steps we still found it inflexible in parts and didn't feel we were able to adequately describe the situation."* Group 2

When asked about the FMEA for vancomycin and gentamicin specifically, all stated the same positive comments about having a multidisciplinary team and mapping and dividing the process as well as the same general negative remarks about how time consuming it is and the confusion with the scoring scale. However, they made recommendations to further improve this specific FMEA which included dividing the process into smaller sub processes, doing an FMEA for each antibiotic separately and finally having more data and baseline information about the process itself and the specific antibiotics.

The results of the questions answered by our FMEA teams highlighted the same issues brought up by the SPI participants in terms of similar positive comments such as identifying high risk areas and including a multidisciplinary team, as well as negative remarks such as FMEA's subjectivness, difficulty in determining the scoring scale and time consumption.

There are two main differences between the SPI participants interviewed and our FMEA team members. First, the SPI participants interviewed were individuals who took a lead role in SPI but did not necessarily actively participate in the FMEA. Second, the majority of SPI participants actually implemented changes and observed the RPN values go down, while this was not the case for our FMEA participants. Thus it comes at no surprise that some FMEA members stated that FMEA would only be useful if the changes recommended actually implemented and proved to benefit patient safety.

4.5.3 Facilitators' perspective

From a facilitators' perspective, training for the FMEA meetings was important and valuable. The training helped explain the FMEA process clearly to the participants since none had conducted an FMEA before. It allowed us to guide the team effectively through the process and to answer any queries.

Facilitating two different teams with different team composition was the biggest challenge. Group one was more relaxed and managed to reach a consensus for most of the failures easily. Group two, on the other hand, was slightly more difficult to facilitate as there were four pharmacists on the panel who dominated the discussion and a very vocal consultant who had a slightly different perspective than the rest of the team. The effects of differences between the teams' composition was reflected in their FMEA results.

As the FMEA interviews revealed, it proved to be a time consuming process. In spite this, the main positive outcome of FMEA was to gather a group of healthcare professionals to discuss the process and to receive positive feedback from the teams particularly about getting the chance to discuss a process of care with other healthcare professionals and view the process of care from different disciplines' perspectives.

4.6 Conclusion

In this section the overall conclusion of the chapter will summarised. This will be followed by the limitations of this research and proposed future work.

FMEA was defined by participants as a structured subjective process that helps healthcare professionals get together to identify the high risk areas within a process of care. The limitations that are most likely to restrict its wide spread use are its time consuming nature and the perceived lack of validity and reliability as expressed by a number of trusts.

From the participants' experiences, team composition appears to be the most important factor that affected the FMEA results. Having a multidisciplinary team with effective communication skills is important to sustain more reliable results since the same team is required to repeat the FMEA.

In this study however, it is important to remember that since FMEA was undertaken by the trusts as part of the SPI project, there was a strong focus on the FMEA scores and the desire to reduce them; which inevitably may have biased the outcomes of FMEA, the opinions expressed towards FMEA and the attitude of the senior pharmacists towards it.

Only three published papers have reported participants' opinion about FMEA, one from the Netherlands and two from the United States. The first study was conducted in the United States (Wetterneck *et al*, 2004) in which the challenges encountered by the FMEA team where collected from open forum discussion by team members at the end of the FMEA, recording of personal experiences of the facilitator and team leader and post-FMEA structured interviews with the team members. The team stated that the multidisciplinary nature of FMEA was a key strength but it required substantial time commitment and this caused a number of problems with

attendance at meetings. They stated that an experienced facilitator and leader was necessary to guide the team especially since some participants still found a FMEA difficult to understand even after a half-day training session on FMEA was provided. The above challenges mentioned in the study by Wetterneck *et al* (2004) were all reported by the SPI participants.

The second study was also conducted in the United States where structured interviews and questionnaires were administered to team members of two FMEA teams within the same hospital to evaluate the team member perceptions of FMEA team performance and factors influencing team performance (Wetterneck *et al*, 2009). The results were based on input-process-outcome model of team performance. The input node included issues such as team knowledge and management, different disciplines, team objectives and organizational support. The process node included team dynamics, attendance and team progress and finally the output node included accomplishments and value of FMEA. The study reported some similar positive and negative points about FMEA team performances that were similar to the findings in this chapter. For example, positive comments such as including 'different areas of expertise' were similar to those reported by the FMEA team members in chapter 2; while negative comments included 'unfamiliarity of FMEA processes' or having dominating team members in the discussion.

In the final study, the aim of study by Habraken *et al* (2009) was to evaluate the use of Healthcare FMEA (HFMEA) in Dutch healthcare system by means of user feedback. The results reported that positive remarks about HFMEA included: 1- HFMEA analysis was meaningful and that the healthcare process would be safer as

a result of its use 2-it is a systematic, stepwise approach. 3- The multidisciplinary nature of the analysis was pleasant and clear. The negative remarks included: 1-Takes a lot of time. 2-The analysis did not yield significant results or the analysis was difficult. 3-Difficult to score the risks and 4-Problems within the team. Although the results are related to HFMEA rather than FMEA, all the above comments about HFMEA were similar to those described by the SPI participants as well as the team members who conducted the FMEA in chapter 2. However, the results also included two drawbacks about HFMEA that were not mentioned by the SPI participants. First, HFMEA itself provides no guidance for the identification of failures causes and second, it does not include guidelines for the translation of any identified failures into an appropriate countermeasure.

Unlike the results of the SPI participants, the three published studies did not include any comments about the validity or reliability. Perhaps because this was the first time several SPI members have encountered FMEA and thus have questioned the evidence behind its use. In the USA (Wetterneck *et al* 2004; 2006) and Netherlands (Habraken *et al* 2009) FMEA or HFMEA have been widely used during the last couple of years and as its use is widespread, team members may have been overlooking validity or reliability issues.

4.6.1 Limitations and methodological considerations

The main limitation of this work is that the researcher did not conduct the interviews herself. The aims and objectives of the SPI interviews were to understand the process of improvement, organisational readiness, variability, impact and sustainability of benefits associated with complex systems level interventions

such as the Safer Patients Initiative, rather than focus on FMEA; thus more details about the participants' thoughts towards FMEA were not fully explored. The interviews were conducted by more than one researcher from the Imperial College SPI Research Team and transcription of the interviews was carried out by a professional transcribing agent. Furthermore, there was a time gap between the first four interviews part of SPI 1 and the remaining 18 interviews from SPI 2. Following SPI 1, the interview schedules for SPI 2 were slightly modified to ensure the overall aims and objectives of SPI were achieved. This may have resulted in variations of the questions relevant to FMEA and thus perhaps inconsistent information about FMEA. Another limitation is that the interviews were conducted with the individuals that took a lead role in establishing and coordinating SPI within the organisation, and not necessarily individuals who actively participate in FMEA. This is of particular importance because in more than one trust, the lead pharmacist reported their contentment with FMEA while the remaining participants had reservations against FMEA.

4.6.2 Future work

This is the first time participants of FMEA in the UK have been interviewed to account their opinions and familiarities with FMEA. As FMEA becomes more widely spread and used in the UK, more qualitative studies would be useful in exploring the attitudes and opinions towards FMEA in order to help evaluate the readiness of trusts to adopt FMEA and participants to contribute, as well as exploring the means to maximise the success and benefit of FMEA, while limiting its shortcomings.

In chapter 2 the FMEA teams made a number of recommendations to eliminate the failures identified. These recommendations included several relating to the use of technology. To further explore the validity and feasibility of some the groups' recommendations, the next chapter presents a review of the literature in this area.

Chapter 5 Clinical Decision Support Systems and Antibiotics

"Technology presumes there's just one right way to do things and there never is."

Robert M. Pirsig

5.1 Introduction

In chapter 2, a total of 65 recommendations were listed by both groups to improve the prescribing, administering and monitoring of vancomycin and gentamicin. Group one listed 26 recommendations of which seven (27 %) were related to the use of technology. Group two listed 39 recommendations of which five (13%) were related to the introduction of technology. From a total of 65 recommendations, only nine (14%) were common to both groups and from these nine common recommendations three were relevant to the use of health informatics such as introducing electronic prescribing, introducing bar coding and installing a computer programme that informs healthcare professionals that the laboratory has received a sample as well as alarms the healthcare professionals when the results have been reported on the computer system. The JCAHO (2005) reports a number of methods for redesigning a process of care after an FMEA has been completed as described in chapter 1 (section 1.5.2.8). Among the recommendations by the JCAHO is to implement and use technology.

The JCAHO (2005, p.146) states:

> *"Automation or technology can reduce the likelihood of failures associated with inconsistent or variable input or failures associated with processes or process steps that are heavily dependent on human intervention. Computerized medication order entry systems can increase the likelihood of intercepting failures, including drug-drug interactions, allergies, out of range doses and contraindications, before they reach the patient. Electronic medical records can help reduce the amount of paperwork required by medical professionals and free up nursing time for patient care. They can also help enhance error prevention by reducing the reliability on human memory. Checklists and screens for risk assessment, pop-up menus for physical assessment and programmed questions for histories or data collection are just a few of the ways that an electronic medical record can help reduce an organization's reliance on human memory."*

At the same time the JCAHO (2005) advises that the following factors should be considered before changing any process of care:

1. Organisational processes: How does the proposed redesign (or use of technology) relate to other projects currently under way in the organisations?
2. Resources: What financial resources will be required? And what other resources such has staff, time and management are needed?
3. Schedule: What time frame can implementation be completed?

Health information technologies such as electronic prescribing, electronic health records, computerised physician order entry (CPOE), bar coding and automated drug-dispensing systems have been hailed to potentially reduce medication errors. The most extensively studied of these technologies is CPOE, which has been shown in several US-based studies to reduce medication errors (Hughes & Ortiz 2005). Computer systems have also been promoted for their potential to improve the quality of health care, including their use to support clinical decisions (Clayton & Hripcsak 1995). Recently healthcare organisations are increasingly turning to clinical decision support systems (CDSSs), which provide clinicians with patient-specific assessments or recommendations to aid clinical decision making (Kawamoto *et al* 2005). Rommers *et al* (2007) stated that CDSS are built into almost all CPOE systems to varying degrees. Basic CDSS provides computerised advice regarding drug, dose, routes and frequencies, and more sophisticated CDSS can perform drug allergy checks, drug-laboratory value checks and drug-drug interaction checks and can provide reminders about drug orders or guidelines (Kaushal *et al*, 2003; Kuperman *et al*, 2007, Osheroff *et al*, 2007).

The FMEA results in chapter 2 have further indicated that the process of prescribing, administering and monitoring antibiotics is prone to errors that may harm the patients. To further explore the validity of some of the recommendations of the FMEA team and to assess their feasibility, it was decided to explore the literature relating to the use of technology and antibiotics. It was decided to focus on computerised decision support (CDSS) as this incorporated a number of the teams' recommendations which included the use of electronic guidelines, using computerised ordering and requesting for samples, computer systems to flag abnormal level results and computerised documentation of notes and drug orders.

In this chapter the literature describing the use of CDSS and antibiotic use is presented.

5.2 Aims and Objectives

5.2.1 Aim

- To summarise the relevant literature available regarding the use of CDSS and antibiotics.

5.2.2 Objectives

- To report the definition of CDSS and its classification
- To report the history of its use with antibiotics
- To summarise and appraise randomised controlled trials (RCT) and before and after trials published on CDSS used to support the use of antibiotics

- To identify gaps in the existing literature and make recommendations about the feasibility and benefits of CDSS in the UK.

In the next section the definition of CDSS will be reported along with CDSS classification, history and its use with antibiotics.

5.3 What are Clinical Decision Support Systems?

Johnston *et al* (1994) stated that no consensus has been achieved on the definition of CDSS. From the literature the definitions below have been retrieved:

- Any electronic or non-electronic system designed to aid directly in clinical decision making, in which characteristics of individual patients are used to generate patient-specific assessments or recommendations that are the presented to clinicians for consideration (Hunt *et al* 1998; Kawamoto *et al* 2005).
- It is an active knowledge system which uses two or more items of patient data to generate case-specific advice (Wyatt and Spiegelhalter 1991).
- Any computer based application which helps the user makes better decisions. Better is usually defined in terms of improved quality of care and /or reduced costs without loss of quality (Clayton and Hripcsak 1995).
- CDSSs are computer programs that are designed to provide expert support for health professionals making clinical decisions (Musen *et al* 2001).

5.3.1 Classification of CDSS

CDSSs can be classified by more than one method. Kawamoto *et al* (2005) classified CDSS according to their features and functions, for example whether the CDSS monitors physician orders, help with diagnosis, or help with drug prescribing. Randolph *et al* (1999) and Thornett (2001) classify the types of CDSS depending on their function, i.e. whether the CDSS evaluates the clinician's

decision and can suggest alternatives or the CDSS helps formulate the clinical decision from the start.

However, a more common classification of CDSS is by the way knowledge is represented and this classification divides CDSS into either Rule-Based systems or Bayesian systems which are discussed in more detail below.

5.3.1.1 Rule Based Systems

A non-statistical method for building computer-based decision-support programs was proposed in the 1970s by Shortliffe and colleague (Buchanan & Shortliffe, 1984). The basic idea was to collect a large number of if-then rules from experienced clinicians and to use these rules, together with data on patients' signs and symptoms, in a logical reasoning computer programme to classify a patient's condition into diagnostic and therapeutic categories. Rule-based systems are `data-directed', because the decision is entirely dependent upon the data entered. Rules may be based on clinical or demographic characteristics, combinations of features, or results of previous steps. They may be more an aid to communication than to the logical application of knowledge (Delaney *et al*, 1999).

However, a drawback of this approach is the difficulty in dealing with missing information (Lucas, 2001). For this reason, rule-based methods have largely been abandoned. MYCIN, (the name derived from the antibiotics themselves, as many antibiotics have the suffix "-mycin") one of the first rule-based expert systems, was able to identify the microbiological cause of septicaemia and meningitis, and to determine the appropriate anti-infective treatment (Shortliffe, 1976; Yu *et al*,

1979a). Unfortunately, the system was never tested in clinical practice, because of the immature state of the clinical information infrastructure in the 1980s (Shortliffe, 1991). One recent rule based development has been PRODIGY (Prescribing Rationally with Decision Support in General Practice study) (Delaney *et al*, 1999). Prodigy provides decision support to general practitioners within consultations regarding prescribing. The development and evaluation of the system was commissioned by the NHS executive prescribing branch. The intention was to develop a system that would integrate with practice clinical systems and present appropriate drug choices according to the diagnosis. The choices were made by an "expert panel" and were evidence based in nature. The study showed a small restraining effect on inflation of drug budgets in the practices using the system. The validity and clinical and statistical significance of this result, however, has been questioned (Buchan *et al*, 1996).

5.3.1.2 Bayesian systems and cognitive and simulation models

Probabilistic systems model patient data against epidemiological data to predict future events, either for prognostic or diagnostic purposes (Ross & Dutton). Such systems, however, are limited in two important areas: the availability of data and the complexity of possible outcomes. In many specialties in medicine the necessary information on prognostic implications is missing and in few specialties are true base rates available (Thornton *et al*, 1992). Probabilistic systems, however, have the advantage of separating knowledge from inference and can be readily updated. An example of such a system is the cardiovascular "risk calculators," which are becoming a feature of primary prevention in practice (Delaney *et al*, 1999).

5.4 History of CDSS

The use of computers to assist health professionals in their activities has been studied since the 1950s (Miller, 1994). Ledley and Lusted (1959) were the first to address the development of diagnostic systems. They described the use of punch cards for indicating relationships between diseases and their manifestations (Mendonca, 2004). In 1972, De Dombal *et al* studied the diagnostic process using Bayesian probability theory. Their system, the Leeds abdominal pain system, used sensitivity, specificity, and disease-prevalence data for various signs, symptoms, and test results to calculate the probability for abdominal diseases. This system was used in a variety of settings but never obtained the same degree of accuracy in other environments as it did in the original settings, even after adjustments were made for different prior probabilities of disease (Mendonca, 2004). Shortliffe *et al* (1973) used a different approach in the development of the MYCIN system. It was one of the first programs to address the problem of reasoning with uncertain or incomplete information. The performance of the MYCIN system was evaluated on therapy selection for cases of bacteremia (Yu *et al*, 1979a) and meningitis (Yu *et al*, 1979b). Stimulated by increased research on CDSSs, several other representational schemas were used in clinical applications. More recent work on CDSSs has focused on integration of these applications with clinical databases. These integrated systems take advantage of data already recorded for other purposes in order to avoid redundant data entry in the provision of alerts and reminders. These CDSSs may monitor data in a large healthcare organisation or may be part of an electronic patient record installed in a single clinical office or clinic (Mendonca, 2004).

5.5 CDSSs and Antibiotics

One of the first and best-known medical decision support systems for the treatment of nosocomial infections is the Health Evaluation through Logical Processing (HELP) an integrated hospital information system that combines both communication and advice functions. It was developed in the early 1970s in the Latter Day Saints (LDS) Hospital in Salt Lake City, USA, and has been continuously developed over the past years (Schurink *et al,* 2005). Some particular decision support systems for antibiotic therapy that have been developed inside the HELP environment focus on the improvement of antibiotic treatment for microbiological confirmed infections (Pestotnik *et al*, 1990), antibiotic surgical prophylaxis (Classen *et al*, 1992) and empirical antibiotic treatment (Evans *et al*, 1994).

Observed clinical effects were a significant increase in the improvement of antibiotic surgical prophylaxis, appropriate changes in physicians' prescriptions due to the alerts generated by the decision support systems, and a decrease of the rate antibiotic associated adverse events. Main observed financial effects were a steady decrease of the percentage of total pharmacy drug expenditures represented by antibiotics and a decrease of the defined daily doses per 100 occupied bed-days (Pestotnik *et al*, 1996). Based on previous experiences, a computer anti-infections management programme was used and evaluated in the ICU at the LDS Hospital from July 1994 to June 1995. The patients cared for with the aid of the anti-infection management programme were compared with patients admitted to the same unit during the 2 years before that period. The use of the programme led to significant reductions in orders for drugs to which the patients had reported

allergies, excess drug dosages and antibiotic-susceptibility mismatches. There were also relevant reductions in the mean number of days of excessive drug dosage, adverse events and cost (Evans *et al*, 1998).

Another expert system for improving anti-microbial therapy was developed in the North Carolina Baptist Hospital in 1991. The expert system simultaneously examines data on patient demographics, culture results, associated susceptibility test results, cut off values for susceptibility and anti-microbial therapies downloaded from different databases. The system output consists of one out of four potential problems: no therapy is being given despite the presence of pathogens, the pathogens isolated are resistant to the therapy being given, the therapy cannot be matched with susceptibility data of the isolated pathogens, or the therapy was discontinued too quickly. It was found that a therapy was more likely to be improved when the responsible physician was contacted about the potential problem indicated by the report (Morell *et al*, 1993).

Since 1995 Warner *et al* (1997) have been developing a decision support model called Q-ID which uses a series of knowledge bases about infectious diseases to make recommendations for empirical treatment or to check the appropriateness of a current antibiotic therapy. From disease manifestations and risk factors, a differential diagnosis for the patient is generated. To generate empirical treatment recommendations hospital site-specific data on sensitivity to antibiotics for each organism is used as an estimate of the likelihood of achieving maximum benefit for each disease. Combining this data with drug and patient specific factors, the system recommends the most adequate antibiotics for a patient.

ICONS (Day *et al,* 1999; Schmidt and Gierl, 2001) is another antibiotic therapy advice system for patients in an ICU who have caught an infection as an additional complication. This program uses case-based reasoning to solve a current problem based on similar previously documented cases. The main task of the system is to present a suitable empirical therapy advice for ICU patients with bacterial infections.

The most recent CDSS developed for antibiotics is called TREAT. TREAT is based on the probabilistic model approach, at which the basic probabilities of each pathogen per site of infection are included in the model according to the place of acquisition, hospital and risk factors specific for the site of infection. In 2006a, Paul *et al* conducted a randomised trial for improving empirical antibiotic treatment using TREAT. The results of the study concluded that TREAT improved the rate of appropriate empirical antibiotics treatment while reducing costs and use of broad spectrum antibiotics. Another study by the same study group (Paul *et al*, 2006b) assessed the ability of TREAT to predict bacteraemia in a prospective cohort of inpatients. The study concluded that TREAT provided a good prognostic ability to predict bacteraemia and may serve to select patients with low risk for bacteraemia, for whom blood cultures may not be required, and patients with a high likelihood for bacteraemia, for whom further evaluation is essential. A third study by Kofoed *et al* (2009) also evaluated the use of TREAT for guidance of empirical antimicrobial therapy but in an environment with low prevalence of resistant pathogens. The results of that study suggested that TREAT can improve the appropriateness of antimicrobial therapy and reduce the cost of side effects in

regions with a low prevalence of resistant pathogens, however, at the expense of increased use of antibiotics.

5.6 Methods

In the following section the methods followed for the literature review of CDSS and antibiotic use will be described.

5.6.1 Study Identification

As part of my background reading in 2006, the use of CDSS in healthcare was explored and a systematic review describing the use of CDSS and antibiotics subsequently published (Shebl *et al*, 2007).

Following the groups' recommendations this literature review was therefore updated in September 2009. The search was based on the use of MEDLINE including Medical Subject Heading (MeSH) terms (1966-2009), EMBASE (Excerpta Medica, 1980-2009) and International Pharmaceutical Abstracts (IPA, 1970-2009) using combinations of the following terms '(Decision support systems) or (clinical decision support systems) AND (antibiotics) or (anti-infectives) or (antibacterials) or (antimicrobials). The reference sections of all retrieved articles were also manually searched for further publications. Inclusion criteria included any research paper relating to the use of CDSS and antibiotic use. Editorials, letters and case reports/series, small pilot studies and any articles not in the English language were excluded. No *a priori* definition was used for CDSS so as not to limit the articles retrieved to a particular definition of CDSS. A guide published by the Journal of The American Medical Association (Randolph *et al*, 1999) proposed a

set of questions that help highlight the important issues when evaluating CDSS. These questions were used to appraise the papers reviewed and are presented in table 27. The classification of the functions of the CDSS within these studies was also based on this paper and is presented in table 28.

Table 27: Questions used to evaluate studies using computerised clinical decision support systems (CDSS)*

Are the results of the study valid? • Was the method of participant allocation appropriate? • Was the control group uninfluenced by the clinical decision support systems (CDSS)? • Aside from the CDSS, were the groups treated equally?
What were the results? • What was the effect of CDSS?
Can you apply the computer-based CDSS in your clinical setting? • What elements of the CDSS are required? • Is the CDSS exportable to a new site? • Is the CDSS likely to be accepted by clinicians in your setting? • Do the benefits of the CDSS justify the risks and costs?

*Adapted from Randolph *et al*, 1999.

Table 28: Functions of computer-based Clinical Decision Support Systems (CDSS)*

Function	Example
Alerting	Highlighting out-of-range laboratory values
Reminding	Reminding the clinician to schedule a mammogram
Critiquing	Rejecting an electronic order
Interpreting	Interpreting the electrocardiogram
Predicting	Predicting risk of mortality from a severity-of-illness score
Diagnosing	Listing a differential diagnosis for a patient with chest pain
Assisting	Tailoring the antibiotic choices for liver transplantation and renal failure
Suggesting	Generating suggestions for adjusting the mechanical ventilator

*Adapted from Randolph *et al*, 1999.

Although no specific study designs were initially excluded, this chapter focuses on randomized controlled trials (RCT) and before and after studies. RCT are viewed as the 'gold standard' in the evaluation of healthcare. Randomisation provides a safeguard against bias and the inclusion of control groups enables the researcher to attribute differences in outcomes between the groups to the intervention evaluated (Smith, 2002).However, because it is not always feasible to conduct RCT, a before and after study, preferably with a control group, is the next best alternative (Bowling, 2002).

5.7 Results

The search yielded 69 research papers. Only 37 were relevant. The remaining 32 papers were excluded because they were related to either CDSS or antibiotics independently rather than simultaneously. The reference sections of all retrieved papers were manually searched and an additional 13 relevant papers identified. A total of 50 papers were therefore reviewed (table 29).

Table 29: Study designs used in the 50 studies identified

Evaluation Methodology	Number of Articles	%
Descriptive Studies	13	26%
Review Articles	12	24%
*Before/ After Studies	6	12%
Randomised Controlled Trials	6	12%
Cohort Studies	4	8%
Time Series	3	6%
Retrospective analysis of charts or prescription orders	3	6%
Cross-over trial	1	2%
Cross-sectional studies	1	2%
Qualitative study	1	2%
Total	**50**	**100%**

* Only five controlled before and after studies were included in the review.

Six RCTs have been conducted to evaluate the use of CDSS for antibiotic prescribing. A summary of all the RCT studies is presented in table 30. Four were conducted in the USA [three in the hospital setting (Shojania *et al*, 1998; Christakis *et al*, 2001; McGregor *et al*, 2006) and one in the community (Samore *et al*, 2005)], one in Switzerland (Senn *et al*, 2004) and one study was a cluster RCT conducted in

three different hospitals, one hospital in Israel, one in Italy and one in Germany (Paul *et al*, 2006a). The study conducted in secondary care in Switzerland evaluated the use of a paper-based CDSS in the form of a questionnaire (Senn *et al*, 2004). Three of the US-based studies evaluated the use of an electronic CDSS (Shojania *et al*, 1998; Christakis *et al*, 2001; McGregor *et al*, 2006) and one study evaluated the combination of both paper and electronic CDSS (Samore *et al*, 2005). The latter (Samore *et al*, 2005) used two paper-based versions plus one programmed on to a Personal Digital Assistant (PDA) in primary care. The cluster RCT conducted in three different hospitals evaluated the use of an electronic CDSS called TREAT (Paul *et al*, 2006a). Only two studies (Senn *et al*, 2004; Paul *et al*, 2006a) provided information regarding the sample size and the study's power. Furthermore, only three studies (Senn *et al*, 2004; Samore *et al*, 2005; McGregor *et al*, 2006) specified inclusion and exclusion criteria for participating patients and communities. The lack of inclusion and exclusion characteristics in the remaining three studies (Shojania *et al*, 1998; Christakis *et al*, 2001; Paul *et al*, 2006a) leaves them open to bias from baseline differences in health care providers' performance, experience and work schedules.

The unit of randomisation for two studies was the health care providers (Shojania *et al*, 1998; Christakis *et al*, 2001). Senn *et al* (2004) and McGregor *et al* (2006) randomised patients to either an intervention group or a control group, Samore *et al* (2005) randomised communities, while Paul *et al* (2006a) randomised wards. Only Shojania *et al* (1998), McGregor *et al* (2006) and Paul *et al* (2006a) addressed the potential problem of contamination of the control group through communication among physicians. This may be even more difficult to address if patients are

randomised and the physician is responsible for patients in both control and intervention groups. This contamination could be minimised if the setting did not permit contact between participants in different groups. For example, Samore *et al* (2005) included six communities in the control group and six in the intervention group. These communities were geographically wide-spread and so potential contamination was minimal. McGregor *et al* (2006), on the other hand, blinded the antimicrobial management team from receiving system alerts on patients assigned to the control arm of the trial. However, the authors further stated that the management team was not blinded to the randomisation status of the patients in general and thus there remained a potential for bias. Paul *et al* (2006a) stated that they chose to randomise wards rather than patients to avoid contamination that may have occurred if physicians were treating patients in both study groups.

The outcomes for each study were different (table 30), as four studies focused on the process of care (Shojania *et al*, 1998; Christakis *et al*, 2001; Samore *et al* 2005; McGregor *et al*, 2006) and only two studies examined the cost effectiveness of the CDSS as well as patient outcomes (McGregor *et al*, 2006; Paul *et al*, 2006a). In the study by Paul *et al* (2006a) antibiotic costs and duration of hospitalisation significantly decreased but there was no significant difference in overall mortality. While McGregor *et al*, (2006) states that although the hospital expenditure on antibiotics decreased, there was no significant difference in mortality or length of hospitalisation for patients. Four of the five studies showed a significant improvement in the process of patient care when an electronic CDSS was implemented and used (Shojania *et al*, 1998; Christakis *et al*, 2001; Samore *et al*

2005; Paul *et al*, 2006a), while the paper-based CDSS (Senn *et al*, 2004) showed a non-significant reduction in the time to modify intravenous antibiotic therapy.

Table 30: Randomised Controlled Trials of Clinical decision support systems (CDSS) and antibiotic use

Study	Number of participants	Study Setting	Type of intervention studied	Function of the CDSS*	Primary Outcome	Main findings
Shojania *et al*, 1998	396 physicians & 1,798 inpatients	Teaching Hospital (secondary care) in Boston, USA	Computer screen displaying the Centre for Disease Control & Prevention guidelines	Assisting or suggesting	Frequency of initiation & renewal of IV vancomycin therapy as well as duration of therapy.	Significant reduction in the frequency (p=0.03) & duration of vacomycin use (p=0.05) in the intervention group & an insignificant reduction in the renewal of vancomycin (p=0.16).
Christakis *et al*, 2001	38 care providers &14,414 patient visits.	Primary care centre in Washington (USA)	An electronic point-of-care evidence-based message system	Alerting	Reduction in the duration of therapy below the frequent 10-day course used for otitis media in children	Intervention group had a 34% greater reduction in the proportion of the time they prescribed antibiotics for <10 days compared to the control group (p=0.000).
Senn *et al*, 2004	251 Inpatients	University Hospital (secondary care) in Switzerland	Short paper-based questionnaire to encourage reassessment of intravenous antibiotic therapy after 3 days	Assisting	The time elapsed from randomisation until first modification of the initial intravenous antibiotic therapy	Time to modify the intravenous antibiotic therapy was 14% shorter in the intervention group compared to the control group but not statistically significant (p=0.06)
Samore *et al*, 2005	334 clinicians & 407,460 inhabitants	12 rural communities in Utah & Idaho (USA) (primary care setting)	6 communities received intervention alone and 6 communities received community intervention & written or PDA CDSS (interventions included educational materials, meeting with community leaders & mailing	Diagnosing and suggesting	Prescribing rates per 100 person-years in the community	Significant reduction in prescribing rates with in the intervention community using CDSS (p= 0.03)

Table 30: continued

			parents of children to deliver the key message 'Do not treat viral infections with antibiotics).			
McGregor *et al*, 2006	1 infectious disease physician and 1 clinical pharmacist and 4,507 patients.	University Hospital (secondary care) in Maryland, USA	Web-based clinical decision support system.	Alerting	Primary outcome of interest was hospital antimicrobial costs. Secondary outcomes included patient mortality and length of hospitalisation.	Hospital expenditures were $285,812 in the intervention arm and $370, 006 in the control, i.e. a saving of 23% or $37.64 per patient. No significant difference was observed in mortality (p=0.55) and length of hospitalisation (p=0.38)
Paul *et al*, 2006a	2326 patients.	Three hospitals, one in Israel, one in Germany and one in Italy	The use of TREAT- a computerised decision support system for antibiotics.	Diagnosing, predicting, assisting and suggesting	Primary outcome was appropriate empirical antibiotic treatment and secondary outcomes included length of hospital stay, mortality and antibiotic costs.	The rate of appropriate empirical antibiotic treatment was higher in the intervention (73%) versus control wards (64%). All antibiotic costs components were significantly reduced in the intervention wards. Duration of hospitalisation shortened significantly as well but there was no significant difference in overall mortality.

*Adapted from Randolph *et al* [23]. PDA: Personal Digital Assistant. IV: Intravenous

It is not always feasible or practical to conduct a RCT. Therefore, a range of alternative analytical methods have been developed. Before and after trials are examples of an alternative study design (table 31). Randolph *et al* (1999) explains that this method allows the investigators to compare outcomes before a technology is implemented with those after the system is implemented. However, the validity of this approach is threatened by the possibility that changes over time in patient mix or in aspects of health care delivery may result in changes in behavior that appear to attributable to the CDSS. Also, before and after studies may or may not include a control group. Absence of a control group makes the study design seriously flawed (Bowling, 2002) The potential problems of before and after studies without a control group is attributing changes to the intervention, rather than any other circumstances or events.

Six before and after studies were initially identified, but only five were included in this review as they included a historical control group (Larsen *et al*, 1989; Evans *et al*, 1998; Mullett *et al*, 2001; Sintchenko *et al,* 2005; Thursky *et al*, 2006). Table 26 summaries the controlled before and after studies. Four studies included the participants' characteristics to demonstrate that the control and experimental group were similar (Larsen *et al*, 1989; Evans *et al*, 1998; Mullett *et al*, 2001; Thursky *et al*, 2006). Three of five studies (Larsen *et al*, 1989; Evans *et al*, 1998; Mullett *et al*, 2001) were conducted in Utah, USA. This limits the generalisability of the results outside this setting. All the studies were in favour for the use of CDSS even though the primary outcomes of each study differed (table 31). All five studies evaluated patient outcomes as well as the process of care.

Table 31: Before and After Trials of clinical decision support systems (CDSS) and antibiotic use

Study	Number of participants	Study Setting	Duration of study	Type of intervention studied	Function of the CDSS*	Primary Outcome	Main findings
Larsen *et al*, 1989	Pre-intervention: 3,263 patients Post intervention: 3,568 patients	LDS Hospital, Utah, USA (secondary care)	2 years (1 year pre-intervention, 1 year post intervention)	Computer-generated reminders regarding preoperative antibiotics.	Assisting and reminding	- Frequency of preoperative antibiotic use -Timing of antibiotic use -Rates of postoperative wound infection.	No significant impact on the frequency of preoperative antibiotic use per patient on the day of the operation (pre-intervention 79%, post intervention 82%). Significant improvement in the optimal timing of antibiotic use ($p<0.001$). Significant reduction in rates of postoperative wound infection ($p<0.03$)
Evans *et al*, 1998	Pre-intervention: 1136 patients Post intervention: 545 patients	Shock trauma ICU in LDS Hospital, Utah, USA (secondary care)	3 years (2 years before intervention period, 1 year during intervention period)	CDSS linked to computer-based patient records.	Assisting and suggesting	-Number of defined daily doses per 100 occupied bed-days. -Costs of hospitalisation -Number of adverse events -Number of days of excessive antibiotic dosage -Length of hospital stay	Significant reduction in primary outcomes: -Number of defined daily doses per 100 occupied bed-days ($p<0.001$). -Costs of hospitalisation ($p<0.001$). -Number of adverse events ($p<0.02$). -Number of days of excessive antibiotic dosage ($p<0.002$). -Length of hospital stay ($p<0.001$).

Table 31: Continued

Mullet *et al*, 2001	Pre-intervention: 809 patients Post intervention: 949 patients	Children's medical centre in Utah (USA) (secondary care)	12 months (6 months control period & 6 months intervention period)	Computerised anti-infective decision support tool.	Assisting and suggesting	-Rate of pharmacist intervention -Rate of antibiotic sub therapeutic & excessive patient days. -Number of orders placed per anti-infective course	Significant reduction in rate of pharmacist intervention as dose adjustments ($p<0.01$). Significant reduction in rate of antibiotic sub therapeutic & excessive patient days ($p<0.001$). Significant reduction in number of orders placed per anti-infective course ($p<0.01$).
Sintchenko *et al*, 2005	12 intensivists and advanced trainees.	ICU of Westmead Hospital (tertiary centre), Sydney Australia	12 months (6 months control period & 6 months intervention period)	Handheld computer-based decision support system was used.	Assisting	Defined daily doses of antibiotics per 1,000 patient-days, patient length of stay in hospital and mortality	There was a significant reduction in mean patient length of stay ($p<0.02$). There was a significant reduction in the defined daily doses of antibiotics per 1,000 patient-days ($p<0.04$), & no change in mortality (p value not specified).

Thursky *et al*, 2006	Pre-intervention: 524 patients Post intervention: 536 patients	Tertiary care hospital, Australia	12 months (6 months control period & 6 months intervention period)	Computerised anti-infective decision support tool.	Assisting and suggesting	-Number of courses of antibiotics prescribed. -Antibiotic utilization (defined daily doses of antibiotics per 100 ICU bed-days). -Antibiotic susceptibility mismatches. -System uptake.	-Significant reduction in the number of carbapenems prescribed (0.04), cephalosporins (0.001) & vancomycin (0.05). -Defined daily doses of antibiotics per 100 ICU bed-days reduced from 166 to 149 (10.5% reduction) - Significant reduction in Antibiotic susceptibility mismatches (p=0.02) - The system was accessed 6,028 times but no information regarding its significance was mentioned.

*Adapted from Randolph *et al* (1999); ICU: Intensive Care Unit; LDS Hospital: Latter Day Saints Hospital

5.8 Discussion

In this chapter, the use of CDSS for antibiotics was reviewed following the recommendations of the FMEA participants to implement technology to improve the process of vancomycin and gentamicin use. In doing so, 50 articles were identified of which descriptive studies and review articles comprised the majority, followed by before and after studies and RCT (table 29). Six RCT (Shojania *et al*, 1998; Christakis *et al*, 2001; Senn *et al*, 2004; Samore *et al*, 2005; McGregor *et al*, 2006; Paul *et al*, 2006a) and five before and after studies (Larsen *et al*, 1989; Evans *et al*, 1996; Mullett *et al*, 2001; Sintchenko *et al*, 2005; Thursky *et al*, 2006) were reviewed. Nine of the 11 studies identified a statistically significant advantage for CDSS (Larsen *et al*, 1989; Shojania *et al*, 1998; Evans *et al*, 1998; Christakis *et al*, 2001; Mullett *et al*, 2001; Samore *et al*, 2005; Sintchenko *et al*, 2005; Paul *et al*, 2006a; Thursky *et al*, 2006). Four RCT studies focused on the process of care (Shojania *et al*, 1998; Christakis *et al*, 2001; Senn *et al*, 2004; Samore *et al*, 2005) and two studies examined the cost effectiveness of the CDSS as well as patient outcomes (McGregor *et al*, 2006; Paul *et al*, 2006a). All five before and after studies focused on, both process of care and patient outcomes.

4.8.1 Implications

The results of this review indicate that CDSS may be a useful tool to help optimise antibiotic use and improve patient care. However, generalising the success and benefit of CDSS is not possible as seven of 11 studies reviewed were conducted in the USA. On a practical level, the limited range of clinical settings in which the CDSS were created and tested also limits the generalisability to succeed outside these settings.

CDSS should be developed according to the need and requirements of the specific setting. Different settings and practice policies will dictate the type of CDSS required. Physicians' and patients' attitudes toward CDSS may also dictate its potential failure or success within a system. Kaplan (2001) points out the CDSS evaluation literature focuses on performance or specific changes in clinical practice but lack in studies employing methodologies that could indicate reasons for why clinicians may or may not use CDSS or change their practice behaviour. Only one study (Mullett *et al*, 2001) used a questionnaire to determine clinicians' satisfaction with the use of CDSS or the effect it had on their practice. Clinician satisfaction was not a primary aim of any of the studies. One RCT (Samore *et al*, 2005) included two versions of CDSS, paper-based and PDA, to enhance clinicians' willingness to participate. Educational lectures and small group meetings were also conducted. The idea of increasing the clinicians' willingness to use CDSS indicates that even in the presence of CDSS many clinicians may choose not to use it. The reasons for this are unknown.

It is also important to consider whether the use of CDSS during a particular study was optional or compulsory. Only one study directly stated that the use of CDSS was mandatory (Mullett *et al*, 2001) and one stated that the there was no incentive or pressure to use the CDSS (Sintchenko *et al*, 2005). Paul *et al* (2006a) stated that the primary analysis of the CDSS was performed by intention to treat regardless of the physician's compliance with the CDSS. Although the authors do not specifically report whether the CDSS's use was mandatory or not or how many physicians chose not to use it, they concluded that in practice more effort can be directed in convincing physicians to adopt the CDSS's recommendations.

Furthermore, not all the studies reviewed in this paper included all the important features when evaluating CDSS as described by Randolph *et al* (1999). Future RCT and before after trials should include information regarding the baseline characteristics for the control and intervention group along with the sample size and unit of allocation. Efforts to prevent contamination and to ensure that both the control and intervention groups are treated equally should also be addressed.

The positive results associated with CDSS in this review are in line with the conclusion of several large systematic reviews evaluating the use and benefit of CDSS (Johnston *et al*, 1994; Hunt *et al*, 1998; Kaplan, 2001) in general. However, each of these reviews had different inclusion and exclusion criteria and different definitions of CDSS. Two reviews (Johnston *et al*, 1994; Hunt *et al*, 1998) only included studies that met predefined criteria, while Kaplan (2001) included all studies that evaluated CDSS, irrespective of their study design. Walton *et al* (2006), on the other hand, included only RCT, interrupted time series, and controlled before and after studies, while Mollon *et al* (2009) only reviewed RCTs. Following the recommendations of Kaplan (2001) and the example of Walton *et al* (2006), before and after studies were included in the present review. However, all the before and after studies identified in this chapter used historical control groups rather than separate, parallel control groups. The main disadvantage of using historical control groups is there may be differences between the intervention arm and the historical group other than the intervention studied (Bowling and Ebrahim, 2006). Four studies included the participants' characteristics to demonstrate that the control and experimental group were similar (Larsen *et al*, 1989; Evans *et al*, 1998; Mullett *et al*, 2001; Thursky *et al*, 2006).

Although RCT are considered a 'gold standard', their application to the evaluation of health services present a number of difficulties, and therefore their suitability for this purpose has been questioned (Smith, 2002). Kaplan (2001) argues that even though RCT and other experimental designs are excellent for studying system performance or specific changes in clinical practice behaviours, they are not well suited for investigating other issues such as the influences over whether or not systems are used. The review by Mollon *et al* (2009) stated that when reviewing RCT for CDSS only a small number of trials were retrieved and there was lack of consistent reporting of features in the individual studies. The authors concluded that there was a lack of mature research programmes in the field of CDSS as such complex intervention trials are difficult to organise and complete.

During the last decade, research in the field of clinical informatics has led to the development of health care information technology that enhances decision making by improving the connectivity between patient data and knowledge (Hersh *et al*, 2002; Pestotnik, 2005). However, this literature review revealed that the UK lags behind other countries such as the USA in implementing electronic CDSS and evaluating them.

In the UK, the most well known decision support programme is PRODIGY. It is a computer-based decision and learning support tool for GPs, offering a series of recommendations for the treatment of a condition. Currently it is in use in over 200 practices throughout the UK (Eddy & Purves, 1998) at which the GP enters a diagnosis and PRODIGY then suggests a range of therapy options to prescribe, as well as specific non-drug advice, or recommend a referral (Department of Health,

1998). However, the literature review did not identify any RCT or before and after studies evaluating any CDSS within the UK. Reasons for this may simply be because of the lag for the use of technology in general in comparison with countries as the USA. It may be due to the lack of standardised definition of CDSS as described earlier or it maybe because RCT and before and after trials are complex and difficult to organise and complete. Another important factor to consider is that the development and use of CDSS usually require electronic prescribing which is rare in the UK unlike in most American hospitals. In addition to this the NHS is a publicly funded health service from the national taxation and thus the money spent on developing implementing and evaluating electronic prescribing first and thus CDSS may not be feasible within most hospitals.

5.8.2 Limitations

No strict inclusion and exclusion criteria were used for the studies reviewed in comparison to larger systematic reviews. However the focus of this chapter was on the use of CDSS relating only to antibiotics and the aim was to identify all studies and specifically appraise RCT and before and after trials. Furthermore, the literature search may have missed key papers not indexed in the databases searched and articles published in languages other than English were excluded.

5.8.3 Future work

Success of the CDSSs within a specific setting is perhaps dependant upon its need, application and specified outcomes. The lack of a standardised definition of CDSS and the difference between the outcomes measured does not permit us to generalise their success outside the settings they were created in. Most of the research

available identifies CDSS as computer software rather than implying that a CDSS maybe non-electronic as well as described by Hunt *et al* (1998) and Kawamoto *et al* (2005). Furthermore, Finch and Low (2002) have considered published guidelines for patient management as one type of decision support system. Kaplan (2001) states that there is little reference in the CDSS literature, in general, to a theoretical basis of understanding the many issues that arise in developing and implementing CDSSs.

CDSS should be developed according to the need and requirements of the specific setting to aid the health care providers make the most appropriate decisions for their patients. Different setting and practice policies will dictate the type of CDSS intervention required. Also the physicians' and patients' attitudes toward CDSS may dictate its potential failure or success of this within a system.

One of the main gaps identified during this review is the lack of a standard definition for CDSS. Most of the research available identifies CDSS as computer software rather than implying that a CDSS may also be non-electronic. Furthermore, little information is provided regarding the barriers to implicating electronic CDSS. Before introducing CDSS it is important to consider the users' needs, attitude and gaps in their knowledge. Perhaps the gradual introduction of paper-based decision support systems before investing large sums of money in a computerised system would be beneficial. These paper-based systems should be designed by the clinicians (users) to enhance their knowledge. Once the first step

has been established, implementing an electronic CDSS maybe encouraged and its benefit or lack of benefit evaluated.

Ruland and Bakken (2002) also address an important concept in CDSS. The authors state that we may improve patient-centred care by developing systems that support the inclusion of patient preference in clinical decision making. They describe a system called CHOICE which adopts the concept of shared decision making between the health care provider and the patient. This form of CDSS may be promising but requires more research.

5.9 Conclusion

Clinical decision support systems are proving to be a powerful tool that may improve clinical care and patient outcomes. As they present a promising future for optimising antibiotic use and improving patient care, more studies need to be conducted within different settings. Although RCT are the 'gold standard' in research, they may not be feasible to conduct, and realising that different study designs answer different questions would allow researchers to choose the most appropriate study design to evaluate CDSS in its specified setting. Although the FMEA participants have recommended the use of such technology, it is essential to clarify that CDSS have been proven to be useful and successful, however their development and implementation would require a lot of work, time and costs with no guarantee that its use will be supported by healthcare professionals and that all the failures identified in chapter 2 would be eliminated. This further highlights a disadvantage of FMEA in that it does not take into account the cost or ease of implementing improvements (Cheung *et al*, 2006; Van Tilburg *et al*, 2006).

Chapter 6 Discussion

'Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives.'

William Foster (1917-1945)

6.1 Introduction

At the beginning of this thesis, the literature review highlighted that FMEA's use in healthcare is expanding, particularly in the USA, with a number of other developed countries following the USA's lead. However, the literature review also identified that while the reliability and validity of FMEA have been occasionally questioned, they have never been explored in healthcare. In 2002, three years before starting this thesis, the NPSF's patient safety ListServ had a discussion forum for the use of FMEA in healthcare (NPSF, 2006). Only one contribution was critical of FMEA among hundreds of positive reports and shared experiences. In this one critical post in the forum, FMEA was criticised for lacking any formal evaluation and that it was being misused as a prospective tool. Seven years later the question of validity and reliability has still not been answered. This thesis evaluated FMEA's validity and reliability and examined its use in healthcare.

The reliability of FMEA was tested by recruiting two multidisciplinary teams, within the same hospital, to conduct the same FMEA in parallel. The results showed that there were significant differences between the failures identified and their scores. Following this the validity of FMEA was tested by four different methods: face, content, criterion and construct. Chapter 3 provided some evidence for reasons to doubt the results of FMEA especially as the validity tests conducted confirmed that FMEA's validity was questionable particularly when identifying failures and scoring them. The use of clinical decision support for antibiotics was also reviewed following the FMEA teams' recommendation in order to determine whether CDSS has been proven to improve patient care and whether idea of implementing CDSS were feasible or not. The literature search identified that CDSS for antibiotics

presents a promising future for optimising antibiotic use and improving patient care, however their development and implementation would require a lot of work, time and costs with no guarantee that its use will be supported by healthcare professionals. Finally the perceptions and experiences of the SPI participants with FMEA were reported. FMEA was perceived by participants as a structured subjective process that helps healthcare professionals get together to identify the high risk areas within a process of care. The limitations that are most likely to restrict its widespread use are its time consuming nature and the perceived lack of validity and reliability as expressed by a number of healthcare professionals.

In this final chapter, possible reasons for FMEA's questionable reliability and validity will be explored and the relationship between validity and reliability will be described. The use of CDSS for antibiotics will be summarised along with the SPI participants' experiences with FMEA. A comparison of healthcare systems with other high risk industries will then be presented and future areas of study are identified to build on and add to the research in the field along with recommendations for the use of FMEA in healthcare. The conclusion draws attention to the original contribution made by this work.

In the next section reliability and validity of FMEA are revisited and reasons for FMEA's lack of reliability and validity will be proposed.

6.2 Reliability of FMEA

Reliability concerns the extent to which an experiment, test or any measuring procedure yields the same results on repeated trials. However the measurement of

any phenomenon always contains a certain amount of chance error (Carmines and Zeller, 1979). Stanley (1971, p.356) states:

> *'The amount of chance error may be large or small, but it is universally present to some extent. Two sets of measurement of the same features of the same individuals will never exactly duplicate each other.'*

Therefore, it is important to realise that since no two sets of measurements can be exactly duplicated, unreliability will always be present to some extent. But Carmines and Zeller (1979) state that while repeated measurements of the same phenomenon never precisely duplicate each other, they tend to be consistent from measurement to measurement. This consistency is what is expected when using a human reliability technique such as FMEA.

In chapter 2, two multidisciplinary teams were recruited to conduct the same FMEA, in parallel, for the use of vancomycin and gentamicin. Each group identified a number of failures, scored them and made recommendations to eliminate them. However, only 17% of the failures identified were common to both groups; there were significant differences between the scores attributed to the failures, and subsequently the recommendations to eliminate the failures were different. Before conducting the meetings, the researcher tried to ensure consistency between the teams when using FMEA in order to attempt to ensure that any discrepancies between the team's results would indeed be due to inherent limitations within the FMEA technique rather than error or inconsistency with team leadership or facilitation as described in chapter 2.

As it was attempted to ensure that the FMEA technique was followed correctly and precisely according to the guidelines, practice sessions conducted and ground rules set for both groups, the lack of reliability of FMEA does not appear to be due to our inability to perfectly recreate the industrial FMEA process. However, it is possible that the reasons for the significant differences between the groups' FMEA results may have been due to the lack of training in FMEA for the participants or due to the groups' dynamics.

In the next section I first describe two reasons, related to the FMEA participants, that may be have contributed to the lack of reliability of the FMEA results; and then give a third reason inherent within the FMEA tool itself.

1. *Lack of training in FMEA*: This was the first time all the participants had conducted an FMEA. Although the leader and facilitator ensured they were familiar with FMEA and were capable of leading the team, the participants did not receive any formal training for FMEA. However, during the first meeting, an introductory presentation was given explaining FMEA and an example was provided, and any questions or clarifications during the meetings were addressed. Furthermore, all FMEA guidelines state that no pre-training is required for participants and that only 5% (3 studies) of FMEA studies published in healthcare stated that training for FMEA was provided for the participants.

The most relevant study evaluating the effect of training in HRA techniques was a study conducted by Stanton and Stevenage in 1998. In their study, two groups were requested to identify errors that would occur when buying a chocolate bar from a

vending machine. One group acted as a control, receiving no training for the use of the HRA technique, called SHERPA (Systematic Human Error Reduction & Prediction Approach)[16], while the second group received training. In this study, participants trained in SHERPA performed better, as they were able to correctly predict more errors, than individuals with no training in the technique. However, the authors report that the trained group, in comparison to the untrained group, also identified a substantial number of false positives– i.e., they predicted errors that were not borne out by observation. The authors thus concluded that there appears to be a trade-off in terms of training such that more error identification is achieved at a cost of a greater number of false positives.

Since all participating members were not trained and all attended the same introductory presentation for FMEA, lack of training does not appear to be a sufficient explanation for the significant discrepancy between the teams' results.

The other potential reasons for the discrepancy between the groups' results may have been due to the groups' dynamics.

2. *Group dynamics*: The second step of FMEA is to recruit a multidisciplinary team to conduct the FMEA. The purpose of inviting a multidisciplinary team is to ensure that the team includes at least one individual with expertise relating to each step of the process. Qualitative studies (Wetterneck *et al*, 2004; Habraken *et al*,

[16] SHERPA is a human error predication technique that involves using a Hierarchical Task Analysis (HTA) and identifies potential solutions to errors in a structured manner. HTA is based upon the notion that task performance can be expressed in terms of hierarchy of goals, operations and plans. The classification of the task then leads the analyst to consider credible errors (from a predefined set of errors) associated with that activity. This is followed by identifying the consequences of the errors and to propose solutions.

2009; Wetterneck *et al*, 2009) as well as other quantitative FMEA studies (Cheung *et al*, 2006; Riehle *et al*, 2008; Nickerson *et al*, 2008) have reported that one of the main advantages and benefits of FMEA is the idea of gathering a group of healthcare professionals to discuss a process of care. It allows the professionals to gain an insight into their colleagues' daily practice and challenges faced, especially since in healthcare the steps in most processes of care are interdependent and require teamwork rather than an individual approach. Furthermore, SPI participants and both FMEA groups also indicated that one of the benefits of FMEA is the inclusion of a multidisciplinary team:

"Allows the input of several disciplines..." FMEA participant, group 1

"Good to have multidisciplinary views of process." FMEA participant, group 2

"...but actually what it was, was just getting people to talk"
Director of Pharmacy, Trust 4

However, the discrepancy in the results may have been attributed to the different dynamics and experiences of the participants in each group. Hollnagel (1993) emphasises that different participants, with different experiences, make different predictions regarding the same problem. Similarly the same participant may make different judgments on different occasions and this subjectivity of analysis weakens the confidence that can be placed in any predictions made. In 1972 (p.8), Janis reported the theory of "groupthink" and defined it as:

'A mode of thinking that people engage in when they are deeply involved in a cohesive in-group, when the members' strivings for unanimity override their motivation to realistically appraise alternative courses of action.'

In other words, 'groupthink' results in systematic errors made by groups when taking collective decisions. It is a type of thought exhibited by group members who try to reach consensus without critically testing, analysing, and evaluating ideas (Janis, 1972). Janis (1972) further describes that there are eight symptoms indicative of 'groupthink' (table 32).

Table 32: Eight symptoms of 'groupthink' (adapted from Janis, 1972, p.197-198):

1) *Illusions of invulnerability:* creating excessive optimism and encouraging risk taking.
2) *Rationalizing warnings* that might challenge the group's assumptions.
3) *Unquestioned belief* in the morality of the group, causing members to ignore the consequences of their actions.
4) *Stereotyping* those who are opposed to the group as weak, evil, biased, spiteful, disfigured, impotent, or stupid.
5) *Direct pressure* to conform placed on any member who questions the group, couched in terms of "disloyalty".
6) *Self censorship* of ideas that deviate from the apparent group consensus.
7) *Illusions of unanimity* among group members-silence is viewed as agreement.
8) *Mind guards* — self-appointed members who shield the group from dissenting information.

None of the above eight symptoms of 'groupthink' (table 32) were observed during the facilitation of both groups. There was no stereotyping, direct pressure or questioning of the participants' morality. Furthermore, each participant focused on their part of the process and their clinical role, thus there was no rationalisation of warnings, censorships or mind guards. Illusion of unanimity among members was perhaps the only symptom which could have occurred but was not directly sensed or observed during the meetings. There were moments of silence among members

when one healthcare professional spoke about failures occurring in their field of expertise. For example, when the laboratory manager spoke about failures related to the laboratory, the remaining participants listened attentively without challenging what was being said and participants occasionally asked questions to better understand the nature of the laboratory's work. Thus this silence among other participants was perceived to be due to the fact that they were simply unaware of this part of the process and to allow the 'expert' to contribute to the FMEA and educate them about their nature of the laboratory's work. Hence, it does not appear that the FMEA groups suffered from the 'groupthink' phenomena as described by Janis (1972).

Healthcare professionals, in general, are used to interacting with different members of a multidisciplinary team. In their daily practice doctors, nurses and pharmacists interact during their ward rounds and throughout the day, thus working as a team is not an unfamiliar idea. Yet there are reports in the literature about communication problems amongst healthcare professionals (MacKay *et al*, 1991, BMA 2004, Astrom *et al* 2007, Nijjer *et al* 2008), particularly nurses or junior with more senior doctors or consultants due to their perceived status from the hierarchical structure within the profession (Davies, 2000; Nijjer *et al* 2008). It has also been documented that healthcare professionals tend to interact with less difficulty with others in their own discipline than with those from other disciplines (Ker, 1986).

However, these communication problems did not seem to emerge during the meetings. All participants seemed happy with the idea of getting together as a team. In addition to this, the meetings' atmosphere felt comfortable and relaxed.

Participants were aware that they were participating in a research project involving a 'problem-solving' exercise for two high risk antibiotics and that their specific contributions would remain anonymous; thus they did not feel threatened to express their opinions. Furthermore, participants were unaware that their results would be compared to one another and thus there was no sense of competition or risk of information contamination. The main debate during the meetings was regarding steps in the process in which the exact role of the healthcare provider was undefined. In group two particularly, the group argued whose responsibility it was to check for the laboratory results and who should record them. In other steps, for example, that only involved the nurses administering the drug, the participating nurse led the discussion with other members asking questions to better understand the nurses' work and to be able to make a sound judgment when reaching consensus for the scoring scale. Since the meetings were voluntary, if members of the team felt threatened or uncomfortable they would have probably not attended all four meetings. Furthermore, when given the choice between scoring the failures separately and scoring them during the meeting as a team, both groups preferred scoring the failures as a team.

The previous section could be described as criticism related to how the FMEA was conducted; however the lack of training for participants and the group dynamics do not appear to be sufficient explanations for the significant discrepancy between the two FMEA teams' results. Thus the lack of reliability may be inherent within the FMEA process itself and in particular steps 3 and 4 of the FMEA. In the next section the subjective identification of failures and their scores will be discussed as a third potential reason for the lack of reliable results.

3. *Subjective identification of failures and their scores:* Kirwan (1996) reports that the field of failure identification is less mature than other aspects of HRA. There are no guidelines for identifying potential failures but the JCAHO (2005) recommends brainstorming as well as identifying failures from different sources such as incident reports or published papers. Published studies have reported using observations of the process mapped (Janofsky, 2009; Koppel *et al*, 2008; Day *et al*, 2007; Day *et al,* 2006; Wetterneck *et al*, 2006), data from the literature (Day *et al,* 2007; Jeon *et al*, 2007, Wetterneck *et al,* 2006; Linkin *et al*, 2005, Apkon *et al*, 2004), interviewing healthcare professionals (Redfern *et al,* 2009; Ford *et al*, 2009; Koppel *et al*, 2008; Jeon *et al*, 2007; Day *et al*, 2006, Lenz *et al*, 2005, Linkin *et al*, 2005) and using the incident report system within the hospital (Day *et al*, 2007; Robinson *et al*, 2006; Wetterneck *et al*, 2006). Yet, one of the known limitations of FMEA is that can not identify all potential failures (Croteau and Schyve, 2000; Bramstedt, 2002; JCAHO, 2005). However, Stanton and Baber (2002) argue that if we know an activity that is to be performed and the characteristics of the product being used, then it should be possible to indicate the principle types of errors which may arise and that the aim is not necessarily to predict all errors, rather to predict the most likely or most annoying. In the present study participants were completely dependent on their knowledge and experience when listing the potential failures. This method of producing a failure list depending only on subjective data proved to be unreliable in the present study. From a total of 100 failures only 17 were common (17%) even though all participants worked in the same trust and followed the same clinical guidelines. This highlights that variability in daily practice and experiences encountered in healthcare may be very different from other high risk industries. Furthermore, because healthcare is very unpredictable and a number of confounding

factors affect patient outcome, subjective data will always be limited and inconsistent.

Lyons *et al* (2004) state that quantification of failures is the most difficult aspect of HRA and that assigning numbers to uncertain events is an enormous challenge. Lyons *et al* (2004) further explains that collection of failure frequency data ideally requires high numbers of descriptive incident reports and systematic observations, which require objective human factors methods of error categorisation and frequency assessment. These data unfortunately are rarely available in a usable form. Since one of the aims of this thesis was to explore the validity of FMEA, the participants in the groups were not provided with data from the hospital and thus the estimated scores were completely subjective and dependant on the participants' experiences and pre-existing knowledge. In addition to this, as with the limitation of identifying potential failures, a single failure may have different effects on the patient and thus the same failure maybe scored differently depending on the anticipated effect. This debate was encountered by the groups during the meetings: a single potential failure may have different consequences. For example, giving an extra vancomycin dose, by mistake, to one patient may have no clinical effect, while in another patient, with renal failure for example, it may result in an adverse event. Thus the effects of the failures are never consistent in every case. Both groups were unsure whether such failures should be addressed more than once depending on the potential effects they can think of, or to identify it as a single failure without considering its effect. Identifying potential effects of failures was only addressed by the JCAHO's book published in 2005. The JCAHO authors (2005) acknowledge that a single failure may have one or multiple effects and that

the team should try and identify as many potential effects as possible. Due to participants' time constraints, the facilitator recommended to both groups that they first identify the failure and then list only the most common expected effect and score the failure accordingly. Thus, rare case scenarios or less common consequences were not included, unlike in a production line for example the steps of the process of manufacturing a car are standard, repetitive and the effects or consequences of the failure are recognised and restricted. This could be a key reason for the significant differences between the groups as there is no standard 'most common consequence of a failure or error in healthcare' and participants dealing with severely ill patients may anticipate worse scenarios than other participants; i.e. one failure can lead to so many clinical scenarios in a single patient and endless scenarios for different patients. In the field of engineering, a study by Amendola *et al* (1992) reported that 11 specialist teams representing a wide range of interests used different methods for chemical risk assessment. Although the teams used the same data for the same risk events, considerable differences were found in the results because the teams adopted different assumptions.

It is unknown whether the use of a different scale would have altered the results but irrespective of the scoring scale used, relying on participant's judgment to score the failures remains the main weakness. This method of scoring, which depends on the participants' subjectivness, will no doubt continue to produce inconsistent results and thus FMEA's reliability will always be questionable to some extent.

In summary, the unreliability of the FMEA results does not appear to be due to limitations related to our particular FMEA participants or how the FMEA was

facilitated or conducted. Instead, the FMEA tool appears to be unreliable due to inherent limitations within the techniques itself and how it is used inconsistently.

6.3 Validity of FMEA

Kirwan (1996) reported that lack of validation evidence leads to two basic problems in the field of HRA: firstly, there is scepticism as to whether the techniques available have any empirical predictive validity, and secondly, technique developers and assessors get little useful feedback on how to improve the technique's predictive accuracy and precision. Furthermore relying on invalid results to improve any process may lead to unnecessary or inappropriate costly changes within an organisation. Validation, therefore are essential as a general quality assurance process and generate the ability to fine-tune techniques. Kirwan (1996) further explained that HRA techniques that depend on significant judgment either by assessors or experts are at risk to fail to accurately quantify the errors, and thus risk assessments could over- or under-estimate risk. Therefore it is necessary that objective tests are carried out to ensure validity of these tools, thereby checking and improving the accuracy of the risk assessment as a whole (Kirwan, 1997).

According to Kirwan (1996, p.360), the concept of validation appears to be straightforward:

> *'Test the technique against known data, and see if the predicted failure probabilities match the known values, where those performing the predictions do not know the true values they are estimating.'*

This was exactly the approach taken in chapter 3 to explore the validity of the FMEA. Four different validity tests were conducted. Face validity proved to be positive as the researcher documented the same process of care as mapped by the

participants. Content validity revealed that there were potential failures that both groups failed to include and thus this supported the notion that not all potential failures could be identified using FMEA. Criterion validity was explored by comparing the FMEA findings with audit data available at the study hospitals, data reported on trust's incident reporting database and data collected from the laboratory. Audit data and data from the Trust's incident reporting database were compared to all the FMEA failures identified within the process. Only the monitoring failures were compared from data collected from the laboratory. Although all three methods of testing criterion validity had their own limitations, the overall results suggested that the FMEA predictions were not accurate. Failures compared to the Trust's incident reporting database showed no agreement between the severity and probability scores identified by the FMEA participants and those reported on the incident report database. Detectability scores were also doubted since a number of FMEA failures identified by the teams were described as not detectable yet there were similar incidents reported on the database. Data from the laboratory highlighted that the groups' FMEA probability scores were not consistent with the actual probability data collected from the laboratory. Overall from the three methods proposed, collecting data from the organisation to compare with FMEA data is our recommended method. Collecting data from the organisations identifies failures that do indeed occur and their probability of occurrence. Audits may also be useful, particularly if specific audits are conducted with the aim of validating the FMEA results, otherwise, as in this study, the audit data may not be comparable with the FMEA failures identified. Finally, using an incident report database can be useful when identifying failures and as an indicator to whether failures were detectable or not, but is less appropriate for comparing

probability and severity scores as these scores are also subjective and may not necessarily be reported.

Finally, construct validity was assessed by exploring the relevant mathematical theories involved in calculating the RPN. Bowles (2003) highlighted four main limitations of using RPN for prioritising failures in the way it is currently used in FMEA:

1. Holes in the scale: Many numbers in the range of 1 to 1000 cannot be formed from the product of severity, probability and detectability (10-point scoring scales are used for each).
2. Duplicate RPN values: 1000 numbers are produced from the product of severity, probability and detectability but only 120 of them are unique.
3. Sensitivity to small change: Small variations in one ranking can lead to very different effects on RPN. For example SxPxD: 3x8x8: 192 ,however a one point change in the severity in this example causes a 64 point change in the RPN: SxPxD: 4x8x8: 256
4. Bowles also argues that comparing the RPN values is generally not possible without some cost function that quantifies how reductions along one dimension relate to changes along another dimension. He further states that calculation of RPN implies that trade-offs can be made between the severity, probability and detectability factors. For example, doubling the severity from 4 to 8 while halving the probability from 4 to 2 and keeping the detection the same has no net effect on the RPN.

Furthermore calculating the RPN by multiplying the severity, probability and detectability scores was invalid because it is based on incorrect calculations that breach the mathematical properties of the scales used.

In summary, recruiting a multidisciplinary team to map a process of care provides valid results; however in order to ensure that the majority of potential failures are listed, then teams are likely to need different sources of information besides their experiences and knowledge. As for the FMEA's methodology for scoring failures, this proved to generate invalid data as the teams' estimates were not comparable to actual data collected from the hospital and the concept of multiplying ordinal scales to prioritise failures is mathematically flawed.

6.4 Relationship between reliability and validity

Are the validity and reliability results of FMEA related? Froman (2000, p.) states that the connection between the concepts of reliability and validity is illustrated through the understanding that valid measurements require consistency of observation but also that reliability is considered a necessary but not sufficient condition for validity (Artinian, 1982). In other words, it is possible for a data set to have high reliability measures but low validity, but in order to have a high degree of validity; the data set must also be reliable (Higgins and Straub, 2006).

Since FMEA produces unreliable results, does this automatically indicate that it is not valid? Because FMEA is a technique that involves a number of steps it may be more appropriate to report reliability and validity results according to each step. Steps 1 and 2 of the FMEA, which included choosing a topic and recruiting a multidisciplinary team, respectively, did not require validation or reliability tests.

Both groups conducted the FMEA on the use of vancomycin and gentamicin and a multidisciplinary team, including at least one doctor, pharmacist and nurse, participated in the meetings. The validity and reliability of step 3 of the FMEA (describing the process and identifying the failures) and step 4 (calculating the RPN) are discussed below.

- Step three: describing the process and identifying the failures:

  - Recruiting a multidisciplinary team to graphically describe the process was found to be a reliable valid step in the present study. Both groups identified the same main steps for the use of vancomycin and gentamicin and very similar sub process steps. In addition to this, when exploring face validity for the mapped process, the researcher mapped a process that included all the steps identified by both groups. The only difference was the style of flowchart used, but this did not affect the flowcharts' contents.

  - Identifying the failures: depending on the teams' subjective opinion to identify failures proved to be an unreliable method and resulted in results of questionable validity. Both groups identified different failures and content validity was questionable as other healthcare professionals, outside the FMEA team, identified other failures and the hospital's incident report database included other failures.

- Step four: calculating the RPN: This step proved to be unreliable and invalid overall. Both teams scored their failures differently and the common failures had significantly different RPN values. Furthermore, validity tests showed that the probability values estimated by the groups were different to those actually identified in the hospital.

In conclusion, steps three and four, which proved to be unreliable, were also invalid. But why is reliability and validity of importance? Vincent (2004, p.243) states:

> *"The process of analysing incidents could be considered simply as a method of engaging teams in reflecting on safety; in that case, formal evaluation may not be critical. However, if we believe it could function as a more formal diagnostic technique exposing flaws in healthcare systems, then questions of inter-rater reliability and the validity of the conclusions become important."*

The purpose of FMEA is to estimate the risk of potential failures and prioritise the failures that require the most attention, whether because they are assumed to be the most severe, the most probable or the least detectable failures or a combination of both (thus the purpose of the RPN). Thus if patient safety becomes reliant on such a technique then it is essential to ensure the results produced are consistent, irrespective of the team using the tool, and accurate especially since FMEA entails a lot of time, effort and resources.

Although HFMEA was not formally evaluated in this thesis, it is assumed that some of the same problems inherent within FMEA will also be present in HFMEA. Some of these problems include the lack of standardised use for HFMEA as the literature review identified, the lack of evidence that the scoring scales used have been standardised or validated and finally the decision tree is based on the subjective opinions and experiences of the participating team and thus it is expected that these similar problems will also affect the reliability and validity of HFMEA's results.

Furthermore, Toft (1996, p.100) reports that:

> *"Unfortunately methodologies used for quantifying the probability that a disaster will occur in any given organisation appears to possess six*

significant implicit assumptions, together with a paradox that would seem to render any predictions, which might be made using them, extremely problematic. As a consequence, making the numerical probabilities derived from such techniques the sole, main or even partial means of making decisions relating to safety is debatable."

Table 33: Six assumptions for quantifying the probability of a disaster occurring.

The six assumptions include (Toft, 1996, p.101):

1. Risks can be treated as though they were concrete physical entities that can be precisely defined and unambiguously measured in objective terms.
2. Risk is a neutral objective activity and therefore the final quantitative assessment will be unbiased and independent of the analyst.
3. That it is possible for the team undertaking risk analysis in an organisation to specify an exhaustive set of failures for the activities under consideration.
4. Reliable historical data is available for the past events which can be utilised for future calculations.
5. The complexity of human behaviour and human errors in particular can be pre-specified and reduced to a simple unitary numerical representation.
6. Finally, future trajectory of an organisation will be similar to that of the past.

All the above assumptions (table 33) are made, most likely unconsciously, when using a technique such as FMEA or HFMEA. It is expected that since they are 'assumptions' then the postulation that the results will always be precisely defined, unbiased and comprehensive is unlikely. Furthermore, relying on historical data or assuming that future incidents will be similar to those that occurred in the past may also contributory factors affecting FMEA's validity and reliability.

In addition to this, when healthcare organisations decide to conduct an FMEA, participating teams must be aware that the conclusions of FMEA are usually short-

lived, particularly in healthcare. As new evidence-based medicine continues to evolve and guidelines and protocols continue to be periodically updated, along with the introduction of new technologies such as electronic prescribing, clinical decision support or bar-coding, a given set of FMEA results will only be valid for a limited time period and should therefore be updated regularly. Furthermore, the policy of doctors 'turnover' or rotations within different hospitals (as within the NHS) should be considered. These doctors might be available to participate in the FMEA discussions but their rotations would mean that they may not be around to implement the new changes or teach them to others and thus the FMEA may need to be repeated.

6.4.1 Generalisability

Another important concept to consider is the generalisability of FMEA. Generalisability, sometimes referred to as external validity, is concerned with the extent to which the results can be applied to individuals or settings beyond the sample (Smith, 2002). FMEA as a technique is theoretically considered generalisable since it is actually adopted from other industries and used across a number of healthcare organisations all over the world. Yet, since the literature review identified inconsistent use of the FMEA technique across organisations and countries, its generalisability or external validity is questionable.

The FMEA *results,* on the other hand, for a certain process of care can not be described as generalisable or externally valid simply because every process of care and healthcare organisation is different and healthcare professionals follows different protocols and guidelines. Although each FMEA serves to address specific

problems within organisations, one of the advantages of FMEA over RCA is that FMEA results can be shared in detail across institutions without concerns of breaching confidentiality, while concerns over confidentiality make it impossible for the Joint Commission for example, to share root cause analysis event-level data with interested healthcare institutions or professionals outside the Joint Commission (Janofsky, 2009).

6.5 Perceptions and experiences with FMEA

In 2004, The IHI and The Health Foundation launched the SPI which aimed to improve patient safety in hospitals. During the SPI programme, participants were expected to do an FMEA on a core process in medicines management. The opportunity arose to explore the SPI participants' experiences and perceptions of FMEA. The themes identified included the perceptions and experiences of participants with the FMEA, validity and reliability issues and FMEA's use in practice. FMEA was defined by participants as a structured subjective process that helps healthcare professionals get together to identify the high risk areas within a process of care. Both positive and negative opinions were expressed with the majority of the interviewees expressing constructive views towards FMEA in terms of it being a useful tool particularly for mapping and identifying problems within a process of care. Other participants criticised FMEA for being subjective and lacking validity. The limitations that were most likely to restrict its widespread use were its time consuming nature as well as the perceived lack of validity and reliability. Initial proper training for FMEA was considered important and from the participants' experiences, team composition appeared to be an important factor that affected the FMEA results.

The SPI research is the first time participants of FMEA in the UK have been interviewed to account their opinions and familiarities with FMEA. The results of these interviews were very similar to those described in the literature in the USA and Netherlands (Wetterneck *et al*, 1994; Wetterneck *et al*, 2004; Habraken *et al*, 2009); however the key difference was that the SPI participants questioned the validity and reliability of FMEA. This may be because healthcare professionals felt that it was a tool that consumed a lot of time and effort and thus they required reassurance that the time and effort spent on conducting an FMEA was not without additional benefit for the patient and that the FMEA results were indeed useful, reliable and valid. Also in the USA, every hospital must conduct an FMEA, and thus perhaps since it has become an obligation from a highly influential authorised body such as the Joint Commission and IHI, healthcare professionals have not questioned its validity or reliability, but instead have taken it for granted that the Joint Commission would not obligate FMEA's use unless it was evaluated and its validity and reliability tested.

This study will help other hospitals, planning to incorporate FMEA, to gain insight about FMEA's benefits and limitations. This would allow hospitals to explore the means by which they can optimise the success and benefit of FMEA while minimising its shortcomings before investing the resources, time and effort.

6.6 Application of HRA in healthcare

Following the reliability and validity results of this present study for FMEA, should healthcare continue exploring the use of HRA techniques used by other industries?

Healthcare is becoming more open to learning safety lessons from other domains, but as van der Schaff (2002) explains it should remain aware of the differing tasks and contexts. Healthcare is somewhat comparable to industries such as aviation and nuclear power in the sense that they all comprise high risk complex processes that require highly skilled individuals and any consequences of errors within these processes may lead to permanent damage and in some cases mortality. Yet healthcare has special characteristics that differ from other high risk industries. Although certain tasks in healthcare are highly structured and governed by guidelines and protocols, healthcare can not be solely characterised as a routine process in which the same steps are followed by all healthcare professionals for all patients. Several factors play a huge role in the success or failure of treatment. These may include the doctor's experience and knowledge, patient's age and co morbidities, and resources and time available, exemplifying it as an unpredictable process. Healthcare staff maybe faced with uncertainties on daily basis in which critical decisions are taken without guarantees for the outcomes. This highly dynamic nature, large variation in practice and lack of standardisation is the most striking difference between healthcare and other industries (van der Schaaf, 2002). In addition to this, van der Schaaf (2002) reports that a unique feature of healthcare safety is that the patients themselves are an additional source of error. Lyons *et al* (2004) further states that more than other industries, the healthcare system relies on human-human interactions as opposed to human-machine interaction. This means that success or failure within patient care can not be attributed to one single individual in contrast to the production line where failures can be traced back to the exact step of the process. This high level of human-human interaction as well the pressure and expectations to make the right decisions all the time adds to the

complexity of healthcare and thus to the difficulties in adapting HRA techniques such as FMEA in healthcare. It is therefore, sometimes inappropriate for the medical community to predominantly look to solutions developed by a domain such as aviation where there's a rigid and consistent standardisation of technology, tasks, procedures and personnel (van der Schaaf, 2002).

Nonetheless, healthcare's efforts should be commended for investing in research related to human errors and risk management and for attempting to learn from other industries with high safety measures. The main concern however lies in the fact that healthcare personnel are not yet well equipped in the field of reliability engineering techniques, thus there is a high risk of choosing inappropriate methods or methods that have not been proven to deliver what they are designed for. And while other industries continue to use these techniques, healthcare should approach them with caution and question their appropriateness rather than 'take them as they are.'

6.7 Clinical decision support and antibiotics

The FMEA results in chapter 2 have highlighted that the process of prescribing, administering and monitoring antibiotics is prone to errors that may harm the patients. Following the participants recommendations, the use of CDSS for antibiotics was explored. CDSS have been hailed for their potential to reduce medical errors (Bates *et al*, 2001) and increase health care quality (Sim *et al*, 2001) and aid physicians to select the appropriate antibiotic therapy. A literature search was carried out for RCT and before and after studies reporting the use of CDSS for antibiotics. Fifty articles were identified and six RCT and five before and after studies were reviewed. The main issue identified was that there was no standard

definition as to what comprises a CDSS. However, the results of the literature review indicated that the majority of studies used a computerised CDSS and concluded significant benefits of CDSS. Although the FMEA participants have recommended the use of such technology, the successful use of CDSS is difficult to generalise as most studies were conducted in the USA. Furthermore CDSS development and implementation would require a lot of work, time and costs with no guarantee that its use will be supported by healthcare professionals or that the failures identified by the FMEA teams would be eliminated. This also highlights the disadvantage of FMEA as it does not take into account the cost or ease of implementing improvements (Cheung *et al*, 2006; van Tilburg *et al*, 2006).

6.8 Limitations

As already discussed in each chapter, there are several potential limitations in this research that should be considered. First, when testing the reliability of FMEA, the main limitation was that only two multidisciplinary teams were recruited. At the beginning of the project it was initially aimed to recruit four teams. However, probably because FMEA required team commitment and attendance at several meetings, 14 participants agreed to attend. In order to ensure that each discipline was represented we were unable to divide the participants into more than two groups. Therefore, there were seven participants in each group which was similar to the average number of eight participants as recommended by the JCAHO (2005) and as reported in several published studies. In addition to this, the team members had different experiences and levels of knowledge which may have contributed to the differences in the results. However, these two limitations are not only relevant to this study, but relevant to any study using the FMEA tool. From guidelines

published about the use of FMEA, it is advised to include a multidisciplinary team in which team members have different levels of familiarity with the process studied. However, in healthcare it is impossible to recruit teams according to their knowledge, rather than hierarchical position or level of experience unless their knowledge it put to test. If, for example, two experts within the same discipline are present in the team it is difficult to determine who was more knowledgeable and who contributed more to the FMEA. Perhaps in future studies other experts, outside the FMEA team, could be involved in the FMEA from the start, i.e. at each step other experts would be consulted rather than wait until the FMEA is completed and thus the work would not seem so overwhelming and time consuming.

As for validity, there were two main limitations: First, when exploring the content validity only three consultants were able to provide feedback for the completed FMEA sheets although reminders to all 56 potential respondents were sent out each week for three consecutive weeks. The low response rate could be attributed to two main issues; either healthcare providers contacted may never have heard about FMEA and thus were not interested to 'learn' about a new tool and then criticise it or they were familiar with FMEA but it was perceived as being too time consuming for them to go through the entire FMEA worksheet and make comments. Second, data was only collected from the laboratory and therefore monitoring failures could be compared and only the probability scores were compared. In future studies, researchers should aim to collect data to validate the entire process of care mapped by collecting the relevant data and the severity of the failures, or incidents may be in the future assessed by the validated reliable method of scoring medication errors proposed by Dean and Barber (1999).

Another limitation was the time difference between collecting data for the reliability study and the validity study. In order to collect the relevant data for the validity study, all the FMEA meetings had to be completed and the results first analysed. Furthermore, a separate ethics application was required for the validity study and this further contributed to the time delay for data collection.

Finally, the main limitation of the qualitative study was that the researcher did not conduct the interviews herself as the interviews had already been conducted by researchers from Imperial College. Although the overall data from the interviews were not only related to FMEA and interesting comments or detailed information about FMEA were not followed up by the researcher, data was collected on a large scale from all four nations of the United Kingdom. In addition to this, as FMEA is not widely incorporated within UK hospitals, this was the most suitable opportunity to explore the views of a relatively large number of participants of FMEA. The views of the SPI participants were also similar to those of our FMEA teams as well as the three qualitative articles previously conducted in the United States (Habraken *et al*, 2009; Wetterneck *et al*, 2009; Wetterneck *et al*, 2004). The main difference was that SPI participants questioned FMEA's validity and reliability whereas other published qualitative studies did not.

6.9 Future research

In this thesis, exploring the reliability and validity of FMEA served to provide a baseline for future research work in the area of validating prospective HRA tools and ensuring their reliability, particularly in the healthcare setting. Although a number of HRA techniques have been validated in other industries (Kirwan, 1998;

Stanton and Stevenage, 1998; Kirwan, 1997a, Kirwan, 1997b, Stanton and Barber, 2005), none of them including FMEA. This indicates that the idea of validating HRA techniques is not a new concept but it is of importance and has been addressed for several other HRA techniques used in other fields.

As the use of HRA techniques in healthcare are relatively new and unexplored, future research in the field could be approached by three different research strategies all of which are worth of pursuing. First, by improving the currently used FMEA/HFMEA and testing whether these improvements will enhance its reliability and validity. Second, by using an approach based on principle, i.e. we identify the problem and prioritise the failures based on a set of principles that improve the safety of healthcare systems; or finally by exploring the use of other HRA techniques which have been used successfully in other industries. Each approach is described below.

1) Improving current FMEA: In this study only a limited set of approaches to exploring the reliability and validity of FMEA were utilised. Future studies should explore using other validity and reliability testing techniques. For example the reliability of the scales alone may be tested by providing participants with case-scenarios and asking them to score them individually and then testing the scores' reliability using the statistical test Cronbach's alpha or conducting a 'test-retest' by asking two or more groups to determine the severity, probability and detectability scores again on a different occasion in order to assess whether their responses had changed or not. As for the validity, collecting data from the hospital for the all the

failures identified may have provided a more comprehensible picture about FMEA's validity.

More research is also required to identify the factors that may have affected the reliability of the FMEA. Future studies may aim to include participants with the same baseline knowledge or to explore whether training for FMEA affects the reliability.

In addition to this, standardising the scales used and accompanying numerical values with appropriate descriptions, suitable for specific use of FMEA within healthcare, maybe the next appropriate step. Although the VA NCPS have recommended the use of HFMEA, work needs to be done to validate the scales used and the hazard scoring matrix as well as the decision tree analysis method. The inclusion or exclusion of detectability scores should be further evaluated. Incorporating the views of healthcare professionals who have used FMEA or HFMEA would help identify the key dynamics within a tool that engineers or ergonomists might not be familiar with the healthcare setting. In the UK, although FMEA is not currently widely used among practicing healthcare professionals and only three published papers were identified (Redfern *et al* 2009; Gilchrist *et al,* 2008; Marwick *et al*, 2007), a number of abstracts from databases indicate that many hospitals have used it on a small scale. Future qualitative studies should include interviewing team members who have actively participated in FMEA rather than interviewing managers who have only overseen the FMEA meetings without active participation.

At the same time, it is important to remember that identifying failures should not only be dependent on participants' previous experiences. Instead, incidents from the hospital data base and previous audits should be provided for the team before they start listing the failures to try and ensure that the majority of potential failures are listed. Second, these identified failures should further be validated by asking the opinions of other experts, outside the FMEA team, and should be supported by observational work. As for calculating the RPN, a number of engineering articles proposed solutions to counter the limitations of the current scoring scale and RPN calculation. Proposed solutions have included measuring failure/risk in terms of costs (Rhee and Ishii, 2003; Arunachalam and Jegadheesan, 2006; Dong, 2007), and ranking failures 1 through 1,000 to represent the increasing risk of 1,000 possible severity-probability-detectability combinations. These 1,000 possible combinations were tabulated by an expert in order of increasing risk and the failures having higher rank is given a higher priority (Ravishankar and Prabhu, 2001). There are also new approaches such as prioritising failures based on severity of effect or influence, and direct and indirect relationships between the failures (Seyed-Hosseini *et al,* 2006). However, the above proposed alternative methods for prioritising failures should be further researched and the validity and reliability established first before promoting its use. Finally, studies can focus on evaluating the recommendations set by the FMEA rather than using the RPN as an indicator for the success of the FMEA.

2) The Principle approach: The idea behind this research approach would be to identify a problem and follow a set of principles to address the problem. Garfield *et al* (2009) states that there is a need to examine the impact of errors on the system as

a whole and use that knowledge to develop an approach which will maximise its value to patients. For example, in order to identify which area of a process needs to be prioritised and addressed then healthcare professionals may choose to address failures that have the highest known error rates or can cause high levels of harm. Other organisations may focus on addressing problems depending on their hierarchy within the process, i.e. if we address a prescribing failure then perhaps subsequent administrative failures would be eliminated (for example, addressing the problem of illegible handwriting in prescriptions may eliminate the error of administering the wrong drug). Another approach recommended by Rother and Shook (2003) would be to prioritise processes or failures at the patient end of the system and gradually work backwards, thereby maximising value to the patients. Finally exploring the use of an effective feedback loop may be useful. Several health care organisations have taken lessons from the Aviation Safety Reporting System, the aviation industry's model that has been in place for the past 24 years with an emphasis on near misses. The Aviation Safety Reporting System is voluntary, confidential, and nonpunitive, and it uses uninvolved experts as reviewers of the reports to understand the stories and to assist in analyzing the issues that led up to the event (NPSF, 1998). This type of qualitative reporting system can be used by bedside care providers as well as health care administrators to problem-solve system issues. It is designed to target safety concerns before they cause injury (Napier *et al*, 2006).

3) Using other HRA techniques: The final approach would be to explore the use of other HRA techniques used in other high risk industries. From the literature review two published papers by Lyons (2004; 2009) reviewing the use of HRA techniques

in healthcare were retrieved. In the first paper by Lyons *et al* (2004) a literature review was conducted to identify the popular HRA techniques used in other industries and to consider their feasibility for use in healthcare. The authors conclude that there was considerable scope to use a number of HRA techniques in healthcare and that the HRA techniques that were already used are not fully explored. The second paper by Lyons (2009) aimed to support the novice user in selecting an HRA technique for healthcare from the broad array of choice. The author concluded that there was a lack of practical experiences described in the literature to conclusively define a technique and dedicated research in this area was necessary to make it accessible for healthcare. Thus research in this field is novel and likely to be rich. A good starting point would be to list the most popular HRA techniques described by Lyons (2004; 2009). Then depending on the purpose of applying the HRA technique choose a validated and reliable technique. Examples of such techniques are the SHERPA which has only been used to identify errors in endoscopic surgery (Joice *et al*, 1998; Malik *et al*, 2003) and its validity and reliability has been tested in other settings (Kirwan, 1992; Stanton and Stevenage, 1998). Another HRA technique that could be explored is HAZOP (Hazard and Operability Study). It is also a validated and reliable technique used in industry (Kirwan, 1992) but has not been widely used in healthcare (Lyons *et al*, 2004). Other techniques such as HEART (Human Error Assessment and Reduction Technique) and THERP (Technique for Human Error Rate Prediction) have also been validated and their reliability tested; they have been widely used in industry (Kirwan, 1992; Kirwan *et al*, 1996) but not yet applied in healthcare (Lyons *et al*, 2004).

As this thesis has focused on FMEA, the following section presents recommendations for the use of FMEA in healthcare. These suggestions are based on the findings of the present study and will be followed by the conclusions.

6.10 Recommendations

Practical recommendations for conducting an FMEA have been extensively published including guidelines about how to choose high risk topics, who should participate in the FMEA meetings, how the meetings should be conducted and even how to reach consensus with the participating team. Reviews related to the use of FMEA in healthcare have all supported its application in healthcare and have encouraged its use indicating that the Joint Commission in the USA, as well as several organisational bodies, promote its use. There is no denying that FMEA is a useful prospective tool that allows healthcare professionals to discuss a process of care as a team. However the results of this thesis have indicated that FMEA's reliability and validity are questionable and thus the absolute promotion of its use in healthcare may be inappropriate.

The JCAHO (2005) states that FMEA is by no means perfect, instead it has several limitations which an organisation could overcome if it recognises them. These main limitations include its time consuming nature, its inability to reveal complete consequential and causal sets of any singular failure and its inability to consider multiple or interacting failures. One must acknowledge that no one single technique or tool will be prefect, however the limitations above and those identified in the literature review (section 1.5.2.10) are all limitations that, as the JCAHO (2005) stated, could be overcome and modified. However, how do you overcome or modify the limitation of a technique producing unreliable, invalid results? As

described in the previous section (6.9 future work), the FMEA technique itself requires a number of modifications to improve its reliability and validity.

Spath (2004, p.116) has stated that:

> *'One of the worst practices used in conducting FMEA projects is to use only FMEA techniques to make a process safer since the FMEA methodology for improving the safety of processes has some known limitations.'*

The results of this research further identified two additional fundamental limitations for its use; its lack of reliability and validity particularly for the last two FMEA steps. Some published studies in healthcare have actually used FMEA along side other safety techniques to improve patient safety (McNally *et al*, 1997; Gowdy &Godfrey, 2003; Nichols *et al*, 2004; Lenz *et al*, 2005; Builles *et al*, 2006; Marwick *et al*, 2007; Koppel *et al*, 2008). These seven studies used the FMEA as an additional method to contribute to their findings or to support and strengthen them. However, in the remaining published articles it was unclear whether FMEA was the sole tool used within the organisation.

However, in light of the lack of reliability and validity of the FMEA results I would not recommend the use of FMEA alone as a tool for preventing patient harm. The benefits of gathering a multidisciplinary team to discuss a process of care are clear; however organisations do not necessarily need to gather a team under the term of 'FMEA'. Identifying potential failures is beneficial as it allows the team to share experiences, yet as they are 'potential failures' there is no need to translate these failures into numerical representatives including severity, probability and detectability scores. The scores might be useful to guide the team as they would

probably discuss the severity and probability of the failures during the meeting anyways; however the scores should not become the main focus of the tool where the aim of the FMEA becomes reducing the RPN values rather than find solutions to avoid failures or errors from reaching the patient. Furthermore, focusing the FMEA to reduce the RPN values may result in bias results as participants' focus shifts from patient safety to lowering numerical values. I would only recommend the use of the traditional FMEA tool alone, as it currently is, in three situations:

First, as an educational tool for junior healthcare professionals. It would allow participants from different disciplines to discuss a specific problem and allow all team members to gain insight about each discipline. It may even promote the juniors' communication skills especially since they are discussing a potential problem rather than an actual incident which may involve shame and blame. As participants in this study and other published papers have quoted (Riehle *et al*, 2008; Nickerson *et al*, 2008; Cheung *et al*, 2006), it allows the team to think of problems in a more detailed and structured form. Involving senior healthcare professionals to share their experience and narrate the types of failures that they have encountered during their practice may be favourable.

Secondly, I would recommend the use of FMEA in practice when new technology or equipment may be installed or used, where the steps of the process may be relatively standardised and the effects of potential failures are limited. Conducting an FMEA for new technologies or equipment may serve as a training tool for users to become more familiar with the new systems and help new users understand the shortfalls of any new technology and thus become better equipped at handling its

shortcomings. However, based on the results of this thesis, FMEA should not be used alone to completely dismiss or promote the use of new equipment or technology.

Thirdly, I would recommend the use of FMEA when comparing two systems or processes of care, perhaps an old existing process and a new process before it is implemented. The purpose of the FMEA would be a stimulus to compare different systems to weigh the pros and cons of each system or process rather than operate as a safety tool.

If organisations were still keen to conduct an FMEA for a process of care involving patients then they must ensure that FMEA is not the only method patient safety is reliant on or the sole technique by which organisations decide which failures in a process deserve the time, money and resource investment. It is important to remember that FMEA's results are short-lived as a process of care continues to improve and advance. From a facilitator's point of view, the important recommendations before conducting a traditional FMEA include:

- Ensuring the facilitator and team leader are well informed of FMEA and its steps and can guide the team.
- Ensure that the topic chosen is not too complicated or unmanageable.
- Ensuring that the FMEA is supported by managers and lead organisational figures especially since it is a time consuming process.
- Ensure that the team has access to information from the literature, hospital incident database or audits.
- Ensure that the feasibility of implementing the recommendations has been considered in terms of resources and costs. It is easy to recommend the use of electronic prescribing or bar coding, but is it viable?

- Avoid recalculating the RPN values as an indicator for improvement. Instead focus on testing any new recommendations in terms of patient benefit.

- Finally, use FMEA as a technique among others to enhance patient safety.

6.11 Conclusions

The work in this thesis has made a number of new contributions to existing knowledge. First, it is the first study worldwide to recruit two multidisciplinary teams to conduct the same FMEA in order to compare their results. Second, it is also the first study in the UK to complete a traditional FMEA in a hospital setting related to a medication-related process of care including the prescribing, administering and monitoring steps in the process. Thirdly, it is the first study published worldwide to use FMEA for the use of vancomycin and gentamicin. Furthermore, no published studies have compared data collected from the healthcare setting using different methods, with data generated by the FMEA participants. Therefore, this study provides the first formal evaluation of the reliability and the validity of the FMEA in the healthcare setting as well as any other setting. This is particularly important in the present time as FMEA is becoming more popular and more patient safety organisations are supporting its use. Finally, this is also the first time that participants in the UK expressed their experiences and perceptions of FMEA in a research context. This was of particular importance because the majority of the SPI participants were unfamiliar with the FMEA technique and were able to identify FMEA's limitations as a tool rather than only comment about their specific FMEA process and team dynamics.

The following are the key conclusions:

1. Although FMEA is popular and published studies have reported its successful use, there is inconsistent use of the tool in healthcare.

2. Unlike other high risk industries, healthcare is unique in terms of the confounding factors that contribute to errors and failures, its unpredictable nature and the implementation of evidence based medicine that is constantly reviewed and updated.

3. FMEA lacks reliability as the results are dependant on the participating team. Failure identification and the scoring method are mostly dependant on subjective perception and thus it is not possible to obtain consistent accurate results with different teams.

4. The validity of FMEA, in particular step 4 of the FMEA (calculating the RPN), is questionable as healthcare participants tend to over estimate the frequencies and severities of failures as well as the detectability scores.

5. FMEA Participants in the UK were able to identify more weaknesses in the FMEA process in general rather than focus on the limitations within the team.

6. There is a need to standardise components of the FMEA/HFMEA such as the scoring scales.

7. This thesis should be considered a starting point for the journey of producing a valid reliable prospective technique that would be useful to promote patient safety.

8. Recommendations for the use of the traditional FMEA in the meantime should be for educational purposes or when implementing new technologies

or equipment. Until FMEA's reliability and validity is further tested and confirmed, it should not be used solely to promote patient safety.

References

Adachi, W., and Lodolce, A.E. (2005).Use of failure mode and effects analysis in improving the safety of IV drug administration. *Am.J.Health Syst.Pharm;* **62** (9): 917-920.

Amendola, A., Contini, S. and Ziomas, I. (1992). Uncertainties in chemical risk assessment: Results of a European benchmark exercise. *Journal of Hazardous Materials*; **29** (3): 347-363.

Apkon, M., Leonard, J., Probst, L., DeLizio, L., and Vitale, R. (2004). Design of a safer approach to intravenous drug infusions: failure mode effects analysis. *Qual Saf Health Care*; **13** (4): 265-271.

Artinian, B. M. (1982). Conceptual mapping: development of the strategy. *Western J Nurs Research*; **4**: 379-393

Arunachalam, V.P., and Jegadheesan, C. 2006. Modified failure mode and effects analysis. A reliability and cost-based approach. *The ICFAI Journal of Operations Management*; 7-20.

ASHRM- 2002. American Society for Health Care Risk Management Strategies and tips for maximizing failure mode and effect analysis in your organization. Available at: www.ashrm.org/ashrm/resources/files/FMEAwhitepaper.pdf (Accessed June 4, 2008)

Astrom, K., Duggan, C., and Bates, I. (2007). Developing a way to improve communication between healthcare professionals in secondary care. *Pharmacy Education*; **7**(3): 279-285.

Bates, D.W., Leape, L.L., Cullen, D.J., Laird, N., Petersen, L.A., Teich, J.M., *et al.* (1998). Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors. *J Am Med Assoc.*; **280**:1311-1316.

Bates, D.W., Teich, J.M., Lee, J., Seger, D., Kuperman, G.J., Ma'luf, N. *et al.* (1999). The impact of computerised physician order entry on medication error prevention. *J Am Med Inform Assoc*; **6** (4): 313-321.

Bates, D.W. (2000). Using information technology to reduce rates of medication errors in hospitals. *BMJ;* **320**: 788 - 791.

Bates, D.W., Cohen, M., Leape, L.L., Overhage, J.M., Shabot, M.M., Sheridan, T. (2001). Reducing the frequency of errors in medicine using information technology. *J Am Med Inform Assoc;* **8**(4):299-308.

Battles, J.B., Dixon, N.M., Borotkanics, R.J., Rabin-Fastmen, B., Kaplan, H.S. (2006). Sense making of Patient Safety Risks and Hazards. *Health Services Research;* **41**(4):1555- 1575.

Benn, J., Burnett, S., Parand, A., Pinto, A., Iskander, S., & Vincent, C. (2009). Perceptions of the impact of a large-scale collaborative improvement programme: Experience in the UK Safer Patients Initiative. *Journal of Evaluation in Clinical Practice*; **15**(3):524-540.

Benn, J., Burnett, S., Iskander, S., Parand, A., Pinto, A., & Vincent, C. (2008). Experience in the Safer Patients Initiative: A complex intervention for quality improvement at the micro and macro systems levels. Paper presented at the International Conference on Healthcare Systems Ergonomics and Patient Safety (HEPS) June 25-27th 2008, Strasbourg.

Benn, J., Burnett, S., Iskander, S., Parand, A., Pinto, A., & Vincent, C. (2009). Experience in the UK Safer Patients Initiative: Understanding improvement at the organisational level. Poster presented at the International Forum for Quality and Safety in Health Care, Berlin, Mar 2009.

BMA (2004)-British Medical Association. Communication education skills for doctors: an update. Available at: http://www.bma.org.uk/images/communication_tcm41-20207.pdf (Accessed 14th May 2009).

Bonnabry, P., Cingria, L., Sadeghipour, H., Ing, H., Fonzo-Christe, C., Pfister, R.E. (2005). Use of a systematic risk analysis method to improve safety in the production of paediatric parenteral nutrition solutions. *Qual.Saf Health Care*; **14** (2): 93-98.

Bonnabry, P., Cingria, L., Ackermann, M., Sadeghipour, F., Bigler, L., Mach, N. (2006). Use of a prospective risk analysis method to improve the safety of the cancer chemotherapy process. *Int J Qual Health Care.*; **18** (1): 9-16.

Bonnabry, P., Despont-Gros, C., Grauser, D., Casez, P., Despond, M., Pugin, D., Rivara-Mangeat, C., Koch, M., Vial, M., Iten, A., Lovis, C. (2008). A risk analysis method to evaluate the impact of a computerized provider order entry system on patient safety. *J Am Med Inform Assoc.*; **15**(4):453-460.

Bowles, J.B. (2003) An Assessment of RPN Prioritization in a Failure Modes Effects and Criticality Analysis. *Journal of the IEST* ; 51-55.

Bowling, A. (2002) *Research methods in health-Investigating health and health services* (2nd edition), Buckingham: Open University Press.

Bowling, A and Ebrahim, S. (2006) *Handbook of health research methods: investigation, measurement and analysis*. England: Open University Press.

Bramstedt, K.A. (2002) Failure Mode and Effects Analysis as an informed consent tool for investigational cardiothoracic devices. *ASAIO*; **48**: 293-295.

Brennan, T.A., Leape, L.L.. Laird, N.M., Hebert, L., Localio, A.R., Lawthers, A.G. (1991). Incidence of adverse events and negligence in hopitalised patients: results of the Harvard medical practice study I. *New Engl J Med.*; **324:** 370-376.

Buchanan, B.G. and Shortliffe, E.H. *Rule-based expert systems: the MYCIN experiments of the Stanford heuristic programming project*, Addison-Wesley, Reading (1984).

Buchan, I.E., Hanka, R., Pencheon, D., Bundred, P. (1996).Introduction of the computer assisted prescribing scheme Prodigy was premature. *BMJ;* **313**:1083.

Builles, N., Perraud, M., Reverdy, M., Burillon, C., Crova, P., Brun, F. *et al* (2006) Reducing contamination when removing and storing corneas: a multidisciplinary, transversal, and environmental approach. *Cornea;* **25**(2):185-192.

Burgmeier, J. (2002) Failure mode and effect analysis: an application in reducing risk in blood transfusion. *Jt Comm J Qual Improv*; **28**(6):331-339.

Burnett, S (2009). Improving Patient Safety: Learning from the Safer Patients Initiative. *Health Care Risk Report*; 16 (1): 16-17.

Burnett, S, Benn, J, Pinto, A, Parand, A, Iskander, S, Vincent, C, (In press) Organisational readiness: Exploring the preconditions for success in organisation-wide patient safety improvement programmes. *Quality and Safety in Healthcare*

Burnett, S., Benn, J., Pinto, A., Parand, A., Iskander, S., Vincent, C. (2009) Organisational Readiness: Exploring the preconditions for success in organisation-wide patient safety improvement programmes. Patient Safety Congress, April 30th-May 1st 2009, Birmingham, UK.

Capunzo, M., Cavallo, P., Boccia, G., Brunetti, L., Pizzuti, S.A. (2004) FMEA clinical laboratory case study: how to make problems and improvements measurable. *Clinical Leadership & Management Review*; **18** (1):37-41.

Carmines, E.G. and Zeller, R.A. (1979) *Reliability and Validity Assessment.* 18th Edition, USA: SAGE.

Cheung, D.S., Maygers, J., Khouri-Stevens, Z., De Grouchy, L., Magnuson, T. (2006) Failure modes and effects analysis: minimizing harm to our bariatric patients. *Bariatric Nursing and Surgical Patient Care*; 1 (2): 107-114.

Chiang, H.Y., Pepper, G. (2006) Barriers to nurses' reporting medication administration errors in Taiwan. *J Nurs Scholarsh.*; **38**(4):392–399.

Chiozza, M. L. and Ponzetti, C. (2009) FMEA: a model for reducing medical errors. *Clin Chim Acta.;* **404** (1):75-78.

Christakis, D.A., Zimmerman, F.J., Wright, J.A., Garrison, M.M., Rivara, F.P., Davis, R.L. (2001) A randomized controlled trial of point-of-care evidence to improve the antibiotic prescribing practices for otitis media in children. *Pediatrics*; **107** (2): 1-4.

Classen, D.C., Evans, R.S., Pestotnik, S.L., Horn, S.D., Menlove, R.L., Burke, J.P. (1992) The timing of prophylactic administration of antibiotics and the risk of surgical wound infection. *New Engl J Med*; **326** (5): 281-286.

Clayton, P.D., and Hripcsak, G. (1995).Decision support in healthcare. *International Journal of Bio-Medical Computing;* **39**: 59-66.

Cohen, M.R, Senders, J, Davis, N.M (1994). Failure mode and effects analysis: a novel approach to avoiding dangerous medication errors and accidents. *Hosp Pharm.* **29**(4):319-330.

Cohen, M. R. M. (1997). New, Safer Cisplatin Packaging: Confusion With Oral Liquid Opiates; Literature on Potassium Chloride Error Prevention; Modification of Labeling on Look-Alike Dextrose Container; ISMP Safe Medication Management Fellowship Program. *Hospital Pharmacy*; 338-344.

Coles, G., Fuller, B., Nordquist, K. and Kongslie, A. (2005). Using failure mode effects and criticality analysis for high-risk processes at three community hospitals. *Jt.Comm J.Qual.Patient Saf*; 31 (3): 132-140.

Croteau, R.J., and Schyve, P.M. Practively (2000) Error-proofing healthcare processes (chapter 7) In: Spath, P.L. (Editor) *Error Reduction in healthcare: a systems approach to improving patient safety*, pp: 179-197. New York: John Wiley and sons Inc.

Cullen, D., Bates,W., Small, S., Cooper, J.B., Nemeskal, A.R., Leape, L.L, *et al.* (1995) The incident reporting system does not detect adverse drug events: A problem in quality assurance. *Joint Commission Journal on Quality Improvement*; **21**:541-548.

Davies, C. (2000) Getting health professionals to work together- There's more to collaboration than simply working side by side. *BMJ;* **320**: 1021-1022.

Davis, P., Lay-Yee, R., Briant, R., Ali, W., Scott, A., Schug, S. (2002) Adverse events in New Zealand public hospitals I: occurrence and impact. *N Z Med J*; **115:** 1167-1172.

Dawson, A., Orsini, M.J., Cooper, M.R. and Wollenburg, K. (2005) Medication safety-reliability of preference cards. *AORN*; **82** (3): 399-414.

Day, D., Lubowski, T.J., Yamaga, C.C., Main, J., Van Vleet, J., Ambegaonkar, (1999) A. Computer assisted evaluation of antibiotic regimen coverage and cost. *Clin Ther*; **21** (8): 1418-1425.

Day, S., Dalto, J., Fox, J., Turpin, M. (2006). Failure Mode and Effects Analysis as a Performance Improvement Tool in Trauma. *Journal of Trauma Nursing;* **13** (3):111-117.

Day, S., Dalto, J., Fox, J., Allen, A., Ilstrup, S. (2007) Utilization of failure mode effects analysis in trauma patient registration. *Qual Manag Health Care.* **16**(4):342-348.

Dean, B. and Barber, N. (1999) A validated, reliable method of scoring the severity of medication errors. *Am J Health-Syst Pharm*; **56**: 57-62.

Dean, B., Schachter, M., Vincent, C., and Barber, N. (2002) Causes of prescribing errors in hospital inpatients: a prospective study. *Lancet*; **359**: 1373-1378.

Delaney, B.C., Fitzamaurice, D.A., Riaz, A., Hobbs, F.D.R. (1999).Can computerized decision support systems deliver improved quality in primary care. *BMJ.* **319**: 1281-1283.

De Dombal, F.T., Leaper, D.J., Staniland, J.R., McCann, A.P., Horrocks, J.C. (1972). Computer-aided diagnosis of acute abdominal pain. *Br Med J.*; **2**: 9-13.

Dennison, R. (2005) Creating an Organizational Culture for medication safety. *Nurs Clin N Am.*; **40**: 1-23.

Department of Defense Patient Safety Center (2003). Guidelines for Failure Mode and Effect Analysis for automotive, aerospace and general manufacturing industries: Dyadem Press-CRC Press, USA.

DeRosier, J., Stalhandske, E., Bagian, J.P., and Nudell, T. (2002) Using health care Failure Mode and Effect Analysis: the VA National Center for Patient Safety's prospective risk analysis system. *Joint Commission Journal on Quality Improvement;* **28**(5):248-267.

Dhillon, B. S. (2003) Methods for performing human reliability and error analysis in health care. *International Journal of Health Care Quality Assurance;* 16.6/7: 306.

Department of Health (DoH) (1998). Doctors To Get Latest Medicine Advice At The Touch Of A Button [http://www.dh.gov.uk/PublicationsAndStatistics/PressReleases/PressReleasesNotices/fs/en?CONTENT_ID=4025065&chk=o7rxcm] (January 5th 2006)

DOH- Department of Health (2000). An organization with a memory. Available at: [http://www.dh.gov.uk/assetRoot/04/08/89/48/04088948.pdf] (Accessed 31st August 2006).

DOH-Department of Health (2001). Building a safer NHS. Available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4084961.pdf (Accessed 17th November 2009).

Dong, C. (2007) Failure mode and effects analysis based on fuzzy utility cost estimation. *International Journal of Quality and Reliability Management*; **24** (9): 958-971.

Duwe, B., Fuchs, B. D., and Hansen-Flaschen, J. (2005) Failure mode and effects analysis application to critical care medicine. *Crit Care Clin.*; **21** (1): 21-30.

Eddy, D., and Purves, I.N. (1998). PRODIGY: Implementing clinical guidance using computers. *British Journal of General Practice,* **48**: 1552-1553.

Esmail, R., Cummings, C., Dersch, D., Duchscherer, G., Glowa, J., Liggett, G., Hulme, T., Patient Safety and Adverse Events Team. (2005). Using Healthcare Failure Mode and Effect Analysis tool to review the process of ordering and administrating potassium chloride and potassium phosphate. *Healthc Q*; **8**: 73-80.

Evans, R.S., Classen, D.C., Pestotnik, S.L., Lundsgaarde, H.P., Burke, J.P. (1994) Improving Empiric Antibiotic Selection using computer decision support. *Arch Intern Med*; **154**: 878-884.

Evans, R.S., Pestotnik, S.L., Classen, D.C., Clemmer, T.P., Weaver, L.K., Orme, J.F Jr, *et al.* (1998) A computer-assisted management program for antibiotics and other antiinfective agents. *New Engl J Med*; **338** (4): 232-238.

Evans, S.M., Berry, J.G., Smith, B.J., Esterman, A., Selim, P., O'Shaughnessy, J., DeWit, M. (2006) Attitudes and barriers to incident reporting: a collaborative hospital study. *Qual Saf Health Care.;* **15**(1):39-43.

Fechter, R.J. and Barba, J.J. (2004) Failure mode effect analysis applied to the use of infusion pumps. *Conf Proc IEEE Eng Med Biol Soc.*; 5:3496-3499.

Fletcher, C. (1997) Failure mode and effects analysis. An interdisciplinary way to analyse and reduce medication errors. *J Nurs Adm*; **27**(12): 19-26.

Fliorence, G., and Calil, S.J. (2006) Health failure mode and effect analysis for clinical engineering: Application on cardiac defibrillators. *Journal of Clinical Engineering*; **31**(2): 108-113.

Field, A. (2005) *Discovering statistics using SPSS.* 2nd edition, London: SAGA publications Ltd.

Finch, R.G. and Low, D.E. (2002) A critical assessment of published guidelines and other decision support systems for the antibiotic treatment of community-acquired respiratory tract infections. *Clinical Microbiology and Infection;* **8** (2): 69-91

Food and Agriculture Organization of the United Nations-(2006). FAO/WHO guidance to governments on the application of HACCP in small and/or less-developed food businesses Available at: ftp://ftp.fao.org/docrep/fao/009/a0799e/a0799e00.pdf. Accessed 16th October 2009).

Ford, E.C., Gaudette, R., Myers, L., Vanderver, B., Engineer, L., Zellars, R., Song, D.Y., Wong, J., Deweese, T.L. (2009) Evaluation of safety in a radiation oncology setting using failure mode and effects analysis. *Int J Radiat Oncol Biol Phys.*; **74**(3):852-858.

Forsman, R.W. (1996) Why is the laboratory an afterthought for managed care organizations? *Clinical Chemistry*; **42** (5): 813-816.

Franklin, B. D., O'Grady, K., Paschalides, C., Utley, M., Gallivan, S., Jacklin, A., Barber, N. (2007). Providing feedback to hospital doctors about prescribing errors; a pilot study. *Pharm World Sci.*; 29(3):213-220.

Franklin, B.D., Birch, S., Savage, I., Wong, I., Woloshynowych, M., Jacklin, A., Barber, N. (2009) Methodological variability in detecting prescribing errors and consequences for the evaluation of interventions. *Pharmacoepidemiol Drug Saf.;***18**(11):992-999.

Froman, R. D. (2000). Measuring our words on measurement. *Research in Nursing and Health*; **23**: 421-422.

Garfield, S., Barber, N., Walley, P., Willson, A., Eliasson, L. (2009) Quality of medication use in primary care--mapping the problem, working to a solution: a systematic review of the literature. *BMC Med*; **21**(7):50-58.

Gering, J., Schmitt, B., Coe, A., Leslie, D., Pitts, J., Ward, T., Desai, P. (2005) Taking a patient safety approach to an integration of two hospitals. *Jt.Comm J.Qual.Patient Saf;* 258-266.

Gilchrist, M., Franklin, B.D., Patel, J.P. (2008) An outpatient parenteral antibiotic therapy (OPAT) map to identify risks associated with an OPAT service. *J Antimicrob Chemother.*; **62**(1):177-183.

Gowdy, M., and Godfrey, S. (2003) Using tools to assess and prevent inpatient falls. *Jt Comm J Qual Saf.*; **29**(7):363-368.

Guchelaar, H.J., Colen, H.B., Kalmeijer, M.D., Hudson, P.T., Teepe-Twiss, I.M. (2005) Medication errors: hospital pharmacist perspective. *Drugs.*; **65**(13):1735-1746.

Habraken, M.M., Van der Schaaf, T.W., Leistikow, I.P., Reijnders-Thijssen, P.M. (2009) Prospective risk analysis of health care processes: a systematic evaluation of the use of HFMEA in Dutch health care. *Ergonomics*; **52**(7):809-819.

Hambleton, M. (2005) Applying Root Cause Analysis and Failure Mode and Effect Analysis to our Compliance Programs. *Journal of Health Care Compliance;* **7** (2): 5-12.

Healthcare Foundation (2009). Safer Patients Initiative. http://www.health.org.uk/current_work/demonstration_projects/safer_patients.html (14th May 2009).

Hersh, W.R., (2002) Medical informatics: improving health care through information. *J Am Med Assoc;* **288**: 1955-1958.

Higgins, P.A. and Straub, A.J. (2006) Understanding the error of our ways: mapping the concepts of validity and reliability. *Nursing outlook;* **54**:23-29

Hollnagel, E. 1993 Human Reliability Analysis: Context and Control. Academic Press, London

House of Commons Health Committee. Patient Safety. Sixth Report of Session 2008-09. Volume 1. http://www.publications.parliament.uk/pa/cm200809/cmselect/cmhealth/151/151i.pdf (Accessed 17th November 2009)

House of Lords Select Committee on Science and Technology (1998) Seventh Report. Resistance to Antibiotics and Other Antimicrobial Agents. Available at: [http://www.parliament.the-stationery-office.co.uk/pa/ld199798/ldselect/ldsctech/081vii/st0702.htm] (Accessed January 4th 2006).

Hughes, R.G., and Ortiz, E. (2005) Medication errors. *Journal of Infusion Nursing;* 28 (2 suppl.): 14-24.

Hulgan, T., Rosenbloom, S.T., Hargrove, F., Talbert, D.A., Arbogast, P.G., Bansal, P., *et al.* (2004) Oral quinolones in hospitalized patients: an evaluation of a computerized decision support intervention. *J Intern Med*; **256**(4):349-57.

Hunt, D.L., Haynes, R.B., Hanna, S.E., Smith, K. (1998). Effects of computer-based clinical decision support systems on physician performance and patient outcomes. *JAMA*; **280**: 1339-1346.

IHI- Institute for Healthcare Improvement (2009). Closing the quality gap- An introduction to IHI. Avaialble at: http://www.ihi.org/NR/rdonlyres/9FEE1B6D-9B26-481D-B29C-A5D99E6CCFF8/0/IntrotoIHIFinal.pdf (Accessed 14th May 2009).

IHI- Institute for Healthcare Improvement (2009). Safer Patients' Initiative. Available at: http://www.ihi.org/IHI/Programs/StrategicInitiatives/SaferPatientsInitiative.htm (Accessed 14th May 2009).

IOM- Institute of Medicine (1999) *To err is human: building a safety health system.* Washington, DC: National Academy Press.

Israelski, E.W., and Muto, W.H. (2004) Human factors risk management as a way to improve medical device safety: a case study of the therac 25 radiation therapy system. *Jt Comm J Qual Saf.*; **30**(12):689-695.

Janis, J.L. (1972) *Victims of groupthink.* Boston: Houghton Mifflin.

Janofsky, J.S. (2009) Reducing inpatient suicide risk: using human factors analysis to improve observation practices. *J Am Acad Psychiatry Law.*; **37**(1):15-24.

JCAHO- Joint Commission on Accreditation of Healthcare Organzations (2005) *Failure Mode and Effects Analysis in Health Care: Proactive Risk Reduction*-2nd Edition, USA: Joint Commission Resources Inc. (JCR).

Jeon, J., Hyland, S., Burns, C.M., Momtahan, K. (2007) Applying FMEA on the process for reading the labels on ampoules and vials for injectable drugs. Procceding of the 51st annual meeting of the Human Factors and Ergonomics Society. Baltimore, MD.

Johnston, M.E., Langton, K.B., Haynes, R.B. Mathieu, A. (1994). Effects of computer-based clinical decision support systems on clinician performance and patient outcome. *Annals of Internal Medicine*; **120** (2): 135-142

Joice, P., Hanna, G.B., and Cuschieri, A. (1998) Errors enacted during endoscopic surgery- a human reliability analysis. *Applied Ergonomisc;* **29** (6):409-414.

Kaplan, B. (2001) Evaluating informatices applications-clinical decision support systems literature review. *Int J Med Inform*; **64**: 15-37.

Kaushal, R., Shojania, K.G., Bates, D.W. (2003) Effects of Computerized Physician Order Entry and Clinical Decision Support Systems on Medication Safety. *Arch Intern Med* ; **163**:1409-1416.

Kawamoto, K., Houlihan, C.A., Balas, A., Lobach, D.F. (2005) Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. *BMJ;* **330**: 765-768.

Kerr, J. (1986) The interpersonal distance of hospital staff. *Western Journal of Nursing Research;* **8**(3): 350-364.

Kim, G.R., Chen, A.R., Arceci, R.J., Mitchell, S.H., Kokoszka, K.M., Daniel, D., Lehmann, C.U. (2006) Error reduction in pediatric chemotherapy- computerized order entry and failure mode and effects analysis. *Arch Pediatra Adolesc Med*, **160**: 495-498.

Kimchi-Woods, J., and Shultz, J.P. (2006) Using HFMEA to assess potential for patient harm from tubing misconnections. *Jt Comm J Qual Patient Saf.*; **32**(7):373-381.

Kirwan, B. (1992) Human error identification in human reliability assessment. Part 1-Overview of approaches. *Applied Ergonomics*; **23** (5): 299-318.

Kirwan, B. (1996). The validation of three human reliability quantification techniques- THERP, HEART and JHEDI: Part 1-technique descriptions and validation issues. *Applied Ergonomics;* **27** (6): 359-373.

Kirwan, B. (1997a). Validation of human reliability assessment techniques: Part 1-Validation issues. *Safety Science*; **27** (1): 25-41.

Kirwan, B. (1997b). Validation of human reliability assessment techniques: Part 2-Validation results. *Safety Science*; **27** (1): 43-75.

Kirwan, B. (1998). Human error identification techniques for risk assessment of high risk systems. Part 1-review and evaluation of techniques. *Applied Ergonomics*; **29** (3): 157-177.

Kofoed, K., Zalounina, A., Andersen, O., Lisby, G., Paul, M., Leibovici, L., Andreassen, S. (2009) Performance of the TREAT decision support system in an environment with a low prevalence of resistant pathogens. *J Antimicrob Chemother.*; **63**(2):400-404.

Koppel, R., Wetterneck, T., Telles, J.L., Karsh, B.T. (2008). Workarounds to barcode medication administration systems: their occurrences, causes, and threats to patient safety. *J Am Med Inform Assoc.*; **15**(4):408-423.

Kovner, C., Menezes, J., and Goldberg, J.D. (2005). Examining nurses' decision process for medication management in home care. *Jt Comm J Qual Patient Saf.*; **31**(7):379-385.

Kozakiewicz, J.M., Benis, L.J., Fisher., S.M., and Marseglia, J.B. (2005) Safe chemotherapy administration: Using failure mode and effects analysis in computerized prescriber order entry. *Am J Health-Syst Pharm.*; **62**: 1813-1816.

Kunac, D.L., and Reith, D.M. (2005) Identification of Priorities for Medication Safety in Neonatal Intensive Care. *Drug Saf*; **28** (3): 251-61.

Kuperman, G.J., Bobb, A., Payne, T.H., Avery, A.J., Gandhi, T.K., Burns, G., Classen, D.C., and Bates, D.W. (2007) Medication-related clinical decision support in computerized provider order entry systems: a review. *J Am Med Inform Assoc.*; **14**(1):29-40.

La Pietra, L., Calligaris, L., Molendini, L., Quattrin, R., Brusaferro, S. (2005) Medical errors and clinical risk management: state of the art. *Acta Otorhinolaryngol Ital.*; **25**(6):339-346.

Larsen, R.A., Evans, R.S., Burke, J.P., Pestotnik, S.L., Gardner, R.M., Classen, D.C. (1989). Improved perioperative antibiotic use and reduced surgical wound infections through use of computer decision analysis. *Infect Control Hosp Epidemiol*; **10** (7): 316-320.

Latino, R.J. (2000). Automating root cause analysis. In: Spath, P.L. (Editor) *Error Reduction in Health Care*, pp.155-164. New York: John Wiley & Sons.

Leape, L.L. (1994) Error in medicine. *JAMA;* **272**:115-117.

Leape, L.L., Brennan, T.A., Laird, N., Lawthers, A.G., Localio, A.R., Barnes, B.A., Hebert, L., Newhouse, J.P., Weiler, P.C., Hiatt, H. (1991). The nature of adverse events in hospitalized patients. Results of the Harvard Medical Study II. *N Engl J Med*; **324**:377-384.

Lee, K.R., Leggiadro, R.J., Burch, K.J. (1994) Drug use evaluation of antibiotics in a paediatric teaching hospital. *Infect Control Hosp Epidemiol*; **15**: 710-712.

Ledley, R.S and Lusted, L.B (1959).Reasoning foundation of medical diagnosis, Science; **130**(3366):9-21.

Lenz, R., Buessecker, F., Herlofsen, H., Hinrichs, F., Zeiler, T., Kuhn, K.A. (2005) Demand-driven evolution of IT systems in healthcare--a case study for improving interdisciplinary processes. *Methods Inf Med.*; **44**(1):4-10.

Linkin, D.R., Sausman, C., Santos, L., Lyons, C., et al. (2005) Applicability of Healthcare Failure Mode and Effects Analysis to Healthcare Epidemiology: Evaluation of the Sterilization and Use of Surgical Instruments. *Clinical Infectious Diseases;* **41** (7): 1014-1019.

Lucas, P.J.F. (2001) Certainty-factor-like structures in Bayesian networks, *The Knowledge-based Systems Journal;* **14**: 327–335.

Lyons, M., Adams, S., Woloshynowych, M., and Vincent, C. (2004) Human reliability analysis in healthcare: a review of techniques. *International Journal of Risk and Safety in Medicine*; **16**: 223-237.

Lyons, M. (2009) Towards a framework to select techniques for error predicition: Supporting novice users in the healthcare sector. *Applied Ergonomics*; **40:** 379-395.

MacKay, R., Matsuno, K. and Mulligan, J. (1991) Communication problems between doctors and nurses. *Quality Assurance in Health care*; **3**(1): 11-19.

Malik, R., White, P.S., and Macewen, C.J. (2003) Using human reliability analysis to detect surgical error in endoscopic DCR surgery. *Clin Otolaryngol*; **28**: 456-460.

Marwick, C., Watts, E., Evans, J., Davey, P. (2007) Quality of care in sepsis management: development and testing of measures for improvement. *J Antimicrob Chemother.*; **60**(3):694-697.

Marx, D. A. and Slonim, A. D. (2003) Assessing patient safety risk before the injury occurs: an introduction to sociotechnical probabilistic risk modelling in health care. *Qual Saf Health Care*; **12** (Suppl 2): ii33-8.

McDermott, R., Mikulak, R.J. and Beauregard, M.R. (1996) *The basics of FMEA.* USA: Productivity Inc.

McGregor, J. C., Weekes, E., Forrest, G. N., Standiford, H. C., Perencevich, E. N., Furuno, J.P., Harris, A.D. (2006) Impact of a computerized clinical decision support system on reducing inappropriate antimicrobial use: a randomized controlled trial. *J Am Med Inform Assoc.*; **13**(4): 378-84.

McNally, K. M., Page, M. A., and Sunderland, V. B. (1997). Failure-mode and effects analysis in improving a drug distribution system. *Am J Health Syst Pharm.*; **54** (2):171-177.

Mendoca, E.A. (2004) Clinical decision support systems: perspectives in dentistry. *Journal of Dental Education;* **86** (6): 589-597.

Mollon, B., Chong, J. Jr., Holbrook, A.M., Sung, M., Thabane, L., Foster, G. (2009) Features predicting the success of computerized decision support for prescribing: a systematic review of randomized controlled 91993trials. *Med Inform Decis Mak.*; **11**: 9-11.

Morell, R., Wasilauskas, B., Winslow, R. (1993) Personal computer-based expert system for quality assurance of antimicrobial therapy. *Am J Hosp Pharm;* **50:** 2067-2073.

Morelli, P., Vinci, A., Galetto, L., Magon, G., Maniaci, V., Banfi, G. (2007). FMECA methodology applied to two pathways in an orthopaedic hospital in Milan. *J Prev Med Hyg.;* 48(2):54-59.

Mullett, C. J., Evans, R.S., Christenson, J.C., and Dean, J.M. (2001). Development and impact of a computerized pediatric anti-infective decision support program. *Pediatrics*; **108** (4): 75-81.

Mullet CJ. and Thomas JG. Database-driven computerized antibiotic decision support: Novel use of expert antibiotic susceptibility rules embedded in a pathogen antibiotic logic matrix. In: Musen M, editor. AMIA 2003 Symposium- Biomedical and Health Informatics: From Foundations to Applications [Proceedings] 480-483. Washington DC, American Medical Informatics Association, 2003.

Murff, H. J., Patel, V. L., Hripcsak, G., Bates, D. W. (2003) Detecting adverse events for patient safety research: a review of current methodologies. *Journal of Biomedical Informatics;* **36**: 131-143

Musen, M.A., Shahar, Y., and Shortliffe, E.H. (2001) Clinical decision-support systems. In: Shortliffe, E.H., Perreault, L.E., Wiederhold, G, Fagan, L.M.(Editors) *Medical informatics: computer applications in healthcare and biomedicine,* pp: 573-609. 2nd edition. New York: Springer-Verlag.

Napier, J. and Knox, E. (2006) Basic Concepts in Pediatric Patient Safety: Actions Toward a Safer Health Care System. *Clin Ped Emerg Med*; 7:226-230.

Nichols, J.H., Bartholomew, C., Brunton, M., Cintron, C., Elliott, S., McGirr, J., Morsi, D., Scott, S., Seipel, J., Sinha, D. (2004) Reducing medical errors through barcoding at the point of care. *Clin Leadersh Manag Rev.*; **18**(6):328-334.

Nickerson, T., Jenkins, M., Greenall, J. (2008) Using ISMP Canada's framework for failure mode and effects analysis: a tale of two FMEAs. *Healthc Q.*; **11**:40-46.

Nijjer, S., Gill, J., and Nijjer, S. (2008) Effective collaboration between doctors and pharmacists. *Hospital Pharmacist;* **15**: 179-182.

NPSF-National Patient Safety Foundation; 1998. Billings, C.E. Incident reporting systems in medicine and experience with the aviation safety reporting system. Available at http://www.npsf.org/rc/tts/billings.html

NPSA-National Patient Safety Agency NHS. (2004) Seven steps to patient safety. Available at: http://www.npsa.nhs.uk/site/media/documents/499_sevensteps_overview(2).pdf. (Accessed June 19, 2006).

NPSA (2007) National Patient Safety Agency Safety in doses: medication safety incidents in the NH National Patient Safety Agency (NPSA) S: The fourth report from the Patient Safety Observatory. Available at: http://www.nrls.npsa.nhs.uk/resources/?entryid45=61625 (Accessed 15th November 2009).

NPSF-National Patient Safety Foundation Discussion Forum (ListServ). Available at: **http://www.npsf.org/psf/** (Accessed 3rd October 2009)

Osheroff, J.A., Teich, J.M., Middleton, B., Steen, E.B., Wright, A., Detmer, D.E. (2007) A roadmap for national action on clinical decision support. *J Am Med Inform Assoc.*; **14**(2):141-145.

Ouellette-Piazzo, K., Asfaw, B., Cowen, J. (2007) CT healthcare failure mode effect analysis (HFMEA): the misadministration of IV contrast in outpatients. *RadiolManage.*; **29**(1):36-44.

Paparella, S. (2007) Failure mode and effects analysis: a useful tool for risk identification and injury prevention. *J Emerg Nurs.*; **33**(4):367-371.

Parand, A., Burnett, S., Benn, J., Pinto, A., Iskander, S., Vincent, C. (2009) Frontline Staff versus Senior Managers: Perceptions of a Patient Safety Initiative. Poster presented at the 2nd North British Patient Safety Symposium, Aberdeen, UK.

Paul, M., Andreassen, S., Tacconelli, E., Nielsen, A.D., Almanasreh, N., Frank, U., Cauda, R., Leibovici, L. (2006*a*) TREAT Study Group. Improving empirical antibiotic treatment using TREAT, a computerized decision support system: cluster randomized trial. *J Antimicrob Chemother.*; **58**(6):1238-1245.

Paul, M., Andreassen, S., Tacconelli, E., Nielsen, A.D., Tacconelli, E., Almanasreh, N., Fraser, A., Yahav, D., Ram, R., Leibovici, L. (2006*b*) TREAT Study Group. Prediction of bacteremia using TREAT, a computerized decision support system. *Clinical Infectious Diseases*; **42**:1274-1282.

Pestotnik, S.L., Evans, R.S., Burke, J.P., Gardner, R.M., Classen, D.C. (1990) Therapeutic antibiotic monitoring: surveillance using computerized expert system. *Am J Med*; **88**(1): 43-48.

Pestotnik, S.L., Classen, D.C., Evans, R.S., Burke, J.P. (1996) Implementing antibiotic practice guidelines through computer-assisted decision support. *Ann Intern Med*; **124** (10): 884-890.

Pestotnik, S.L. (2005) Expert clinical decision support systems to enhance antimicrobial stewardship programs: insights from the society of infectious diseases pharmacists. *Pharmacotherapy*; **25**(8):1116-1125.

Pinto, A., Burnett S., Benn J., Brett S., Parand, A., Iskander, S., and Vincent, C. Implementation of a ventilator bundle as part of the "Safer Patients Initiative": a qualitative case study, Poster presented at the International Society for Quality in Healthcare Conference. October 2009. Dublin.

Randolph, A.G., Haynes, B., Jeremy, C., Wyatt, M.D., Cook, D.J., Guyatt, G.H.(1999) How to Use an Article Evaluating the Clinical Impact of a Computer-Based Clinical Decision Support System. *J Am Med Assoc;* **282**:67-74.

Ravishankar, N. and Prabhu, B.S. (2001) Modified approach for prioritization of failures in a system failure mode and effects analysis. *International Journal of Quality and Relibaility Management;* **18** (3): 324-335.

Reason, J. (1990) *Human error.* Cambridge: Cambridge University Press.

Reason J. Understanding adverse events: human factors (1993). In: Vincent, C. (Editor). *Medical Accidents,* pp: 1-16.Oxford: Oxford Medical Publication.

Reason J. Understanding adverse events: human factors (1995). In: Vincent, C. (Editor) *Clinical risk management,* pp: 31-54. London: BMJ Publishing Group.

Reason, J. (2000) Human error: models and management. *BMJ;* **320**: 768 – 770

Redfern, E., Brown, R., and Vincent, C.A. (2009) Improving communication in the emergency department. *Emerg Med J.*; **26**(9):658-661.

Reid, R.D. (2005) FMEA-something old, something new. *Quality Progress*; 38 (5): 90-93.

Reiling, J.G., Knutzen, B.L., and Stoecklein, M. (2003) FMEA-the cure for medical errors. *Quality Progress*; **36**(8): 67-71.

Report of the Bristol Royal Infirmary Enquiry (2001). The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995 Learning from Bristol. Available at: http://www.bristol-inquiry.org.uk/final_report/the_report.pdf (Accessed 2nd October 2009).

Rhee, S.J. and Ishii, K. (2003) Using cost based FMEA to enhance reliability and serviceability. *Advanced Engineering Informatics*; **17** (3-4): 179-188.

Riehle, M. A., Bergeron, D. and Hyrkäs, K. (2008) Improving process while changing practice: FMEA and medication administration. *Nursing Management*; **39** (2): 28-33.

Robinson, D.L., Heigham, M., and Clark, J. (2006) Using Failure Mode and Effects Analysis for safe administration of chemotherapy to hospitalized children with cancer. *Jt Comm J Qual Patient Saf.*; **32**(3):161-166.

Rommers, M.K., Teepe-Twiss, I.M., and Guchelaar, H.J. (2007) Preventing adverse drug events in hospital practice: an overview. *Pharmacoepidemiol Drug Saf.*; **16**(10):1129-1135.

Ross, P. and Dutton, A.M. (1972) Computer analysis of symptom complexes in patients having upper GI examinations. *Dig Dis;* **17**: 248-254.

Rother, M. and Shook, J. (2003) *Learning to see: value-stream mapping to create value and eliminate muda.* Massachusetts: The Lean Enterprise Institution.

Ruland, C.M., and Bakken, S. (2002) Developing, implementing and evaluating decision support systems for shared decision making in patient care: a conceptual model and case illustration. *J Biomed Inform*; **35**: 313-321.

Samore, M.H., Bateman, K., Alder, S.C., Hannah, E., Donnelly, S., Stoddard, G. J, *et al* (2005). Clinical decision support and appropriateness of antimicrobial prescribing. *J Am Med Assoc;* **294**: 2305-2314.

Sankar, N.R. and Prabhu, B.S. (2000) Modified approach for prioritization of failures in a system failure mode and effects analysis. *IJQRM*; **18** (3): 324-335.

Sari, A.B., Sheldon, T.A., Cracknell, A. and Turnbull, A. (2007) Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. *BMJ;* **334** (79): 1-4.

Saxena, S., Kempf, R., Wilcox, S., Shulman, I. A., Wong, L., Cunningham, G., Vega, E., Hall, S. (2005) Critical Laboratory Value Notification: A Failure Mode Effects and Criticality Analysis. *Jt Comm J Qual Patient Saf.;* **31**(9):495-506.

Schiøler, T., Lipczak, H., Pedersen, B.L., Mogensen, T.S., Bech, K.B., Stockmarr, A., Svenning, A.R., Frølich, A.(2001). Incidence of adverse events in hospitals. A retrospective study of medical records. Danish Adverse Event Study. *Ugeskr Laeger*; **163**(39):5370-5378.

Schmidt, R. and Gierl L. (2001) Case-based reasoning for antibiotics therapy advice: an investigation of retrieval algorithms and prototypes. *Artif Intell Med;* **23**: 171-186.

Schneider, P.J. (2002) Applying human factors in improving medication-use dafety. *Am J Health-Syst Pharm*; **59**: 1155-1159.

Schurink, C.A.M., Lucas, P.J.F., Hoepelman, I.M., Bonten, M.J.M. (2005) Computer-assisted decision support for the diagnosis and treatment of infectious diseases in intensive care units. *Lancet Infect Dis*; **5**: 305-312.

Semple, D. and Dalessio, L. (2004) Improving telemetry alarm response to noncritical alarms using failure mode and effects analysis. *JHQ Online*; W5-W19.

Senders ,J.W. (2004) FMEA and RCA: the mantras of modern risk management. *Qual Saf Health Care.*; **13**(4):249-50.

Senn, L., Burnand, B., Francioli, P., Zanetti, G. (2004) Improving appropriateness of antibiotic therapy: randomized trial of an intervention to foster reassessment of prescription after 3 days. *J Antimicrob Chemother*; **53**(6):1062-1067.

Seyed-Hosseini, S.M., Safaei, N., and Asgharpour, M.J. (2006) Reprioritization of failures in a system failure mode and effects analysis by decision making trial and evaluation laboratory technique. *Reliability Engineering & System Safety*; 91(8): 872-881.

Scott, J, 1990. A Matter of Record. Documentary sources in social research, Cambridge: Polity Press.

Shebl, N.A., Franklin, B.D., and Barber, N. (2007). Clinical decision support systems and antibiotic use. *Pharm World Sci.*; **29**(4):342-349.

Shojania, K.G., Yokoe, D., Platt, R., Fiskio, J., Ma'luf, N., Bates, D.W. (1998) Reducing vancomycin use utilizing a computer guideline. *J Am Med Inform Assoc*; **5**: 554-562.

Shortliffe, E.H., Axline, S.G., Buchanan, B.G, Merigan, T.C., Cohen, S.N. (1973) An artificial intelligence program to advise physicians regarding antimicrobial therapy. *Comput Biomed Res*; **6**: 544-560.

Shortliffe, E.H., (1976). *Computer-based medical consultations: MYCIN.* New York: Elsevier.

Shortliffe, E.H., (1991). *Knowledge-based systems in medicine.* Berlin: Springer-Verlag.

Siegel, S. (1956) *Nonparametric statistics for the behavioral sciences.* Tokyo: McGraw-Hill Kogakusha, Ltd.

Sim, I., Gorman, P., Greenes, R.A., Haynes, R.B., Kaplan, B., Lehmann, H. *et al.* (2001) Clinical decision support systems for the practice of evidence-based medicine. *J Am Med Inform Assoc;* **8** (6): 527-534.

Singh, R., Servoss, T., Kalsman, M., Fox, C., Singh, G. (2004) Estimating impacts on safety caused by the introduction of electronic medical records in primary care. *Inform Prim Care.*; **12**(4):235-242.

Sintchenko, V., Iredell, J.R., Gilbert, G.L., Coiera, E. (2005) Handheld computer-based decision support reduces patient length of stay and antibiotic prescribing in critical care. *J Am Med Inform Assoc;* **12**(4): 398-402.

Smith, F. (2002). *Research Methods in Pharmacy Practice*. London: Pharmaceutical Press.

Spath, P.L. (2003) Using failure mode and effects analysis to improve patient safety. *AORN J.*; **78**(1):16-37.

Spath, P. (2004) Worst practices used in conducting FMEA projects. *Hospital Review*; **29**(8): 114-116.
Stalhandske, E., DeRosier, J., Patail, B., Gosbee, J. (2003) How to make the most of failure mode and effect analysis. *Biomed Instrum Technol.*; **37**(2):96-102.

Stamatis, D.H. (2003). *Failure Mode and Effect Analysis: FMEA from theory to execution*. 2nd edition, Wisconsin: ASQ Quality Press.

Stanley, J.C. (1971) *Reliability*. In: Thorndike R.L. (Editor). Educational measurement' pp: 356-442. Washington DC: American Council on Education.

Stanton, J., Korus, G., Israelite, C.L., Fogt, F. (2007) Propsective risk assessment and intervention to reduce blood transfusion errors. *JCOM.*; **148:**441-446.

Stanton, N.A., and Stevenage, S.V. (1998) Learning to predict human error: issues of acceptability, reliability and validity. *Ergonomics*; **41** (11): 1737-1756.

Stanton, N.A. and Baber, C. (2002) Error by design: methods for predicting device usability. *Design Studies;* **23** (4): 363-384

Stanton, N.A. and Baber, C. (2005) Validating task analysis for error identification: reliability and validity of a human error prediction technique. *Ergonomics;* **48** (9): 1097-1113.

Stelfox, H.T., Palmisani, S., Scurlock, C., Orav, E.J., Bates, D.W.(2006) The 'To Err is Human' report and patient safety literature. *Qual Saf Health Care.*; **15**(3):174-178.

Taxis, K and Barber, N. (2003) Causes of intravenous medication errors: an ethnographic study. *Qual Saf Health Care*; **12**(5):343-347.

Taylor-Adams, S, Vincent, C and Stanhope, N. (1999) Applying human factors methods to the investigation and analysis of clinical adverse events. *Safety Science*; **31**: 143-159.

Thomas, E.J., Studdert, D.M., Burstin, H.R., Orav, E.J., Zeena, T., Williams, E.J, *et al.* (2000) Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care*; **38** (3):261-271.

Thornett, A.M. (2001) Computer decision support systems in general practice. *International Journal of Information Management*; **21**: 39-47.

Thornton, J.G., Liford, R.J. Johnson, N. (1992) Decision analysis in medicine. *BMJ*; **304**: 1099-1103.

Thursky, K.A., Buising, K.L., Bak, N., Macgregor, L., Street, A.C., Macintyre, C.R., Presneill, J.J., Cade, .JF., Brown, G.V.(2006) Reduction of broad-spectrum antibiotic use with computerized decision support in an intensive care unit. *Int J Qual Health Care.*; **18**(3): 224-231.

Toft, B. (1996) *Limits to Mathematical Modeling of Disasters.* In: Hood, C. and Jones, K.C. (Editors) Accident and Design: contemporary debates in risk management. London: University College London Press.

Trucco, P. and Cavallin, M. (2006) A quantitative approach to clinical risk assessment: The CREA method. *Safety Science*; **44** (6): 491-513.

Uslan, M.M., Burton, D.M., Chertow, B.S., Collins, R. (2004) Accessibility of insulin pumps for blind and visually impaired people. *Diabetes Technol Ther.* ; **6**(5):621-634.

Van Leeuwen, J.F., Nauta, M.J., de Kaste, D., Odekerken-Rombouts, Y.M., Oldenhof, M.T., Vredenbregt, M.J., Barends, D.M. (2009) Risk analysis by FMEA as an element of analytical validation. *J Pharm Biomed Anal.*; **50**(5):1085-1087.

Van der Schaaf, T.W. (2002) Medical applications of industrial safety science. *Qual Saf Health Care.*; **11**: 205-206.

Van Tilburg, C.M., Leistikow, I.P., Rademaker, C.M., Bierings, M.B., van Dijk, A.T.H. (2006) Health Care Failure Mode and Effect Analysis: a useful proactive risk analysis in a pediatric oncology ward. *Qual Saf Health Care.*; **15**(1):58-63.

VA NCPS- Veteran's Administration National Center for Patient Safety (2005). The basics of healthcare failure mode and effect analysis. Available at: (http://www.va.gov/ncps/SafetyTopics/HFMEA/HFMEAIntro.doc). (Accessed 11th October, 2006).

Vincent, C., Ennis, M., and Audley, R.J. (1993) *Medical Accidents.* Oxford: Medical Publication.

Vincent, C., Neale, G., Woloshynowych, M. (2001) Adverse events in British hospitals: retrospective record review. *BMJ;* **322**:517-519.

Vincent , C. A. (2004) Analysis of clinical incidents: a window on the system not a search for root causes. *Qual Saf Health Care*; **13**:242-243.

Vincent, C., Aylin, P., Franklin, B.D., Holmes, A., Iskander, S., Jacklin, A., Moorthy, K. (2008). Is health care getting safer? *BMJ*; 337: 1205-1207.

Wakefield, B.J., Uden-Holman, T., Wakefield, D.S. Development and validation of the medication administration error reporting survey. In: Henriksen K, Battles JB, Marks ES, Lewin DI, eds. Advances in Patient Safety: From Research to Implementation. Rockville, MD: Agency for Healthcare Research and Quality; 2005:475–489. Concepts and Methodology; vol 3. AHRQ Publication No. 05-0021-4.

Wald, H., and Shojania, K. G. (2001) *Incident Reporting and Root Cause Analysis.* In: Markowitz, A. J., Wachter, R. M. (Editors). Making Health Care Safer: A Critical Analysis of Patient Safety Practices, pp. 41–56. Rockville, MD: Agency for Healthcare Research and Quality.

Walton, R.T., Harvery, E., Dovey, S., and Freemantle, N. (2006) Computerised advice on drug dosage to improve prescribing practice. *The Cochrane Library;* **1**: 1-22.

Warner H Jr, Blue SR, Sorenson D, Reimer L, Li L, Nelson M, Barton M, et al. New computer-based tools for empiric antibiotic decision support. In: Masys D R, editor. AMIA 1997 Annual Fall Symposium [Proceedings] 238-242. Washington DC, American Medical Informatics Association, 1997.

Weeks, S.K., Bijkersma, F., Hubbartt, E., Murphy, B., Anderson, M.A. (2004) Failure mode and effects analysis. *The American Journal of Nursing*; **104** (4): 72A

Wehrli-Veit, M., Riley, J.B., Austin, J.W. (2004) A failure mode effect analysis on extracorporeal circuits for cardiopulmonary bypass. *J Extra Corpor Technol.*; **36**(4):351-357.

Wetterneck, T. B., Skibinski, K., Schroeder, M., Roberts, T. L., & Carayon, P. (2004). Challenges with the Performance of Failure Mode and Effects Analysis in Healthcare Organizations: An IV Medication Administration HFMEA. Paper presented at the Human Factors and Ergonomics Society 48th Annual Meeting, New Orleans, Louisiana.

Wetterneck, T.B, Skibinski, .KA, Roberts, T.L, Kleppin, S.M, Schroeder, M.E, Enloe M, Rough, S.S, Hundt, A.S, Carayon, P. (2006) Using failure mode and effects analysis to plan implementation of smart i.v. pump technology. *Am J Health Syst Pharm.*; **63**(16):1528-38

Wetterneck, T.B., Hundt, A.S., and Carayon, P. (2009) FMEA Team Performance in Health Care: A Qualitative Analysis of Team Member Perceptions. *J Patient Saf.*; **5** (2):102-108.

Williams, E. and Talley, T. (1994) The use of failure mode effect and criticality analysis in a medication error subcommittee. *Hosp Pharm*; **29**: 331-338.

Wilson, R.M., Runciman, W.B., Gibberd, R.W., Harrison, B.T., Newby, L., Hamilton, J.D. (1995) The Quality in Australian Health Care Study. *Medical Journal Australia*; **163**:458-471.

Win, K.T., Phung, H., Young, L., Tran, M., Alcock, C., Hillman, K. (2004) Electronic health record system risk assessment: a case study from the MINET. *Health Information Management*; **33** (2): 43-48.

Woloshynowych, M., Rogers, S., Taylor-Adams, S .and Vincent, C. (2005) The investigation and analysis of critical incidents and adverse events in healthcare. *Health Technology Assessmen;* **9** (19): 1-158.

Woodhouse, S. (2005) Engineering for safety: use of failure mode and effects analysis in the laboratory. Labmedicine.; 36(1): 16-18.

WHO-World Health Organisation (2003). Patient Safety: Rapid Assessment Methods for Estimating Hazards Report of the WHO working Group meeting. www.who.int/entity/patientsafety/activities/system/en/rapid_assessment_methods.pdf (last assessed: 15th November 2009)

WHO-World Health Organisation (2002). Resolution WHA 55.18. Quality of care: Patient safety. In: Fifty-fifth World Health Assembly, Geneva. Volume 1.

Wreathall, J., and Nemeth, C. (2004) Assessing risk: the role of probabilistic risk assessment (PRA) in patient safety improvement. *Qual Saf Health Care.*;**13**(3):206-212.

Wyatt, J., and Spiegelhalter, D. (1991) Field trials of medical decision-aids: potential problems and solution. *Proc Annu Symp Comput Appl Med Care*; 3-7.

Yu, V.L., Fagan, L.M., Wraith, S.M., Clancey, W.J., Scott, C., Hannigan, J. *et al* (1979a). Antimicrobial selection by a computer. *JAMA;* **242**: 1279-1282.

Yu, V.L., Buchanan, B.G., Shortliffe, E.H., Wraith, S.M., Davis, R., Scott, A.C., Cohen, S.N. (1979b) Evaluating the performance of a computer-based consultant. *Computer Programs in Biomedicine*; **9**: 95-102.

Appendices

Appendix 1: Example of the 1 to 5 scoring scale adapted from Spath (2003)

Severity Rating Scale for Failure Mode Effects

1 = No patient harm

2 = Minimal patient harm

3 = Moderate, short-term patient harm

4 = Significant, long-term patient harm

5 = Permanent patient harm

Failure Mode Probability and Detectability Rating Scales

Probability

1 = It is highly unlikely/has never happened before

2 = Low/relatively few failures

3 = Moderate/occasional failures

4 = High/repeated failures

5 = Very high/failure almost inevitable

Detectability

1 = Almost certain to be detected and corrected

2 = High likelihood of detection and correction

3 = Moderate likelihood of detection and correction

4 = Low likelihood of detection and correction

5 = Remote likelihood of detection and correction

Appendix 2: 1 to 10 scoring scale

(adapted from McDermott *et al* (1996) and the Department of Defense Patient Safety Center, USA. * Guidelines for Failure Mode and Effect Analysis for automotive, aerospace and general manufacturing industries 2003, Dyadem Press-CRC Press.)

SEVERITY*		
Rating	**Description**	**Definition**
10	Catastrophic	Death of individual or complete system failure
9		
8	Major injury	Major injury of individual or major effect on system
7		
6	Minor injury	Minor injury of individual or minor effect on system
5		
4	Moderate	Significant effect on individual or system with full recovery
3		
2	Minor	Minor annoyance to individual or system
1	None	Would not affect individual or system

PROBABILITY		
Rating	**Description**	**Potential Failure Rate**
10	Very High: Failure is almost inevitable	More than one occurrence per day or a probability of more than 1 occurrence in every 2 events
9		One occurrence every three to four days or a probability of 1 in 3
8	High: Repeated Failures	One occurrence per week or a probability of 1 in 8.
7		One occurrence per month or a probability of 1 in 20.
6	Moderate: Occasional failures	One occurrence every three months or a probability of 1 in 80.
5		One occurrence every six months to one year or probability of 1 in 400.
4		One occurrence per year or a probability of 1 in 2,000.
3	Low: Relatively few failures	One occurrence every one to two years or a probability of 1 in 15,000.
2		One occurrence every three to five years or a probability of 1 in 150,000.
1	Remote: Failure is unlikely	One occurrence in greater than five years or a probability of 1 in >150,000.

DETECTABILITY		
Rating	**Description**	**Likelihood of Detection**
10	**Absolute Uncertainty**	Control **cannot** detect potential cause and subsequent failure mode
9	**Very Remote**	**Very remote** chance the control will detect potential cause and subsequent failure mode
8	**Remote**	**Remote** chance the control will detect potential cause and subsequent failure mode
7	**Very Low**	**Very low** chance the control will detect potential cause and subsequent failure mode
6	**Low**	**Low** chance the control will detect potential cause and subsequent failure mode
5	**Moderate**	**Moderate** chance the control will detect potential cause and subsequent failure mode
4	**Moderately High**	**Moderately High** chance the control will detect potential cause and subsequent failure mode
3	**High**	**High** chance the control will detect potential cause and subsequent failure mode
2	**Very High**	**Very high** chance the control will detect potential cause and subsequent failure mode
1	**Almost Certain**	Control **will** detect potential cause and subsequent failure mode

Appendix 3: Scoring scale developed by the VA National Center for Patient Safety (2001)

SEVERITY RATING	
Catastrophic (4) Failure could cause death or injury	**Major (3)** Failure causes a high degree of customer dissatisfaction
Patient Outcome: Death or major permanent loss (sensory, motor, physiologic, or intellectual), suicide, rape, hemolytic transfusion reaction, Surgery/procedure on the wrong patient or body party, infant abduction or infant discharge to the wrong family. Visitor Outcome: Death or hospitalisation of 3 or more. Staff Outcome: Death or hospitalisation of 3 or more staff. Equipment or facility: Damage equal to or more than $250,000 Fire: Any fire that grows larger than an incipient stage	Patient Outcome: Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increased level of care for 3 or more patients. Visitor Outcome: Hospitalisation of 1 or 2 visitors Staff Outcome: Hospitalisation of 1 or 2 staff or 3 or more staff experiencing lost time or restricted duty injuries or illnesses Equipment or facility: Damage equal to or more than $100,000 Fire: N/A – see moderate or catastrophic
Moderate (2) Failure can be overcome with modifications to the process or product, but there is minor performance loss.	**Minor (1)** Failure would not be noticeable to the customer and would not affect the delivery of the service or product.
Patient Outcome: Increased length of stay or increased level of care for 1 or 2 patients. Visitor Outcome: Evaluation or treatment of 1 or 2 visitors (less than hospitalisation) Staff Outcome: Medical expenses, lost time, or restricted-duty injuries or illness for 1 or 2 staff. Equipment or facility: Damage more than $10,000 but less than $100,000 Fire: Incipient stage or smaller	Patient Outcome: No injury nor increased length of stay nor increased level of care. Visitor Outcome: Evaluated and no treatment required or refused treatment. Staff Outcome: First aid treatment only, with no lost time or restricted-duty injuries or illnesses. Equipment or facility: Damage less than $10,000 or loss of any utility without adverse patient outcome (e.g., natural, gas, electricity, water, communications, transport, heat/air conditioning)

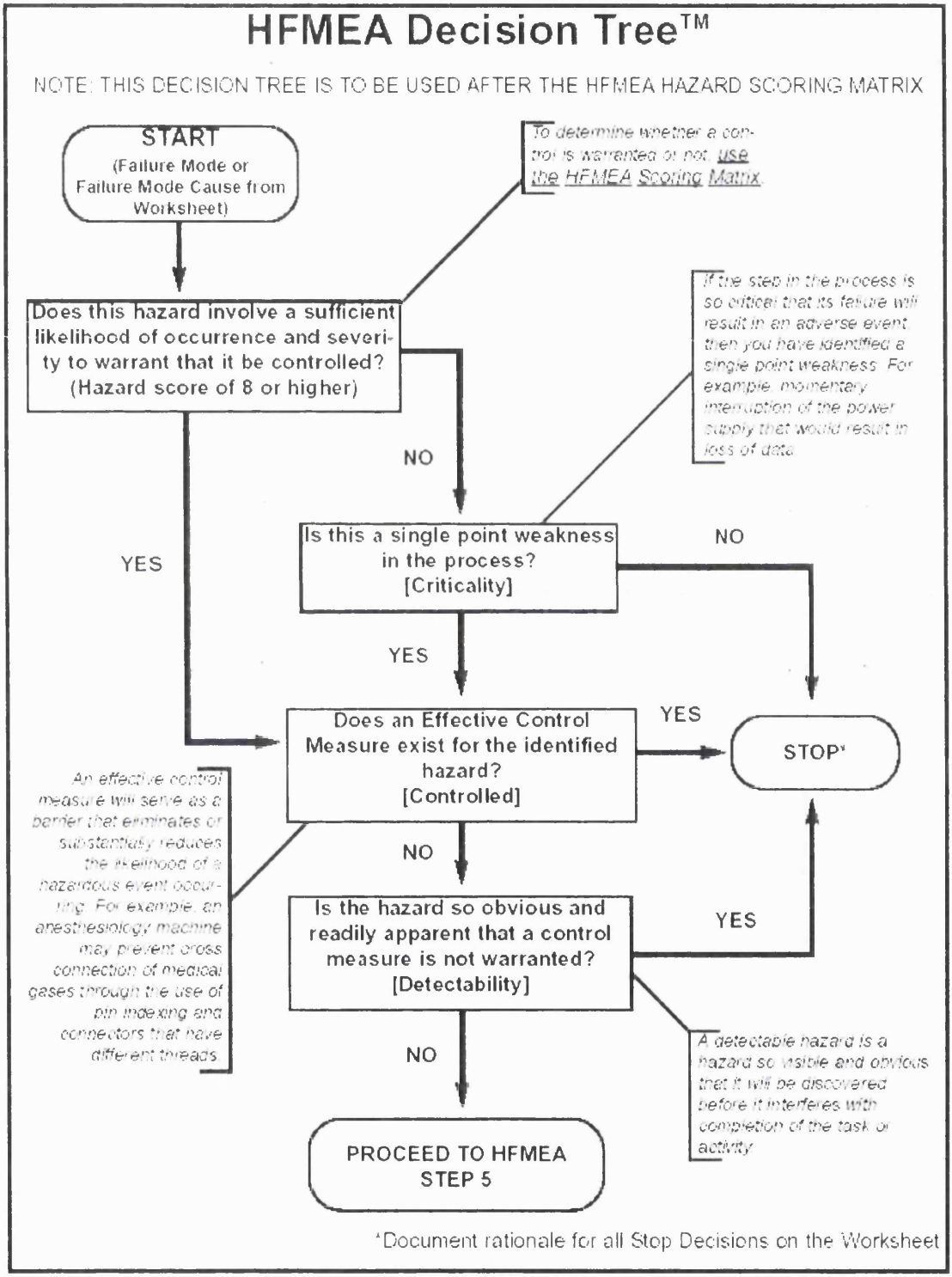
	Fire: N/A – see moderate or catastrophic

PROBABILITY RATING	
Frequent (4)	Likely to occur immediately or within a short period (may happen several times in 1 year)
Occasional (3)	Probably will occur (may happen several times in 1 to 2 years)
Uncommon (2)	Possible to occur (may happen sometime in 2 to 5 years)
Remote (1)	Unlikely to occur (may happen several sometime in 5 to 30 years)

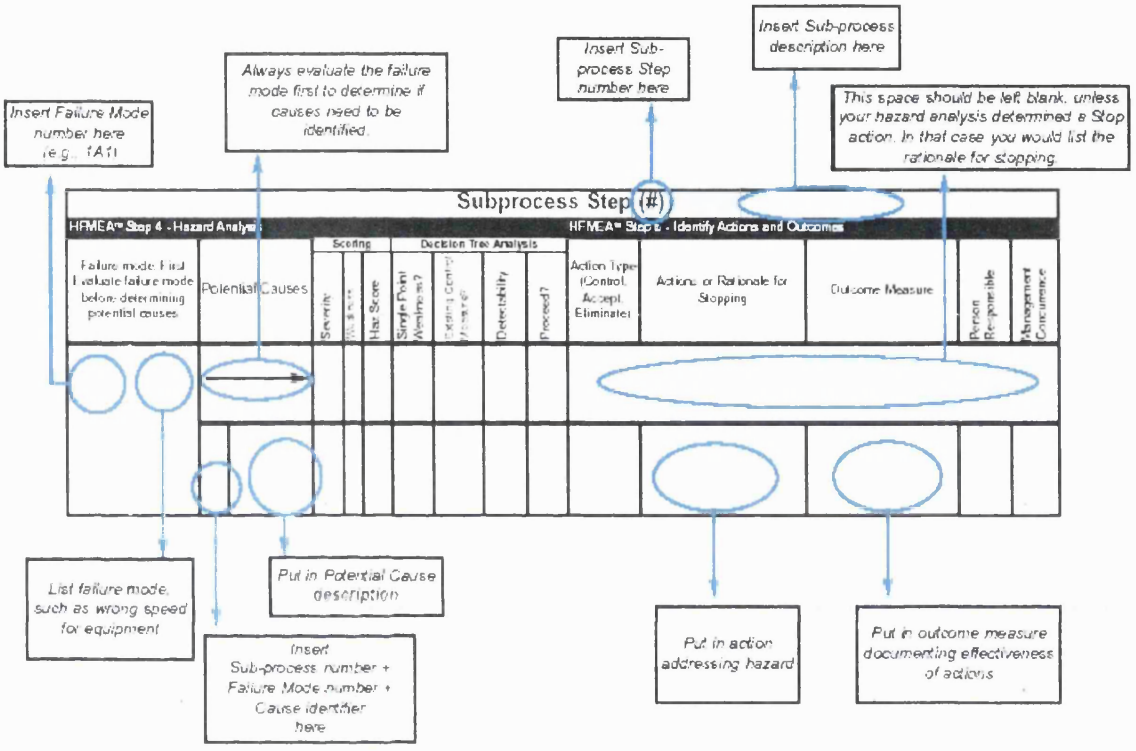
Appendix 4: Hazard Scoring Matrix developed by the VA NCPS (2001)

HFMEA™ Hazard Scoring Matrix™					
Probability	Severity of Effect				
	Catastrophic	Major	Moderate	Minor	
	Frequent	16	12	8	4
	Occasional	12	9	6	3
	Uncommon	8	6	4	2
	Remote	4	3	2	1

Appendix 5: HFMEA Decision Tree developed by the VA NCPS (2001)



Appendix 6: HFMEA worksheet developed by the VA NCPS (2001)



Appendix 7: Summary of FMEA studies in healthcare:

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Habraken *et al*, 2009	Clinics and hospitals in the Dutch healthcare system, The Netherlands	HFMEA	Qualitative study to determine the feedback of healthcare professionals who have used HFMEA.	At the end of HFMEA sessions, all team members were asked to fill out an evaluation form about their experiences with HFMEA. The form included multiple choice questions as well as open-ended questions. 62 participants from 77 completed the evaluation form.		Positives: HFMEA can be successfully applied to the Dutch healthcare system. Negatives: time consuming and lack of guidance with regard to the identification of failures, causes and effects.		
Janofsky, 2009	Secondary care hospital in Baltimore, Maryland, USA	FMEA	To improve psychiatric observation practices.	A large clinical group including senior & junior physicians, nurses & staff nursing assistants	No information provided	Solutions were adopted and piloted to reduce inpatient suicides	No information provided	No information provided
Van Leeuwen *et al*, 2009	Medicines Control Laboratory, The Netherlands	FMEA	To conduct an FMEA for Near-Infrared (NIR) analytical method used in the laboratory	Four people participated, an NIR expert, a senior technician, an expert in quality assurance and senior pharmacist	A one-day course was set for the participants and the team first visited the facility with NIR equipment. The team met for six sessions each lasting two hours.	Recommendations made for the top six failures were implemented and the FMEA was repeated with the new recommendations.	Scale 1-10 used. RPN value obtained by consensus.	Six failures (from 31) with the top RPN values were addressed

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Redfern *et al*, 2009	Secondary care hospital in London, UK	FMEA/HFMEA	To conduct and FMEA to examine the process of communication between healthcare professionals in the emergency department (ED)	A multidisciplinary team including an ED registrar, ED consultant and a professor working at the Clinical Research Safety Unit mapped the process. However the failures were identified through interviews with 16 healthcare members. These 16 healthcare members were shown the mapped process and asked to identify failures and score them.	The FMEA steps were followed but the steps were modified.	Failures were identified and scored but no actions were recommended.	In step four the authors used HFMEA's hazard scoring matrix but FMEA's worksheet and identified the causes and effects	RPN values calculated but no actions or recommendations were made.
Wetterneck *et al*, 2009	Secondary care hospital in Wisconsin, USA	FMEA	Qualitative study to determine the feedback of healthcare professionals who have used FMEA.	Structured interviews and survey questionnaires were administered to 2 FMEA teams. 24 members from a total of 39 participated in the interviews and answered the questionnaire.		Positive experience: Team must be multidisciplinary, good knowledge of FMEA Negative experience: lack of participation from some members, unfamiliarity with FMEA slows down the progress, dominating discussions and pushing points of views.		

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Bonnabry *et al*, 2008	Secondary care university hospital, Geneva, Switzerland	FMEA	To conduct a comparative risk analysis of the drug prescription process before & after implementation of CPOE using FMEA.	2 physicians, 2 nurses, 2 representatives of the medical informatics department, a pharmacist and psychologist.	Five basic steps followed. Duration: 4 meetings each lasting 2 hours plus 3-4 hours for the moderator to summarise the results	Drug prescription process using CPOE had a lower total RPN value than handwritten prescription process. Failures in the CPOE process with a high RPN were identified and implemented.	Severity and detectability scores were scored on a scale of 1-9, while probability scores were ranked 1-10. Scores were obtained by consensus.	Failures with high RPN (>100) were addressed.
Ford *et al*, 2009	Secondary care hospital in Baltimore, USA	FMEA	To apply an FMEA for an external beam radiation therapy service.	Multidisciplinary team from different departments including administrators, nurses, clinical research coordinators, radiation therapists, physicists, information technologists and physicians	The FMEA was completed over a 5 months period	FMEA was useful in identifying vulnerabilities in the process.	Scale 1-10 used. RPN value obtained by consensus.	Failures with an RPN >75 were addressed (15 failures) and implementation of the recommendations is ongoing.

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Gilchrist *et al*, 2008	Secondary care hospital in London, UK	HFMEA	To conduct an HFMEA for an outpatient parental antibiotic therapy (OPAT) service	A multidisciplinary team including 2 infectious diseases consultants, clinical pharmacist, 2 nurses, risk manager and a patient representative	Only steps 1-3 of the HFMEA are reported in the study. Meetings were schedules at ~2 weeks interval and the team met 4 times. Each meeting lasted 2 hours.	Failures in the process were identified but no failures were prioritised. Only four main suggestions were made by the team following the identification of failures.	The scores were not calculated in this study.	Failures in the process were identified but no scores were obtained, and thus no failures were prioritised.
Koppel *et al*, 2008	Secondary care hospital in Wisconsin, USA	FMEA	The main aim was to identify the workarounds when using barcoded medication administration systems (BCMA). FMEA was among the several methods used to identify the causes of each workaround.	Multidisciplinary team including 4 pharmacists, 6 nurses, pharmacist & nurse manager of BCMA, risk manager, 2 industrial engineers, 2 physicians, 1 quality improvement facilitator and a nurse patient safety officer	No information provided	FMEA, among other techniques such as interviews and observational studies was used to obtain information about the use of BCMA.	No information provided	No information provided

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Nickerson *et al*, 2008	Annapolis Valley Health Authority, Nova Scotia, Canada	FMEA	To conduct an FMEA on transcription of medication orders for inpatients & overcrowding in the emergency department (ER)	Transcription of medication team: Physician, two nurses, ward clerk and a pharmacist ER team: physician, nurse manager, staff nurse &clinical leader for the site.	Five basic steps followed. Duration: more than 30 hours of meeting time over seven months (between 150-180 person-hours)	FMEA completed but no recommendations implemented yet.	No information provided	No information provided
Riehle *et al*, 2008	Medical Centre, Maine, USA	FMEA	To conduct an FME to determine the impact of using or not using dosing windows for administration of medicines.	Multidisciplinary team including nurses, pharmacists and information technology representatives	Basic FMEA steps followed, Group met for two sessions.	The authors only concluded that the scoring process demonstrated that moving from multiple dosing schedules to dosing windows was better for the patient.	Scores 1-10 for severity, probability and detectability were used but no information how the scores were derived.	No information provided
Day *et al*, 2007	Secondary care hospital in Salt Lake City, Utah, USA	FMEA/ HFMEA	To reduce risks & improve patient safety during registration of trauma patients.	No information provided	Five steps followed but a mixture of using some FMEA and some HFMEA aspects on the worksheet but no details provided.	FMEA helped identify risk to patient registration. New recommendations were made and implemented.	In step four the authors used HFMEA's hazard scoring matrix but FMEA's worksheet and identified the causes and effects	Scored the failure modes using the Hazard Scoring Matrix only with no mention of using the Decision Tree Analysis. Failures with a score >8 were addressed and recommendations implemented

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Jeon *et al*, 2007	No information on setting, but study was conducted in Canada.	FMEA	To conduct an FMEA for reading the labels on ampoules and vials for injectable drugs. However the study focused on reporting the challenges the team faced when using the FMEA rather than how they conducted the FMEA and its outcomes.	Multidisciplinary team including 6 pharmacists and 1 nurse	No information provided	The outcomes focused on the challenges the team met rather than the FMEA process itself. These challenges included: difficulty to rate failures without specific scenarios,	A scale of 1-5 for severity and probability was used and a scale of 1-4 for detectability was used. The participants were asked to rate each failure individually based on the reasonable worst case scenario. The median values of the ratings across participants for each severity, probability and detectability was calculated for each failure. Then the three median values were multiplied to calculate the RPN.	No information provided.
Marwick *et al*, 2007	Secondary care hospital in Scotland, UK	FMEA	FMEA was used to ensure that a multidisciplinary team has identified the main measures of quality in the process of sepsis management.	No information provided	No information provided	The FMEA meetings did not identify any additional areas of concern not already covered by other measures of quality of care.	No information provided	No information provided

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Morelli *et al*, 2007	Orthopaedic institute, Milan, Italy	FMEA	Two FMEA's were formed. One for an existing pathway: the analysis of the blood and hemoderivatives supply. The other for a new pathway: physical retention usage in accidental drops (an orthopaedic service for patients with locomotor apparatus illnesses).	First FMEA: process analysed by blood bank service persons in charge of servicing orders for blood products. Second FMEA: head nurses of the hospital's orthopaedic and rehabilitation departments. No other details were provided.	No information provided	Recommendations were made and implemented for both processes. The FMEA was repeated with the new recommendations and RPN values decreased.	Scale 1-10 used. No other information provided.	No information provided regarding how the high risk failures were identified or which failures addressed.
Ouellett-Piazzo *et al*, 2007	Secondary care hospital in Massachusetts, USA	HFMEA	To prevent the misadministration of intravenous (IV) contrast in outpatients in the CT department.	No information provided	No information provided	Recommendations were made to avoid the misadministration of IV contrast and two short term solutions were implemented.	HFMEA Scores obtained by consensus	Scored the failure modes using the Hazard Scoring Matrix and used the Decision Tree Analysis. Failures with a score >8 were addressed and recommendations implemented

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Stanton *et al*, 2007	Tertiary care hospital, Philadelphia, USA	FMEA	To conduct an FMEA to reduce the risk of errors of blood transfusion and to reduce same-day surgery delays due to absence of adequate data or lack of product.	A team including 2 surgeons, 2 nurses, 2 blood bank staff members, and nursing staff from the preoperative and operating suites.	FMEA basic steps followed. The group met twice per month for 3 months	Actions for the top 10 failures were implemented and RPNs recalculated. All the RPNs were decreased following the implementation of the recommended actions.	Severity, probability and detectability scores were obtained on a scale of 1-5. No information on how the team members derived the scores.	The top 10 failures with the highest RPN were addressed.
Bonnabry *et al*, 2006	Secondary care university hospital, Geneva, Switzerland	FMEA	To perform a risk analysis of cancer chemotherapy process by comparing five different strategies from decentralisation to centralisation production with several levels of information technologies.	-4 pharmacists (head of quality assurance, head of production, head of cytostatic reconstitution unit, &chief pharmacist) -Oncologist -Oncology nurse	No information provided	Centralisation to the pharmacy was associated with a less failures than the decentralisation process.	Severity and detectability scores were scored on a scale of 1-9, while probability scores were ranked 1-10. Scores were obtained by consensus.	27 failures identified. The sum and mean of the RPN for the new and old processes were compared. RPN > 100 were specifically identified.
Builles *et al*, 2006	Secondary care hospital in Lyon, France	FMEA	To perform an FMEA for contamination risk analysis in the processing of corneas in organ culture.	No information provided	No information provided	Actions were implemented for failures with RPN >100.	Scale 1-10 used. No information how the scores were derived.	Failures with a score >100 were addressed and recommendations implemented

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Cheung *et al*, 2006	Secondary care hospital in Baltimore, Maryland, USA	FMEA	To perform an FMEA to assess the care of obese patients and identify areas for improvement.	(14 members) Surgeons, nurses, administrators & representatives from engineering, rehabilitation, nutrition, imaging and quality management.	90 minute meetings on 5 separate occasions every other week	Solutions were recommended to help improve the care of obese patients.	Scale 1-10 used. RPN value obtained by consensus.	The group identified 6 potential failure points for consideration (only 2 were considered).
Day *et al*, 2006	Secondary care hospital in Salt Lake City, Utah, USA	FMEA-HFMEA	An FMEA of inpatient dialysis process was conducted following an incident involving a trauma patient inadvertently receiving contraindicated heparin.	No details- The author only mentions that the process included physician, nursing and allied health representatives.	Five steps followed but a mixture of using some FMEA and some HFMEA aspects on the worksheet but no details provided.	Recommendations were made to improve hospital care delivery in trauma patients requiring dialysis.	In step four the authors used HFMEA's hazard scoring matrix but FMEA's worksheet and identified the causes and effects	Scored the failure modes using the Hazard Scoring Matrix only with no mention of using the Decision Tree Analysis. Failures with a score >8 were addressed and recommendations implemented

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Florence and Calil, 2006	Surgical Centre in a Brazilian public hospital.	HFMEA	Application of HFMEA to cardiac defibrillators to identify the common conditions for defibrillator failures.	A clinical engineer and an anaesthesiologist participated.	HFMEA steps followed but no other details were provided.	Problems that interfere with the performance of cardiac defibrillators were identified and some actions were proposed to help reduce the risk of these potential problems.	No information provided	Scored the failure modes using the Hazard Scoring Matrix of HFMEA and working through the Decision Tree Analysis to identify the failures that require further action
Kim *et al*, 2006	Secondary care hospital in Baltimore, Maryland, USA	FMEA	FMEA was used to evaluate the implementation of computerised provider order entry (CPOE).	Team consisting of physicians, nurses, physician assistants, pharmacists & staff from the hospital information systems.	No details.	FMEA helped guide the implementation of CPOE and provided data for further improvements.	No information provided	All failures identified were considered.
Kimchi-Woods and Shultz, 2006	Secondary care university hospital, Ohio, USA.	Modified HFMEA	To conduct an HFMEA to determine the risks inherent in the use of labelling of various enteral, parenteral and other tubing types in patient care.	No specific team details but the team included representatives from several units and variety of disciplines-nursing and speciality areas.	Five HFMEA steps followed. Team met every two weeks for a total of four times. Team leader and facilitator gave the team the HFMEA instructions and ground rules	Three recommendations were implemented and new data is now being collected to determine whether these changes were really useful.	Although it states that HFMEA was used, the scoring scales did not use the traditional HFMEA's Hazard scoring Matrix. A scale of 1-4 was used and detectability scores were included. Scores were obtained by consensus.	Five failures were identified and three recommendations were made to address all five failures

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Robinson *et al*, 2006	Secondary care university hospital, Washington, USA.	FMEA	To identify risk and implement appropriate strategies for the prescribing and administration of chemotherapy to children	Team members: -Haematology-oncology physician -Haematology-oncology nurse -Pharmacy manager -Staff pharmacist -Inpatient nurse manager -Outpatient nurse manager -Quality improvement consultant.	FMEA steps followed buy no other information provided	New recommendations for prescribing and administration of chemotherapy were implemented. Success of the new recommendations following the FMEA was shown in decreased prescribing and administering error rates.	Scale 1-10 used. No information how the scores were derived.	Team focused on the 2 failures with the highest RPN.
Van Tilburg *et al*, 2006	Secondary care university hospital, The Netherlands.	HFMEA	To investigate whether HFMEA can be used to evaluate prescribing and administration of vincristine in the paediatric setting.	9 regular members & 2 advisors.	HFMEA steps followed. Introductory 1 hour session. Team needed 7 meetings each lasting 1.5 hours.	A number of recommendations were implemented and used but the effect of these changes was not reported.	Scores obtained by consensus	Scored the failure modes using the Hazard Scoring Matrix of HFMEA and working through the Decision Tree Analysis to identify the failures that require further action (failure modes with a score of 8 or more should be given highest priority).

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Wetterneck *et al*, 2006	Tertiary care, academic medical centre in Madison, Wisconsin, USA.	States FMEA but trained the team in HFMEA and tried to use the HFMEA matrix scoring scale.	FMEA was used to evaluate a smart IV pump as it was implemented into a redesigned medication-use process.	22 team members included representatives from anaesthesiology, biomedical engineering central supply, industrial engineering, internal medicine, nursing, pharmacy and quality improvement.	Five FMEA basic steps followed. The team first underwent training in the use of HFMEA. They then met for 46 hours over four and a half months.	FMEA helped identify potential problems in the medication-use process with the implementation of new smart IV pumps.	Severity and probability of failure were ranked as low, moderate or high. Moderate-to-high scoring failure modes proceeded to action. No further information provided	Failures with low or low-moderate scores were assessed for detectability, & only detectable failures were considered for further action.
Adachi and Lodolce, 2005	Secondary care hospital in San Jose, California, USA.	FMEA	To describe the application of FMEA to prevent dosing and administration errors with IV medications	Director of pharmacy, chair of medication safety committee and representatives from pharmacy and nursing.	No information provided.	Two main interventions were performed. One-year follow-up of the hospital incidence data revealed that the number of medication errors related to dosing had decreased slightly (from 59 to 46) & pump-related errors decreased from 41% to 22%.	Scale 1-10 used. RPN value obtained by consensus.	Team chose to focus on the 5 highest RPN related to programming the IV infusion pump.

Authors and year	Setting	Choice of FMEA approach	Objective/ Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Bonnabry *et al*, 2005	Secondary care university hospital, Geneva, Switzerland	FMEA	To compare the risks associated with the old and new processes of preparing paediatric parental nutrition formulations	Team members included several pharmacists as: -head of quality assurance -head of production -head of quality control -clinical pharmacist specialised in nutrition.	Team was required to meet as many times as necessary to do the FMEA. The analysis was performed between October 2002 and January 2003 during 4 meetings each lasting about 2 hours.	FMEA confirmed that the new process of preparing paediatric parental nutrition formulations resulted in a significant risk reduction compared to the old process.	Severity and detectability were scored on a scale of 1-9, while probability was ranked 1-10. Scores were obtained by consensus.	Sum of the RPN (for all the failures) for the old and new process were calculated and compared.
Coles *et al*, 2005	Three hospitals in Washington, USA	Modified FMEA	FMEA was conducted for six processes in three hospitals. The results of only 3 processes are reported (prevention of patient falls, mediation ordering and delivery of solid oral medication and blood type transfusion for adults)	5-8 participants familiar with different parts of the medical process participated.	Basic FMEA steps followed. Sessions took between 12-16 hours to complete.	Recommendations were made but not yet implemented.	Different terminology was used; severity was identified as consequence on a descriptive scale of 1-5. Probability was described as frequency as a descriptive scale 1-4 and detectability was described as safeguard effectiveness category on a scale of 1-5 (no numerical values were assigned for the scales.	No information about how the top failures were chosen but for patient falls: from 36 failures 14 were considered high risk. Medication ordering: from 62 failures 20 were considered high risk and blood transfusion: from 59 failures, 7 were considered high risk.

Authors and year	Setting	Choice of FMEA approach	Objective/ Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Dawson *et al*, 2005	Secondary care hospital in New York, USA.	FMEA	To conduct an FMEA about the use and maintenance of preference cards used to communicate physician preferences for surgical procedures.	An interdisciplinary team including perioperative nurses, surgical technologists, pharmacists and two members of the patient safety department.	FMEA was conducted over an 11 week period and the team met weekly.	The analysis highlighted that the system is outdated and that risk of potential errors was greater than expected.	Scale 1-10 used. RPN value obtained by multiplying the average of each score.	Top five failures identified and the top two were addressed
Esmail *et al*, 2005	Secondary care hospital in Alberta, Canada.	HFMEA	To provide a framework for systematic analysis and prioritisation of areas for improvement regarding the use of intravenous potassium chloride (Kcl) & potassium phosphate.	11 members: -2 intensivists -3 respiratory therapists -2 nursing educators -2 nursing staff -2 pharmacists.	Five HFMEA steps followed. The team met every other week over a two month period	Recommendations made were implemented. Specific ICU recommendations with specified timelines were delegated to pharmacy, unit patient care managers and unit directors.	Hazard Scoring Matrix was used but no information how the scores were derived.	Scored the failure modes using the Hazard Scoring Matrix of HFMEA and working through the Decision Tree Analysis to identify the failures that require further action.

Authors and year	Setting	Choice of FMEA approach	Objective/ Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Gering *et al*, 2005	Medical Centre, Chicago, USA	FMEA/ HFMEA	Two medical-surgical inpatient facilities were to be integrated with a larger medical centre. An FMEA was conducted for the transfer process of patients.	Multidisciplinary team from nursing, emergency management, performance improvement, patient safety, infection control, transportation, physician and patient administration.	Basic FMEA steps followed but the steps were modified. The team were given a flow diagram about how the move will take place rather than they mapping it out	Three key areas of risk were identified and addressed. The recommendations were implemented in the moving plan. Patient care was not disrupted during the move.	In step four the authors used HFMEA's hazard scoring matrix but no information how the scores were derived.	No information about the RPN and the failures identified but only the top three failures were addressed.
Kovner *et al*, 2005	Home health care in New York, USA	FMEA	To conduct and FMEA for medication management process	Nine researchers including 3 nurses, a statistician, political scientist, epidemiologist, computer scientist, social worker and data manager.	Five basic steps followed but no probability scores were included.	Recommendations were made but no information about their implementation	Probability scores were not included	No information

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Kozakiewicz *et al*, 2005	Secondary care hospital in New Haven, Connecticut, USA	FMEA	To examine all the processes involved in chemotherapy ordering and administration using FMEA.	9 members: Team leader Team advisor with FMEA experience Recorder Clinical pharmacist Oncology nurse manager Staff oncology nurse Oncology clinical nurse specialist Attending oncologist. Representative from information services	No information provided.	The FMEA helped develop a uniform and safe system for ordering chemotherapeutic and adjuvant agents.	No information provided.	Mean of the RPN were calculated. The team decided to address any failures with a RPN greater than the mean.
Kunac and Reith, 2005	Secondary care hospital in New Zealand	FMEA	To identify and prioritise potential failures in the neonatal intensive care unit medication process.	8 team members: 4 management representatives 1 nurse 2 medical staff 1 pharmacist	A series of nine meetings of the panel were held throughout the study.	72 failures were identified. Top ranking issue was the lack of awareness of medication safety issues due to lack of medication safety training.	10-point scale used. Initially each member scored the failures independently, then the median RPN for every failure was used.	72 failures were identified. The team focused on the 30 failures with the highest RPN.
Lenz *et al*, 2005	University medical centre, Marburg, Germany	FMEA	To conduct an FMEA to identify the failures in a preoperative autologue blood donation process.	No information provided	No information provided, but the authors state that domain experts were interviewed to estimate the severity of the onsequences for each failure.	Three main failures were identified and addressed.	No information provided	No information provided.

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Linkin *et al*, 2005	Secondary care hospital in Philadelphia, USA	HFMEA	To examine the utility of HFMEA in evaluating the sterilization and use of surgical instruments.	8 team members but information was gathered through interviews, meetings, & published data.	Team met for a total of 26.5 hours in 19 meetings	Proposed actions were set but there is no mention of whether they were implemented or not.	No information provided	Scored the failure modes using the Hazard Scoring Matrix of HFMEA and working through the Decision Tree Analysis to identify the failures that require further action.
Saxena *et al*, 2005	Secondary care hospital in California, USA	FMEA	FMEA was applied to improve the timeliness of reporting & the timeliness of receipt by the caregiver of critical laboratory values (CLVs) for outpatients and non-critical care inpatients	A multidisciplinary team including laboratory service director, medical centre laboratory director, assistant chief administrative laboratory manager, laboratory quality improvement coordinator, information technology representative, customer service supervisor and medical director of ambulatory services.	FMEA steps followed. Initially the team met every two weeks and then meetings were scheduled on a monthly basis. No information how long the FMEA took to complete.	Actions were recommended for the failures with an RPN >250. These actions were implemented and the RPNs were lowered following the implementation of the recommendations.	Scale 1-10 used. No information provided on how the team chose the score.	Failures with a RPN of >250 were considered priorities for redesigning the process.
Apkon *et al*, 2004	Secondary care children's hospital in New Haven, USA	FMEA	To examine the impact of process changes on the reliability of delivering drug infusions.	5 members: paediatric intensivist, pharmacist, nurse, epidemiologist & quality management administrator.	No information about how the team worked together.	FMEA was used to compare an original drug infusion process with a redesigned process only.	A score of 1-10 was used and each team member assigned values and then the average scores was used to calculate the RPN	Failures with a RPN of >150 were considered the riskiest failures.

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Capunzo *et al*, 2004	Clinical laboratory in Salerno, Italy.	FMEA	To experiment with the application of FMEA on three analytical processes in a clinical laboratory (analysis of glucose, cholesterol and total bilirubin).	13 members including: -3 MDs -2 biologists -3 technologists -5 clerical/ administrative & auxiliary personnel	No information about how the team worked together	Recommendations were made and implemented. The recommendations showed a reduction in the risk priority values.	A score of 1-10 was used but unclear who scores were derived among the team members	Improvement actions were designed for the 3 failures with the highest RPN. The RPN for the 3 failures were again compared after improvements were made.
Fechter & Barba, 2004	Medical Centre in San Francisco, USA	FMEA	To conduct an FMEA for the use of infusion pumps	15 members from different departments such as nursing, nursing education, pharmacy, material services and clinical engineering.	FMEA steps followed and the team met for 1-1/2 hours on nine occasions over four months.	Recommendations were made but unclear if they implemented.	A scale of 1-4 was used. 'A lot of time was spent deciding what the numbers should be'	Failures with a PRN >32 were addressed (11 failures).
Nichols *et al*, 2004	Secondary care hospital in Massachusetts, USA	FMEA	An FMEA was conducted to determine the processes that could lead to identification of an error when using point-of-care testing (POCT).	No information provided	No information provided	FMEA results indicate that data entry was determined to be the primary source of error and barcoding was seen as the most suitable solution. Implementation and testing were being set up.	No information provided	No information provided

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Semple and Dalessio, 2004	Secondary care hospital in Waterbury, USA	FMEA	To evaluate the current practice related to the nurses' responding to alarm signals.	A team including the director of clinical engineering, the unit manager, and 3 nurses.	The basic FMEA steps were followed. Meeting were conducted weekly but duration of FMEA not stated.	Actions implemented for the top 3 failures but the RPN was not yet recalculated. Finance department assisted the team to calculate the costs of each resolution.	A scale of 1-4 was used for severity and probability scores and 1-5 for detectability scores. Initially the team tried to score the failures individually; however, they derived the scores by consensus to produce more reliable data.	The highest three scoring failures were addressed.
Singh *et al*, 2004	Primary care practice in New York, USA	FMEA-like approach	FMEA was used to estimate the impact of an electronic medical record (EMR) system.	Multidisciplinary team including physicians, nurses and administrative staff. No other information provided.	The basic FMEA steps were not followed. Instead a list of failures was compiled and then each staff member was asked to briefly comment on these failures and determine their severity and probability scores	The authors compared the high priority failures identified before and after the EMR system was implemented.	A hazard matrix developed by the authors was used and a descriptive scale of 1-4 was used. The average of RPN was used to prioritise the failures.	The top five failures before and after the EMR was implemented were highlighted but no actions or recommendations set. The RPN of some failures improved with the implementation of EMR, while the RPN of others did not.

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Uslan *et al*, 2004	No information, but the study was conducted in West Virginia, USA	FMEA	To conduct an FMEA to identify potential failures in insulin pump functions and prioritise design improvements for the blind and visually impaired people.	No information provided	No information provided	Failures were identified and recommendations were set but not yet implemented.	A scale of 1-5was used for severity, probability and detectability.	No information provided
Weeks *et al*, 2004	Medical Centre in North Carolina, USA	FMEA	To conduct an FMEA to identify the causes of patients' falls and how to avoid them	No information provided	Five basic steps followed with no details except that only severity and probability scores were multiplied together first then the highest risk failures were accessed to see if they were detectable	Main outcome was the need to educate nurses and patients. Educational material is written now in a brochure and distributed to the families and nurses.	Severity and probability scores were multiplied together first then the highest risk failures were accessed to see if they were detectable	No information provided

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
Wehrli-Veit *et al*, 2004	No specific information- but in Glendale, Arizona, USA.	FMEA	FMEA was used to evaluate the 6 different types of extracorporeal circuits for cardiopulmonary bypass.	2 perfusionist 2 manufacturer's clinical specialist 2 physicians	No information.	The FMEA demonstrated different levels of safety between evaluating 6 different routine and miniature circuit types.	Scale 1-5 used and RPN score reported as median values.	Mann-Whitney test was used to rank the difference in median RPN scores. A type I error probability value of <0.10 was considered statistically significant.
Wetterneck *et al*, 2004	Tertiary care, academic medical centre in Madison, Wisconsin, USA.	FMEA	A qualitative study to report the challenges the FMEA team faced when completing an FMEA.	Data was collected from open forum discussions by team members at the end of the FMEA, recoding of personal experiences of the facilitator and team leader, review of meeting minutes and post-FMEA structured interviews with team members.		Challenges identified included: Problems with attendance, time consuming process, level of details for failures was debated, hazard score matrix used was not suitable. Recommendations: multidisciplinary team is essential as well as an experienced facilitator. Define the scope of FMEA and limit the number of processes. Decide on the scoring scale that best suits the team.		
Win *et al*, 2004	Medical centre in Sydney, Australia	FMEA	An FMEA was conducted to identify the possible risks in a health information system called MINET.	No information provided	First four steps of FMEA followed. No actions recommended at the end.	Identification of the possible risk associated with the use of the system.	Severity and probability scores only used on a scale of 1-3.	All failures identified (13 failures) were given a hazard score but not actions recommended for any failures.
Gowdy &Godfrey, 2003	Medical centre in North Carolina, USA	FMEA	Conducting FMEA along with fall risk assessment and root cause analysis for fall prevention programme	No details who participated but team was drawn from rehabilitation services, employee education, risk management, nursing and administration staff.	No details but it took one year for the completion of FMEA.	A number of ideas were developed, piloted and implemented from combing 3 methods. No specific information on the outcomes of FMEA alone.	No information provided	No information provided

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Reiling *et al*, 2003	Secondary care hospital in West Bend, Washington, USA.	FMEA	To apply FMEA in the design process of the new healthcare facility.	No information provided	No information provided	Recommendations following the FMEA were implemented in the design process of the new healthcare facility.	No information provided	Team scored the failures as low medium or high (no numerical values were used). No information regarding the failures that were prioritised.
Burgmeier, 2002	Secondary care hospital in Ohio, USA	FMEA	To reduce risk in blood transfusions.	Representatives from: -Risk management -Blood transfusion services -Administration -Surgery -Intensive care	2 consecutive all-day sessions initially scheduled followed by 2 additional days to complete analysis 2 weeks later.	Failure modes with high priority risk values were addressed. The redesigned steps were further flowcharted and analysed.	Scale of 1-10 used and scores were averaged and entered on the worksheet. Wide discrepancy was discussed and was usually due to confusion about the scale.	The team established a cut-off point for RPNs. Failure modes with RPN ≥ 240 were addressed. (This cut-off was chosen because the team felt it could address the top 7-10 failures within the time frame set.)
Fletcher, 1997	Secondary care hospital in Ann Arbor, Michigan, USA.	FMEA	To study the use of potassium chloride.	No information provided	No information provided	Recommendations were made but no information regarding the effect of these recommendations.	Scale 1-10 used. The mean scores for probability, severity and detectability were calculated and the 3 mean values were used to calculate the RPN.	Calculated the RPN by taking the mean of the severity scores, probability scores and detectability scores for a grand mean. No further information!

Authors and year	Setting	Choice of FMEA approach	Objective/Use of FMEA	Team members	Meeting details	Outcomes	RPN calculations	RPN
McNally *et al*, 1997	Secondary care hospital in Perth, Austraila.	FMEA	FMEA was used to identify the problem areas in the ward stock drug distribution system and a unit supply individual-patient dispensing (USIPD) system.	No information provided	No information provided	USIPD system was associated with fewer errors than the ward stock distribution system.	No information provided. No mention of following the FMEA steps except for identifying failures	The 3 system aspects with the highest potential for causing an error were given the most attention (No information provided regarding the RPNs)
Williams and Talley, 1994	Secondary care hospital in North Carolina, USA	FMEA	To address the top five medication-process related failures the subcommittee brainstormed	No information provided.	Basic FMEA steps followed. No other information provided regarding the meeting details.	Solutions have been recommended for the top 4 failures but not implemented and thus no recalculation of the RPN was carried out.	Scale of 1-10 used for severity, probability and detectability scores. The failures were ranked as a group then as subgroups of physicians, nurses and pharmacists. No information on how the groups derived the scores was provided.	The 5 highest ranked RPN were addressed based on the theory that the solutions to the highest ranked failure modes also will be solutions to the less significant failure modes.

Appendix 8: Ethics approval for reliability study

NHS

Riverside Research Ethics Committee

Telephone: 0208 846 7282

Ms Nada Abel Sheb (PhD)
The School of Pharmacy
University of London
Mezzanine Floor
DMS House
Tavistock Square
London
WC1H 9JP

14 February 2007

Dear Ms Sheb

Full title of study:	**Promoting patient safety in antibiotic use using Failure Mode and Effect Analysis (FMEA)**
REC reference number:	**07/Q0401/14**

The Research Ethics Committee reviewed the above application at the meeting held on 06 February 2007.

Ethical opinion

The Committee reviewed the above study and no ethical issues were raised.

The members of the Committee present gave a **favourable ethical opinion** of the above research on the basis described in the application form, protocol and supporting documentation.

Ethical review of research sites

The Committee agreed that all sites in this study should be exempt from site-specific assessment (SSA). There is no need to complete Part C of the application form or to inform Local Research Ethics Committees (LRECs) about the research. The favourable opinion for the study applies to all sites involved in the research.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Application	1	20 December 2006
Investigator CV		

Ethics Committee (Hon) to London Strategic Health Authority

Protocol	1.0	20 December 2006
Covering Letter		20 December 2006
Letter from Sponsor		21 December 2006
Compensation Arrangements		21 December 2006
Letter of Invitation to participant		20 December 2006
Participant Information Sheet	1	20 December 2006
Participant Consent Form	1	20 December 2006
Letter from Funder		21 December 2006
Supervisor CV		

Research governance approval

The study should not commence at any NHS site until the local Principal Investigator has obtained local research governance approval from the R&D Department for the relevant NHS care organisation.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

07/Q0401/14 **Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Serena Law on behalf of
Dr Steve Yentis
Chairman

Email: Slaw@bhnt.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*
Standard approval conditions

Copy to: Dr Jason Ahn
The School of Pharmacy, University of London
29 Brunswick Square
London
WC1N 1AX

The Hammersmith Hospitals NHS

Ms Nada Abd Shebi
[illegible]
[illegible]
[illegible]
[illegible]
WC1H 0AP

Research & Development
Ground Floor
Hammersmith House
Hammersmith Hospital
Du Cane Road
London
W12 0HS
Direct Tel: 020 8383 [illegible]
Direct Fax: 020 8383 3149

Our Ref: SHEN/4001 Trust Approval Letter 22 February 2007

Dear Ms Nada Abd Shebi

Research Governance Approval

Project Title: [illegible] Failure Mode and Effect Analysis (FMEA)

Our Project Reference: [illegible]

Check Reference: [illegible]

College Reference:

This is to confirm that your protocol, plus will all necessary research governance requirements and is therefore officially recognised and approved. It will be added to the list of projects submitted to the National Research Register.

We wish you every success with the progression of this project. Please refer to reference number and by Research Governance Committee.

If you have any questions or need clarification please contact me or my senior team member, John Underhill on [illegible]. If you feel any errors or can suggest ways to make the process run more smoothly, please let me know.

Yours sincerely

Dr Rodney Cole
Director of Research Support

Appendix 9: Choosing the FMEA topic

Kindly answer the following questions for the suggested processes of care.

Process of care	Is there risk of patient harm in this process? Yes/ No/ Not sure	Do failures in this process affect patients' outcomes? Yes/ No/ Not sure	*Is the risk associated with failures in the process Catastrophic or Major or Moderate or Minor?	*Is the risk associated to patients Frequent or Occasional or Uncommon or Remote?	Can the steps of the process be graphically mapped out in a flow chart? Yes/ No/ Not sure	Are there enough experts within the trust to be able to map out the process? Yes/ No/ Not sure	Is there potential for improvements to decrease failures? Yes/ No/ Not sure
Prescribing antibiotics in renal failure (especially vancomycin and gentamicin)							
Monitoring vancomycin or gentamicin (process of monitoring levels and changing the dose)							
Prophylactic use of antibiotics (preoperative)							
Process of changing IV antibiotics to oral							
Antibiotic use in the accident and emergency department							
Management of MRSA or *C.difficile* patients							

* Catastrophic: Failure could cause death or major permanent injury Major: Failure causes a high degree of patient dissatisfaction Permanent lessening of bodily functioning, disfigurement, or surgical intervention required. Moderate: Failure can be overcome with modifications to the process, but there is minor performance loss as increased length of hospital stay or increased level of care for 1 or 2 patients. Minor: Failure would not be noticeable to patient and would not affect the delivery of the service.	*Frequent: Likely to occur immediately or within a short period (may happen several times in 1 year) Occasional: Probably will occur (may happen several times in 1 to 2 years) Uncommon: Possible to occur (may happen sometime in 2 to 5 years) Remote: Unlikely to occur (may happen several sometime in 5 to 30 years)

*Adapted from the Veteran's Administration (VA) National Centre for Patient Safety (NCPS) (http://www.va.gov/ncps/SafetyTopics/HFMEA/HFMEAIntro.pdf)

Appendix 10: Letter for the antibiotic steering group members to prioritise the FMEA topic

20th December 2006

Dear Colleague,

I am conducting research into ways to make the use of antibiotics safer, and I am asking for your help. The work forms part of my PhD at The School of Pharmacy, University of London, and is being supervised by Professors Nick Barber and Bryony Dean Franklin.

For the first part of my work, I am planning to explore the use of Failure Mode and Effect Analysis (FMEA) to improve patient safety relating to a specific process. This is a team-based, proactive technique used with the aim of identifying and preventing problems before they occur.

The first step in performing an FMEA is to select a high risk process to investigate. High risk processes are the ones in which a failure of some kind is likely to threaten patient safety. It is in the selection of this topic that I would like to ask for your help.

Attached is a table including several possible topics and the criteria with which the topic will be chosen. These topics have been identified from published articles and national and international safety organisations.

You are kindly asked to fill in the table to help me prioritise the topic that will be chosen for the FMEA. You can either E-mail me at :nada.shebl@pharmacy.ac.uk or send it by mail to the following freepost address:

Nada Atef Shebl
FREEPOST LON 5212
The School of Pharmacy, University of London
29/39 Brunswick Square
WC1N 1AX
London

If you would like more information regarding FMEA or have any questions or suggestions, please to do not hesitate to contact me at any time.

Thank you for your time and help. It is very much appreciated.

Kind Regards,

Nada Shebl.
PhD student

The School of Pharmacy

University of London
BMA House –
Door A, Mezzanine
Tavistock Square
London WC1H 9JP
United Kingdom
www.pharmacy.ac.uk

Nada Shebl
Department of Practice & Policy
Mobile: 07796445466
Fax: 020 7387 5693
nada.shebl@pharmacy.ac.uk

Appendix 11: Information sheet for participants

The Hammersmith Hospitals NHS
NHS Trust

REC Reference Number: 07/Q0401/14

PARTICIPANT INFORMATION SHEET 20/12/06	Version 1.0	Dated

1. STUDY TITLE:
Promoting patient safety in antibiotic use using Failure Mode and Effect Analysis (FMEA).

2. INVITATION:
You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask if there is anything that is not clear or if you would like more information.

3. WHAT IS THE PURPOSE OF THE STUDY?
Traditional approaches to studying the causes of adverse events focus on retrospective analysis of events that have already happened. However, there are other techniques that allow risks to be analysed prospectively, before an adverse event has actually occurred. One such technique that has recently been introduced to healthcare is Failure Mode and Effect Analysis (FMEA). However, the majority of reports of FMEA's use are from the USA, and we do not know how practical it is to use it in the NHS setting. There has also been no work published on the validity and reliability of the process.

The aim of this study is to conduct an FMEA for patients receiving antibiotics in a UK hospital and to find out whether it is practical for use in this setting. The validity and reliability of FMEA will also be addressed and tested.

4. WHY HAVE I BEEN CHOSEN?
You have been chosen because we are particularly interested in applying the FMEA tool for patients receiving antibiotics, and would like to involve the staff such as yourself who are involved with the care of such patients.

5. DO I HAVE TO TAKE PART?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect your job/ training in any way.

6. WHAT WOULD I DO IF I TAKE PART?

You will be invited to attend up to 5 group meetings alongside the other participants of the study. Meeting will be conducted weekly or fortnightly and each meeting will last for about one hour. In these meetings you will be asked to:

1. Graphically map out the process of care being studied using flow charts.
2. Identify the potential failures that may occur in each step of the process and the causes and effects of these potential failures.
3. Calculate the severity, probability and detectability of the potential failures
   (severity, probability and detectability score guides will be provided)
4. Make recommendations to decrease or eliminate these potential failures.

You will be asked, along with the other group members, if you prefer to attend meetings to calculate the severity, probability and detectability of the potential failures and make recommendations to decrease these potential failures or whether you prefer to do it outside of the meetings and send to the researcher via E-mail.

To test the reliability of the FMEA, you will be asked to calculate the severity, probability and detectability of the potential failures on two different occasions.

We will be asking several groups to complete a similar process. We will then compare the results to find out whether or not different groups draw the same conclusions.

7. WHAT IF NEW INFORMATION BECOMES AVAILABLE?

If any new information becomes available about any aspect of the study we will contact you. If you decide to withdraw you may do so, without any reason. If you decide to continue in the study you will be asked to sign an updated consent form.

8. WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

There is no intended direct benefit to you from taking part in this study. The results of the study may help improve the quality of care for patients

receiving antibiotics and may benefit the future application of FMEA in other processes of care within the NHS.

9. WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?
No personal data is required from participants in this study.

10. WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?
The results of the study will form part of my PhD project and the anticipated completion date is February 2009, at which time you can obtain a copy of the results. You will not be identified in any report/publication.

11. WHO HAS REVIEWED THE STUDY?
The Riverside Research Ethics Committee reviewed the study.

12. CONTACT FOR FURTHER INFORMATION
Your contact point for further information is:

Nada Atef Shebl.
The Department of Practice and Policy
The School of Pharmacy, University of London
Mezzanine Floor, BMA House
Tavistock Square
London WC1H 9JP

Tel: 07796445466
Fax: 020 7387 5693
Email: nada.shebl@pharmacy.ac.uk

YOU WILL BE GIVEN A COPY OF THE INFORMATION SHEET AND A SIGNED CONSENT FORM TO KEEP.

Appendix 12: Letter of invitation to participants.

14 February 2007

Dear Colleague,

I am conducting research into ways to make the use of antibiotics safer, and I am asking for your help. The work forms part of my PhD at The School of Pharmacy, University of London, and is being supervised by Professors Nick Barber and Bryony Dean Franklin.

For the first part of my work, I am planning to explore the use of Failure Mode and Effect Analysis (FMEA) to improve patient safety relating to a specific process. FMEA is a team-based, proactive technique used with the aim of identifying and preventing problems before they occur.

The FMEA topic chosen is '*The use of gentamicin and vancomycin in an acute hospital setting*. This topic has been chosen with the help of the members of the Antibiotic Steering Group at Hammersmith Hospitals NHS Trust.

You are being invited to participate in up to 5 group meetings to help us conduct the FMEA about '*The use of gentamicin and vancomycin in an acute hospital setting*. Meetings will be conducted weekly or fortnightly and each will last for one hour. With other participants, in these meetings you will be asked to:

1. Graphically map out the process of care being studied using flow charts.
2. Identify the potential failures that may occur in each step of the process and the causes and effects of these potential failures.
3. Calculate the severity, probability and detectability of the potential failures (severity, probability and detectability score guides will be provided)
4. Make recommendations to decrease or eliminate these potential failures.
5. To test the reliability of the FMEA, you will be asked to calculate the severity, probability and detectability of the potential failures on two different occasions.

You will be asked, along with the other group members, if you prefer to attend meetings to calculate the severity, probability and detectability of the potential failures and make recommendations to decrease these potential failures or whether you prefer to do it outside of the meetings and send it to the researcher via E-mail.

The information sheet provided will provide you with further details about the study and your participation.

If you would like more information regarding FMEA or have any questions or suggestions, please to do not hesitate to contact me at anytime.

The School of Pharmacy

University of London
BMA House –
Door A, Mezzanine
Tavistock Square
London WC1H 9JP
United Kingdom
www.pharmacy.ac.uk

Nada Shebl
Department of Practice & Policy
Mobile: 07796445466
Fax: 020 7387 5693
nada.shebl@pharmacy.ac.uk

Appendix 13: Consent forms for participating in the FMEA meetings

The Hammersmith Hospitals NHS
NHS Trust

Hammersmith Hospitals
Du Cane Road
London
W12 0HS

LREC Study Number:
Date: 26/11/06
Version: 1.0
CONSENT FORM

Title of project: Promoting patient safety with antibiotic use

Name of Researcher: Nada Shebl

1. I confirm that I have read and understand the information sheet (version 1.0) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that the study is completely anonymous and for research purposes only. ☐

3. I understand that the results of this study will not affect my working/ training rights in any way. ☐

4. I agree to take part in the above study. ☐

Name of Participant	**Date**	**Signature**
Name of Researcher	**Date**	**Signature**
Nada Shebl		

Appendix 14: Presentation for the FMEA teams during the first meeting

Failure Mode & Effect Analysis (FMEA) for the use of vancomycin & gentamicin

Nada Shebl
The School of Pharmacy, University of London
10th May 2007

Failure Mode and Effect Analysis: FMEA

- FMEA dates back more than 30 years.
- Was initially used in aerospace and automotive industries.
- It is a team-based, systematic, proactive technique that is used to prevent process problems before they occur.
- Has been used in the healthcare industry since the early 1990s.
- Has been widely used in the United States as its use is supported by several patient safety organisations.

FMEA steps:

STEP 1: Define the FMEA Topic: topic is usually a high-risk process.

STEP 2: Assemble the Team: An FMEA team should be multidisciplinary. This ensures that different perspectives or viewpoints are taken into consideration.

STEP 3: Graphically Describe the Process: Flowcharts are the most commonly used tool for helping teams understand the steps in a process. Identify the failures that can occur, their causes and effects.

STEP 4: Calculate the risk priority number (RPN): severity X probability X detectability.

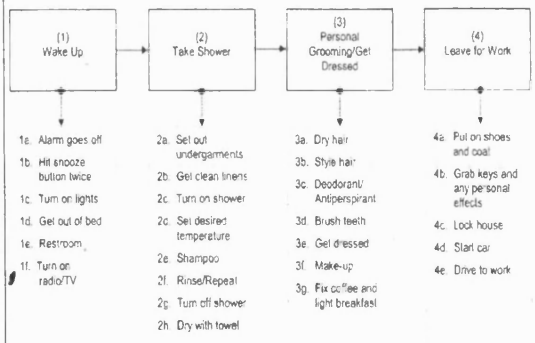
- Severity relates to the seriousness of the injury or impact that could ultimately result if an effect of a failure mode occurs.
- The probability of occurrence is the likelihood that something will happen.
- Detectability is the degree to which something can be discovered or noticed.

STEP 5: Actions and Outcome Measures: The team then makes recommendations to decrease or eliminate the failure.

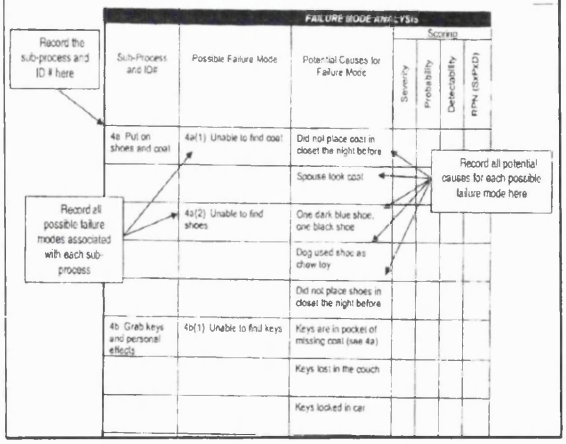
Graphically Describe the Process:

Example:

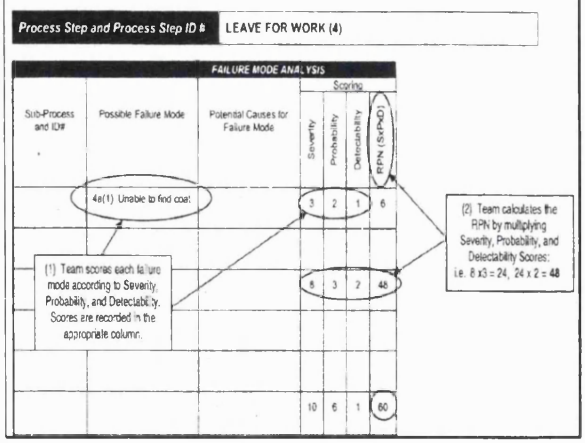
How I Start My Day.



Identify the failures that can occur, their causes and effects:



Calculate the risk priority number (RPN):



Actions and Outcome Measures:

Process Step and Process Step ID # LEAVE FOR WORK (4)

FAILURE MODE ANALYSIS

Sub-Process and ID#	Possible Failure Mode	Potential Causes for Failure Mode	Scoring: Severity	Probability	Detectability	RPN (S×P×D)	Action Plan to Prevent this Failure Mode
4a: Put on shoes and coat	4a(1): Unable to find coat	Did not place coat in closet the night before	3	2	1	6	
		Spouse took coat					
	4a(2): Unable to find shoes	One dark blue shoe, one black shoe	6	3	2	48	Store dark blue and black shoes separately in closet
		Dog used shoe as chew toy					Purchase dog bones and chew toys. Keep shoes out of reach in closed closet
		Did not place shoes in closet the night before					Move shoe storage to a more convenient location
4b: Grab keys and personal effects	4b(1): Unable to find keys	Keys are in pocket of missing coat (see 4b)	10	5	1	50	Buy key rack to mount by main entry to place keys
		Keys lost in the couch					Place keys on key rack upon arriving home. (see above)
		Keys locked in car					Have spare key made and place in secure location.

SEVERITY*		
Rating	Description	Definition
10	Catastrophic	Death of individual or complete system failure
9		
8	Major injury	Major injury of individual or major effect on system
7		
6	Minor injury	Minor injury of individual or minor effect on system
5		
4	Moderate	Significant effect on individual or system with full recovery
3		
2	Minor	Minor annoyance to individual or system
1	None	Would not affect individual or system

PROBABILITY		
Rating	Description	Potential Failure Rate
10	Very High: Failure is almost inevitable	More than one occurrence per day or a probability of more than 1 occurrence in every 2 events
9		One occurrence every three to four days or a probability of 1 in 3
8	High: Repeated Failures	One occurrence per week or a probability of 1 in 8.
7		One occurrence per month or a probability of 1 in 20.
6	Moderate: Occasional failures	One occurrence every three months or a probability of 1 in 80.
5		One occurrence every six months to one year or probability of 1 in 400.
4		One occurrence per year or a probability of 1 in 2,000.
3	Low: Relatively few failures	One occurrence every one to two years or a probability of 1 in 15,000.
2		One occurrence every three to five years or a probability of 1 in 150,000.
1	Remote: Failure is unlikely	One occurrence in greater than five years or a probability of 1 in >150,000.

DETECTABILITY		
Rating	Description	Likelihood of Detection
10	Absolute Uncertainty	Control **cannot** detect potential cause and subsequent failure mode
9	Very Remote	**Very remote** chance the control will detect potential cause and subsequent failure mode
8	Remote	**Remote** chance the control will detect potential cause and subsequent failure mode
7	Very Low	**Very low** chance the control will detect potential cause and subsequent failure mode
6	Low	**Low** chance the control will detect potential cause and subsequent failure mode
5	Moderate	**Moderate** chance the control will detect potential cause and subsequent failure mode
4	Moderately High	**Moderately High** chance the control will detect potential cause and subsequent failure mode
3	High	**High** chance the control will detect potential cause and subsequent failure mode
2	Very High	**Very high** chance the control will detect potential cause and subsequent failure mode
1	Almost Certain	Control **will** detect potential cause and subsequent failure mode

Definitions (Spath, 2003):

Failure mode and effects analysis: A procedure to identify and analyze each potential failure mode in a system to determine
- the possible effects on the process,
- the severity of each potential failure mode,
- causes of the failure, and
- the actions to be taken to repair the failure.

Failure effect: The consequences of a failure mode has on the ensuing steps and the ultimate outcome of the process. The effect is described in terms of what the people involved in the process and/or the patient might experience

Failure mode: The manner in which a failure is observed; it generally describes the way the failure occurs.

Detectability: The likelihood that detection methods or current process controls will discover and correct a potential failure mode before a patient is harmed

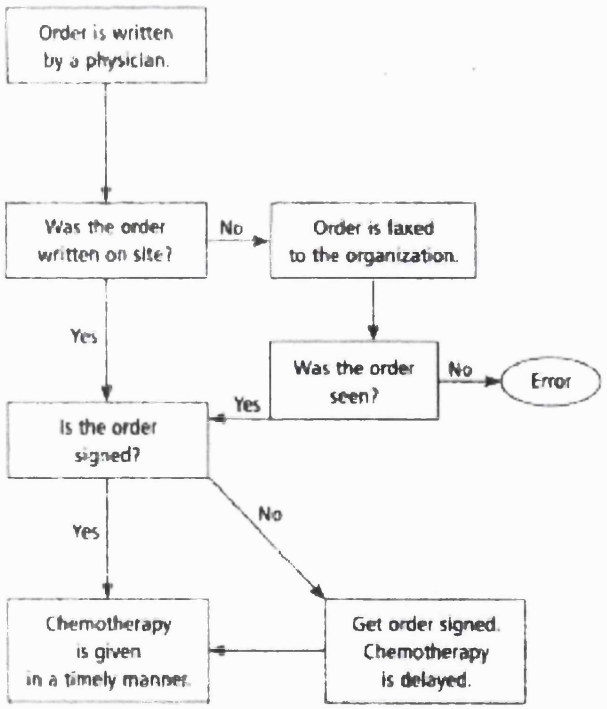
Probability: An assessment of the likelihood that a particular failure mode will happen.

Severity: The consequences of a failure as a result of a particular failure mode. Severity considers the worst potential consequence of a failure determined by the degree of patient injury that could ultimately occur.

FMEA worksheet

Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommend-ed action

Appendix 15: Examples of flowcharts used for the FMEA teams during the first meeting



Appendix 16: Group one FMEA worksheet

STEP 1: Decide if patient needs vancomycin or gentamicin (is the drug appropriate for the patient?)

Sub process	Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommended action
1a-Decide on individualised treatment plan for patient requiring vanc or gent based on: -culture and sensitivity results or -Best empirical treatment (according to doctor's judgment)	1a-Inappropriate treatment decision. 1b-Not checking culture and sensitivities (if available) before starting treatment.	1a-Lack of knowledge 1b-Different levels of experience and judgment.	1a-Therapeutic failure	7	3	3	63	*Educate the doctors & encourage them to ask questions.

STEP 2: Write prescription

Sub process	Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommended action
2a-Check renal function.	2a-Not checking renal function	*No bloods available. *Ignorance, not knowing that renal function needs to be checked.	2a-Giving patient a higher dose may lead to renal failure or worsening of renal function or ototoxicity.	7	7	3	147	*All prescriptions to be supervised by pharmacy. *Education of medical staff.

2b-Identify treatment guidelines to follow.	2b-Not following a treatment protocol at all. *Not communicating with consultant or other team members. *Selecting inappropriate initial treatment plan.	*Ignorance. *Not finding the treatment protocol online or in the ward. *Junior doctors too scared to communicate with consultant.	2b-Exposing patient to wrong drug or treatment plan but not necessarily causing harm	4	9	3	108	*All prescriptions to be supervised by pharmacy. *Educate medical staff. *Train doctors and undergraduates.
2c-Find doctor to write prescription.	2c-Not finding the doctor.	2c-Doctor very busy elsewhere.	2c-Delay in onset of treatment	3	8	4	96	*Pharmacists to become independent prescribing specialists. *More medical staff to cover wards.
2d-Write prescription	*No infusion fluid or rate mentioned. *Wrong dose. *Not considering renal function *(as 2a)*. *Unclear handwriting. *Not using ideal body weight in dose calculation (i.e. wrong dose). *Not following the right treatment protocol *(as 2b)*.	*Ignorance. *Not finding the treatment protocol online or in the ward.	* Patient given drug with wrong infusion fluid or at the wrong infusion rate. #Patient given wrong dose. Patient treated according to unsuitable protocol *(as 2b)*.	*10 #5	2 8	2 2	*40 #80	*All prescriptions to be supervised by pharmacy. *Use pre-printed specific charts for vanc and gent prescribing to accommodate all information and dose changes. *Dosing guidelines to be more easily accessible and available.
2e-Write/record treatment plan on chart or notes.	2e-Failure to document treatment plan in notes.	2e-Doctor very busy.	2e-Longer treatment days than necessary.	2	9	6	108	*Train and educate doctors

STEP 3: Administer drug

Sub process	Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommended action
3a-Nurse becomes aware of new prescription order written.	3a-Nurse not informed of new prescription order written	3a-Lack of communication	3a-Delay in finding drug and administering it. *Delay in ordering drug from pharmacy if out of stock.	2	7	1	14	*Install and use electronic prescribing.
3b-Nurse finds antibiotic.	3b-*Nurse unable to read prescription order. *Drug out of stock. *Drug out of date. *Drug sent to wrong ward. *Required drug concentration not available.	3b-illegible prescription order.	3b-Minor delay in treatment	2	8	1	16	*Pharmacists responsible to update drug stock & tidy drug cupboards. *Nurses to inform pharmacists about any missing stock.
c-Reconstitute antibiotic.	3c-Using wrong diluent for reconstitution. *Not using aseptic technique.	3c-Lack of knowledge	3c-No major effect on patient if mix up of diluents is between saline and dextrose for example (but effect may be severe if diluent as lignocaine is used by mistake- not considered here because it is very very rare)	5	2	9	90	*Train and educate nurses. *Clear labeling on bags. *Store different fluid bags separately.

3d-Administer antibiotic.	1*Wrong patient identified. 2#Patient not cannulated. 3†Wrong dose given. 4†Dose given at the wrong time. 5†Dose given at the wrong rate. 6†Wrong route of administration.	1*Nurse doesn't check patient identification. 2#Doctor or phlebotomist not available to cannulate patient. Nurse not trained to cannulate patient.	1*Giving drug to wrong patient. 2#Delay in starting treatment. 3-6†Dose may be given twice or omitted completely. Giving patient a higher dose, may lead to renal failure or worsening of renal function or ototoxicity. Giving patient sub therapeutic dose may lead to therapeutic failure	*6 #2 †4	1 8 5	2 1 5	*12 #16 †100	*Not likely to happen- but reinforce checking or use barcodes for patients. #Train nurses to cannulate. †Train nurses to follow guidelines. Use pre-made bags. Use pumps.
3e-Record administration data.	3e-Failure to recorded administration data on drug chart. *Wrong information recorded (wrong labeling).	3e-Lack of communication especially if nurse's shift changes.	3e-Dose may be given twice or omitted completely. *Makes it difficult to interpret when levels were taken and therefore affects monitoring.	3	7	3	63	*Training of nurses.

STEP 4: Monitoring

Sub process	Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommended action
4a-Doctor or pharmacists documents monitoring instructions.	4a-No documentation of monitoring guidelines.	4a-No one taking responsibility to write instructions (no specific policy).	4a-Drugs and patient not monitored. Patient suffers from side effects as decline in renal function or ototoxicity.	9	3	3	81	Drs/pharmacist should write as per hospital policy (that means clearly and legibly).
4b-Take blood from patient.	4b-Not finding a phlebotomist to take the blood. *Difficulty in withdrawing blood from patient.	4b-No phlebotomist present.	4b-Delay in taking patient's blood and thus delay in monitoring.	3	8	1	24	*All nursing staff should be able to take bloods and insert canulas as a basic feature in their care. *Phlebotomists to have 2 rounds daily rather than just one in the morning.
4c-Fill lab form	4c-Filling in the wrong form	4c-Confusion with different forms available.	4c-Sample sent to the wrong lab causing a delay.	2	8	1	16	*Use pre-filled forms. *Install & use computerised ordering or requests.

4d-Send sample to lab & lab receives sample	4d-Sample sent down wrong pneumatic tube. * Incorrect sample and form labeling. *Delay in sending sample at appropriate time.	4 d-Incorrect forms filled.	4d-Lab does not receive sample.	3	7	4	84	*Set a specimen book where all specimens are timed and dated before sending them to the lab so there is a record on the ward that its been taken and then sent. It would be difficult to manage but not very practical &time consuming. *Install & use computerised ordering or requests.

STEP 5: Lab analysis

Sub process	**Potential Failure**	**Cause of failure**	**Effect of failure**	**Severity**	**Probability**	**Detectability**	**Risk Priority Number (SxPxD)**	**Recommended action**
5a-Check for patient identification	5a-Wrong labeling on sample and/or form.	5a-Two patients with the same name also when the technician/nurse has not labeled the specimen before gathering another sample from another patient (Mislabeling by sender).	5a-wrong patient been given wrong results. *Sample may not be analysed.	3	8	1	24	*Use preprinted labels on request forms. *Educate staff responsible for sample collection.

5b-Analyse the sample.	5b-Samples analysed in batches at specific times, therefore failure to send sample at appropriate analysis time resulting in delays.	5c-Wrong form filled resulting in delays. *Analysis failure.	5b-Delays in receiving results. *Repeating analysis.	3	8	1	24	*Repeat analysis.
5c-Report results via phone or on the IT system	5c-Results not reported. *Computer system not working	5c-laboratory error or transcription error	5c-Delays in sending results	3	8	1	24	*Use computerised alarm to inform doctors/nurses whether or not lab received sample and reported results.

STEP 6: Doctor checks results

Sub process	**Potential Failure**	**Cause of failure**	**Effect of failure**	**Severity**	**Probability**	**Detectability**	**Risk Priority Number (SxPxD)**	**Recommended action**
6a-Doctor receives/checks results.	6a-Doctor does not receive results via phone nor does he/she check results on the IT system	6a-Person receiving results via phone does not inform doctor. *Doctor fails to check computer system for results.	6a-Patient treatment not modified	4	7	6	168	*Text results to doctor's pager if abnormal results. *Results could be recorded next to the record of the specimen when it was first sent. *Encourage ward clerk or nurses to record results in notes if results were received by phone.
6b-Doctor interprets results	6b-Failure to understand/interpret reported results	6b-Ignorance. * Guidelines/monogram. not available	6b-Patient treatment not modified accordingly.	7	3	4	84	*Reinforce information & education to doctors during induction.

STEP 7: Modify treatment

Sub process	Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommended action
7a-Seek advice from Microbiology/ infectious disease consultant or SpR/ or pharmacist.	7a-Failure to seek advice.	7a-Lack of knowledge.	7a-Patient treatment not modified	7	5	4	140	*Reinforce information & education to doctors during induction.
7b-Write new prescription if needed or modify existing one.	7b-Unclear changes, e.g. not crossing out wrong dose, not writing correct changes clearly. *Failure to monitor treatment changes	7b-DR in a rush not seeing that the previous drug needs crossing off	7b-Can cause confusion on the ward resulting in double doses given or no dose given at all. *Patient treatment not modified.	7	8	3	168	*Nurse giving medication should be aware of this occurrence and query Dr or pharmacist. *Have a specific section in the drug chart for vanc and gent prescribing to accommodate the variable doses and drug levels.

STEP 8: Decide to Stop or continue treatment

Sub process	Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommended action
Decide to Stop or continue treatment	8a-Failure to stop treatment when it should be stopped. *Failure to continue monitoring treatment. *Failure to continue treatment	8a-No information recorded in notes, follow up doctors unclear of treatment plan. * New drug chart written but antibiotic not written on new chart accordingly.	8a-Treatment failure and patient gets worse. *Adverse reactions.	8 *6	2 *3	3 *3	48 *54	*Reinforce education of medical staff. *Install and use electronic prescribing.

Appendix 17: Group two FMEA worksheet

STEP 1: Decide to start vancomycin or gentamicin

Sub process	Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommended action
1a-Check renal function before first dose	1a-Choosing wrong dosing regimen. *Renal function checked but not related to drug prescribing	1a-Lack of knowledge	1a-Renal function deteriorates.	2	8	2	32	*Educate the doctors about: basic prescribing information, vanc & gent & other high risk drugs, raise awareness of protocols & how to access them. *Install & use electronic prescribing. *Simplify number of protocols and guidelines available.
1b-Send sample for culture & sensitivities & screen for MRSA	1b-Not sending sample for culture & sensitivities or screening for MRSA. *Delays in sending samples. *Samples get lost & therefore not getting any results back.	1b-Ignorance *Sample lost because lab is not onsite. *Difficulty to take C& S. *Sample requests not passed on.	1b-Delayed sample results. *Treatment failure (inappropriate treatment)	4	8	10	320	*Better documentation that sample has been taken. *Standardising documentations for sample requests. *Use computerised request orders.

1c-Follow local treatment protocol	1c-Not following a treatment protocol. *Not following the correct protocol.	1c-No protocol for specified patient condition. *No one checks them. *Protocols not accessible *No printed copies. *Time constraints. *Clinicians base their treatment on their judgment and previous experiences.	1c-No major effect on patient but may lead to sub therapeutic or toxic doses prescribed (i.e. incorrect dosing)	4	8	3	96	*Simplify number of protocols and guidelines available. *Improve search engine on the Trust's intranet. *Make protocols and guidelines more easily accessible.

STEP 2: Prescribe Antibiotic

Sub process	Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommended action
2a-Calculate dose required for patient	2a-Wrong dose prescribed.	2a-Time constraints to find dosing guidelines. *Ignorance. *Using different references or following previous Trust's guidelines.	2a-Patient overdosed (toxicity) or under dosed (sub therapeutic).	5	8	4	160	*Install &Use electronic prescribing. *Pharmacy should be informed & notified. *Educating the doctors. *More frequent pharmacists available on weekends and out of hours.

2b-Write prescription empirically	2b-Failure to write prescription especially junior or locum doctors.	2b-Doctor very busy and forgets	2b-Patient doesn't get the drug and may deteriorate.	8	2	5	80	*Setting responsibilities within the team by the consultant. *Documentation of plan in patient notes, therefore detecting that an antibiotic prescription needs to be written
2c-Write prescription according to C&S	2c-Failure to write prescription especially junior or locum doctors.	2b-Doctor very busy and forgets	2b-Patient doesn't get the drug and may deteriorate.	8	2	5	80	*Setting responsibilities within the team by the consultant. *Documentation of plan in patient notes, therefore detecting that an antibiotic prescription needs to be written
2d-Write prescription according to specific treatment protocol	2d-Failure to write prescription especially junior or locum doctors.	2b-Doctor very busy and forgets	2b-Patient doesn't get the drug and may deteriorate.	8	2	5	80	*Setting responsibilities within the team by the consultant. *Documentation of plan in patient notes, therefore detecting that an antibiotic prescription needs to be written

STEP 3: Initial pharmacy review

Sub process	Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommended action
3a-Check prescription	3a-Prescription not checked	3a-Pharmacist not available when prescription was written (e.g. after pharmacy round or on weekends)	3a-Errors may be missed before drug is given to patient.	5	8	4	160	*Install &Use electronic prescribing. *Pharmacy should be informed & notified. *Educating the doctors. *More frequent pharmacists available on weekends and out of hours.

STEP 4: Administer antibiotic

Sub process	Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommended action
4a-Check patient has IV access	4a-Patient not cannulated. *Patient is difficult to cannulate.	4a-Patient difficult to cannculate-need some senior to do it. *Nurses not trained to canulate patient.	4a-Delay in onset of treatment	6	8	5	240	*Set up a special IV team. *Train more nurses to cannulate. *Improve feedback system between nurses and doctors. *Increase number of doctors on wards.

4b-Nurse obtains drug	4b-Drug not in stock. *Drug order written but nurse is not informed (especially during out-of-hours)	4b-Lack of communication between pharmacy and nurses or doctors and nurses.	4b-Delay in onset of treatment.	6	7	5	210	*Training nurses about the importance of giving the antibiotic on time. *Introduce computerized prescribing.
4c-Calculate required drug concentration and diluent.	4c-Wrong amount of diluent. *Incorrect calculations.	4c-Not following guidelines. *Not enough training or experience.	4c-May result in phlebitis.	6	6	8	288	*Training nurses. *Pharmacists should write the dilution and concentration details on drug chart.
4d-Reconstitute drug	4d-Using wrong diluent. *Not following reconstitution guidelines	4d-Not following guidelines. *Not enough training or experience.	4d-May result in phlebitis.	6	6	8	288	*Training nurses. *Pharmacists should write the dilution and concentration details on drug chart.
4e-Check patient identity.	4e-Wrong patient gets drug	4e-Nurses don't check patient identity.	4e-One patient might miss a dose and another will take an extra one.	7	3	8	168	*Emphasise importance of checking patient's identity by nurses. *Barcoding patients. *If possible, put name or hospital number on top of each bed.
4f-Administer drug	4f-Failure to administer drug at correct time *Failure to give drug correctly (wrong rate for example). *Delays in giving following doses while waiting for drug levels.	4f-very busy wards-understaffed. *Lack of knowledge and nurses not knowing the drug's properties and effects.	4f-Adverse drug reactions-if wrong rate. *Inaccurate monitoring levels if the drugs are given at the wrong time.	8	9	8	576	*Use IV pumps. *Educate nurses.

STEP 5: Pharmacy Review

Sub process	Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommended action
5a-Check prescription	5a-Prescription not checked. *Patient and chart not on ward	5a-Pharmacist not available when prescription was written (e.g. after pharmacy round or on weekends). *Patient goes for procedure & drug chart is with patient.	5a-Errors may be missed before 2nd or 3rd dose of drug is given to patient.	6	7	3	126	*Install and use electronic charts. *Pharmacists to selectively scan patients that are taking high risk drugs. * Have another copy of the patient chart on the ward incase the patient goes for a procedure or chart gets lost.

STEP 6: Monitor levels

Sub process	Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommended action
6a-Take blood	6a-Delay in taking blood. *Blood taken at incorrect time.	6a-No phlebotomist available. *Time of last dose not stated.	6a-Delay in monitoring drug levels. *Level results not reliable if blood withdrawn at incorrect time.	5	8	7	280	*Microbiology request forms to have several carbon copies to keep track of request sent to the lab.

6b-Send sample to lab & lab receives sample	6b-Wrong form filled. *Lab not onsite so delay in lab receiving sample. *Incorrect labeling.	6b-Mixing up with specific forms.	6b-Delay in receiving drug levels.	5	8	4	160	*Coordinate sample sending with lab analysis times. *Lab to be onsite- if not possible then to improve transportation of samples to other labs). *Porters to be educated about the importance of transporting the samples quickly & efficiently to avoid delays as much as possible.
6c-Lab analysis	6c-Wrong reference range used. *Delay in analysis because samples are run in batches at specified times.	6c-Chemistry lab not familiar with correct reference ranges. *Time sample was taken and last dose given are not recorded on the request forms.	6c-Delay in receiving drug levels. *Results not reliable.	6	7	5	210	*Staff not aware of out-of-hours-services provided by lab. *Train lab personnel.
6d-Lab reports results	6d-Results not reported via telephone if toxic levels. *Time lag between sending sample &receiving results. *Results not accurate.	6d-Lab not onsite. *Failure to record time sample was taken on request form &therefore can generate inaccurate results.	6d-Delays in receiving results. *Results may not be reliable or accurate.	6	10	6	360	*Educating who takes blood about the importance of recording the time the blood was taken.

6e-Act upon results	6e-Results not checked. *Not acting upon results because unable to interpret results.	6e-No one taking responsibility for checking results. *Lack of knowledge in relation to drug monitoring.	6e-The patient continues to take the wrong dose!	7	8	5	280	*Pharmacists to complete request forms. *Pharmacists mark on the drug chart using a box-shape that a level is required. *Educate staff involved in this step. *Improve IT used.

STEP 7: Review culture and sensitivity

Sub process	Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommended action
7a-Check C&S requested earlier and MRSA screening	7a-C&S and MRSA not checked.	7a-No one taking responsibility for checking results.	7a-Inappropriate or ineffective antibiotic treatment	6	8	5	240	*Education. *Receiving handwritten notes/fax from micro if it's a positive result along with micro's advice. *If results are recorded on the IT-record micro's advice as well.
7b-Request new C&S if patient not responding	7b-New C&S not requested.	7b-Doctors very busy. *Understaffing on weekends.	7b-Treatment continued without guide.	7	6	5	210	*Education. *Ensure enough staffing on wards.
7c-Act upon results	7c-Not acting upon results.	7c-No one taking responsibility for checking results. *Lack of knowledge in relation to drug monitoring.	7c-Inappropriate antibiotic treatment.	7	6	6	252	*Education *Receiving handwritten notes/fax from micro if it's a positive result along with micro's advice. *If results are recorded on the IT-record micro's advice as well.

STEP 8: Review biochemistry

Sub process	Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommended action
8a-Check renal function	8a-Not checking renal function *-Renal function checked but not related to drug prescribing.	8a-Lack of knowledge	8a-Renal function deteriorates.	8	7	5	280	*Education. *Results appear on IT system and system flags it if abnormal results to warn doctors.
8b-Send U&E to lab & lab receives sample	8b-Incorrect labeling.	8b-Forms filled in a rush.	8b-Delay in receiving results.	4	6	4	96	*Make requests via IT.
8c-Check for results	8c-Results not checked.	8c-No one taking responsibility for checking results.	8c-Inappropriate treatment continued.	5	6	4	120	*Education. *Use computers to alert doctors of results.
8d-Act upon results	8d-Not acting upon results.	8d-Lack of knowledge in relation to drug monitoring.	8 d-Inappropriate treatments continued.	7	5	5	175	*Education. *Use computers to alert doctors of results with recommendations for action.

STEP 9: Review Clinical condition:

Sub process	Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommended action
9a-Review patient response	9a-Doctors not checking on patient especially during weekend.	9a-Understaffing	9a-Clinical deterioration if patient not improving. *Continuing using the wrong antibiotic	9	6	4	216	*Better staffing during weekends. *Nurses should be encouraged to contact doctor if patient deteriorates besides recording it in the patient's notes. *Educate medical staff. *Using computerised technology to help doctors notice that there is a problem.

STEP 10: Decide to stop or continue treatment:

Sub process	Potential Failure	Cause of failure	Effect of failure	Severity	Probability	Detectability	Risk Priority Number (SxPxD)	Recommended action
10a-Decide to stop or continue treatment	10a-Stopping treatment inappropriately *Continuing treatment inappropriately #Failure to switch from IV to oral antibiotic if appropriate.	10a-IV access lost, resistance, toxicity, side effects. *Not reviewing patient condition & C&S. *Not checking patient's response.	10a-Patients may not be adequately treated. *Increased risk of line infection if IV access not required. *Increase patient inconvenience if delayed discharge if patient still on IV. *Increase hospital costs if increased treatment time without need.	a-8 *5 #5	a-6 *8 #8	a-5 *5 #5	a-240 *200 #200	*Record stop dates on drug charts. *Record indication for using antibiotic on drug chart. *Review treatment after a specific time period. *Encourage or promote IV to oral switch policy.

Appendix 18: FMEA failures and RPN.

Group one

	Failures	RPN
1	Unclear changes, e.g. not crossing out wrong dose, not writing correct changes clearly	168
2	Failure to monitor treatment changes (during monitoring)	168
3	Doctor does not receive level results via phone nor does he/she check results on the IT system	168
4	Not checking renal function (before prescribing)	147
5	Not considering renal function (when prescribing)	147
6	Failure to seek advice from Microbiology or ID consultant, registrar or pharmacist.	140
7	Selecting inappropriate initial treatment plan.	108
8	Not following the right treatment protocol	108
9	Not following a treatment protocol at all.	108
10	Not communicating with consultant or other team members.	108
11	Failure to document treatment plan in notes.	108
12	Wrong route of administration	100
13	Wrong dose given.	100
14	Dose given at the wrong time.	100
15	Dose given at the wrong rate.	100
16	Not finding the doctor to write prescription.	96
17	Using wrong diluent for reconstitution.	90
18	Not using aseptic technique.	90
19	Sample sent down wrong pneumatic tube	84
20	Incorrect sample and form labeling (for levels).	84
21	Failure to understand/interpret reported level results	84
22	Delay in sending sample at appropriate time (for levels).	84
23	No documentation of monitoring guidelines	81
24	Wrong dose prescribed	80
25	Unclear handwriting.	80
26	Not using ideal body weight in dose calculation (i.e. wrong dose)	80
27	Inappropriate treatment decision.	63

28	Not checking culture and sensitivities (if available) before starting treatment.	63
29	Wrong information recorded (wrong labeling).	63
30	Failure to record administration data on drug chart	63
31	Failure to continue treatment	48
32	Failure to continue monitoring treatment leading to adverse effects.	54
33	Failure to continue monitoring treatment leading to treatment failure.	48
34	Failure to stop treatment when it should be stopped.	54
35	No infusion fluid or rate mentioned.	40
36	Wrong labeling on sample and/or form (for drug levels).	24
37	Samples analysed in batches at specific times, therefore failure to send sample at appropriate analysis time resulting in delays.	24
38	Results (for drug levels) not reported.	24
39	Not finding a phlebotomist	24
40	Difficulty in withdrawing blood from patient.	24
41	Computer system not working	24
42	Required drug concentration not available	16
43	Patient not cannulated.	16
44	Nurse unable to read prescription order.	16
45	Filling in wrong form	16
46	Drug sent to wrong ward.	16
47	Drug out of stock.	16
48	Drug out of date	16
49	Nurse not informed of new prescription order written	14
50	Wrong patient identified.	12
	Total	**3589**

Group two

	Failures	RPN
1	Failure to administer drug at correct time	576
2	Failure to give drug correctly (e.g. wrong rate)	576
3	Delays in giving following doses while waiting for drug levels	576
4	Time lag between sending sample &receiving results	360
5	Results not reported via telephone if toxic levels.	360
6	Results not accurate.	360
7	Not sending sample for culture & sensitivities or screening for MRSA (before 1st dose is given)	320
8	Delays in sending samples (before 1st dose is given)	320
9	Samples get lost & therefore not getting any results back (before 1st dose is given)	320
10	Wrong amount of diluent	288
11	Incorrect calculations (for diluent)	288
12	Using wrong diluent.	288
13	Not following reconstitution guidelines	288
14	Results not checked (levels).	280
15	Not acting upon results because unable to interpret results (for drug levels)	280
16	Renal function checked but not related to drug prescribing (during drug monitoring).	280
17	Not checking renal function (during drug monitoring)	280
18	Delay in taking blood.	280
19	Blood taken at incorrect time	280
20	Not acting upon (C&S) results (for follow up)	252
21	Stopping treatment inappropriately	240
22	Patient not cannulated.	240
23	Patient is difficult to cannulate	240
24	C&S and MRSA not checked (for follow up).	240
25	New C&S not requested (for follow up).	210
26	Doctors not checking on patient especially during weekend.	216
27	Wrong reference range used.	210
28	Drug order written but nurse is not informed (especially during out-of-hours)	210
29	Drug not in stock	210

30	Delay in analysis because samples are run in batches at specified times.	210
31	Failure to switch from IV to oral antibiotic if appropriate	200
32	Continuing treatment inappropriately	200
33	Not acting upon results (for U &Es during drug monitoring).	175
34	Wrong patient gets drug	168
35	Wrong form filled (for requesting levels)	160
36	Wrong dose prescribed	160
37	Prescription not checked (after 1st prescription is written)	160
38	Lab not onsite so delay in lab receiving sample.	160
39	Incorrect labeling (for requesting levels)	160
40	Prescription not checked (2nd time- after drug is administered)	126
41	Patient and chart not on ward	126
42	Results not checked (for U &Es during drug monitoring).	120
43	Incorrect labeling (for requesting U &Es during drug monitoring).	96
44	Not following a treatment protocol	96
45	Not following the correct treatment protocol	96
46	Failure to write prescription empirically especially junior or locum doctors.	80
47	Failure to write prescription according to C&S especially junior or locum doctors.	80
48	Failure to write prescription according to a specific treatment protocol especially junior or locum doctors.	80
49	Renal function checked but not related to drug prescribing (before 1st dose is given)	32
50	Choosing wrong dosing regimen	32
	Total	**11585**

Appendix 19: Ethics approval for validity study

National Research Ethics Service

Riverside Research Ethics Committee

Room AW12, 8th Floor West
Charing Cross Hospital
Fulham Palace Road
London
W6 8RF
Telephone: 020 8846 [illegible]
Facsimile: 020 8846 [illegible]

Ms [illegible]
PhD Student
The School of Pharmacy, University of London
Mezzanine Floor, BMA House
Tavistock Square
London
WC1H 9JP

07 January 2008

Dear Ms [illegible]

Full title of study:	**Patient safety and antibiotic use.**
REC reference number:	**07/H0706/111**

The Research Ethics Committee reviewed the above application at the meeting held on 20 December 2007.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation.

Ethical review of research sites

The Committee agreed that all sites in this study should be exempt from site-specific assessment (SSA). There is no need to submit the Site-Specific Information Form to any Research Ethics Committee. The favourable opinion for the study applies to all sites involved in the research.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Application	1	17 October 2007
Investigator CV		
Protocol	1	15 October 2007
Protocol	2	26 November 2007
Covering Letter		12 October 2007

The Research Ethics Committee is an advisory committee to London Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within
the National Patient Safety Agency and Research Ethics Committees in England

Letter from Sponsor		10 July 2007
Letter of invitation to participant	1	08 August 2007
Participant Information Sheet: For Nurses	1	08 August 2007
Response to Request for Further Information		30 November 2007
Insurance Arrangements		31 October 2007
Supervisor CV		

R&D approval

You should arrange for the R&D office at all relevant NHS care organisations to be notified that the research will be taking place and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research at a NHS site must obtain final approval from the R&D office before commencing any research procedures.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

Here you will find links to the following:

a) Providing feedback: You are invited to give your view of the service that you have received from the National Research Ethics Service on the application procedure. If you wish to make your views known please use the feedback form available on the website.

b) Progress Reports: Please refer to the attached Standard conditions of approval by Research Ethics Committees.

c) Safety Reports: Please refer to the attached Standard conditions of approval by Research Ethics Committees.

d) Amendments: Please refer to the attached Standard conditions of approval by Research Ethics Committees.

e) End of Study/Project: Please refer to the attached Standard conditions of approval by Research Ethics Committees.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email [redacted]

07/H0706/111	Please quote this number on all correspondence

Appendix 20: Reported incidents and their corresponding FMEA failures

Reported incident on DATIX	Severity of reported incident	Likelihood of recurrence (probability) of reported incident	Corresponding FMEA failure	Severity of FMEA failure	Likelihood of recurrence (probability) of FMEA failure
1-Patient was written up for vancomycin 1g twice daily. His renal function was 23mls/min and so this dose was not appropriate. He received two doses. He should have been receiving 1g once only doses, which are given only when the levels are less than 10mg/l.	Minor- minimal harm, extra observation or minor treatment required.	Unlikely- expected to occur at least annually.	A-Not considering renal function before prescribing (group 1) OR B-Wrong dose prescribed (Group 1 and 2)	A-Severity score: 7 B- Group 1&2: Severity score: 5	A-Probability score 7 (one occurrence per month or a probability of 1 in 20 B- Group 1& 2: probability score 8 (one occurrence per week) or a probability of 1 in 8 events.
2-Patient complaint of fast heartbeat with slight tightness of a jaw, redness/rashes visible to most part of the body immediate after administration of vancomycin 1gram via bolus with just 20mls normal saline.	Minor- minimal harm, extra observation or minor treatment required.	Rare- not expected to occur for years.	Failure to give drug correctly -for example wrong rate (group 2).	Severity score: 8 (Major injury- Major injury of individual or major effect on system)	Probability score 9 (One occurrence every three to four days or a probability of 1 in 3)

Reported incident on DATIX	Severity of reported incident	Likelihood of recurrence (probability) of reported incident	Corresponding FMEA failure	Severity of FMEA failure	Likelihood of recurrence (probability) of FMEA failure
3-Noticed vancomycin injection was administered on 10/03/07 at 17:00 hrs in spite of vancomycin levels taken on the 10/03/07 at 05:00 hrs being elevated.	Minor- minimal harm, extra observation or minor treatment required.	Possible- expected to occur at least monthly.	a-Failure to understand/ interpret reported level results (group 1) b-Not acting upon results because unable to interpret drug level results (group 2)	A-Severity score: 7 B-Severity score: 7	*Group 1:* Probability score 3 (One occurrence every one to two years or a probability of 1 in 15,000) *Group 2:* Probability score 8 (One occurrence per week or a probability of 1 in 8).
4-A patient received 2g vancomycin (1g at 15:30 and 1g at 10pm on 26/4/07) within 6 hours. This patient has a creatinine clearance of 36.64 ml/min and therefore should have a dose of 1g once daily (every 24hours) as per trust policy.	Minor- minimal harm, extra observation or minor treatment required.	Unlikely- expected to occur at least annually.	A-Not considering renal function before prescribing (group 1) OR B-Wrong dose prescribed (Group 1 and 2)	A-Severity score: 7 B- Group 1&2: Severity score: 5	A-Probability score 7 (one occurrence per month or a probability of 1 in 20 B- Group 1& 2: probability score 8 (one occurrence per week) or a probability of 1 in 8 events.

Reported incident on DATIX	Severity of reported incident	Likelihood of recurrence (probability) of reported incident	Corresponding FMEA failure	Severity of FMEA failure	Likelihood of recurrence (probability) of FMEA failure
5-Patient prescribed 750mg vancomycin once daily. It was given late on 23rd and 24th April as staff assumed they had to wait for the results of the level to come back. When level taken on 25th April, this was therefore only 12 hours or so after the previous dose, level therefore "artificially" high at 16.0.	None-no harm	Not recorded	A-Delays in giving following doses while waiting for drug levels (group2). B-Level results not accurate (group2).	A-Severity score: 8- Major injury- Major injury of individual or major effect on system B-Severity score: 6- Minor injury- Minor injury of individual or minor effect on system	A- Probability score 9 (One occurrence every three to four days or a probability of 1 in 3). B- Probability score 10 (More than one occurrence per day or a probability of more than 1 occurrence in every 2 events)
6-Vancomycin level out of range significantly (level = 31.1 reference range 15-25). No change to regime made by doctor, nor prompted by nurse.	None-no harm	Not recorded	A-Failure to understand/interpret reported level results (group1) B-Not acting upon results because unable to interpret drug level results (group2)	A-7 B-7	*Group 1:* Probability score 3 (One occurrence every one to two years or a probability of 1 in 15,000) *Group 2:* Probability score 8 (One occurrence per week or a probability of 1 in 8).

Reported incident on DATIX	Severity of reported incident	Likelihood of recurrence (probability) of reported incident	Corresponding FMEA failure	Severity of FMEA failure	Likelihood of recurrence (probability) of FMEA failure
7-Patient on vancomycin 1g once daily at 20h00. Level was taken at incorrect time and pharmacy advised to do another level before dose and give next dose. Noticed the next day that the dose of vancomycin on the 16/02 had been omitted, staff under the impression level needed to be taken and come back before dose given. No problems with renal function and no need to miss dose	None-no harm	Not recorded	Delay in giving following doses while waiting for drug levels (group 2).	Severity score: 8-Major injury-(Major injury of individual or major effect on system)	Probability score 9 (One occurrence every three to four days or a probability of 1 in 3).
8-Noted on Wed 11 October, that the intravenous vancomycin dose was omitted in error on 10th October.	None-no harm	Not recorded	Neither groups mentioned omitting doses as a failure.		

9-This patient was under shared care between the oncologists and acute medicine. It was suggested on 26/4 by an Intensive Care Unit consultant to consider starting patient on vancomycin. As the pharmacist, I then documented in the notes that, should this patient be started on vancomycin they would need stat dosing, with the next dose only being given when the levels have fallen to between 5-10mg/L (this was because the patient had a creatinine clearance of 25ml/min). I later had a conversation with the oncology senior house officer to this effect and they prescribed 1g as a stat dose which was given at 5pm. The patient was then seen by the acute medicine registrar and after speaking to microbiology; they prescribed 1g twice daily, with the first dose to be given at 6am on 27/4. This dose was given, resulting in the patient receiving 2g of vancomycin within 13 hours.	None-no harm	Possible-expected to occur at least monthly.	Not communicating with consultant or other team members (group 1)	Severity score: 4-Moderate-(Significant effect on individual or system with full recovery)	Probability score 9 (One occurrence every three to four days or a probability of 1 in 3).

Reported incident on DATIX	Severity of reported incident	Likelihood of recurrence (probability) of reported incident	Corresponding FMEA failure	Severity of FMEA failure	Likelihood of recurrence (probability) of FMEA failure
10-Vancomycin 1g twice daily prescribed regularly at 8am & 8pm for this patient (for past 3 weeks). Pharmacist required level to be taken before dose this morning. Noticed that drug was in treatment area (11am) waiting to be drawn up and administered. Chart was not signed. Asked phlebotomist to take blood. Asked nurse not to give dose until after blood taken. I was informed by nurse that dose had already been given. This was not the case. Patient had received meropenem that morning but not vancomycin. At this point porters had arrived to take patient to theatres. Vancomycin must be given over 100minutes therefore no time to give before theatre. Doctor informed. Agreed patient should go to theatre without dose	None-no harm	Rare- not expected to occur for years.	Neither groups mentioned omitting doses as a failure.		

Reported incident on DATIX	Severity of reported incident	Likelihood of recurrence (probability) of reported incident	Corresponding FMEA failure	Severity of FMEA failure	Likelihood of recurrence (probability) of FMEA failure
11-Patient was admitted with admitted with infected leg ulcers. She was prescribed vancomycin 1g daily orally rather than intravenous. Two doses were not administered and the drug chart endorsed as 4 (drug not available).	None-no harm	Unlikely-expected to occur at least annually.	Wrong route prescribed-but this error was not addressed by either groups.		
12-Patient who'd come in for pseudoaneurysm repair, written up for prophylactic cefuroxime, metronidazole intravenous but vancomycin written up as 1g orally twice a day Vancomycin oral not available as ward stock and not appropriate for prophylaxis. Route of administration was not queried and one dose omitted.	None-no harm	Unlikely-expected to occur at least annually.	Wrong route prescribed-but this error was not addressed by either groups.		

Reported incident on DATIX	Severity of reported incident	Likelihood of recurrence (probability) of reported incident	Corresponding FMEA failure	Severity of FMEA failure	Likelihood of recurrence (probability) of FMEA failure
13-On handover this morning it was reported to me that the IV vancomycin had not been given yesterday morning at 11:00 hrs. On investigation the drug had indeed not been given	None-no harm	Unlikely-expected to occur at least annually.	Neither groups mentioned omitting doses as a failure.		
14-Patient prescribed vancomycin 750mg twice daily from 6th May. Vancomycin level sent on the 8th of May at 4 pm-level reported as 10.8mg/l 0n 9th May. Vancomycin level taken on 9th May was reported as 18.6mg/l (reference range 10-15mg/l). High level, drug should have been withheld-was given for further 2 days.	Minor-minimal harm, extra observation or minor treatment required.	Unlikely-expected to occur at least annually.	A-Failure to understand/interpret reported level results (group1) B-Not acting upon results because unable to interpret drug level results (group2) OR C- Failure to stop treatment when it should be stopped (group 1) D-Continuing treatment inappropriately (group 2)	A-7 B-7 C-6: Minor injury-Minor injury of individual or minor effect on system D-5	*A-Group 1:* Probability score 3 (One occurrence every one to two years or a probability of 1 in 15,000) *B-Group 2:* Probability score 8 (One occurrence per week or a probability of 1 in 8). C- Probability score 3 (One occurrence every one to two years or a probability of 1 in 15,000. D-Probability score 8 (One occurrence per week or a probability of 1 in 8).

Reported incident on DATIX	Severity of reported incident	Likelihood of recurrence (probability) of reported incident	Corresponding FMEA failure	Severity of FMEA failure	Likelihood of recurrence (probability) of FMEA failure
15-Vancomycin not given as any access at 18:00 hrs. However access obtained at approximately 19:00 and at 23:00 hours still not given when arrived to the ward.	None-no harm	Possible-expected to occur at least monthly.	Neither groups mentioned omitting doses as a failure.		
16-Patient prescribed on admissions ward gentamicin 620mg q24h based on actual body weight. The admissions pharmacist had gone home. Patient was obese and dose should have been based on ideal body weight at 450mg q24h. A level had been taken after the first dose; although time not recorded the prescriber did write take 6-14 hours after the first dose. If this was the case then it was within range after the first dose.	Minor-minimal harm, extra observation or minor treatment required.	Possible-expected to occur at least monthly.	Not using ideal body weight in dose calculation (i.e. wrong dose) (group1)	Severity score: 5	Probability score 8 (One occurrence per week or a probability of 1 in 8).

Reported incident on DATIX	Severity of reported incident	Likelihood of recurrence (probability) of reported incident	Corresponding FMEA failure	Severity of FMEA failure	Likelihood of recurrence (probability) of FMEA failure
17-Infectious diseases doctor recommended the patient to be started on imipenem and given a stat dose of gentamicin 7mg/kg. The patient was prescribed 651mg stat, as the patient weighs 93kg. As the patient is obese, the dose that the patient should have been prescribed was 525mg (rounded to 520mg or 530mg), based on the patients ideal body weight.	Minor-minimal harm, extra observation or minor treatment required.	Unlikely-expected to occur at least annually.	Not using ideal body weight in dose calculation (i.e. wrong dose) (group1)	Severity score: 5	Probability score 8 (One occurrence per week or a probability of 1 in 8).
18-Gentamicin not given. Prescribed on the 'once only' prescription side of chart.	Minor-minimal harm, extra observation or minor treatment required.	Not recorded	Neither groups mentioned omitting doses as a failure.		

Reported incident on DATIX	Severity of reported incident	Likelihood of recurrence (probability) of reported incident	Corresponding FMEA failure	Severity of FMEA failure	Likelihood of recurrence (probability) of FMEA failure
19-Gentamicin prescribed at a dose of 7mg/kg (500mg) on advice of microbiology. This is a once daily dose. Prescribed on front of chart & given at 0745 on 7/7. Prescribed again for 0700 on 8/7 but date changed and given 1700 on 7/7. This is 2 doses in 12hours. Also prescribed again for 0700 on 8/7.	Minor-minimal harm, extra observation or minor treatment required.	Not recorded	Unclear changes (for example not crossing out wrong dose, not writing correct changes clearly) (group 1)	Severity score: 7	Probability score 8 (One occurrence per week or a probability of 1 in 8).

Reported incident on DATIX	Severity of reported incident	Likelihood of recurrence (probability) of reported incident	Corresponding FMEA failure	Severity of FMEA failure	Likelihood of recurrence (probability) of FMEA failure
20-Patient was prescribed gentamicin 480mg IV. Original dosing interval was 36 hourly, but after the 1st level was taken, the dosing interval was amended to 48 hourly. A dose was correctly given at 22:10 on 26th May but another dose was incorrectly given about 12 hours later at 09:30 on the 27th May. The prescribing of the gentamicin on the drug chart was not very clear. "Give 48 hourly" was written on the drug chart, but this was not in the frequency box on the drug chart and the 8am time was still circled on the drug chart even though the dose should not have been given at 8am (only at 8pm). Gentamicin 480 mg IV was prescribed in the drug chart. Frequency was not written in the space provided. Doctors had just encircle the time 0800 and 2000 and had marked some X and squares in the prescription. I had the impression that it was prescribed twice daily. It was also given at 2000 on the 26/05/07.The prescription is confusing. There was a square mark in the 0800 dose on the 27/05/07 so I checked the gentamicin level taken on the 26/05/07 which is <1.0 and later gave it. The level was also taken before I gave at 0930 of the 27th.	Minor-minimal harm, extra observation or minor treatment required.	Likely-expected to occur at least weekly.	A-Unclear changes (for example not crossing out wrong dose, not writing correct changes clearly) (group 1) OR B-Nurse unable to read prescription order (group 1)	A-7 B-2: Minor: Minor annoyance to individual or system	A& B-Probability score 8 (one occurrence per week) or a probability of 1 in 8.

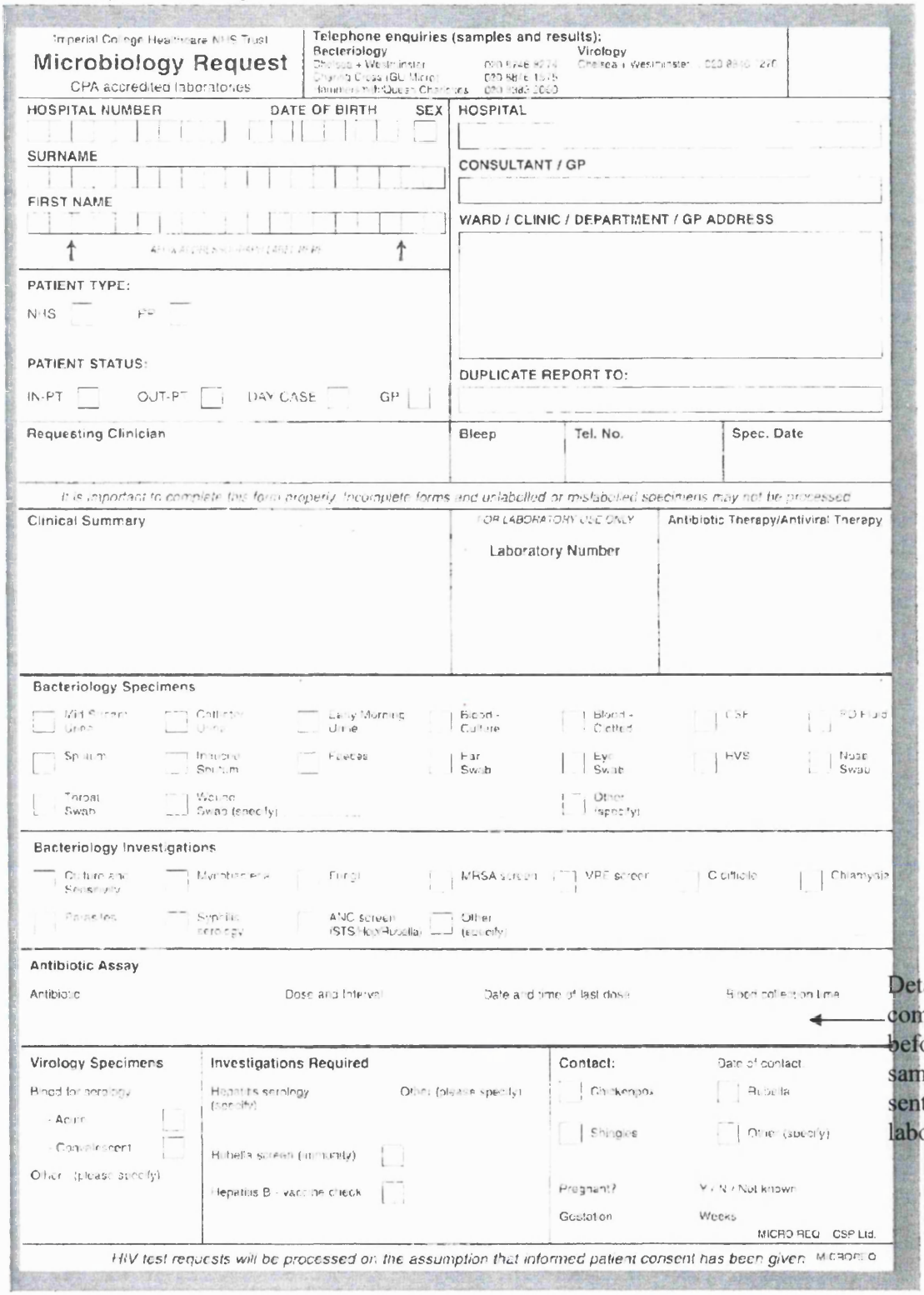
Reported incident on DATIX	Severity of reported incident	Likelihood of recurrence (probability) of reported incident	Corresponding FMEA failure	Severity of FMEA failure	Likelihood of recurrence (probability) of FMEA failure
21-Gentamicin dose not given, prescribed as once only dose. Nurses prompted to give twice, still not given 48 hours later. No reason why not.	Moderate-short term harm-further treatment or procedure required.	Unlikely-expected to occur at least annually.	Neither groups mentioned omitting doses as a failure.		
22-The patient was prescribed gentamicin 460mg intravenous once daily. The patient correctly received a dose at 22:00 hours on the 13th December. On the morning of the 14th December, the patient incorrectly received another dose of 460mg intravenous gentamicin (the dose was due to be given at 22:00 hours on the 14th December rather than in the morning on the 14th December)	None-no harm	Possible-expected to occur at least monthly.	A-Dose given at wrong time (group1) B-Failure to administer drug at correct time (group2)	A-Severity score: 4-Moderate-(Significant effect on individual or system with full recovery) B-Severity score: 8- Major injury- (Major injury of individual or major effect on system)	A- Probability score 5 (One occurrence every six months to one year or a probability of 1 in 400) B- Probability score 9 (One occurrence every three to four days or a probability of 1 in 3).

Reported incident on DATIX	Severity of reported incident	Likelihood of recurrence (probability) of reported incident	Corresponding FMEA failure	Severity of FMEA failure	Likelihood of recurrence (probability) of FMEA failure
23-Patient did not receive a dose of gentamicin, written on the Stat side of the drug chart so missed by nursing staff. Renal function normal	None-no harm	Possible-expected to occur at least monthly.	Neither groups mentioned omitting doses as a failure.		

Appendix 21: Data collection sheet.

Number	Hosp Number	Ward	Date of birth	Sex	Date of level	Pre, post, random	Level normal	result	Time sample collected	Time lab receives sample	Time level reported	Form used for request	Information on form	Are creatine clearance, weight and monitoring guidelines on chart?	Level reported on chart?	Action taken
1																
2																
3																
4																
5																
6																
7																
8																
9																

Appendix 22: Handwritten microbiology request forms for vancomycin and gentamicin



Imperial College Healthcare NHS Trust

Microbiology Request

CPA accredited laboratories

Telephone enquiries (samples and results):

Bacteriology

Virology

HOSPITAL NUMBER | DATE OF BIRTH | SEX

SURNAME

FIRST NAME

HOSPITAL

CONSULTANT / GP

WARD / CLINIC / DEPARTMENT / GP ADDRESS

PATIENT TYPE:

NHS | PP

PATIENT STATUS:

IN-PT | OUT-PT | DAY CASE | GP

DUPLICATE REPORT TO:

Requesting Clinician | Bleep | Tel. No. | Spec. Date

It is important to complete this form properly. Incomplete forms and unlabelled or mislabelled specimens may not be processed

Clinical Summary

FOR LABORATORY USE ONLY

Laboratory Number

Antibiotic Therapy/Antiviral Therapy

Bacteriology Specimens

Mid Stream Urine | Catheter Urine | Early Morning Urine | Blood - Culture | Blood - Clotted | CSF | BAL Fluid

Sputum | Induced Sputum | Faeces | Ear Swab | Eye Swab | HVS | Nose Swab

Throat Swab | Wound Swab (specify) | Other (specify)

Bacteriology Investigations

Culture and Sensitivity | Mycobacteria | Fungi | MRSA screen | VRE screen | C difficile | Chlamydia

Parasites | Syphilis serology | ANC screen (STS+HBsAg+Rubella) | Other (specify)

Antibiotic Assay

Antibiotic | Dose and Interval | Date and time of last dose | Blood collection time

Details to be completed before the sample is sent to the laboratory

Virology Specimens

Blood for serology

- Acute
- Convalescent

Other (please specify)

Investigations Required

Hepatitis serology (specify) | Other (please specify)

Rubella screen (immunity)

Hepatitis B - vaccine check

Contact: | Date of contact

Chickenpox | Rubella

Shingles | Other (specify)

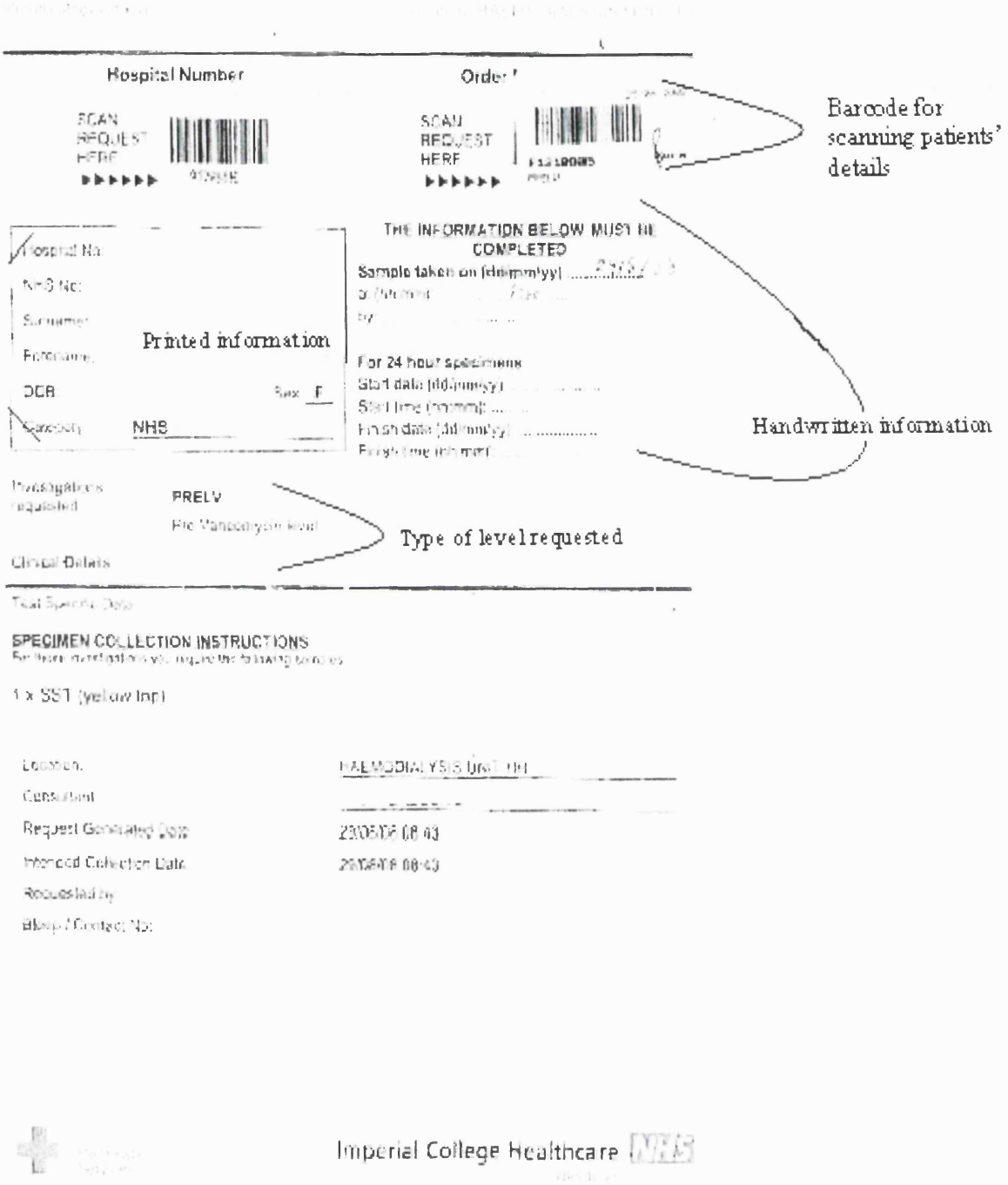
Pregnant? Y / N / Not known

Gestation | Weeks

MICRO REQ CSP Ltd.

HIV test requests will be processed on the assumption that informed patient consent has been given. MICROREQ

Appendix 23: Computerised request forms



Appendix 24: Guidelines for prescribing and monitoring gentamicin and vancomycin in the hospital

Intravenous Vancomycin

Stage	Renal Function (CrCl)	Dosage Regime ≥ 50 kg	Dosage Regime < 50 kg
5	>100 ml/min	1.25 g bd	1.25 g bd
4	61-100 ml/min	1 g bd	750 mg bd
3	51-60 ml/min	750 mg bd	1 g od
2	20-50 ml/min	1 g od	750 mg od
1	<20 ml/min	1 g STAT wait for level before repeat	750 mg STAT wait for level before repeat

Where possible prescribe bd regimes at 10am and 10pm. Document time at which level taken

Administration and monitoring for toxicity and efficacy

- Take first trough level before 3rd or 4th DOSE after start of therapy or following a change in dosing / renal function
- Aim for trough levels of 10-15 mg/L
- If level and renal function stable, repeat levels twice weekly
- For CrCl >20 ml/min do not routinely wait for levels before administration of subsequent dose
- Adjust dose/frequency of vancomycin using table below

Trough level (mg/L)	Action
>20	Omit one dose and **move down** one 'stage' in dosing regime
16-20	**Move down** one 'stage' in dosing regime
10-15	ON TARGET repeat trough level twice weekly
<10	**Move up** one 'stage' in dosing regime

- Intermittent IV infusion in 250 ml sodium chloride 0.9% or glucose 5%
- The infusion must be given at a rate no greater than 10 mg/min to prevent infusion related adverse effects. 1.25 g must be administered over 125 minutes, 1 g must be administered over 100 minutes and 750 mg over 75 minutes

Gentamicin

Renal function (CrCl)	Dosage Regime
> 40 ml/min	5 mg/kg* **OD** x 1-2 doses as **STAT Rx**
20-40 ml/min	3 mg/kg* **OD** x 1-2 doses as **STAT Rx**
< 20 ml/min	1.5 mg/kg* **STAT**

* Obese patients require a lower dose: ask pharmacy or use the dosing weight calculation in the box

Exclusions: Endocarditis, prophylaxis (e.g. urinary catheter insertion), pregnancy, children, patients with ascites, major burns, cystic fibrosis - seek specialist advice

Administration and monitoring for toxicity

- Only give >48 hrs under direction from micro/ID
- Monitoring is only required if given for >48 hrs. Then aim for trough level <1mg/L
- IV infusion in 100 ml sodium chloride 0.9% or dextrose 5% over **60 minutes**

Creatinine clearance (CrCl)

The eGFR appears with biochemistry results and can be used as a quick estimate for calculating initial doses. A more accurate estimate can be obtained using the Cockcroft-Gault equation (N=1.23 males, 1.03 females):

$$\text{CrCl (ml/min)} = \frac{\text{N} \times [140 - \text{age (years)}] \times \text{Wt}^{\#}\text{(kg)}}{\text{Serum creatinine (mol/l)}}$$

#Ideal Body Weight (IBW)

Use IBW if actual weight > 120 % IBW

IBW (kg) = 50 kg (male) or 45 kg (female) + 1 kg per cm over 152 cm

Dose Determining Weight (DDW)

Use DDW for Gentamicin and Amikacin prescriptions if actual body weight > 120% IBW

DDW (kg) = IBW + 0.4 (Actual weight - IBW)

Appendix 25: Publications

Journal articles

Shebl, N.A., Franklin, B.D., and Barber, N. (2009) Is failure mode and effect analysis reliable? *J Patient Saf.* ; **5** (2):86-94.

Shebl, N.A., Franklin, B.D., and Barber, N. (2007). Clinical decision support systems and antibiotic use. *Pharm World Sci.*; **29**(4):342-349.

Conference abstracts

Shebl, N.A., Franklin, B.D., and Barber, N. (2009). Is failure mode and effect analysis a reliable and valid technique in healthcare? Poster at the NPSA 3rd Annual UK Patient Safety Research Workshop-Implementation Science and Patient Safety. London, 16th December 2009.

Shebl, N.A., Franklin, B.D., and Barber, N. (2010). Failure Mode Effect Analysis (FMEA): What do hospital staff in the United Kingdom think of it? Poster presented in the 16th Health Services Research and Pharmacy Practice Conference, Manchester, 11-12th April 2010. Abstract published in a special edition of the International Journal of Pharmacy Practice (IJPP), June 2010; 18.