Modelling risk in healthcare based on simulation of episodes of interactions relating to patient care

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Modelling Risk in Healthcare Based on Simulation of Episodes of Interactions Relating to Patient Care

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Summary

Risk reduction processes in healthcare remain at the core of 21st century health care provision, though the continuing scale of the problem gives little room for complacency. While other areas of complex technological activity such as air transportation can demonstrate improvements in safety performance, comparable progress eludes modern healthcare. A review of risk reduction techniques within healthcare identifies that there exists a lack of tools involving simulation of risk. It has been necessary in the context of the research to establish many wholly original information structures representing healthcare activity and associated risk related interactions

This Thesis describes a new risk simulation environment for the Critical Care Unit of University Hospital, Coventry which is a 1200 bed modern acute hospital which fully opened in 2006. Available sets of patient admission/discharge information and records of patient treatment records used for cost charging together with extensive direct observation of clinical activity are used to create simulated patient episodes within the Critical Care environment. Specific patient interventions are sub divided into a series of up to 7 sub tasks which are associated with sub competencies and a linked adverse effect. Such sub competencies can be coded to reflect three levels of task complexity. Separate codes can be allocated to identify sub competencies which are supervised and sub competencies for which additional competency can be requested from other team members.

A fuzzy logic framework has been adopted to combine empirically derived mathematical functions which for a specific sub task, translate values of individual effectiveness, distraction, competency mismatch of individual/team together with the level of supervision to a specific risk value for each adverse effect. This fuzzy logic framework, referenced as the 'risk engine' has specific responses for levels of sub task complexity and can be modified by indicators relating to sub task supervision and competency sharing. In addition, each sub task/competency is associated with an adverse effect whose probability of occurrence can be reduced through identified safe working practices which are referenced as 'preventive measures'. Individual effectiveness is identified as being influenced by cirdadian rhythm, physical effort, emotional/stress effort, intellectual effort, sleep deficit and long term factors. Organisational factors influencing individual effectiveness are identified as patient admission and shift handover.

The risk simulation process is implemented within a 10 bed Critical Care Unit which utilises a specifically designed nurse rostering process for 12 hour shift periods. Sub grades of nurse skills (1 to 15) are used to structure skill mix within each rostered group and which are based on

representative nurse grades (band 5, 6 and 7). Available competencies of nursing staff for a specific sub task are allocated on the basis of sub grade value and the parameter of individual competency mismatch is derived from values of required competency and available competency for each sub task. The team competency mismatch for a specific sub task linked to a specific individual is derived from the maximum available competency within the active nursing team. Nursing staff are allocated to patients on the basis of clinical need at the start of each shift.

A novel feature of the model identifies modes of interaction between nursing individuals on a 'bed to bed' basis as relating to parameters of distraction, supervision and competency sharing and which are related to the physical layout of the active clinical area. A fuzzy logic sub system for determining values of such interaction coefficients and which uses the same design methodology as the 'risk engine' is described.

The risk simulation model is operated for a sequence of 9 months of simulated clinical activity and the outcome expressed in a number of ways including the relative occurrence of types of adverse effects based on occurrences per patient day stay. Comparison is made with the level of occurrence of locally reported clinical adverse events within the Critical Care Unit at University Hospital Coventry using the coding system of types of adverse effects of the simulation system. The lack of agreement between the two sets of data is attributed to mismatch between the basic information content of the two data sets, under reporting of the local clinical adverse incident reporting system (as confirmed with comparison with results of relevant clinical studies) and the need of further refinement in the complex process of simulation of clinical interventions. Modes of reporting of simulated risk activity are also described in the context of a normalised patient day where the resulting risk profile is related to the patterns of clinical activity simulated within the model. This replicates some of the expected characteristics of simulated data such as circadian factors and of the morning shift changeover but may indicate the need for further refinement in the process of simulation of clinical interventions.

Acknowledgements

In particular I would like to thank Professor Keith Burnham of CTAC for initially suggesting further research within the subject area of the Thesis. In addition, the valued support of Dr. Olivier Haas is acknowledged in navigating a novel area of application within clinical risk simulation. It is relevant to acknowledge the excellent team spirit and focus of constructive engagement within CTAC which has made working with this group a positive experience.

The invaluable assistance of staff within the Critical Care Unit of University Hospital Coventry is acknowledged, in particular the enthusiasm of Modern Matron Angela Himsworth and the support of Dr. Adrian Porter. The assistance of clinical staff, in particular nursing staff, is acknowledged in providing information relating to clinical practices within the Critical Care Unit. The considerable practical help provided by Sister Eunice Arnold in providing details of clinical interventions is also acknowledged. Thanks are also extended to Mr Andrew Roberts, Information Manager within the Critical Care Unit for making available data sets from the data management system of the Critical Care Unit.

The research has in particular benefitted from extensive core literature relating to risk in the Critical Care community and related areas of clinical practice. The hard work and dedication of those involved in many centres round the world is appreciated. The assistance of the staff of the Library Services within University Hospital Coventry is acknowledged for provision of an excellent service.

I would like to acknowledge the invaluable support and encouragement provided at many levels by Professor Adrian Wilson of the Department of Clinical Physics and Bioengineering. In no small measure I would also like to indicate the great help provided by my wife, Anne, towards this project.

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Nomenclature

a	Set one rule selection (1 to 5) based on value of input parameter e, equation 6.1
A0	Initial loss of individual effectiveness at the start of the shift due to handover function, equation 3.3
a_k	Value of competency assigned for an individual for specific identified competency C_k, equation 5.1
ans	Parameter value in equation 3.5 to select time of minimum value of function. Value expressed in fraction of day.
Ao	Maximum value of probability transfer function at xol=8.3333
Attend(i).	Availability of nursing co-worker i as present (1) or not present (0),equation 6.6
avail_compet	Available level of competency, range 0 to 1; equation 6.4
b	Intersection value with rule one, equation 6.1
bedoc(i)	Bed occupation status of bed i (0 or 1); i in range 1 to 10, equation 6.10
b_i	Component of competency required with competency i ; equation 5.2
bns	Parameter value in equation 3.5 to determine slope of response on either side of minimum value.
c	Set two rule selection (1 to 5) based on input parameter e, equation 6.1
c1	Time constant for recovery in handover function (equation 3.3)
'centroid'	Argument for selection of 'centroid' defuzzification technique
$C_{individual}$	Set of competencies associated with an individual within a specific clinical staff group, equation 5.1
C_k	identified competency k within a specific clinical staff group, equation 5.1
CM	Competency mismatch (generic – linear scale 0 to 10) ; equation 6.4
CmCd(1)	Supervision flag; 0 or 1; input to 'risk engine'; equation 6.11
CmCd(2)	Ability to ask flag: 0 or 1 ; input to 'risk engine'; equation 6.11
CmCd(3)	level task complexity: 1, 2 or 3 ; input to 'risk engine'; equation 6.11
CMI	Competency mismatch (individual – linear scale 0 to 10), input to 'risk engine'; equation 6.11
CMT	Competency mismatch (team – linear scale 0 to 10), input to 'risk engine', equation 6.11

c_{ncw}	Coefficient of supervision related to nursing co-workers, equation 6.7
c_{oc}.	Coefficient of supervision related to non clinical staff; equation 6.7
Comp(i)	Competency level of nursing co-worker at bed i; equation 6.6
C_{task}	Competencies associated with a specific task; equation 5.2
Cum(p(n))	Cumulative sum of all components of probability from p(1) to p(n); equation 7.3
Cumsum	Sum of all contributions of probability in the series; equation 7.3
d	Intersection value with rule two, equation 6.1
Dc (i)	Distraction coefficient of bed i - based on patient condition
Dist	Value of distraction associated with level of bed occupancy and associated levels of patient complexity (linear scale 0 to 10), input to 'risk engine'; equation 6.11
Dist_ncw(j)	Distraction parameter applicable for nursing co-worker at bed j; equation 6.10
dns	Parameter value in equation 3.5 to select minimum value of function at time where (t-ans)=0.
e	Input value to function - range 0 to 10, equation 6.1
E_{adm}	Effectiveness function of individual related to admission of a new patient
E_{eff1}	Effectiveness function of individual derived from E_h, E_{ns}, E_{sd} and E_{adm}
E_{em}	Effectiveness function of individual based on emotional/stress 'exertion' and based on task activities over a 12 hour nursing shift cycle
Eff	Value individual effectiveness (linear scale 0 to 10), input to 'risk engine'
E_h	Effectiveness function of individual related to handover of 12 hour shifts
E_{lt}	Effectiveness function for long term effects
E_{me}	Effectiveness function of individual based on intellectual 'exertion' and based on task activities over a shift cycle
EMval	Component of a discrete emotional/stress effort associated with an intervention; equation 3.7
EMwgt	Relative weighting factor associated with element of emotional/stress effort; equation 3.7

E_{ns}	Effectiveness function of individual based on night shift Circadian component.
E_{ph}	Effectiveness function of individual based on physical exertion and based on task activities over a shift cycle.
E_{sd}	Effectiveness function of individual due to sleep deficit value
Fask(j)	'Ability to Ask' function as probability that staff member j will ask for assistance from other nursing co-workers ; equation 6.6
Fract	Fraction of time available to nursing co-worker to assist with supervision; equation 7.1 & 7.2
Fz1comp	Fuzzy look up function, effectiveness/distraction for complex tasks; equation 6.11
Fz1int	Fuzzy look up function, effectiveness/distraction for tasks of intermediate complexity; equation 6.11
Fz1low	Fuzzy look up function, effectiveness/distraction for tasks of low complexity; equation 6.11
Fz2	Fuzzy lookup function for individual and team competency mismatch; equation 6.11
Fz3comp	Fuzzy look up function for modified individual effectiveness and modified competency mismatch for complex tasks; equation 6.11
Fz3int	Fuzzy look up function for modified individual effectiveness and modified competency mismatch for tasks of intermediate complexity; equation 6.11
Fz3low	Fuzzy look up function for modified individual effectiveness and modified competency mismatch for tasks of low complexity; equation 6.11
Fz4	Fuzzy look up function for likelihood of adverse effect and supervision factor; equation 6.11
Grad	Parameter value which scales probability transfer function; equation 6.5
hr	Value in hours
Intr	Intrinsic flag value : (default 0), input to 'risk engine'; equation 6.11
M1	Constant driving competency mismatch value; equation 6.4
Max_look_up_comp	Maximum available team competency value; equation 7.2
maxv	Function derived from maximum of separate intersections of output fuzzy functions prior to defuzzification
MEval	Component of a discrete intellectual effort associated with an intervention; equation 3.8

MEwgt	Relative weighting factor associated with element of intellectual effort; equation 3.8
mf	Specific output intersection function as output of Mamdani fuzzy function; equation 6.2
Nsup	Component of supervision from nursing co-worker; equation 6.9
OutAE	output likelihood (range 0 to 10) from 'risk engine'; equation 6.5
$Output_{cent}$	Output value from defuzzification process (centroid mode); equation 6.3
p(i)	Value of likelihood of adverse effect of element (i) for interval of probability value; equation 7.3
PHval	Component of a discrete physical effort associated with an intervention; equation 3.6
PHwgt	Relative weighting factor associated with element of physical effort; equation 3.6
Prob_atn	Mean probability estimation value (equation 7.1 & 7.2)
Req_compet	required level of competency (range 0 to 1) ; equation 6.4
res	Recovery coefficient associated with emotional/stress effort, equation 3.7
rme	Recovery coefficient associated with intellectual effort, equation 3.8
rph	Recovery coefficient associated with physical effort, equation 3.6
s	Output rule which 'fires' in basic Mamdani fuzzy function; equation 6.2
Sep_comp(i,j)	Probability value that competency is shared between nursing co-worker at bed j and nursing co-worker at bed i; equation 6.6
Sep_dist(i,j)	Probability value of distraction between nursing co-worker at bed j and nursing co-worker at bed i; equation 6.10
Sep_sup(i,j)	Probability value of supervision between nursing co-worker at bed j and nursing co-worker at bed i; equation 6.8
Sf(i)	supervision factor associated with a specific nursing c-worker i
Sncw(j)	Contribution to supervision from nursing co-worker j and derived from interactions from other nursing co-workers, equation 6.7
So	Contribution to supervision from other clinical staff (non nursing)
Stat	Status flag of risk computation, output from 'risk engine'
Step	Interval value of output likelihood, equation 6.5

Subg	Sub grade level of non specific nursing co-worker (in range 1 to 15)
Subg(j)	Sub grade level of nursing co-worker j (in range 1 to 15)
Sup	Value of supervision specific to a given individual (linear scale 0 to 10), input to ‘risk engine’; equation 6.11
Sv(j)	Combined supervision value nursing co-worker for bed j based on contributions from nursing co-workers and other clinical staff
t	Value of time
t(i).	Indication if bed is active/non active or if the staff member present/not present – value 0 or 1; equation 6.8
Team_Max_Comp(j)	Maximum available team competency for staff member j relative to a specific competency; equation 6.6
t0	Reference time value
tx	Range of x function value (default 0 to 10) for defuzzification process, equation 6.3
y	Value of intersection with selected rule in basic Mamdani fuzzy function, equation 6.2
Y	Output value of probability transfer function (transforms a value in range 0 to 10 to an absolute probability value in range 0 to 1); equation 6.5
Z1(n)	Output value of input X and rule n; table 6.1
Z2(n)	Output value of input Y and rule n; table 6.1

Glossary A: Terms Related to Risk and Clinical Risk

Adverse effect	*An outcome related to a sub task which increases or has the potential to increase the risk of the patient and which is defined within the risk simulation system described in this Thesis*
Adverse event	*A generic description of an incident in which has resulted in harm to a person*
Clinical adverse event	*An occurrence which is registered using the formal system of identification of unsafe clinical practice within UHCW NHS Trust and is part of a national system for reporting of such events.*
Clinical risk	*Clinical risk is an avoidable increase in the probability of harm occurring to a patient*
Clinical Risk management	*Systematic identification and reduction/elimination of clinical risk*
Harm	*Injury (physical or psychological) disease or death*
Near miss	*A clinical or non-clinical incident where no immediate harm, loss or damage was suffered but if not investigated could be repeated*
Risk	*'A combination of the likelihood of an occurrence of a hazardous event or exposure(s) and the severity of injury or ill health that can be caused by the event or exposure(s)' (British Standards Institution 2007c)*
Sentinel event	*An occurrence that harmed or could have harmed a patient as referenced within the SEE study (*Valentin *et al. 2006).*

Glossary B: Acronyms

ABGS	*Arterial blood gas sample*
A&E	*Accident and Emergency*
APACHE	*Acute Physiology and Chronic Health Evaluation*
APS	*Acute physiology score*
C2ITU	*Intensive care unit within Walsgrave Hospital (functioning till July 2006)*
C5ITU	*Intensive care unit within Walsgrave Hospital (functioning till July 2006)*
CAE	*Clinical Adverse Event*
CCU	*Critical Care Unit*
CMV	*Controlled Mechanical Ventilation*
CNSI	*Critical Care Nursing Situation Index*
CPAP	*Continuous positive airway pressure*
CPOE	*Computerized Physician Order Entry*
CTAC	*Control Theory and Applications Centre*
CVP	*Central venous pressure*
CVVH	*Continuous veno-venous hemofiltration*
C&W	*Coventry and Warwickshire (Hospital)*
ECG	*Electro cardiography*
EEG	*Electro encephalography*
ENT	*Ear, nose and throat*
EOG	*Electro oculography*
ET	*Endotracheal tube*
EVD	*Extra ventricular drain*
FMEA	*Failure mode and effects analysis*
GI	*Gastro Intestinal*
ICNARC	*Intensive Care National Audit & Research Centre*
ICS	*Intensive Care Society*
ICU	*Intensive Care Unit*
ICUSRS	*Intensive Care Unit Safety Reporting Study*
ID	*Identification*
IMV	*Intermittent mandatory ventilation*
ILT	*Immediately life threatening*
ITU	*Intensive Therapy Unit*
IV	*Intravenous*
MESH	*Managing Engineering Safety Health*
MDD	*Medical Devices Directive*

MHRA	*Medicines and Healthcare Regulatory products Agency*
MRSA	*Methicillin-resistant Staphylococcus aureus*
NHS	*National Health Service*
NASA	*National Aeronautics and Space Administration*
NICE	*National Institute of Clinical Excellence*
NLT	*Non life threatening*
NPSA	*National Patient Safety Agency*
PCA	*Patient controlled analgesia*
PICU	*Paediatric intensive care unit*
PEEP	*Positive end expiratory pressure*
PRA	*Probabilistic risk assessment*
QS	*Quality Sentinel*
RCA	*Root Cause Analysis*
RCN	*Royal College of Nursing*
RFID	*Radio frequency identification device*
SAPS	*Simplified Acute Physiology Score*
SEE	*Sentinel Events Evaluation*
SIMV	*Synchronized intermittent mandatory ventilation*
SLT	*Secondary life threatening*
TISS	*Therapeutic Intervention Scoring System*
TPN	*Total parenteral nutrition*
USA	*United States of America*
UTI	*Urinary tract infection*
VAP	*Ventilator acquired pneumonia*

Chapter 1: Introduction

1.1 Background

In spite of numerous initiatives to target a reduction of incidence of medical errors, the scale of the problem of 'avoidable' adverse incidents remains significant. The publication, for example, of the Institute of Medicine report in 1999 (Institute of Medicine 1999) which claimed that between 44,000 and 98,000 people die each year in American hospitals due to avoidable medical error provided a strong focus to improve healthcare safety. The publication of the report also drew attention to the unsatisfactory nature of many of the systems which had been developed within modern healthcare. At the same time, the immensity of the task to put in place systems designed to improve the safety of healthcare practices was also recognized.

Literature relating to Clinical Risk in all its aspects is very extensive but typically reflects the enthusiasm and conscience of individuals and small teams rather than of well funded research groups. Research into Clinical Risk is not 'big science'. The development of the risk model subsequently described draws from a wide range of peer reviewed publications and from observations within the Critical Care Unit at University Hospital, Coventry.

The impetus to improve healthcare, however, has not at the same time led to significant development of models of health interaction that seek to enhance understanding of 'why clinical incidents happen'. Hospitals do not develop models of clinical risk based on identifying all possible adverse outcomes of the associated clinical activity. Specific areas may be reviewed as part of 'Clinical Audit' but this is more the objective assessment of outcomes than the determination of background level of potential clinical risk. Reduction of clinical risk by all relevant means, however, remains at the core of modern Acute Trust Clinical policies.

Key data sets created routinely within the Critical Care Unit at University Hospital, Coventry have been extensively utilised to structure activity models and develop associated risk models. These data sets relate primarily to admission/discharge data and details of patient interventions. In addition, extensive time has been spent observing operational activities and interviewing associated clinical staff.

1.2 Aims and Objectives

The aim of this research is to develop and justify a model of risk simulation based on clinical interventions within a Critical Care Environment. A linked objective of the research is to look for structural factors within risk causation which conventional risk reduction techniques have failed to quantify effectively.

1.3 Outline of Thesis Structure

The existing extensive literature relating to clinical risk does not look to simulation models of health care activity for its current solutions. The process of structuring and implementing the risk model has essentially involved researching, creating and developing almost all of its key components rather than developing or refining already established elements.

Chapter one of the Thesis provides an overview of the various elements of the research and how elements from the various chapters are used to develop the risk model. A perceived requirement of this process is to express the activity of the Critical Care Unit within a framework of discrete patient interventions which, as far as possible, replicate the natural variations of workload, level of patient care and staff utilisation. In addition, a set of associated possible adverse effects linked with such interventions is also identified. The risk model seeks to simulate periods of clinical activity and identify the base level of simulated adverse effects. The risk model can be simulated for variations in a wide range of input parameters to the model.

Chapter two of the Thesis contains the core literature review which links to subsequent chapters. This review is naturally dominated by medical literature referencing clinical risk within the Critical Care environment. Most references dealing with clinical risk, however, relate to clinical risk as a process where outcomes are linked to specific changes in work practice, such as administration of medication, clinical management or the use of specific drugs/equipment. This deterministic approach which quantifies the benefit of finite changes to patient care does not at the same time lead to the development of models to simulate a broad spectrum of associated risks.

Clinical research is naturally driven by the wish to improve patient care. Such deterministic studies, will therefore provide guidance on the relative merits of specific approaches to patient care. The knowledge base that this represents is disseminated widely within the existing medical literature. While this medical literature does not provide any real focus for developing risk models, it does describe the nature and relative occurrences of adverse incidents within the Critical Care environment.

This provides valuable insight into elements of risk model development. It is apparent, also, that this subset of literature suffers from inconsistency in definitions of even basic terms which describe the nature and causal factors associated with clinical risk. Elements also included within the literature of this chapter relate to basic aspects of the links between gaps in competency and levels of errors in work practice and also factors such as fatigue and sleep deprivation which can reduce individual effectiveness. Risk reduction initiatives within other sectors such as transportation and industrial are also referenced. In addition, applications of fuzzy logic for risk determination are described.

The approach described in this Thesis relates to representing risk as a sequence of values associated with highly detailed structured activity and involving complex interactions between functions associated with such activity. Such an approach has not been encountered within the literature search undertaken.

Chapter three seeks to identify factors which can affect individual effectiveness within the clinical work environment. This chapter draws from wide collective experience within the clinical literature of factors which can affect individual performance. The most relevant of these factors were identified and formulated within empirically derived mathematical functions to allow them to be incorporated within the risk model. Specific key elements are identified as:

- Circadian rhythm day shift and night shift working
- Effects related to handover at start/end of nursing shift and for admission of new patient
- Effect due to sleep deficit
- Level of physical fatigue based on task activity
- Level of emotional/stress fatigue based on task activity
- Level of intellectual fatigue based on task activity
- Long term effects

Factors which relate to depletion of individual effectiveness as a result of undertaking interventions have been identified with each intervention. These include factors relating to physical effort, emotional/stress and intellectual effort. As a specific member of staff undertakes a sequence of such interventions, these factors will be depleted and the individual's effectiveness thus altered. Individuals are also allocated a recovery rate for each parameter. References to such 'depletion' modes are more developed within the literature describing 'job shop' models but are not a typical feature within current medical literature.

Most referenced literature in this context describes the involvement of components such as shift pattern, sleep deprivation and task difficulty as influencing individual effectiveness. Such inferences appear, however, not to be carried forward within the literature to define any form of model development that would predict quantitative variations in individual performance. This literature,

however, has been used to empirically identify a range of mathematical functions to quantify variations in individual performance within the work environment and related to the listed parameters. The relevance of these functions are subsequently reviewed in the context of their role in risk simulation scenarios.

Chapter 4 of the thesis identifies patterns of clinical activity within an existing Critical Care unit. This is chiefly facilitated by access to data relating to patient admission/discharge episodes and details of clinical interventions undertaken on a daily basis for all patients. Details of routine patient interventions have been identified by direct interview of a cross section of staff members of the Critical Care unit including Nursing staff, Medical staff, Dieticians and Pharmacists and Radiographers. Such direct contact is identified as an essential component of the information collection exercise. Data relating to clinical activity has been used from July 2006, which co-incides with the opening of the new integrated Critical Care Unit within the new University Hospital, Coventry. A summary of data sets used is outlined in Appendix 1.

Analysis of patterns of actual admission/discharge data allows the generation of simulated sets of such data over specific time intervals. Such patterns of simulated activity are validated against the intrinsic characteristics of the original data set. Similarly, using the extensive sets of information relating to clinical interventions, sets of simulated interventions can be generated for patients as a function of specialty and severity of illness.

The process of replicating episodes of care of individual patients relates to determination of sets of possible interventions and the pattern/frequency of such interventions within the unit. The determination of such interventions has been undertaken by direct observations within the critical care department and analysis of TISS (therapeutic intervention scoring system) data, as records of interventions undertaken on each patient on a daily basis. The analysis of intervention based data is highly complex and includes strong dependencies, for example, between the ventilation status of patients and the level of associated interventions. The replication of interventions based on this complex data set has been implemented within a specific Matlab programme where interventions are allocated to 5 minute ‘slots’ within 24 hour periods (288 ‘slots’ per day).

Chapter 5 of the thesis outlines the basic concept of the structuring of an intervention into a set of elements linking required level of competence, identified competency item, associated adverse effect if the specific task/competency is inappropriately undertaken and also linked ‘preventive measures’. This approach is partly derived from observations in the literature of specific adverse incidents which can be associated with components of competency gaps in undertaking a specific clinical intervention. A specific intervention can identify up to seven specific competencies, each of which is associated with a specific ‘adverse effect’ and required level of competency. Specific tables of available competencies are identified with each staff group such as nursing or medical. Individual

competencies have values between 0 and 1. Within these tables, there is further identification of available levels of competency at different levels of staff grade. For band 5, 6 and 7 nurses a series of 5 sub levels are identified to cover the range of competencies within each band.

At this stage it was also identified that competencies need additional definition in relation to pathways within the 'risk engine' used to calculate levels of risk. These factors have been identified in relation to:

- Team component flag (is the task supported by the team?)
- Supervision flag (is the task able to be supervised?)

In addition, chapter 5 describes studies of risk causation within Critical Care Units which provides a framework for establishment of the 'risk engine' within chapter 6.

Chapter 6 of the Thesis develops the components of a 'risk engine' used to evaluate the specific values of likelihood of 'adverse effects' associated with each competency element within an intervention. Use is made of a conventional two-input single output Mamdani fuzzy function to construct the specific computation pathways. The inputs tend to be balanced opposites such as 'effectiveness' and 'distraction' with the output of 'modified effectiveness'. At an early stage in the design of the 'risk engine' factors within the structure of the 'risk engine' were identified to take account of components such as the degree of optimisation of protocols and the organisational cohesion of the clinical group but are not included in the core risk model used. This is referenced in greater detail in section 6.2. A range of functions have been derived based on fuzzy rules membership functions to implement the component Mamdani functions within an identified risk model. The function of the 'risk engine' has been extensively tested using a range of input parameters to validate its operation.

Chapter 6 also integrates together the various elements of the risk simulation processes and develops further the elements introduced in previous chapters. Figure 1.1 summarises the essential structure of the 'risk engine' utilised to structure the risk simulation process.

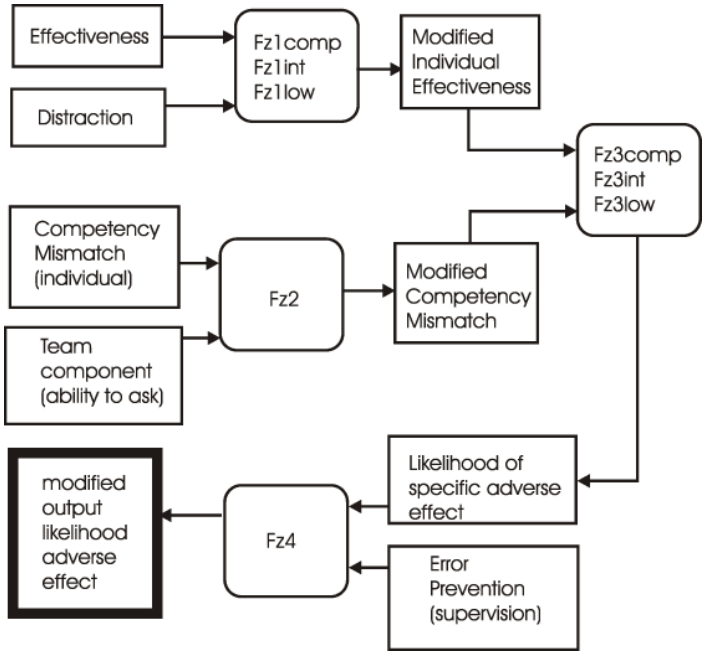

Figure 1.1. Essential relationships within the defined model of the 'risk engine' used for risk simulation.

Figure 1.2 summarises the various strands of input that feed into the risk engine. This process of definition of variables within the risk simulation system is necessary so that all aspects of the model are appropriately defined. The complexities of the simulation process arise from the large number of variable states that require to be functionally defined.

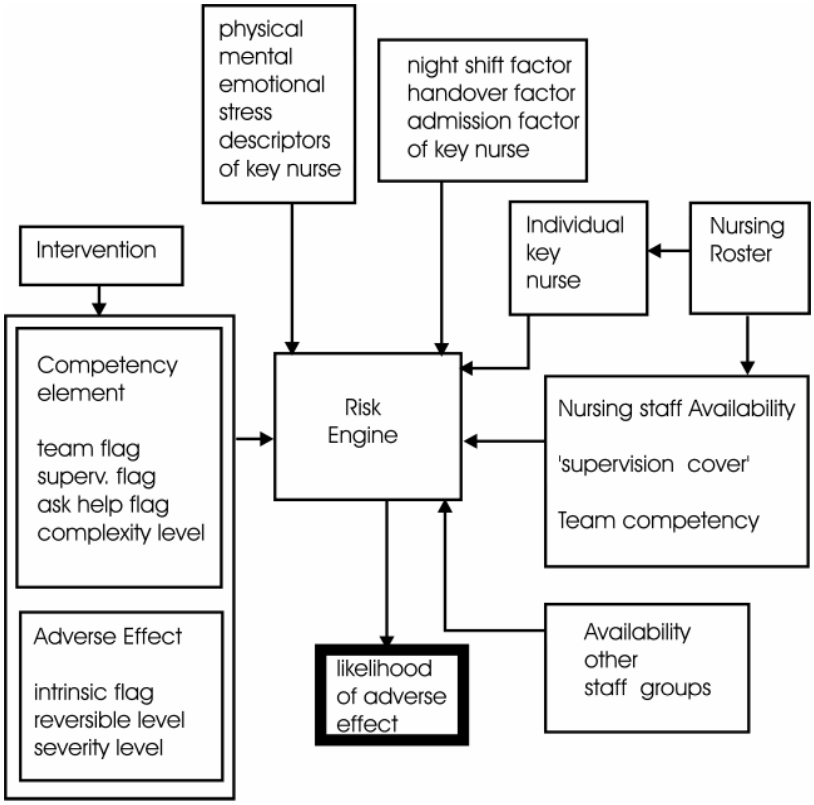

Figure 1.2. Input elements of the 'risk engine'.

Functions are introduced to model staff effectiveness including physical, emotional/stress and intellectual reserve factors. Additional structure of handover/admission functions are defined. Functions are described for nursing supervision and distraction based on patterns of clinical workload and staff allocation.

At this stage of process definition it becomes evident how the physical layout of a Critical Care Unit can influence factors relating to competency sharing, supervision and distraction. Design factors which minimise time spent 'out of unit', for example for the stores/consumables function and which also improve 'quality' of 'person to person contact' for competency sharing and supervision are seen to quantitatively improve patient care by reducing risk estimations.

While the Critical Care Unit at University Hospital, Coventry, has a full bed complement of 26 beds, this is structured within sub units of 8, 8 and 10 beds. A system for allocation of staff roster for nursing staff is defined to simulate the activity of 10 beds based on the existing 10 bed sub unit within the Critical Care Unit. Core sets of admission/discharge episodes are simulated based on historical patterns of activity between July 2006 and August 2008 as outlined in Appendix 1. This is matched with simulation of patient interventions based on patterns of critical care activity. Finally the output adverse effects are simulated as an output of the model.

Chapter 7 outlines processes undertaken to evaluate the performance of the risk simulation model with sub sets of simulated intervention data and associated admission/discharge data. This process identified characteristics of the internal functioning of the risk model and also how risk estimations alter for variation of factors such as the competency mix of staff groups. The key focus related to simulation of nurse based activity since this was identified with the majority of patient interventions and this represented the most complex level of functional interactions within the risk model. Chapter 7 also identifies the outcomes of simulation results with respect to the relevant medical literature and the records of Clinical Adverse Events linked with the Critical Care department.

Chapter 8 reviews the findings of the research and outlines areas of further work.

Figure 1.3 identifies the main processes of the research project, indicating the processes of structuring/simulating patterns of clinical activity and processing within the derived 'risk engine'.

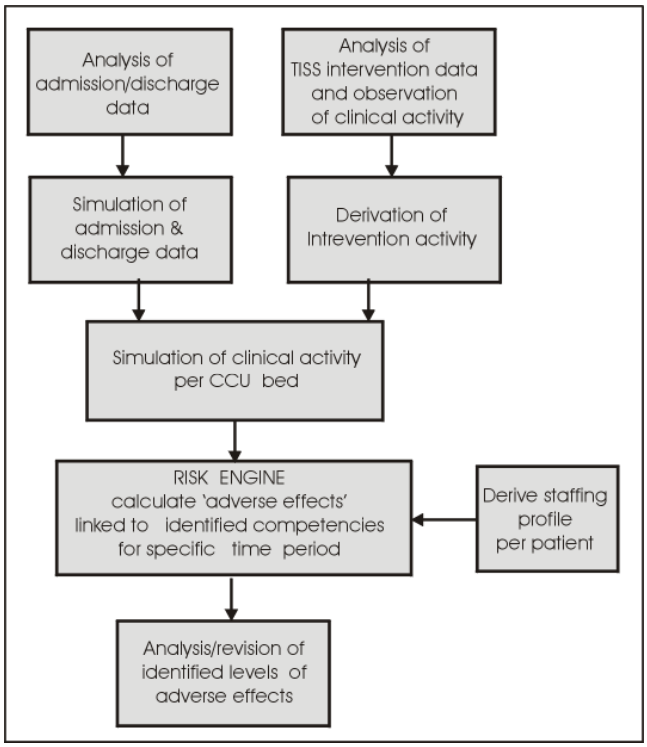

Figure 1.3. Main processes of the research project.

1.4 Focus of Risk Prevention as a Risk Management Tool

A dominant component of risk culture within the NHS and Healthcare is in general that key improvements take place as a response to breakdown or failures in systems of care. Key examples of this mechanism are the Bristol Enquiry (Bristol Royal Infirmary 2001) and the Allitt enquiry (Department of Health 2004a) where significant markers for change were based on a response to situations of significant failure.

This contrasts with the approach in this research which relates to developing a risk model based on identifying risk before it actually manifests. This method of analysis could be described as the 'pre-mortem' approach compared with the 'post-mortem' approach. The terminology of the 'premortem' process has been identified by recent business circles in the USA as a viable risk assessment process within the facilitation of new business start-ups.

1.5 Evidence Based Medicine and Simulation Techniques

The basis on which medical 'progress' has largely been developed has been 'evidence based medicine'. This is illustrated in figure 1.4 where in a notional study of data relating to factors a) to f) are collected under controlled conditions and possible correlations are identified between indicated specific data sets.

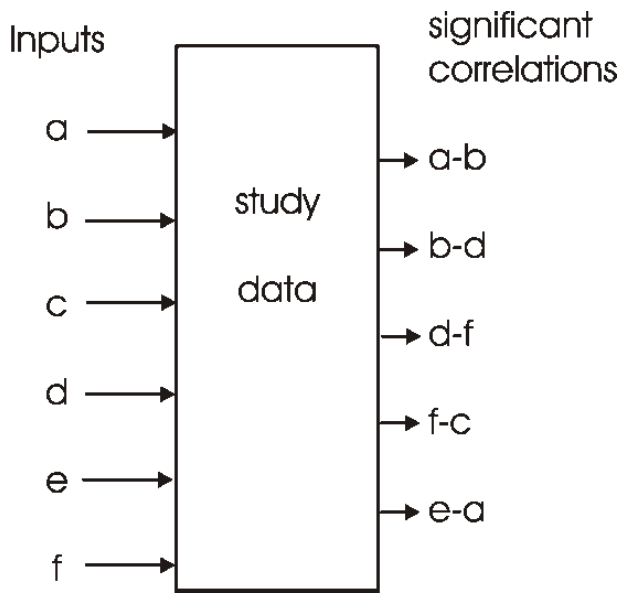

Figure 1.4. Data structure of typical evidence based medicine study.

The scope of such studies can be limited by the number of input factors that can be reliably collected. In addition, there is an inherent level of uncertainty/error in the data which is collected. Also, there may be limitations in the size of data sets of the defined data items that can be collected, based on the levels of activity of the sampled process. This latter factor confirms the advantage of pooling data from several similar clinical groups either in the same country or internationally.

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The levels of complexity identified within this Thesis based on simulation techniques identify the inherent limitations of the approach of 'evidence based medicine' where there are a significantly larger number of variables which may be difficult to define objectively and hence to incorporate into research.

It is prudent to ask why have models of 'predictive risk' not been more highly developed within the clinical environment. In part, it may not be apparent how such models of risk could be designed, populated by data and operated within a simulation environment. This may be due to the high level of complexity of data structures and of computational data processing required within the simulation process. The resource of peer reviewed medical literature, however, has been an invaluable resource to assist in structuring of the risk model and associated reports and especially of the basic 'risk engine' structure as outlined in chapter 6.

1.6 Summary of Contributions

The following key contributions are identified:

- The identification and implementation of the concept of expressing levels of clinical risk within a specific clinical environment with expression as finite probabilities of occurrence.

- Structure of patient care as a series of interventions and where interventions are described at the level of sub tasks which are associated with linked levels of competency, adverse effects and also preventive measures.

- System for simulation of clinical activity based on admission/discharge data and analysis of clinical intervention data. This consists of two main components of admission/discharge details : date time admission and date time discharge, specialty etc. and interventions associated with specific admission/discharge episodes

- Derivation of competency mismatch function to describe gap between available competence and required level of competence and implementation of concept of team competency levels.

- Development of empirical effectiveness functions to structure the ‘individual effectiveness’ value of clinical staff with component functions relating to circadian rhythm, physical exertion, intellectual exertion, stress, shift handover, influence of admission of patient and sleep deficit.

- Development of ‘risk engine’ consisting of four Fuzzy transitions to calculate output probability of occurrence of specific adverse effect based on five input functions with individual effectiveness linked with distraction, individual competency mismatch linked with team competency mismatch and moderating effect of supervision

- The introduction of ‘coefficients of interaction’ based on physical layout of Critical Care sub unit which identifies role of physical environment on influence of supervision, competency sharing and distraction

- Integration of all elements into the risk simulation system listing all elements of the identified components.

These are subsequently discussed in more detail in section 8.3 of chapter 8.

Chapter 2: Risk in Healthcare : Literature Review

2.1 Introduction

The literature related to risk in healthcare is very extensive but mainly reflects the enthusiasm, or conscience, of individuals and small teams rather than of well funded research groups. The aim of the Thesis is to develop and justify a model of risk determination based on clinical interventions within a Critical Care environment. The associated literature review has identified a wide scope of clinical observation but focuses on a subset of work within the Critical Care environment. The development of the model, however, draws from diverse reported findings as part of a process to develop a risk model which has its roots in known procedures and practice and reflects also the insight of clinicians. Section 2.16 provides a summary of key elements identified from the literature survey.

2.2 Scale of Problem: Awareness and Communication

As indicated previously, the publication, for example, of the Institute of Medicine report (Institute of Medicine 1999) which claimed that between 44,000 and 98,000 people die each year in American hospitals due to avoidable medical error provided a strong focus to improve healthcare safety. The publication of the report also caused a wide recognition of the unsatisfactory nature of many of the systems which had been developed within modern healthcare. There is also identified to be a threshold of perception within the public of the significance of adverse events in medicine. Incidents with multiple casualties, for example within the transportation or industrial sector, draw more public attention than a much higher number of avoidable deaths in healthcare which are geographically separate which are apparently not linked by any common factor. The review by Baker *et al.* (2004) essentially confirms within the Canadian Healthcare system the findings elsewhere relating to adverse medical events. The figure of 7.5% of adverse events of patients within a 20 hospital study (3720 hospital admissions) is comparable with other typical studies.

Governments with direct or implied responsibility for health systems such as the NHS in the UK are, however, acutely aware of the public perception of such failures in healthcare. In addition, adverse medical outcomes are being increasingly translated to the cost of litigation. Governments are also minded to reduce the associated drain on the national purse as indicated by Fenn *et al.* (2000) and Department of Health (2003a) where the later report indicated a cost of litigation settlement of £446 million in 2001/2002. In recognition of the need to be aware of rising costs of litigation and initiate appropriate action, the Department of Health has published a series of documents which focus on the need of Health Care organisations to take all reasonable steps and measures to reduce risk. The key initial publication ‘An organisation with a memory’ (Department of Health 2000a) was subsequently

followed by ‘Implementing an organisation with a memory’ (Department of Health 2002). These initiatives are also identified with the establishment of the National Patient Safety Agency as a vehicle for centralised reporting in England and Wales of adverse clinical events and which subsequently is an active vehicle for safer healthcare practices (National Patient Safety Agency 2007). Included within this process was the system of Clinical Governance as an extension of the processes of Financial Governance within the NHS. Since around 2001, NHS Trusts have been required to report progress within a set of Healthcare Standards (Department of Health 2004b) which address key issues to reduce outcomes of Clinical Risk such as levels of patient mortality by specialty/discipline and generally increase the profile of organisational governance (Department of Health 2006a).

2.3 Regulatory Frameworks: Roles for Risk Evaluation and Risk Reduction

The ongoing development of medical technology within healthcare continues to provide an expanding range of diagnostic/therapeutic technologies and there is introduced potentially a higher level of risk due to the increase of interventions and their potential for harm to the patient. The framework within which medical devices are designed, manufactured, used and maintained within the EEC has at the same time undergone significant revision. The introduction of the Medical Device Directive in 1997 within the EEC (Medical Device Directive 2002) has provided a framework to introduce a base level of safety and product certification for use of a wide range of medical devices and products.

In addition, specific standards have been developed as a framework for design/manufacturing of medical devices (British Standards Institution 2003a) and also for a structured process of risk assessment of product design (British Standards Institution 2007a). Specific standards have also been introduced for a wide range of medical device types of which defibrillators (British Standards Institution 2003b) and high frequency surgical equipment (British Standards Institution 2007b) are specific examples. In addition, the NHS uses a specific risk management approach for non clinical applications (SAI Global 2004).

The Medical Device Directive (Medical Device Directive 2002) and associated standards documentation provide a focus for the function and development of such devices rather than the management of such devices once they are in use within a health care organisation. In the UK, guidance on systems of work to ensure appropriate management of such devices is currently provided by the Medicines and Healthcare Regulatory Products Agency (MHRA). While guidance is often provided as guidance on specific topics such as sterilisation (MHRA 2002) advice is also provided on generic systems of device management within the cycle of procurement, acceptance, repair and planned maintenance and disposal of medical equipment (MHRA 2006). This provides a framework to reduce the risk of utilisation of such products within modern healthcare (MHRA 2000). It is noted that the focus of such framework documents is placing increased emphasis on the training of users of medical equipment.

2.4 Error in Medicine

Leape (1994, 1998) summarises in a highly effective manner the developments in the basic understanding of the ways in which human error can arise. One important development in the theory of human error outlined by Leape (1994) and also described in Reason (1990) is that the concept of modes of cognition which include that of 'automatic and unconscious processing' or 'schematic control mode' and 'attentional control mode' where a problem is handled by slower modes of sequential thought effort. The individual skill based tasks are called 'schema'. This model is referenced in a framework by Rasmussen (1981) which identifies factors of skill based, rule based and knowledge based interventions.

Within this framework, 'slips' are described as events which occur while undertaking a skill based activity. Such 'slips' may be due to loss of attention. One mechanism identified as taking place is where the wrong schema is applied. This is described as an error of capture. A description error is one where the right action is performed on the wrong object. A loss of activation error is one where temporary memory loss takes place possibly triggered by interruption.

Such loss of attention in the causation of 'slips' can arise from a wide range of circumstances and including fatigue/sleep loss, alcohol/drugs/illness, boredom/frustration/fear/anxiety and environmental factors. Allnutt (1987) identifies that poor performance will occur at the extremes of stress as defined as 'panic' and 'boredom'.

Latent errors are associated with intrinsic sources of error within potentially highly complex systems. Classic examples are given as Three Mile Island and Chernobyl where the systems had intrinsic flaws of safety practice which could not be readily appreciated by operational staff. Latent errors can manifest in medical systems in a range of guises, such as the potential to administer epidural infusions through intravenous lines. In terms of the prevention of accidents, there is identified the possibility to structure activity so as to reduce the chance of error and also reduce the consequence of any error taking place as outlined by Norman (1984). A particularly relevant form of observation of health systems at risk via 'vulnerable system syndrome' is described by Reason *et al.* (2001).

A highly relevant review of medical errors in the field of surgery has been developed by Cuschieri (2003). The author indicates that while within the industrial sector there has been effort to classify human errors after the taxonomy of Rasmssen (1981), there has been no equivalent system within the medical field. Cuschieri (2003) proceeds to identify two separate classes of medical errors as Endogenous (Errors arising within the immediate work area by healthcare practitioners) and Exogenous (Errors arising within the environment in the system of health care practice). The

significant study by Vincent, Neale and Woloshynowych (2001) describes, however, a worrying level of incidence of adverse events of 10.8% based on analysis of two acute hospitals in Greater London.

Relevant work of assessment of errors in an ITU environment has been provided by Leape *et al.* (1995). According to this study around 178 activities are undertaken per patient per day with 1.7 errors being associated with each patient per day, indicating around 96 % proficiency. A particularly revealing study by Taxis and Barber (2003) identified an error rate of 49% in preparation and administration of intravenous drugs. Within various health systems, reduction of such errors has been implemented by computer driven prescription systems.

2.5 Shift Pattern in Risk Evaluation and Risk Reduction

Several studies have tried to assess the factors associated with shift pattern and satisfaction of staff involved with a range of types of shift pattern with typical studies reported by Josten *et al.* (2003) and Jansen *et al.* (2003). For the specific risk model being developed, there are specific factors which are identified to influence the relative ability of clinical staff and nursing staff to function effectively based on work time patterns.

The study by Josten *et al. (*2003) argues that studies prior to 1982 indicated that 12 hour shifts tended to be considered favourably, possibly due to the fact that prior to significant utilisation of technology in nursing, nursing was less complex than is currently. Jansen *et al.* (2003) found that there was associated higher fatigue levels with shift working. It was determined, however, that increased fatigue levels appeared stable within shift groups, with no appearance of significant deterioration with time spent within each shift pattern. Jansen *et al.* (2002) identified that significant differences potentially existed in need for recovery from work patterns based on shift pattern and gender. Similar associations are also identified by Jansen *et al.* (2003).

Various models of resource planning utilise 'job shop scheduling' where resources are optimally matched to demand. Thus factors such as turn round time, efficiency of process, minimisation of resources and labour are optimised against a specific pattern of demand. Ozkarahan (1995), for example, describes a system for allocation of surgical procedures to operating theatres which is designed to optimise utilisation factors, but without any component of risk analysis of activity schedules.

The general indication of studies assessing individual performance during night shifts as described by Borges and Fischer (2003) and Fischer *et al.* (2000) is for a reduction of effectiveness within the period of night time working. More detailed analysis by Wilkinson *et al.* (1989) indicated a deterioration in individual performance levels around 03.30 am.

2.6 Team Working

There is increasing awareness of the importance of team working in reducing risk in healthcare as described by Kavanagh and Cowan (2004). The authors describe various initiatives and studies that have been undertaken to demonstrate the improvements to service provision and associated reduction of clinical risk that can be achieved through more effective team working. It is significant to note that the key finding of the Bristol Enquiry (Bristol Royal Infirmary 2001) was to identify key failings within teams rather than at the level of the individual.

Work described by Bleakley *et al.* (2004) outlines a novel means of developing team working within the theatre environment. Outcomes of cohort studies are further described by Bleakley *et al.* (2006). Often, however, there are many factors that can restrict the development of team issues. Varma and Neil-Dwyer (2002) indicate that while the desirability of team working is well understood, and various initiatives are described to establish team working, it is considered that intrinsic problems relating to lack of resources and pressure to deliver workloads will hinder such initiatives. The issue of developing the true potential of teams is further reviewed by Salas *et al.* (2006).

One review by Bradley *et al.* (2003) structured a review of a range of studies based on the 'temporal framework' of team organisation. There was evidence from a range of studies that teams which were established for longer periods had more developed inter personal skills which made such teams more effective. In the context of intensive care working, for example, there is the issue of how team cohesion can be identified and developed where, due to the nature of the workload, the staff 'team' rarely can be assembled as one entity. This is in contrast to a team in industry/commerce where it is likely that team members would interact fully with all team members on a daily basis.

2.7 Extended Working Hours and Related Factors

In terms of the effects of long hours of work on efficiency, Savery and Luks (2000) describe a specific study within Australia and give insight into perceived wisdom of long work hours and social consequences. Consideration of such factors are relevant for estimation of 'individual effectiveness' within task completion studies.

There are also the more complex stress factors involving burnout and clinical depression. Iacovides *et al.* (2003) argued that while some work activity can be stressful due to the nature/complexity of the activity, the development of 'burnout' can potentially trigger more significant loss of effectiveness when the feeling of individual worth based on career expectations and appreciation of personal competence are undermined and diminished. This type of loss of effectiveness is subsequently referenced as 'long term effects'.

In determining risk models in the Critical Care Unit, the prevailing model is not one of selecting patients in order to optimise the most efficient use of resources. Rather it is one of providing appropriate care to patients that meet specific clinical criteria based on need. Within the model of activity, however, the effectiveness of staff remains a critical element. Within job shop models, as described by Koszalka and Skworcow (2003), factors such as staff resilience/fatigue are identified as being important and are identified for use within an equivalent model within the intensive care environment.

Most scheduling problems, however, relate to situations where there is a much higher control over the processes being optimised and the individual tasks can be included/excluded within the model confines. In the clinical environment however, the tasks are essentially scheduled on the basis of clinical requirements and the level of control on use of resources is limited.

The alertness and hence effectiveness of staff does also vary during the day. Within the road transport industry, work has been reported by Moore-Ede *et al.* (2004) in relation to determination of an alertness parameter based on evaluation of circadian alertness and also its utilisation in reduction of road traffic accidents. The algorithm for the alertness simulator was derived from extensive analysis of work data of truck drivers.

2.8 Patient Assessment Algorithms in Critical Care

It has been recognised for some time that the evaluation of performance between critical care units depends on an effective means of evaluating the likelihood of patient survival based on key parameters of the patient condition.

The APACHE system (Acute Physiology and Chronic Health Evaluation) was first reported by Knaus *et al.* (1981) and utilised a total of 34 variables on a limited set of patient admissions. The Simplified Acute Physiology Score (SAPS) model with a reduced set of 14 parameters was subsequently developed by Le Gall *et al.* (1984) and represented a simplification of the acute physiology score (APS) system which had been in use previously. A revised version is also described by Le Gall *et al.* (1993).

A refinement of the APACHE classification system as APACHE II as referenced by Knaus *et al.* (1985) extended the data set to 5815 admissions from 13 hospitals and with the derivation of a point score based on initial values of 12 patient measured parameters. At this stage such systems are also identified as having value for prioritising the resources of critical care departments. A subsequent development of system in the form of APACHE III was further developed by Knaus *et al.* (1991) where

data sets from some 40 USA hospitals were incorporated with the additional inclusion of an expanded diagnostic list.

A large study of intensive care scoring models has been undertaken by Livingston *et al.* (2000) in which five severity of illness scoring systems were evaluated within a large Scottish data set comprising 10,393 active entries. The SAPS II model was found to provide the best overall performance though the APACHE II system was found to be more appropriate for comparisons of mortality rates within intensive care units.

Predictive mortality systems such as APACHE and SAPS utilise the technique of logistic regression to compute outcome values based on validated sets of clinical data using the Hosmer-Lemeshow method. Kramer and Zimmerman (2007) indicate that while in general the use of the method is appropriate, other factors which may influence predictive mortality within a set patient group require to be taken into consideration. Work reported by Zimmerman *et al.* (2006) in the development of APACHE IV has highlighted the fact that predictive mortality models need revision as part of the natural progression taking place within modern critical care medicine. Within the UK, the ICNARC research group has been active in tuning risk prediction models for the specific characteristics of Critical Care Units within the UK (Harrison *et al.* 2006, 2007). Such predictive mortality systems are important for individual case management and also for assessment of overall levels of clinical performance.

2.9 Promoting Safer Patient Care and Management

There has been an increased focus on practice improvement in order to reduce incidence of adverse events, in contrast to techniques which studied epidemiology of errors. One significant review of practice based clinical intervention has been structured by Shojania *et al.* (2001) and which identifies a broad cross section of acute clinical interventions and how the likelihood of adverse outcomes can be reduced.

Benjamin (2003) provides a practical overview of medication errors within the USA health system and proposes a set of remedies to correct deficient practice. Within the context of medication error, for example, the removal of ambiguous handwritten prescription systems and use of computerised requests has been shown by Bates *et al.* (1998) to reduce non intercepted serious medication errors by around 55% from 10.7 events per 1000 patient days to 4.86 events per 1000 patient days.

There is increasing clinical focus on evaluating level of care and clinical outcomes based on levels of clinical supervision in intensive care units. Kahn *et al.* (2007) identified that in the American model, the provision of 'Intensivist physician' staffing increased the level of standardised process review measures for patients receiving mechanical ventilation. No attempt, however was made to relate mortality outcome with level of such supervision. A systematic review by Pronovost *at al.* (2002) between 1965 and 2001 analysed ICU morality and length of stay as a function of ICU physician staffing. It was shown that there was clear improvement in parameters with provision of highest level of 'intensivist' compared with the lowest level of provision. The approach reported by Berenholtz *et al.* (2007) develops the concept of a safety scorecard which translates the provision of interventions and structure of a safety framework into objective measure of relative 'safety' of a patient within the intensive care unit.

Within the USA a specific focus for implementation of a safety culture within critical care has been developed by the Leapfrog Group as described by Eikel and Delbanco (2003). This group is a consortium of over 140 large healthcare purchasers which promote patient safety criteria within the purchase of healthcare. Specific points of reference for the group include computerised physician order systems (e.g. prescriptions), evidence based hospital referral and appropriate intensive care physician staffing. A study by Angus *et al.* (2006) however, draws attention to the existing structure of many 'ITU' units in the USA which fall far short of the recommendations set out in the Leapfrog initiative.

The development of appropriate practice within the Critical Care environment continues to attract considerable interest within the sphere of nursing professionals in order to realise the significant policy statements of the Department of Health in respect of Critical Care provision (Department of Health 2000b, 2000c, 2001, 2003b, 2005, 2006b). Also relevant are policy statements from representative professional bodies (Intensive Care Society 1997, 2002) and the Royal College of Nursing (2003). At an international level, there is also increasing awareness of the need to develop systems for risk reduction in healthcare that 'close the loop' in terms of identification/elimination/reduction of clinical risks (Runciman *et al.* 2006).

2.10 Physical Environment

The provision of adequate space and also structured infrastructure within the Critical Care environment are important for safe and effective practice. Specific methods have been developed for the evaluation of space requirements within the Critical Care environment as described by Hignett and Lu (2007) in the evaluation of space requirement for specific high-risk clinical tasks. While such evaluations can be undertaken to determine minimum space for clinical procedures, there are also considerations based on infrastructure details of specific space utilisations. Research described

within this Thesis has identified novel elements of physical work environment relating to competency sharing, supervision and distraction which appear not to be referenced in existing literature.

2.11 Competency Factors in Assessment and Training

The element of competency is in the process of being re-inforced within medical educational systems. Leach (2002) describes how the system of medical education in the USA has been undergoing a major review in order to introduce greater elements of outcome based learning which can be more objectively assessed.

In the USA residency training facilities are structured to focus on the set of six basic competencies and determine how this is implemented and measured. One small study of local evaluation of interpersonal skills described by Jouriles *et al.* (2002) indicates that while such processes of evaluation by 'shadowing' staff at specific phases of their training appears to provide a consistent set of results, the very act of measurement can influence outcomes as staff take on 'best behaviour' mode.

In a more open challenge to the concept of objective competency evaluation, Huddle and Heudebert (2007) dispute the link between objective measures of competency within the six classes described by Leach (2002) and the ability to be an effective and safe clinician. The main argument put forward is that the higher cognitive instincts and skills do not necessarily lend themselves to the process of objective assessment.

A relevant European response to the trend to move towards competency based training, planning and assessment for postgraduate medical training has been outlined by ten Cate and Scheele (2007). Rather than describe competencies, the authors describe these as 'Entrustable Professional Activities' and anticipates between 50 to 100 of these describing a full postgraduate medical training scheme of five to six years. This approach confirms a trend to move towards more highly structured medical training based on identification of roles, responsibilities and the need to be able to undertake specific interventions. Nursing practice in the UK is dominated by competency based learning, where the scope of personal development is dominated by the framework of a competency based training system.

2.12 Risk Reduction Initiatives: Non Medical Sectors

The airline industry is often identified as an excellent example of how the implementation of a safety culture can reduce the incidence and severity of associated accidents. The INDICATE programme as described by Edkins (1998) is a safety programme initially developed for regional aircraft traffic within

Australia. In its development, analysis was undertaken of existing aviation safety programmes such as MESH (Managing Engineering Safety Health) as developed by British Airways and also the Boeing Safety Programme Model and core elements of systems incorporated into INDICATE. The key components of such a system include:

- Appointing of operational safety manager
- Creation of staff focus groups to identify hazards
- Establishment of confidential safety hazard reporting system
- Regular meeting with management
- Establishment and maintenance of safety information data base
- Regular distribution of safety information to staff

The structure of such safety systems is based on the model of Reason (1995) and is designed to reduce both the set of latent failures that may exist within an organisation and also the errors and violations that may exist at the individual or team level.

The analysis by Santos-Reyes and Beard (2003) of the safety systems with the British Rail network, indicates that the many tiers of companies and lines of communication within the railway system probably increases the difficulty of removal of latent errors within such organisations. Kozine (2007) describes the application of the single-channel theory of selective attention to the simulation of human actions in time-pressured scenarios as a mechanism of describing errors in control interface technology.

2.13 Fuzzy Models

A basic outline of the potential for application of fuzzy logic to risk evaluation is outlined by Ciresi and Akay (1996) where the imprecise nature of medical decision making and evaluation of clinical situations is described as being suited to fuzzy expression. Examples of application relating to control of arterial blood pressure using infusion systems with fuzzy logic feedback are cited as appropriate solutions where mathematical modelling of system parameters produced more complex and hence unstable solutions. Steimann (1997) makes the relevant observation that Zadeh (1969) had identified the unique value of fuzzy sets to meet the reality of ‘a substantial degree of fuzziness in the description of the behavior of biological systems as well as their characterization’. Steimann (2001) also references the application of fuzzy systems in medical artificial intelligence. A useful review of artificial techniques in medicine including fuzzy logic is described by Pandey and Mishra (2009).

The predictive ability of fuzzy logic within a specific clinical area has been outlined by Cundell *et al.* (2001) where input demographic variable of age (4 ranges), blood type (4 types), gender and race (4

types) were mapped to outputs of presence of Staphylococci, Streptococci, E Coli and Non-E.Coli. With data from 187 patients available, a training set of 155 patients was used to predict the outcomes of the remaining 32 patients in the set. Using a set of 159 active fuzzy rules, a predictive rate of 84.4 % was achieved which the authors state would be significantly higher than clinical guesswork.

Carr and Tah (2001) describe a system for evaluation of risk in the construction industry using fuzzy techniques. Inputs relating to local factors such as plant suitability, weather, plant availability, site investigation and contract documents are described as feeding forward to conditions of plant productivity and ground conditions which in turn feed forward to changes in performance change details relating to duration, cost, quality and safety. Rue and Eloff (1996) describe the application of fuzzy logic techniques to model risk related to computer network access and utilisation.

2.14 Factors Affecting Individual Effectiveness

Individual effectiveness has been identified as a 'significant' risk factor and is associated with an 'enabling' factor for successful task completion. The process of simulation of factors which influence individual effectiveness requires to take account of relevant studies which seek to determine the significance and relevance of a range of factors. Extensive studies by van Dongen *et al.* (2003) have attempted to quantify the effect of sleep deprivation on individual effectiveness. Specific studies such as those by Dorrian *et al.* (2006) indicate the general reduction of effectiveness within periods of night shift working. In terms of shift working, one common element of observation, as evidenced in studies by Borges and Fischer (2003) and Fischer *et al.* (2000) is a reduction in effectiveness during night shifts, with the suggestion of lowest effectiveness around 03.30 am.

Numerous studies provide a focus on stress experienced by staff in healthcare and its effect on individual performance. The study of Elfering *et al.* (2006) provides some detailed insights into patient related stress episodes though the greatest source of stress was identified as friction between other staff members. It is also relevant to confirm that the Critical Care environment is probably the most stressful work area in acute healthcare, based on the findings of Fischer *et al.* (2006) which identified elevated levels of the stress hormone cortisol were only found within the Critical Care environment of an acute hospital. One relevant observation by Sallinen *et al.* (2004) was that in a simulated experiment related to industrial type processes, tasks which required minimal levels of cognitive skill, such as monitoring of a console, tended to produce an effect equivalent to sleep deprivation.

More specific simulation of effectiveness factors is, however, identified within studies of job shop models as outlined by Koszalka and Skworcow (2003). The technique of optimisation of production/output by maximising individual productiveness to take account of work, rest periods and individual stamina does not match with the organisational model of the Critical Care work environment.

Studies thus referenced, however, provide a means of development of a model where effectiveness factors are identified within the Critical Care environment.

2.15 Risk in the Critical Care Environment

Significant work has been undertaken in determining the frequency, nature and causation of adverse incidents within the Critical Care environment. Such studies can provide a 'before' and 'after' comparison with the implementation of a specific component of improved patient management. In the study undertaken by Sinopoli *et al.* (2007), no significant difference was found between the rates of adverse events of 'medical' and 'surgical' patients, with nature and causation showing similar values.

In a study into medication errors in the hospital environment, Cullen *et al.* (1997) identified that contrary to expectation, adverse events tended to occur during routine work phases and not during periods of heightened stress and anxiety. It was surmised that the core of errors were probably originating within the structure of medication processes, such as the dependence on hand written prescriptions.

A significant study by Kollef *et al.* (1999) identified that the mortality of patients who received inadequate or delayed antimicrobial treatment was four times higher than those treated appropriately. An in depth study as reported by Giraud *et al.* (1993) highlighted both the distribution of adverse incidents and associated factors, though medication errors were not recorded. The study reported by Bracco *et al.* (2001) identifies the use of 'planning', 'execution' and 'surveillance' as categories of causation with reference to a common core of 'types of error'. This approach adds value to a linked programme to reduction of incidence of adverse incidents. In addition, this study indicates that errors associated with 'planning' tend to have greater significance for prolonging of patient stay.

In the study by Rothchild *et al.* (2005), detailed analysis is undertaken of levels of error corresponding to 391 patients within 1490 patient days, with indication of a level of 149.7 per 1000 patient days. Identified categories of adverse incidents provide useful benchmarks for comparison with results of simulated studies. The so called SEE study of Valentin *et al.* (2006) took a 'snapshot' of adverse events reported within a 24 hour period on 21st January 2004, with the participation of 220 Critical Care Units around the world. Key areas of concern were identified as 'lines, catheters, drains' and 'medication' which accounted for around 64% of reported incidents.

The study by Kern and Kox (1999) reported a significant reduction in mortality within a cardiac critical care facility with the implementation of improved systems of documentation, standardisation of treatment protocols and team communication. This theme is also reported by Jain *et al.* (2006), where the introduction of procedural improvements such as multidisciplinary rounds, hand hygiene protocol and 'non vertical' cultural change brought about a significant reduction in length of patient

stay. The study of Needham *et al.* (2004) which identified factors associated with airway related adverse incidents identifies a highly relevant set of main factors and associated sub factors linked with such events. The set of sub factors corresponds significantly with the parameters identified within the 'risk engine' structures developed in this research.

The study undertaken by Graf *et al.* (2005) among its findings on adverse incidents and staff related errors identifies 'disregard of standards, rules, and orders' as a dominant source of error. In addition, a base line level of adverse events of 0.07 per eligible patient day is identified. The study by Schuerer *et al.* (2006) confirmed aspects of errors due to 'disregard of standards, rules, and orders' though it is likely that this is manifesting as a collective lack of awareness of practice rather than deliberate disregard for work structures.

In a study undertaken by Binnekade *et al.* (2001), the relative frequency of adverse situations was compared for various categories of activity for nursing time per patient less than 30 minutes per hour and greater than 30 minutes per hour. It was identified that significantly more critical situations were identified in the group associated with less than 30 minutes of nurse time per hour. The study of adverse incidents relating to mechanical ventilation by Auriant *et al.* (2002) categorised the types of adverse outcomes as a function of level of severity of outcome. Again, a principal cause is associated with 'human error and failure to follow rules' - though it would have been appropriate to separate these two causes.

The study by Shortell *et al.* (1994) reviewed information from 17,440 patients from 1691 hospitals in the USA in which regression coefficients were evaluated for a range of input criteria such as technological availability against output criteria such as risk adjusted mortality. Specific observations included that increased technological availability would reduce risk adjusted mortality with also increased caregiver interaction reducing risk adjusted ICU length of stay.

One of the most relevant studies in this group seeking to link incidence of adverse clinical events to causal factors was undertaken by Tibby *et al.* (2004) where analysis of adverse incidents was undertaken within a paediatric intensive care unit (PICU) over a period of a year. Strong evidence was identified which linked reduction in levels of adverse incidents with increasing seniority of supervisory nursing staff.

The literature thus cited is associated with the generic process of improving the safety of healthcare. The more relevant clinical literature, however, relates to analysis of adverse incidents within the Critical Care environment. While patient care presents as a series of interventions carried out on patients, the literature does not appear to 'drill down' to the complexity of care at this level. This is the approach, however, which is developed in subsequent chapters and is one that identifies 'sub structures' of risk within the processes of clinical activity.

2.16 Summary Elements of Literature Review

Regulatory and Standards Frameworks: These identify risk reduction through safer equipment, drugs and consumables and backed with appropriate directives within the European Community such as the Medical Devices Directive and within a framework of quality standards and product/equipment standards. This confirms that significant sources of risk through use of unregulated medical equipment and consumables and which may have a higher rate of failure have largely been eliminated. In the development of models of patient risk within the Critical Care environment in chapter 5, components of risk linked to intrinsic device failure are not included as sub tasks within specific interventions. The dominant risk associated through the use of medical equipment and consumables relates to levels of competency of staff to use such items appropriately.

National Regulatory Bodies: These identify risk reduction through guidance and initiatives from agencies which include MHRA, Care Quality Commission, The NHS Litigation Authority, the National Patient Safety Agency and National Institute of Clinical Excellence (NICE). While no specific role for development of detailed risk causation models in healthcare is identified, their role has led to the development of a 'risk reduction' culture in all aspects of patient care. In addition, the most focused risk based approach is introduced via the NHS Litigation Authority. It is noted that while such bodies place great reliance on the use of risk assessment techniques within the organisations that they monitor, such risk assessments do not probe aspects of risk causation through 'understanding' of details of interactions of parameters which have the potential to increase clinical risk. This is further referenced in chapter 8 on aspects of further work.

Simulation of Clinical Activity: Simulation of clinical activity was identified as a core element of the risk simulation model at the outset of the research. This related to admission/discharge episodes and also to the interventions experienced by patients within specific admission/discharge episodes. Sets of data for both types of clinical activity were available within the Critical Care Unit though additional monitoring was required to include 'general' nursing interventions. The literature identified the essential structures of the TISS classification of patient interventions within the Critical Care environment and which was incorporated into generic and specific descriptions of patient interventions. The literature revealed, however, that there can be a significant mismatch between the 'prescription' of care prescribed by the intensive care consultant and the pattern of care that the patient actually receives. A common cause of this mismatch would appear to be the dependency on written case notes and the difficulty of matching up communications from the intensive care consultant to the record of activity within such case notes. Important aspects of care such as monitoring for infections and prescription of antibiotics can be omitted as a result of lack of ability to check if patterns of care are actually implemented. The non delivery of care elements has consequently been incorporated into 'adverse effects' within interventions as structured within chapter 5.

Clinical Micro Systems: A key aspect of the risk model relates to the identification of 'micro systems' as referenced by Carayon and Gurses (2005) and Nelson *et al.* (2002) where a framework of interaction operates within a team environment and within a common set of professional and managerial goals. This is confirmed, for example, in the way in which nursing rosters are structured (chapter 6) from a common set of staff and where a set of locally developed clinical protocols (chapter 5) are generated and developed within the micro system of the Critical Care Unit. This also indicates that if risk simulation models of the type described in the Thesis are to be applied throughout an organisation, then they need to be developed like interconnecting 'cells' within a larger organisational framework. This is referenced in relation to further work in chapter 8.

Error perception and Causes: There are several approaches to the perception of error in medicine. One approach reflects the 'culture' of the clinician where errors are referenced within a peer to peer framework but without in depth reporting of incidence levels or analytical insight into the nature of such risks. One approach is to classify errors using the methodology of Reason (1995) and Rasmussen (1981). There appears to be little if any application of this method of risk analysis to errors in medicine. The identification of 'latent errors', is however relevant and is introduced in chapter 6 and referenced also in section 6.2 in the form of 'level of optimisation' of procedures within the structure of the 'risk engine'. In this context a 'latent error' could be a nursing protocol which forms the basis of nursing practice but which is not optimised in either its effectiveness or level of risk. The improvement of clinical practice is, however, strongly driven to identify 'latent errors' in patient treatment through the formal structures of evidence based medicine. Such factors were not, however, introduced into the 'risk engine' model used for the actual risk simulations undertaken in order to focus on more significant factors.

One approach in the literature, described in detail in chapter 5, is to identify types of adverse incidents within the Critical Care environment as a first stage to identifying mechanisms to reduce them. These studies provide information on both the nature of reported adverse incidents and the relative frequency of occurrence of such events. Such studies tend however to identify different types of adverse incidents and also provide inconsistent values of the likelihood of their occurrence. Such studies provide some relevant information for comparison of outputs of the risk model being proposed, in particular where the level of specific adverse clinical incidents in chapter 7 is described in terms of events per notional patient day.

The literature is essentially identifying adverse clinical events as events which actually harmed the patient or had the potential to do so. In the model developed in the Thesis, the 'adverse effects' are identified more closely with 'risk latency' or underlying factors which have the potential to cause harm. Aspects of combinations of 'adverse effects' to result in incidences of actual patient injury are discussed in chapter 8 with the context of further work.

The approach of identifying causal factors of adverse incidents within the Critical Care environment is more useful from the perspective of risk model development, such as in Tibby *et al.* (2004), where comparisons are made within clinical data and where one or more factors such as the level of training or team communication have been altered. This demonstrates the variation of output risk parameters as a function of input parameters and has some relevance for the risk model being proposed and helped develop the structuring of grade based competency mismatch in chapter 6.

Team Communication: The literature confirms the value of effective team working, with various studies providing objective evidence that better teams provide better clinical outcomes. The medical literature, however, does not develop elements of team working within the scope of model simulation developed in this Thesis and instead tends to focus on measuring change in outcomes. Concepts of team interaction, especially relating to sharing of competency, outlined in the literature were able to be replicated in simulation of skills sharing within teams of nursing staff within a specific physical group of Critical Care beds in chapter 6. In addition important factors relating to team communications and handover of patients at shift transitions as identified in the literature were incorporated into simulation of individual effectiveness in chapter 3 and which are actively incorporated into the main risk simulation system as described in chapter 6.

Shift Working, Elements of Individual Stamina and Sleep Deprivation: While elements of shift working, in particular within critical care, provide a focus for many studies, these tend to be directed towards understanding the culture of shift working in order to mange it more appropriately. Within the few studies which include objective assessment of ability to complete tasks, it is identified as relevant to include in the proposed model an empirically derived function, as described in chapter 3, to replicate a reduction of individual effectiveness during the night shift – with a minimum around 03.30 am.

Elements of individual stamina/stress are referenced within the literature of job shop models with analysis focused on optimising output based on consideration of stamina functions. While the medical literature contains many references to the effect of stamina/stress in the workplace, this is not referenced within the context of individual patient interventions and depletion of individual stamina as structured in chapter 3. The generic references, however, to effectiveness functions within job shop models proved useful in developing these in chapter 3 in the context of acute clinical environments. The proposed model identifies ‘short term’ stress components which relate to specific activity within a shift and ‘long term’ stress components which carry over periods of weeks or months. ‘Long term’ stress is identified but not currently implemented in the risk simulation model though the associated medical literature describes extensively the effects of deterioration of individual performance due to long term effects of motivation/depression.

Studies in relation to sleep deprivation primarily undertaken within the medical community tend not to have sufficient controls to derive relevant findings. Results of more rigorous studies, however, indicate a clear deterioration of performance based on sleep deprivation and this effect is subsequently used in the proposed model as developed in chapter 3. The literature provides no guidance on how separate individual effectiveness functions (physical, stress/emotional and intellectual) should be combined as a single effectiveness value. A structure based on fuzzy logic is outlined in chapter 6 for deriving a single effectiveness value from the set of component effectiveness values. This approach uses linguistic interpretation of fuzzy input parameters.

Competency Factors: The literature reveals a trend towards greater identification of training within a competency based structure. The competency profile of nursing staff tends to be more actively defined than medical staff based on verification that indicated tasks can be appropriately undertaken. This can provide a more directed system of learning where the verification of competency is an assurance of safe and appropriate practice. The literature review, however, found no prior reference to the approach of describing clinical interventions as sub tasks with associated levels of competency as developed within the Thesis in chapter 5. The literature confirmed, however, that nursing tasks are more easily defined in relation to patient 'care' than tasks undertaken by doctors in relation to patient 'management'. This could be described in the context that doctors 'cure' and nurses 'care'. This influenced the decision to initially simulate interventions undertaken by nursing staff rather than medical staff.

Risk Reduction: Non medical sectors: The basic human factors relating to safety in sectors outside the medical field can be expected to have a direct overlap with safety in the Critical Care environment. The relevant literature implies that it is easier to adopt more rigorous practices within the airline industry due to the more streamlined approach to adopt improved working practices. It is identified, also, that processes of risk reduction in the non-medical sectors are more likely to be subject to issues of security and commercial sensitivity and as a result are less likely to be openly reported then those in healthcare.

Fuzzy Models: The literature identifies a set of applications using fuzzy logic within the medical field with also inclusion of review articles. There appears, however, no systems which utilise the specific fuzzy risk methodology subsequently developed in this Thesis. Aspects of further work relating to investigation of alternative Fuzzy functions are outlined in chapter 8.

Chapter 3: Factors Relating to Individual Effectiveness

3.1 Introduction

This chapter identifies factors which are considered to affect individual effectiveness, as a component of a risk model. It is recognised that a significant number of adverse incidents occur in medicine due to individual human error and which can be related to individual competency or the level of effectiveness of the individual. This latter factor can in turn be influenced by workload factors and also factors such as sleep deprivation. This chapter identifies specific empirical mathematical models relating to physical effort/stamina, emotional/stress effort/stamina, intellectual effort/stamina, sleep deprivation, handover and admission functions. The identified models draws from a wide range of both clinical studies and non clinical studies of such factors which can influence individual effectiveness within the work environment.

In seeking to model risk within the Critical Care environment, it is important to take account of human factors that can influence the relative incidence of 'adverse effects'. While task competency is a key factor, aspects of 'effectiveness' of the individual are also relevant and may be influenced by the degree of difficulty of patient care and associated levels of stress and fatigue. There are also considerations linked to patterns of shift working. The literature of 'work effectiveness' is very extensive across all work sectors and with aspects relative to working within the clinical environment identified as a specific subset of this area of investigation. Studies from medical literature tend not to identify clear causation between 'effectiveness' factors and levels of adverse events, but they are of value in identifying potential causal factors and how these can be introduced in models to simulate such interactions. The first part of this chapter aims to identify key concepts/observations made by a range of investigators. Based on these observations, a model of individual effectiveness is proposed.

3.2 Sleep Deprivation and Individual Effectiveness

The work environment within the Critical Care environment is known to impact on the sleep patterns of staff, especially staff who work rostered 12 hour night shifts, though there have been mixed results of studies seeking to relate this to loss of task effectiveness.

A key study by van Dongen *et al.* (2003) where there was complete control of subjects throughout a 14 day sleep deprivation experiment, found that there was clear deterioration of psychomotor vigilance performance, working memory performance and cognitive throughput performance as sleep

deprivation built progressively. Within the study, groups were able to sleep for periods of 4 hours, 6 hours and 8 hours. Within waking periods, tests to evaluate performance were undertaken every two hours. It was found that the level of deterioration of functions was constant within the specific 'waking day' of the individual. Also, subjects who were progressively sleep deprived considered that they were adapting to the sleep deprivation process, even though their measured task responses showed the progressive declines in these determinations. Within the study period of 14 days, the cumulative sleep deprivation was considered to be equivalent to up to two nights of total sleep deprivation. While other studies tend not to show the link between progressive sleep deprivation and 'task ineffectiveness' the positive findings in van Dongen *et al.* (2003) is attributed to the higher level of control of the subjects.

Based on these findings, there are clear implications for work within a Critical Care environment where there is likely to be cumulative sleep deprivation among staff based on combinations of long shift periods and rotations between shifts. A key factor determined in the study is the apparent ability of the human organism to 'feel' bright and alert although there is an obvious decrease in ability to undertake tasks effectively.

The study undertaken by Dorrian *et al.* (2006) into impact on healthcare of levels of sleep of nursing staff sampled the sleep profile and linked adverse events for a set of 23 nurses over a period of 644 days (377 shifts). The authors indicate that the modern directives in healthcare within hospitals, namely to treat patients more rapidly so that they are acutely ill for shorter periods, places increased nursing activity within the time phase of actual nurse contact. Patterns of increased nursing workload can be met in part with increased use of overtime, though this in turn increases the potential risk of increase of errors due to fatigue. Specific items recorded during the study included work hours (scheduled and actually worked), sleep length and quality, level of fatigue/sleepiness/stress and errors which were subdivided into categories of medical, transcription, charting, procedural, slip/fall and 'other'. Categories of alertness, mental exhaustion, physical exhaustion and stress were recorded on 1 to 5 analogue scale. The study indicated a reduction of effectiveness within night shift activity compared with day shift activity.

3.3 Stress as an Indicator of Adverse Events

The study by Jones *et al.* (1988) into links between stress and medical malpractice examined these factors within four separate clinical settings. Stress was measured using the Heath Factors Inventory system as developed by the St. Paul Insurance Company in the USA. Specific measurements of stress related to job stress (29 items), job dissatisfaction (20 items), organisational stress (17 items) and personal stress (25 items). In one sub study a correlation with stress was generally found between hospital departments with higher malpractice rates compared with departments with lower values though no correlation was found with personal stress. The authors indicate, however, that it is

not clear if the effect is that malpractice events are more common because of the high levels of stress or the high levels of stress are a reflection of the high levels of malpractice. In a linked study involving 93 hospitals and also referenced within Jones *et al.* (1988), details were obtained of hospital wide stress levels and prevailing levels of malpractice within the selected hospitals. Again a strong correlation was found between the levels of stress and the level of malpractice, with again no link with personal stress.

As part of another linked study referenced within Jones *et al.* (1988), the level of medication errors was investigated as a programme of stress reduction was implemented within a specific hospital. In phase 'A', the pre-implementation phase, a mean level of 10.25 medication errors per month was recorded, while in phase 'B' , after implementation of the stress reduction programme, this had fallen to a level 5.14. A relevant feature of the study was that hospital staff were not aware that medication errors were being reviewed. One inference of this result is that stress is a causal factor for medication error and probably for other types of adverse clinical event.

3.4 Stress Induced by Adverse Events

An important stressing factor in healthcare can be the psychological impact on staff who feel responsible for adverse events, especially those that could have led to the death of a patient. The study by Christensen *et al.* (1992) where a series of eleven medical practitioners discuss specific medical errors which they consider are wholly or partly 'their fault', reveals stress factors which have the potential to exert a long term negative bias on subsequent work activity. The authors indicate that the problem is not helped by the 'elitist' concepts communicated within medical training programmes and that a more open approach to the acceptance of errors may be beneficial to all parties. It is likely that the very same psychological factors are also active for nursing staff. It is inferred that if errors were handled more appropriately in the Critical Care environment, this could act to relieve associated psychological pressures and stress. Also, units with lower levels of adverse incidents are likely to have reduced levels of stress triggered by this factor. It is generally identified that deaths of patients within the Critical Care environment can be identified as a significant stressing factor.

3.5 Impact of Hours Worked on Individual Effectiveness

The study by Barger *et al.* (2006) which was based on an extensive e-mail survey of 2737 medical residents in the USA, indicated a strong link with extended-duration work shifts and the level of adverse medical errors. Based on a total of 17003 completed monthly returns, table 3.1 summarises the study findings.

Level of extended-duration shifts	Odds ratio of at least one fatigue related preventable adverse event	Odds ratio of at least one fatigue-related significant medical error
Between 1 and 5	8.7	3.5
Over 5	7	7.5

Table 3.1. Summary of study findings after Barger *et al.* (2006).

The authors indicate that while the generation of serious medical errors is undesirable in itself, the impact on such errors on the 'responsible' medical residents can have seriously damaging effects in terms of triggering feelings of fear, guilt, anger, embarrassment and humiliation. These effects have been previously described by Christensen *et al.(*1992).

In the context of typical Critical Care Units in the UK, the element of sleep deprivation will still play a part in influencing risk of adverse events though not at the levels prevailing when doctors were required to regularly work extended hours. In addition, while the effects of sleep deprivation on task competence are widely appreciated, such as by van Dongen *et al.* (2003), adequate sleep is also considered a requirement for memory consolidation and learning after review by Stickgold, James and Hobson (2000). While it has been accepted that effective sleep is required for perceptual learning, the study by Walker *et al.* (2002) has indicated that improvement of a motor skill is dependent on nocturnal sleep and with a link possibly to the level of stage 2 non rapid eye movement sleep. This would imply that uptake of new skills/knowledge would be impaired by poor quality sleep patterns. Thus not only is an adequate sleep pattern important for task completion, it also is a requirement for optimal task learning.

3.6 Stress Monitoring Studies in Healthcare

The study by Elfering *et al.(*2006) investigated factors related to stress within the healthcare environment where over two weeks, all stressful events (minor and major) were monitored by 23 newly qualified nurses within 19 hospitals in Switzerland. The analysis of safety related stressful events is outlined in table 3.2. One subset of questions related to the incident itself where a description of the incident was followed by qualification of likelihood of the event being repeated and also potential of changing the situation for the better. A separate question related to compliance with safety regulations. A series of questions related to the element of 'control' the individual had in work activity e.g. level of planning of day, ability to take breaks during working day, preparing tasks (e.g. information, materials etc.), restrictions caused by problems in other areas, level of multitasking and level of distraction e.g. telephone calls. For each stressful event, therefore, the situational information was qualified by the other factors.

It was determined that 19.7% of recorded stressful events were related to patient safety, though, it could be argued that all stressful events potentially have an impact on the individual's effectiveness to carry out duties with patients. This level, however, could range between 10% and 40% within the group sampled.

Event description	Number (%)
Fragmentary, incomplete or incorrect documentation	25 (40.3)
Medication error/near miss	13 (21)
Forgotten or incomplete briefing	3 (4.8)
Delays in delivery of patient care	6 (9.7)
Patient casualty	4 (6.5)
Violence/aggression	6 (9.7)
Failed bleeper	2 (3.2)
Risky patient behaviour	3 (4.8)

Table 3.2. Summary of event description for patient safety related stressful events after Elfering, Semmer and Grebner (2006).

While the study is focusing on the stressful events that directly related to care of the patient, the events that are not reported (ie personal, social etc.) potentially have an effect on the performance of the individual. Also, there is no severity scale to rank the event, though in most cases this can be inferred from the context of the report. Studies like this are important to reveal issues that would otherwise remain unreported. While the study appears not to have involved the Critical Care environment, its observations would tend to apply generally.

The review by Donchin and Seagull (2002) of the 'hostile environment' of the intensive care unit addresses a wide range of issues which have been identified as potential risk factors within Critical Care Units. In addition, the review draws attention to the ambiguities which exist for alteration of processes. It is, for example, probably easier to purchase the latest model of health technology than modify a specific work practice which is firmly embedded within existing practice. This gives rise to the concept of organisational inertia and the difficulty of making changes to work practices. Also, the extensive use of patient monitoring gives rise to significant streams of data which staff struggle to evaluate and utilise effectively.

The study undertaken by Fischer *et al.* (2006) also found that staff working within the Critical Care environment tend to have raised levels of cortisol – the 'fight or flight' hormone associated with stress. Such elevated levels were also not reported within other acute areas of the hospital, indicating that the Critical Care environment has unique factors which tend to trigger heightened stress within the

individual. Also, the environment of the ITU is full of noise of alarms, the majority of which are false alarms. In addition, where, for example, many items of similar equipment are in operation together in close proximity, recognition of a specific alarming device is a problem as indicated by Seagull and Sanderson (2001). In addition Haas and Casali (1995) have indicated that often the severity of the prevailing situation is not matched by the signature of the auditory warning signal. The study undertaken by Grumet *et al.* (1994) highlighted the significant additional stress which 'a sea of alarms' can trigger. Presumably in units with more space per patient, there would be better 'auditory discrimination' of equipment that was alarming. This is an example of physical environment having an impact on clinical risk.

3.7 Effectiveness and Shift Working

The effect of length of working shifts (day and night) has been extensively studied within a range of work sectors as based on obvious concerns for both the health of the individual and the safety of work practices and associated systems. The study of Sallinen *et al.* (2004) analysed, under laboratory conditions, factors relating to day shifts of 12 hours where a simulated distillation task was used to replicate work activity. Measures of individual functioning included electroencephalography/electro-oculography (EEG/EOG) for objective sleepiness. The Karolinska Sleepiness Scale was used to assess subjective sleepiness. Work/task performance were evaluated separately. The level of task stimulation was found to influence the degree of objective sleepiness, on a par with the level of sleep debt. The authors commented that with many 'tasks' in industry now consisting of a 'supervisory' role, there was an increased risk of lower task performance with the reduction of skill/decision making components of work. Translating this to the Critical Care environment, it is important that work, at any level of staff involvement, retains a stimulating component. This finding gives rise to the concept of an alertness factor derived from task activity and which probably has increased significance for night shift working where level of task activity is generally reduced.

The finding of Sallinen *et al.* (2004) regarding individual performance during the shift indicate that neither sleepiness nor performance errors peak at the end of the 12 hour day shift. This is in agreement with other investigators such as Reid and Dawson (2001). Work simulation and cognitive tests were best at noon and during late afternoon sessions and worst during the morning or mid afternoon sessions. Such 'daytime' circadian components, however, have not been incorporated into the risk simulation model described in this thesis.

Within the extensive literature on shift working and individual effectiveness, there appears to be a consensus on relative alertness within a 12 hour dayshift and 12 hour nightshift working. The study of Budnick *et al.* (1994), describing 12 hour shift systems starting at 06.00 am describes a mid morning peak of alertness at around 9.00 am and in the afternoon around 04.00 pm - with a lowest

alertness at around 02.00 pm. For the night shift, there is a general decline of alertness from around 08.00 pm towards the end of shift and with lowest alertness around 04.00 am.

While night shifts are unavoidable, researchers have been keen to determine which pattern of night shift best preserves individual performance. The study of Wilkinson *et al.* (1989) compared average reaction time of nurses during night shift for a weekly rotating night shift and a three monthly permanent night shift. There was a general deterioration in reaction times measured 'late' in shifts at around 03.30 am for both the 'weekly' and the 'monthly' shift pattern though the differences were not identified as significant.

The study of Borges and Fischer (2003) of nursing 12 hour shifts within the Brazilian health system has identified significant differences between the 7^{th}, 10^{th} and 12^{th} hour of night shift of self declared alertness using the Karolinska Sleepiness Scale and based on shifts in time frame of 07.00 am to 07.00 pm. In a review of implementation of 12 hour shifts within a Brazilian petrochemical plant, an evaluation was undertaken by Fischer *et al.* (2000) of self declared alertness during both day and night shifts at 2^{nd}, 6^{th}, and 10^{th} hour of such shifts. Sequential reductions in alertness values were observed for both day and night shifts, with greater reductions evident for the night shift.

The general evidence of shift working is to identify a variation within the day shift based on circadian rhythm and also during the night shift with a loss of effectiveness towards 03.30 am. It is generally observed that adaption to night shift working after transfer from a day shift pattern accentuates such shift deficiencies.

3.8 Performance Obstacles in Nursing

The identification of 'microsystems' within the provision of Critical Care medicine has been an identified feature of successful units of health provision as expounded by Carayon and Gurses (2005) and Nelson *et al.* (2002). This has facilitated analysis of performance obstacles within healthcare which are relevant to consider within the context of models simulating risk/effectiveness factors. A specific study by Gurses and Carayon (2007) has identified a key set of factors identified as performance obstacles as indicated in table 3.3 and within indicated factors of a work system model.

Identified Obstacle	Response	Work System Model Element
Equipment not available	32%	Technology and Tools
Patient rooms not well stocked	32%	Technology and Tools
Spending time seeking supplies	24%	Technology and Tools
Spending time searching for equipment	20%	Technology and Tools
Spending time dealing with family needs	35%	Tasks
Spending time teaching family	34%	Tasks
Delay in obtaining medicine	36%	Organisation
Searching for patient charts	23%	Organisation
Change of shift report too long	18%	Organisation
Inadequate shift change information	18%	Organisation
Delay in obtaining new medical orders	21%	Organisation
Distractions from family members	42%	Environment
Insufficient space	26%	Environment
Phone calls from family members	23%	Environment

Table 3.3. Summary of performance obstacles - after Gurses and Carayon (2007).

This study by Gurses and Carayon (2007) identifies strongly the component of time required to cope with relatives. This factor surfaces in the study as almost the dominant distracting factor. Presumably this is a component which relates to the actual period of patient visiting and a component relating to other contact such as by phone.

In terms of factors which can influence individual effectiveness, the identification of factors relating to handover are identified as being significant. This can be identified as the initial handover on admission where the handover can be from an emergency department as described by McFetridge *et al.* (2007) or relating to the normal nursing shift handover as reviewed by Currie (2002). It is appropriate to consider 'handover skills' as a specific competency within the range of competencies identified for nursing staff. It is identified that there will be a general loss of effectiveness of an individual starting a shift due to 'handover' factors. The most significant 'handover' effect can be considered to take place on patient admission, since the Critical Care unit as a whole has to structure and implement the relevant care pathway for the patient.

In terms of 'obstacles to care', the study by Gurses and Carayon (2007) also references aspects of the physical environment which undoubtedly does influence individual effectiveness. This is in particular relevant bearing in mind the opening in July 2006 at University Hospital Coventry of a new 26 bed Critical Care Unit as the amalgamation of three previously separate Critical Care facilities within two hospitals. In general, the alteration of the physical characteristics of the Critical Care environment to improve patient space and equipment provision may influence the quality of overall patient care team interaction. It can be considered that factors relating to the physical environment will have a direct effect on individual effectiveness. One example is identified as influencing the amount of time

chasing supplies and equipment and also influencing the degree of team interaction and information sharing. For any specific modelled system, the physical environment can be considered as a 'constant' of the model. It is a significant thought, however, that the quality of the physical environment of a Critical Care Unit will have a direct influence on its corresponding mortality rate, though little information is available to validate this assumed link. It is possible, in the model, however, to include factors which are influenced by the physical environment of a Critical Care Unit. It would seem, however, an important field of study to develop based on the undoubted impact of such a factor or patient survival rates for the lifetime of use of the facility. Elements subsequently identified include factors which influence time spent 'at the bedside' and factors which facilitate 'team communication' which are further addressed in chapter 6 of the Thesis. In addition, factors relating to competency sharing, supervision and distraction are further developed in chapter 6.

3.9 Job Shop Models

Job shop models conventionally relate to optimisation of production of a series of tasks with availability of production resources as described by Kim and Egbelu (1998) and Bagchi (1999). One optimisation technique commonly used for this process is genetic algorithms. In application of such techniques, the key factors relate to process definition identified as configuration of production and availability of machine resources to optimise production.

The inclusion of elements relating to individual 'operator' effectiveness represents the introduction of an additional degree of complexity into such models. The optimisation technique can be considered to be applied to ensure that individuals are not over fatigued by the pattern of allocated work which would result in reduced work throughput. This concept can be considered to be relevant within the framework of industrial process control, but is less applicable within the context of a Critical Care environment. The more general interest for the Critical Care environment, however, is the introduction of simulation of levels of individual effectiveness

Using a job shop methodology within a veterinary practice, Koszalka and Skworcow (2003) outlined a more extensive set of parameters which can describe stamina levels. Specific parameters in this analysis included:

- Operation difficulty
- Endurance
- Recovery rate
- Fatigue threshold - the time of continuous work above which fatigue has impact
- Minimum stamina – level below which a worker is rested

It is therefore within a subset of literature that references to these parameters are made, rather than within that of medical literature. Most scheduling problems, however, relate to situations where there is a much higher control over the processes being optimised and the individual tasks can be included/excluded within the model structure. In the clinical environment however, the tasks are essentially scheduled on the basis of clinical requirements and the level of control on use of resources is limited. It is a characteristic, however, of Critical Care function that levels of activity will fluctuate significantly. In terms of describing the mathematical function of variation of stamina, specific options within 'job shop' models can be implemented as:

- Use of fatigue threshold (time of activity after which stamina tends to reduce)
- Function to simulate reduction of effectiveness with time
- Function to simulate increase of effectiveness with rest

Most clinical papers, however, which reference individual and group 'effectiveness', however, do not model such factors within a mathematical framework.

3.10 Development of Individual Effectiveness Models

The effectiveness of staff remains a key consideration within the model of activity of staff within the Critical Care environment. It is therefore necessary to establish an empirical model of individual effectiveness based on specific elements identified within the literature. Within job shop models factors such as staff resilience/fatigue are identified as being important in terms of achieving effective production/processing. In the context of the model of staffing within an intensive care facility, for example, consideration is required of specific parameters which can include:

- Identification of loss of effectiveness with time during shift working
- Identification of recovery of effectiveness following rest/quiescent periods
- Identification of influence on effectiveness of nature of workload
- Identification of influence on effectiveness of job stress

There is also the factor of more complex stress factors involving burnout and clinical depression as described by Iacovides *et al.* (2003). While some work activity can be stressful due to the nature/complexity of the activity, the development of 'burnout' can potentially trigger more significant loss of effectiveness when the feeling of individual worth based on career expectations and appreciation of personal competence are undermined and diminished. In terms of simulation of 'burnout' effects, this can be identified as developing and recovering over longer time periods such as weeks and months, in contrast to shorter term effects during time scales of specific working shifts.

These stress factors acting over longer term periods are identified but not implemented as factors within the current risk model.

3.11 Summary of Parameters Affecting Individual Effectiveness

The broad range of literature relating to task effectiveness has been generated on account of a wide range of objectives, but lacks the specific clarity to simulate task effectiveness within the Critical Care environment. As an outcome of a review of relevant literature, specific functions listed in table 3.4 are identified which are considered to impact on 'individual effectiveness'.

It is proposed that a generic individual effectiveness function can be described as:

$$Eff = f\,(E_{ns}\,E_{ph}\,E_{em}\,E_{me}\,E_{h}\,E_{adm}\,E_{sd}\,E_{lt}) \quad (3.1)$$

Which signifies *Eff* as a function of the independent elements.

Specific functions are identified which relate to referenced parameter variations.

Reference	Description
E_{ns}	Circadian rhythm day shift and night shift working
E_{ph}	Fatigue, based on physical exertion and based on task activities over a shift cycle
E_{em}	Fatigue, based on emotional/stress 'exertion' and based on task activities over a shift cycle
E_{me}	Fatigue, based on intellectual 'exertion' and based on task activities over a shift cycle
E_{h}	Effects related to handover at the start of a 12 hour shift
E_{adm}	Effects related to admission of a new patient
E_{sd}	Effect due to sleep deficit
E_{lt}	Long term effect

Table 3.4. Parameters/factors affecting individual effectiveness.

3.12 Components of Intervention Independent Effectiveness

The functions identified with aspects of effectiveness have been further developed within chapter 6 to a level for use within the risk simulation process. Specific functions identified as independent of specific interventions include:

- Handover function at start of 12 hour shifts (E_h)
- Effectiveness during night shift (E_{ns})
- Effectiveness reduction due to sleep deficit (E_{sd})
- Effectiveness reduction due to admission (E_{adm})
- Effectiveness reduction due to long term effects(E_{lt})

For effectiveness functions which are not dependent on interventions, a specific function E_{eff1} is defined as the minimum value of component functions.

$$E_{eff1} = Min(E_h\, E_{ns}\, E_{sd}\, E_{adm}\, E_{lt}) \quad (3.2)$$

The value of effectiveness with handover function, E_h, is referenced as:

$$E_h = (1\text{-}A0\ e^{-c1.(t\ -t0)}) \quad (3.3)$$

Where *t* is time expressed in days relative to start of handover period at time *t0* and *A0* determines the initial loss of individual effectiveness at the start of the shift and the value of *c1* relates to the rate of recovery of effectiveness values. Values of *c1* and *A0* are associated with the 'level' of patient condition on a scale of 1 (least care required) to 5 (most care required). It is subsequently considered appropriate to assign values of *c1* and *A0* for specific patients on the basis of patient severity 'grade' in range 1 to 5 and on the nursing band in range 5 to 7 of nurse assigned to the patient.

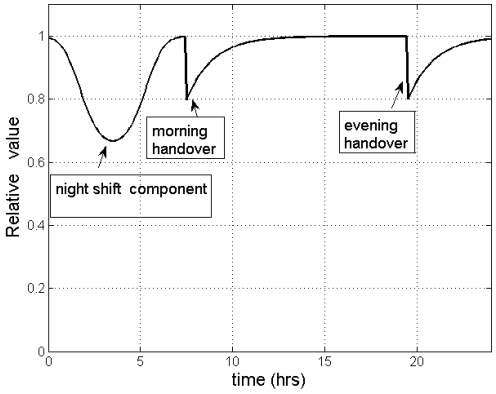

Figure 3.1. Details of typical function E_{eff1} (E_{ns} =1; E_{adm}=1) as the product of component functions where the components indicated relate to the night shift element, morning handover and evening handover.

In figure 3.1, the sleep deprivation component of the function shows a minimum value around 03.30 am which is a common feature described in studies referencing task effectiveness within shift work systems. The handover periods at 07.30 am and 07.30 pm are classified by a sharp reduction in

value followed by a period of recovery. Values of *A0* and *c1* as indicated in table 3.5 were chosen to provide flexibility in model implementation.

	A0	A0	A0	hr	hr	hr
	band 5	band 6	band 7	band 5	band 6	band 7
grade 5	0.25	0.2	0.15	1.5	1.25	1
grade 4	0.275	0.225	0.175	2	1.75	1.5
grade 3	0.3	0.25	0.2	2.5	2.25	2
grade 2	0.325	0.275	0.225	3	2.5	2.5
grade 1	0.35	0.3	0.25	4	3.5	3

Table 3.5. Details of assigned values of *A0* and time to 50% recovery (hr - hours) for specific severity grade of patient (grade 1 most complex) and assigned nursing band.

For a given value of hr, the value of c1 is derived by:

$$c1 = (0.6913) / (24/hr) \quad (3.4)$$

There is also an issue as the how separate functions contribute towards the combined effectiveness function of an individual. Options include a minimum value, a product of components or a function derived from fuzzy logic. Initial simulations of processes have utilised the minimum value of separate identified functions. Section 6.15 outlines the use of fuzzy logic to derive a single effectiveness value from component inputs.

The characteristics of the handover responses indicated in table 3.5 can be anticipated to relate in some measure to the level of experience of the corresponding nursing staff, with initial loss of efficiency being greatest for least experienced staff. This is based on empirical observations that more experienced staff will experience less of a reduction in individual effectiveness at the start of the shift and the recovery process will be faster.

A common theme of observations of day/night shift working is the loss of effectiveness during the night shift - with a maximum loss occurring around 3.30 am but with a mode of recovery towards the time of shift handover. While some variation is identified within the ‘day’ shift hours of the circadian rhythm, this contribution is ignored. Equation 3.5 outlines the empirical function used to implement this component of individual effectiveness and with relative value of function indicated in figure 3.2.

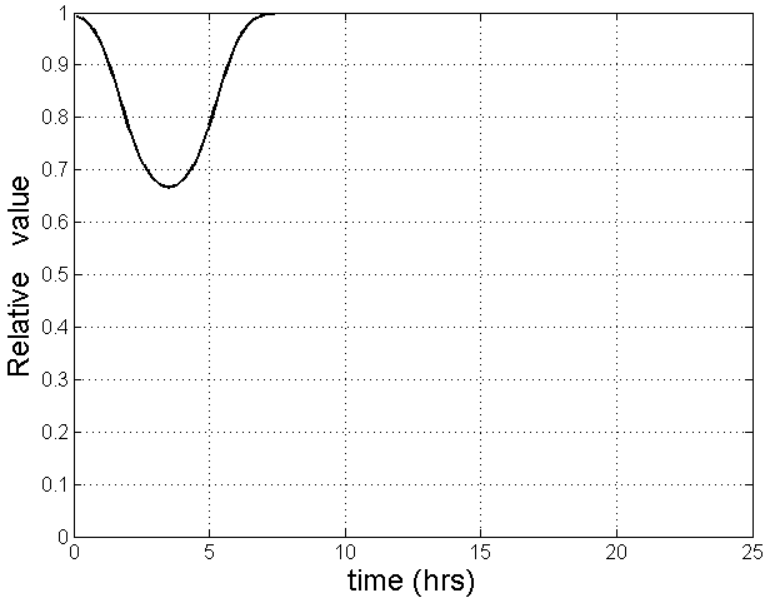

Figure 3.2. Reduction in individual effectiveness during night shift.

$$E_{ns} = \frac{1 + e^{bns(t-ans).(t-ans)}}{1 + e^{bns(t-ans).(t-ans)} + dns} \qquad (3.5)$$

In figure 3.2, *ans*=0.14583, *bns* = 250 and *dns* = 1 and t is the time within day cycle and expressed in days.

At the time of least effectiveness, the value of E_{ns} is 0.6667. Also, when the exponential terms diverge to large values, E_{ns} approaches unity. The value of *ans* is set to produce a minimum at 3.30 am. The value of *bns* is set to ensure that effectiveness returns to unity at shift changeover around 08.00 am.

3.13 Effectiveness Components: Physical, Emotional/Stress and Intellectual (Intervention Dependent)

Specific effectiveness functions have been defined which relate to physical reserve, emotional reserve and intellectual reserve. Each factor is associated with two specific constants, one related to the reduction in parameters with each activity (at a specific point in time) and another with its mode of relaxation back to higher levels. For example, the function identifying physical reserve is:

$$E_{ph}(t2) = E_{ph}(t1) + (1-PHval.PHwgt)\ (1- e^{-rph.(t2-t1)}) \qquad (3.6)$$

Where *PHval* is the component of a discrete physical effort (*PHval.PHwgt*<1), *rph* is a recovery parameter and *PHwgt* is a weighting value based on individual stamina, *t1* is the time at which the

effect is applied, t2 is the current time value and *t2>t1.* Units of *t2* and *t1* are in days. The value of effectiveness experiences a 'dip' at each component of an intervention which is followed by a period of exponential recovery towards a value of unity.

It is apparent that a younger, fitter person will have more physical stamina (smaller value of *PHwgt,* greater value of *rph*) than an older, less fit person (larger value of *PHwgt*, smaller value of *rph*. It is appropriate to identify 'grades' 1 to 5 to identify the grades of physical stamina as outlined in table 3.6, with corresponding values of *PHwgt* and *rph.*

	PHwgt (PHval weighting)	50 % recovery time (minutes)
grade 1 Physical stamina	1.5	20
grade 2 Physical stamina	1.25	20
grade 3 Physical stamina	1	15
grade 4 Physical stamina	0.75	10
grade 5 Physical stamina	0.5	5

Table 3.6. Identification of characteristics of physical reserve as a function of 'grade' where grade 1 is least physical stamina and grade 5 is greatest level of physical stamina.

The value of *PHval* is held within the main interventions file as the value with which the physical reserve value is decremented each time the activity is undertaken for unity value of *PHwgt.* The values of *PHwgt* and recovery times were empirically derived from observations of procedures undertaken by nursing staff.

This function of effectiveness derived from physical effort is associated with variations within a specific shift and where at the start of each new shift, a value of $E_{ph}(t)$ of unity is assigned.

A similar function can be defined for emotional/stress effort:

$$E_{em}(t2) = E_{em}(t1) + (1\text{-}EMval.EMwgt)\ (1 - e^{-res(t2-t1)}) \quad (3.7)$$

and intellectual effort:

$$E_{me}(t2) = E_{me}(t1) + (1\text{-}MEval.MEwgt)\ (1 - e^{-rme(t2-t1)}) \quad (3.8)$$

As previously indicated, the value of effectiveness experiences a 'dip' at each component of an intervention which is followed by a period of recovery.

	EMwgt (EMval weighting)	50 % recovery time (minutes)
grade 1 EM stamina	1.5	15
grade 2 EM stamina	1.25	15
grade 3 EM stamina	1	15
grade 4 EM stamina	0.75	12.5
grade 5 EM stamina	0.5	10

Table 3.7. Identification of characteristics of emotional/stress reserve as a function of 'grade' where grade 1 is least emotional/stress stamina and grade 5 is greatest grade of emotional/stress stamina.

	MEwgt (MEval weighting)	50 % recovery time (minutes)
grade 1 ME stamina	1.5	15
grade 2 ME stamina	1.25	15
grade 3 ME stamina	1	15
grade 4 ME stamina	0.75	12.5
grade 5 ME stamina	0.5	10

Table 3.8: Identification of characteristics of intellectual reserve as a function of 'grade' where grade 1 is least intellectual stamina and grade 5 is greatest grade of mental stamina.

These functions are empirically derived based on observations of nursing staff within the Critical Care Unit within University Hospital, Coventry. A specific shift was populated with interventions associated with a post surgical level 3 patient (ventilated). Values were identified with depletion of reserve values (physical, emotional and intellectual) for each intervention as indicated in table 3.9. This process used a specific look up table indicated in table 3.10.

time	Int.Ref	Activity	Physical Reserve depletion	Emotional Reserve depletion	Intellect. Reserve depletion
07:45	834	suction (vent)	4	4	3
07:50	1173	respond patient monitor alarm	1	2	4
07:55	526	respond to syringe alarm	1	2	5
08:00	11	hourly vital signs	6	4	6
08:05	1341	empty urine bag	4	2	4
08:15	833	monitor ventilation	1	2	4
08:20	872	implement nebulised drugs	3	3	5
08:25	524	administration IV (syringe)	3	4	5
08:30	194	check NG tube ph	3	4	5
08:35	834	suction (vent)	4	4	3
08:40	173	observe wound drainage	2	4	3
08:45	524	administration IV (syringe)	3	4	5
08:50	1173	respond patient monitor alarm	1	2	4
08:55	526	respond to syringe alarm	1	2	5
09:00	11	hourly vital signs	6	4	6
09:05	521	identify drug round	2	4	5
09:10	522	administer drug (drug round)	4	4	4
09:15	1221	update patient notes	2	3	6
09:20	331	routine ABGS (arterial bloods)	3	3	3

Table 3.9. Extract from sample intervention entries of grade 3 patient (surgical) with identified components of ‘reserve’ depletion for specific interventions. (Depletion values shown x 100).

The values of physical, emotional and intellectual reserve depletion are empirically derived based on observations within the Critical Care Unit within University Hospital, Coventry and with utilisation of mapping function structured within table 3.10.

Depletion Value	Physical Reserve	Emotional Reserve	Intellectual Effort/Concentration
1 to 2	Light effort, short time period	Low levels of stress for short time period	Low levels of mental effort for short time period
3	Light effort for medium time period	Low level of stress for medium time period	Low levels of mental effort for medium time period
4 to 5	Moderate effort for short period	Moderate emotional stress for short time period	Moderate mental effort for short time period
6	Moderate effort for medium time period	Moderate emotional stress for medium time period	Moderate mental effort for medium time period
7 to 8	Significant effort for short time period	Significant emotional stress for short time period	Highly complex mental effort for short time period
9	Significant effort for medium time period	Significant emotional stress for medium time period	Highly complex mental effort for medium time period
10	Extreme physical effort	Extreme stress	Extremely difficult mental task

Table 3.10. Derived scale of depletion for physical, emotional and mental reserves based on activity associated with interventions.

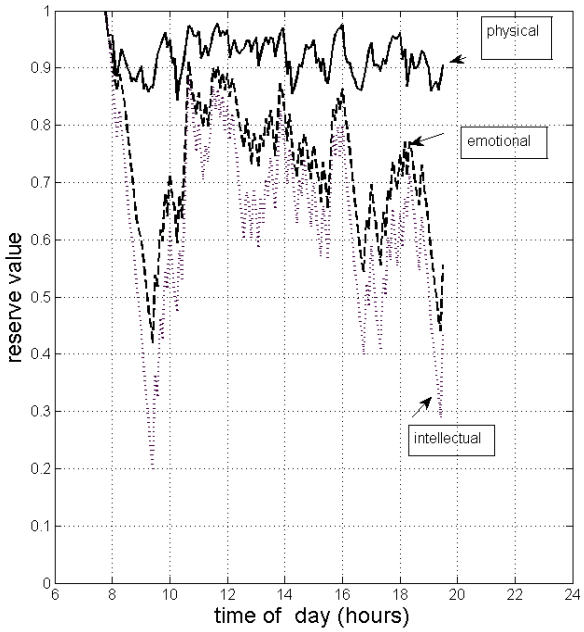

Figure 3.3. Details of variation of grades of physical, emotional and intellectual reserves during a simulated set of shift interventions (Physical : grade 3; emotional: grade 3; intellectual : grade 3).

The characteristics of the simulated specific 'reserve' function will vary significantly with the level of clinical activity simulated. The dip in value of emotion and intellectual reserves between 08.00 am and 09.30 am in figure 3.3 is due to a sequence of continuous interventions with no periods of recovery. For the simulated series indicated in figure 3.3, physical depletion would not appear significant, while that of intellectual effort would seem to vary more widely.

It is an observation that the stress and also intellectual effort of undertaking work will reflect to some extent the relative competence of the individual, with competency gaps increasing the relative stress and intellectual effort involved in completing tasks. At this stage in the model, coupling between competency and stress levels has not been implemented. The function of 'grade' of stamina is intended to relate to the intrinsic characteristics of the individual. It is likely, however, that the effect of gaps in competency would 'depress' the grade of stamina applied to a emotional/stress reserve because the task would be associated with greater stress. It is identified that more extensive review of individual effectives functions as outlined in table 3.4 will arise from operation of the risk simulation system. In general terms, the literature relating to workload analysis in the clinical environment does not identify separate components of physical, emotional/stress and intellectual stamina/reserve to aspects of staff effectiveness though it is considered important to introduce these separate factors into the risk simulation model.

3.14 Summary

This chapter has identified the model elements that describe individual effectiveness as a function of contributing factors which include work activity, shift profile, admission activity and sleep deficit. The following chapter addresses the task of simulating episodes of clinical activity based on both observations within the Critical Care Unit at University Hospital Coventry and analysis of data related to admission/discharge episodes and associated clinical interventions.

Chapter 4: Characterising Clinical Activity

4.1 Introduction

This chapter outlines an approach of simulation of clinical activity within the Critical Care environment based on analysis of patterns of admission/discharge activity and associated clinical interventions. The specific patient 'record' can be considered to consist of a series of clinical interventions between the point of admission and point of discharge, The exposure of risk to a patient is related to the type and number of interventions experienced by the patient within this time.

The chapter describes two main simulation processes, one relating to admission/discharge episodes and the other to the clinical interventions experienced by patients. The simulation of admission/discharge episodes uses the framework of admission/discharge probabilities related to activity within a normalised 168 hour element week. The process of simulation of patient interventions is considerably more complex. One component utilises historical patient activity data within a clinical activity data base to predict likely patterns of interventions as a function of length of patient stay and specialty. A second component is introduced to include components of standard nursing practice based on observation of activity within the Critical Care Unit within University Hospital, Coventry.

4.2 Role of Interventions

Patients in the environment of a Critical Care unit undergo 'interventions'. The majority of these are carefully documented on a daily basis and appear within a patient's clinical data record. Recording of this data is facilitated by the Quality Sentinel (QS) data base system. A formal system for classification of care delivered to the patient is by means of TISS (therapeutic intervention scoring system) (see Appendix 2 and 3). This data provides both details of clinical information and a system for cost recharge for the Critical Care unit. There is obvious importance for accurate updating of each patient record. Each patient is marked up on a daily basis against this TISS data reference.

When a patient is discharged from the unit, this is exported as an 'episode' entry to an Access ® data base with key entries outlined in table 4.1.

Element
Admission date/time
Discharge date/time
Unit (CW, C5ITU, C2ITU,CCU)
Specialty
TISS score
Outcome (discharge/deceased)
Consultant

Table 4.1 QS data base export file data: Key data entries

Interventions are also identified which represent structural functions within the unit, such as admission processes and discharge processes. In addition, numerous basic nursing processes not referenced within the TISS system require to be identified since they represent a significant component of nursing activity. These have been identified by periods of observation within the unit in Coventry and are referenced in Appendix 4.

4.3 Historical Sequences of Clinical Care Data

QS data are available from February 2002 but the more relevant data are available following the opening of the Critical Care Unit within University Hospital in Coventry in July 2006 when the activity of three Critical Care units was combined into a new single facility. Data set #1 is referenced as the set of admission/discharge data TISS data relating to the pre-2006 move and within time frame 2002 to 2005. Data set #2 is the corresponding set between August 2006 to August 2008.

In addition, a more detailed TISS export data set based on patient day episodes has been extracted separately for calendar years 2007 and 2008. This is referenced as data set #3. These data sets are summarised in Appendix 1. Sets of data were analysed mainly using Matlab® though pivot tables in Excel® have also been employed to examine specific sets of extracted data. A basic parameter of the Critical Care facility is the relative activity within each specialty, as indicated in table 4.2.

Specialty	Number Cases	% of total	Specialty Reference
ENT	17	0.43	1
General Medicine	735	18.55	2
General Surgery	785	19.81	3
Gynaecology	26	2.7	4
Neurosurgery	1261	31.8	5
Obstetrics	14	0.35	6
Oral	27	0.68	7
Orthopaedics	135	3.41	8
Other	102	2.57	9
Paediatrics	2	0.05	10
Renal Medicine	87	2.2	11
Trauma	681	17.19	12
Cardiology	69	1.74	13
Urology	21	0.53	14

Table 4.2 . Summary of activity by speciality (data set #1)

Most of the activity for this data set is within the major specialties - General Surgery, General Medicine, Neurosurgery, Trauma and Orthopaedics. When represented as a function of length of stay, figure 4.1 indicates that the relative volumes of data associated with some specialties is limited and cannot be used to derive characteristic measures for the indicated specialty.

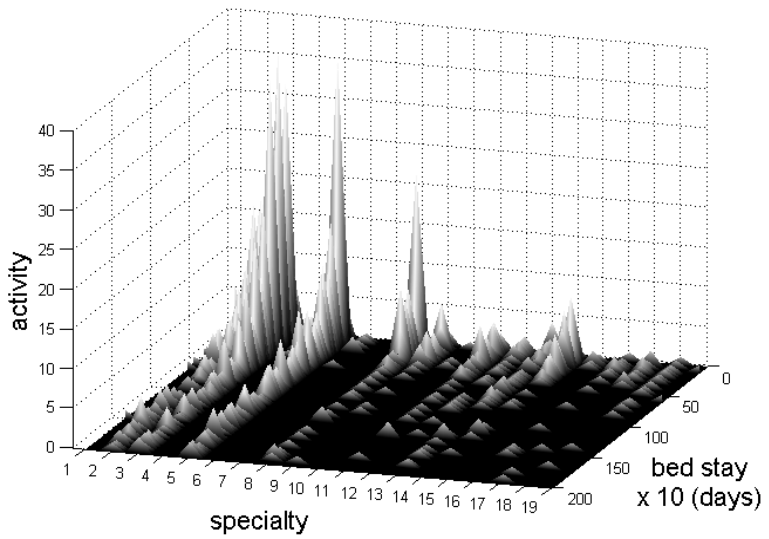

Figure 4.1. Graphical representation of bed stay by specialty for data set #1. Specialty codes as allocated in table 4.2.

For data set #2, a core set of specialties is identified as indicated in table 4.3 and where non-listed specialties are mapped into these specific sets.

Specialty	Specialty Reference Code
General Medicine	1
General Surgery	2
Neurology	3
Orthopaedics	4
Renal	5
Cardiac	6
Urology	7

Table 4.3. Core set of specialties identified for simulation activities.

4.4 Deriving Simulated Sequences of Clinical Activity

A key part of the development of the Clinical Risk model is to derive simulated sequences of clinical activity which mirror that of the available data sets. A key component of this is the admission/discharge profile as a function of specialty. This is strongly associated with a time within day component and also a day of week component by specialty. Typical 'day of week' patterns are identified in figures 4.2 to 4.3, indicating averaged activity for General Medicine and General Surgery.

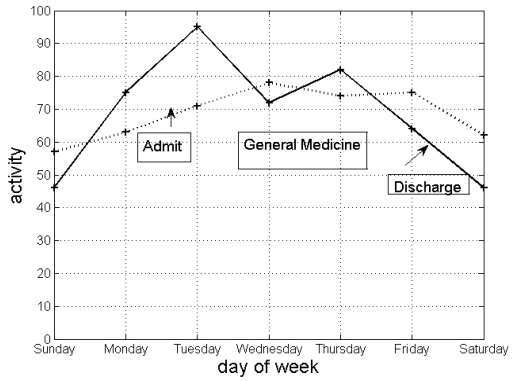

Figure 4.2. Summarised admission discharge activity: Data set #2 for General Medicine.

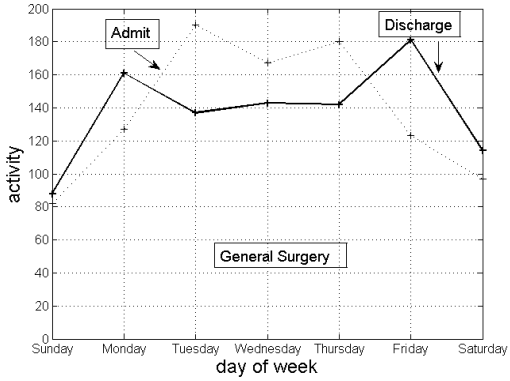

Figure 4.3. Summarised admission discharge activity: Data set #2 for General Surgery.

In figure 4.3 there is an increased level of discharge on Friday for General Surgery patients, while in General Medicine as indicated in Figure 4.2, the peak level of discharge is on Tuesdays.

Of significance is the variation of admission/discharge activity within a typical day as indicated in figure 4.4.

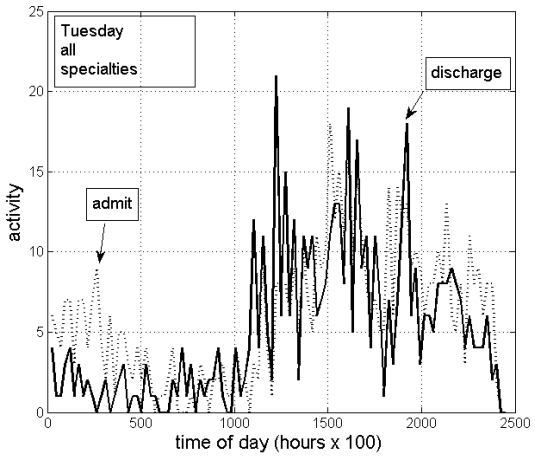

Figure 4.4. Admission/discharge summary for Tuesday for all specialties: data set #1

Figure 4.4 indicates the activity of admission/discharge in each hour interval for all specialties for Tuesdays. In simulating patterns of admission/discharge data, use is made of relative frequency of admission within hourly intervals within a seven day (Sunday-Saturday) cycle on a specialty basis. The available data provides also data relating to bed occupancy, as indicated in figure 4.5.

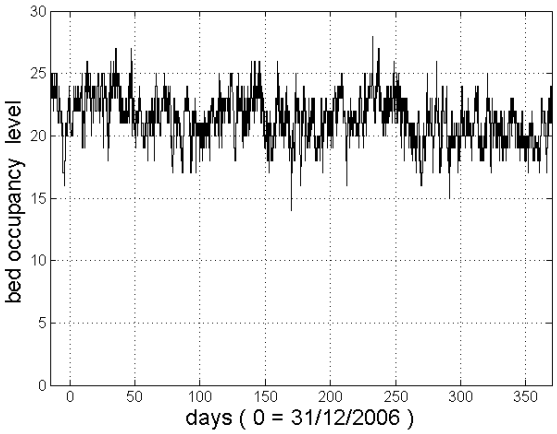

Figure 4.5. Bed occupancy levels as derived from admission/discharge dates/times (data set #2) - all specialties.

Analysis is also possible of the relative levels of activity associated with an identified specialty - as indicated in figure 4.6 - where the activity associated with General Surgery is displayed within a time frame of around 600 days.

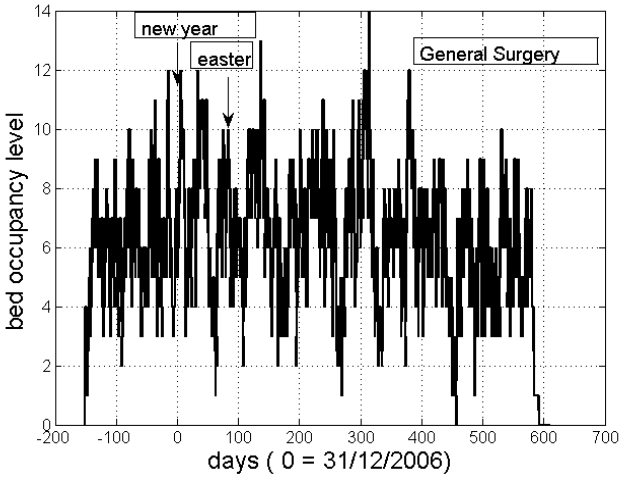

Figure 4.6. Bed occupancy levels as derived from admission/discharge dates/times (data set #2) : General Surgery

This approach provides an insight into 'understanding' the data in terms of trends and variations within the data set. It also provides structured probability distributions of activity to assist in the derivation of simulated sets of data.

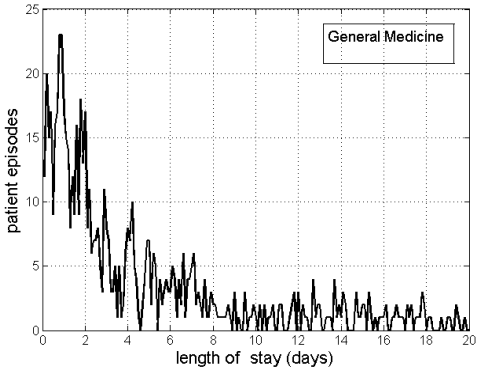

Figure 4.7. Bed stay data for General Medicine (data set #1)

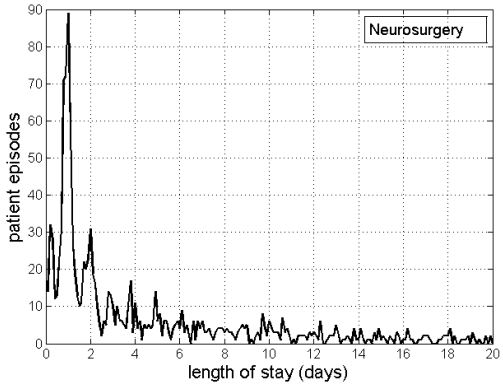

Figure 4.8. Bed stay data for Neurosurgery (data set #1)

A key observation, however, is the characteristic profile of bed stay as a function of specialty – as indicated in figures 4.7 and 4.8.

4.5 Derivation of Simulated Admit/Discharge Activity Sequences

The aim of the model is to provide a framework of clinical activity to allow simulation of sequences of clinical interventions. The model to simulate admission/discharge episodes has been structured to take account of collective activity levels on an averaged week basis (all specialties) and with bed occupancy subsequently structured on historical specialty patterns. Elements have also been incorporated to include delay in bed availability after patient discharge. It is on these sets of simulated data that characteristics of the risk model will be exercised. Such data sets will be used to test derived risk models for specific indications associated with clinical risk. The derived algorithm for driving the simulation component of admission/discharge is outlined in figure 4.9.

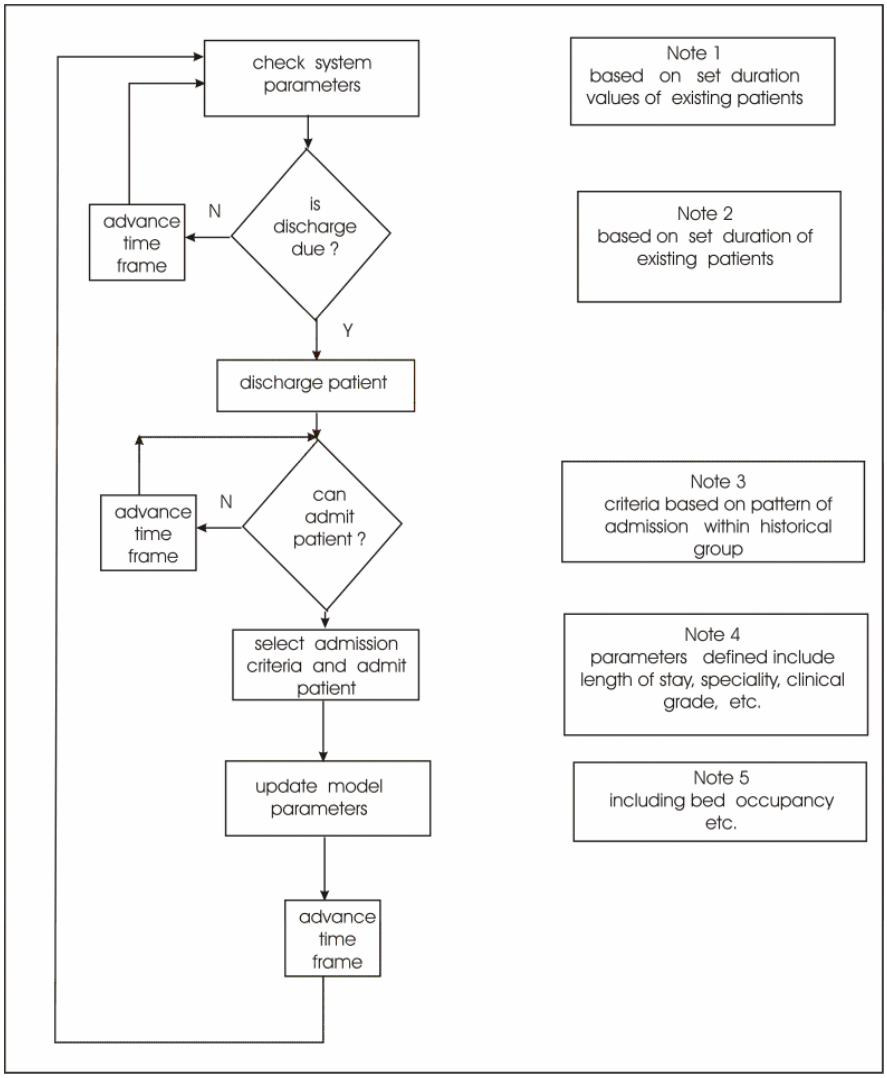

Figure 4.9. Process of generation of time sequence of admission/discharge data based on previous clinical data.

The available data sets (initially #1 and subsequently #2) have been utilised to derive a range of probability functions to simulate similar series of admit/discharge data. Figure 4.10 indicates how a value of bed stay is 'allocated' based on derivation of random value in range 0 to 1. The relative probability of selecting a value is inversely proportional to the gradient of the function value.

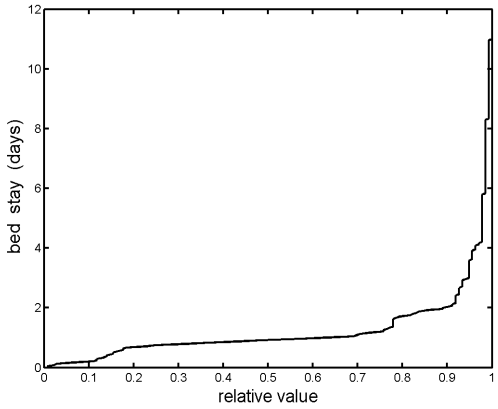

Figure 4.10. Derived bed stay (Orthopaedic Data) as a value of 'relative function' derived from random number selection. (total admissions = 136).

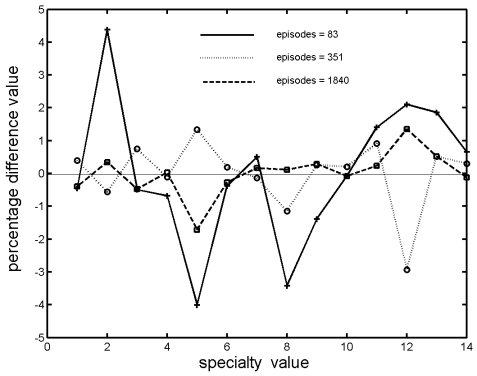

Figure 4.11. Variation of percentage difference (simulated - historical) for specific specialties and sets of simulated data. Maximum number of beds = 8.

A key part of the simulation module is to incorporate values of performance measure to determine the suitability of modelled parameters. Figure 4.11 compares the series of a simulated series admission/discharge sequences as a function of specialty. This indicates a convergence to initial data set for increasing number of episode simulations. This confirms that the 'historical' sequence of admission within specific specialties appears to be replicated in the simulated sequence. Evaluation has also been undertaken of the degree of overlap within the 168 hour week cycle between the historical data set and a finite sequence of simulated episodes as indicated in figure 4.12.

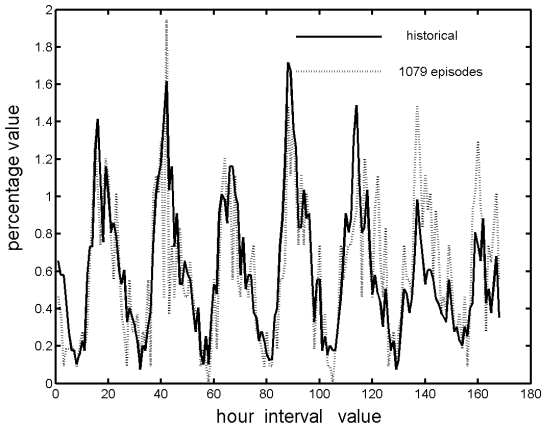

Figure 4.12. Variation of percentage admission rates within the 'normalised' week of 168 hour intervals for historical set #1 and simulated set.

Figure 4.12 indicates the percentage admission rate in 168 hour intervals for the historical set of admission data and also for the set of data for a modelled number of episodes. In general terms the simulated profile appears to follow the historical reference data.

In developing the corresponding algorithm for discharge activity, the time of discharge has to take account of the actual discharge profile, rather than use the admission profile plus information relating to length of bed stay. This is shown in figure 4.13 where the simulated discharge activity appears to overlap with the actual clinical data set. Various measures of conformity have been derived to evaluate functional overlap between the two data sets.

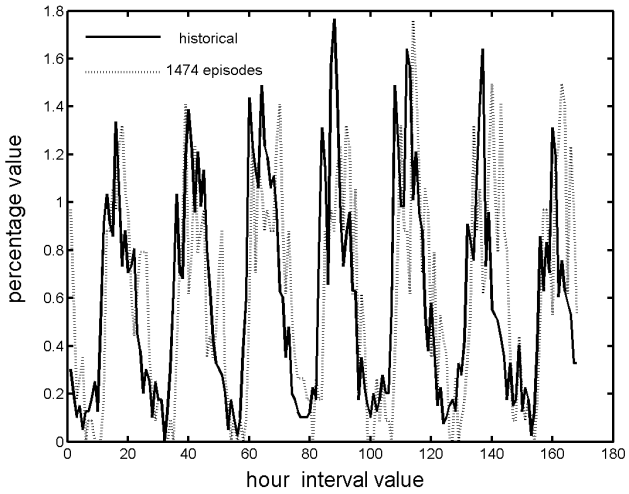

Figure 4.13 Details of percentage value for discharge sequences, with comparison of data set #1 and simulated sequence of 1474 episodes, with improved overlap between data sets.

Table 4.4 outlines sets of typical data derived through admission/discharge activity simulation.

Episode	Admit Time	Discharge Time	Duration	Spec.	Outcome	Bed No.	Occupied beds	Delay
1	2.5612	6.4218	3.8606	5	1	7	1	0.074754
2	2.7096	11.8253	9.1157	12	1	3	2	0.080125
3	3.0791	7.6916	4.6124	3	1	1	3	0.074755
4	4.6862	5.423	0.73684	5	1	8	4	0.046945
5	6.6042	13.6461	7.0419	12	1	2	3	0.029379
6	6.7973	22.4225	15.6252	3	1	8	4	0.021793
7	8.6256	11.0854	2.4598	5	1	1	4	0.082987
8	9.2273	22.8241	13.5968	9	2	7	5	0.034296
9	9.9006	22.6899	12.7894	3	2	6	6	0.030729
10	11.0339	12.8239	1.79	11	1	4	7	0.08161
11	11.9218	20.6002	8.6784	5	1	1	7	0.069916
12	15.9752	32.0007	16.0255	5	1	2	5	0.042485
13	16.5307	21.4682	4.9375	12	1	4	6	0.056841
14	16.8509	66.9133	50.0624	3	1	5	7	0.074457
15	18.7859	21.5122	2.7264	5	1	3	8	0.063646
16	21.1312	23.6012	2.4701	3	1	1	8	0.031862
17	21.9273	47.737	25.8097	3	1	4	7	0.044202
18	22.1007	37.1279	15.0271	2	2	3	8	0.041338

Table 4.4 . Start Sequence of Core Admit/discharge activity – data set #1: (outcome 1 = survival; outcome 2 = non-survival ; Delay = time after discharge of bed unavailability).

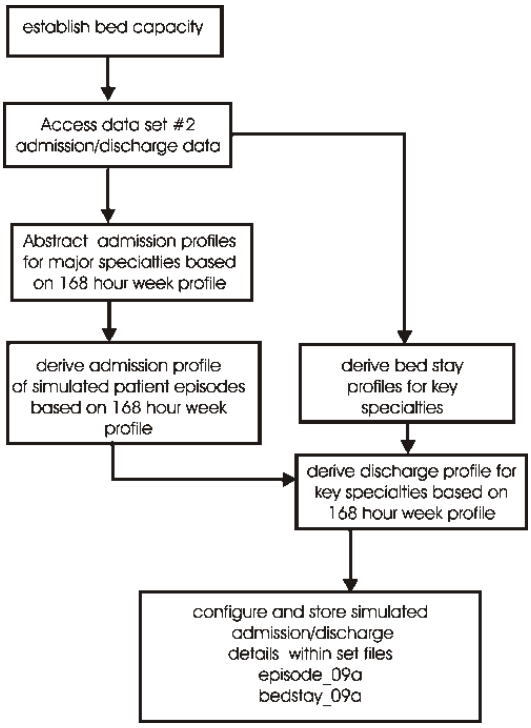

Figure 4.14. Summary of process of derivation of simulated data sets for admission/discharge episodes.

Figure 4.14 indicates the details process of simulation of admission/discharge profiles based on patterns of historical patient activity.

4.6 Simulation of Patient Interventions

A key component of implementation of a risk model within the Critical Care environment, and indeed any clinical environment, is to identify the interventions which patients undergo. In the first instance, this can be considered essentially as a functional model of sequential interventions, such as establishing ventilation, taking routine blood sample etc. as listed in Appendix 2. These are subsequently expanded into a more extensive set as indicated in Appendix 3 and where a specific TISS element is expanded to a related sub set of components.

Within the context of risk analysis, however, abstract 'interventions' are included such as review of patient admission notes, construction of patient care plan, communication of patient care plan and review of patient care plan. The significance of many of these interventions is reinforced within the relevant medical literature. In addition, observation of actual clinical activity within the Critical Care Unit at University Hospital, Coventry has allowed additional components of activity, as referenced in Appendix 4, to be identified.

In depth analysis of TISS activity has been obtained through a specific export from the QS data base system where each day episode of a patient stay is tagged with TISS activity (data set #3). While data has been essentially analysed using Matlab ®, a useful mode of inspecting data is that of Pivot table analysis within Excel. Figure 4.15 indicates the relative frequency of episodes of specific duration (days) with and without ventilation for General Medicine specialty and as a function of episode duration.

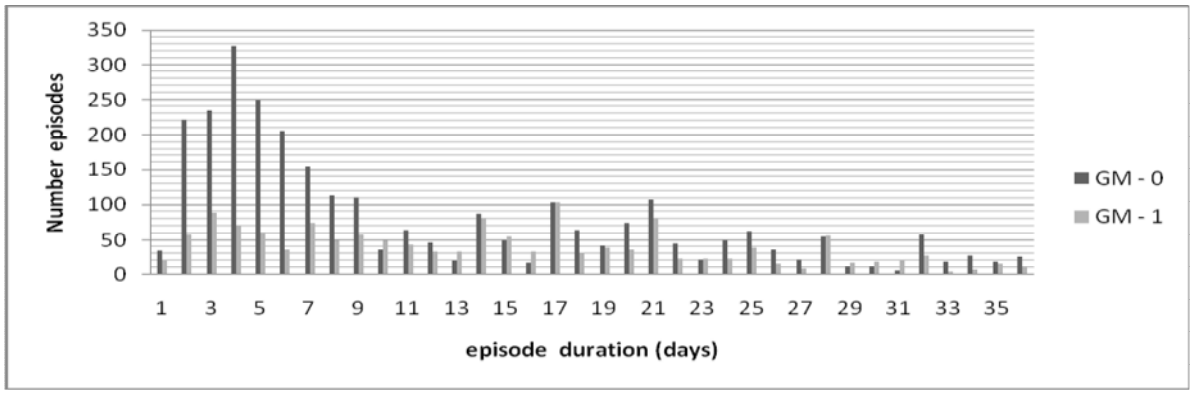

Figure 4.15 Variation of number of episodes of ventilation for General Medicine (GM – 1 (ventilated)) and non ventilated episodes for General Medicine (GM – 0 (not ventilated)).

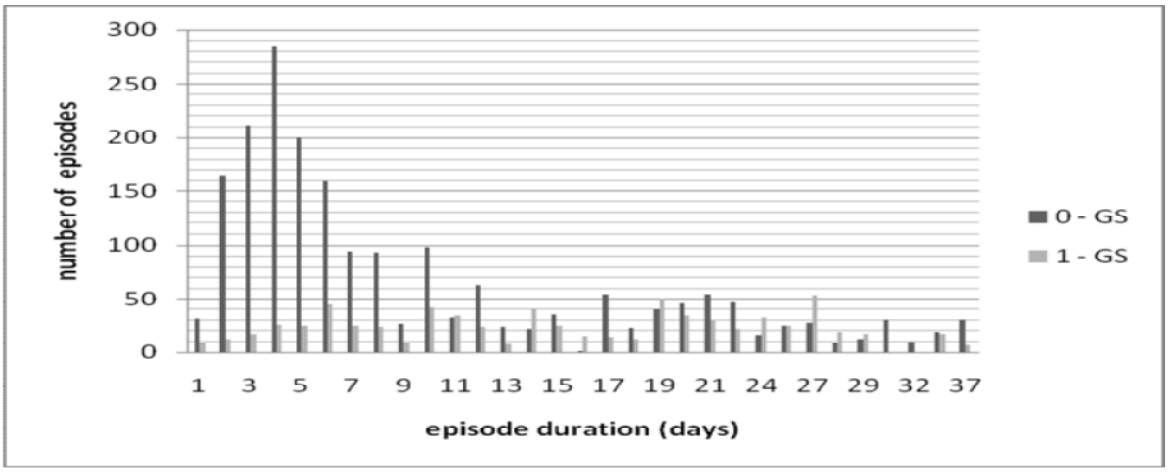

Figure 4.16 Variation of number of episodes of ventilation for General Surgery (GS – 1 (ventilated)) and non ventilated episodes for General Surgery (GS – 0 (not ventilated)).

These figures indicate that longer stay patients tend to have a higher incidence of ventilation. This reflects the pattern of activity of patients who are 'passing through' Critical Care with normal recovery patterns and a core of patients whose recovery is more problematic and prolonged.

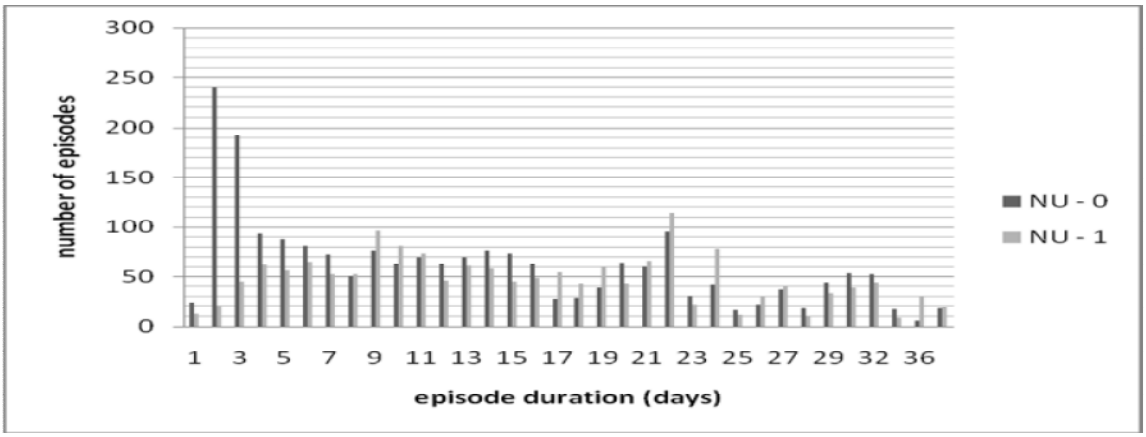

Figure 4.17. Variation of number of episodes of ventilation for Neurology (NU – 1 (ventilated)) and non ventilated episodes for Neurology (NU – 0 (not ventilated))

From the distribution of data within Neurology patients, there is increasing likelihood of ventilation for episodes in excess of 5 days. Analysis of data using Pivot Table methods allows rapid verification of sets of data extracted from within Matlab® programming.

Within the main set of TISS activity identified within Appendix 2, various elements are either inactive or are applied to all patients, so detailed analysis of relative frequency of occurrence of all components is not required. Also, only the most 'populated' seven specialties are included in the TISS analysis

process. For TISS elements which are active, three separate file structures are identified. These are ‘episode’, ‘frequency’ and ‘time’. The details of ‘episode’ data is outlined in figure 4.18.

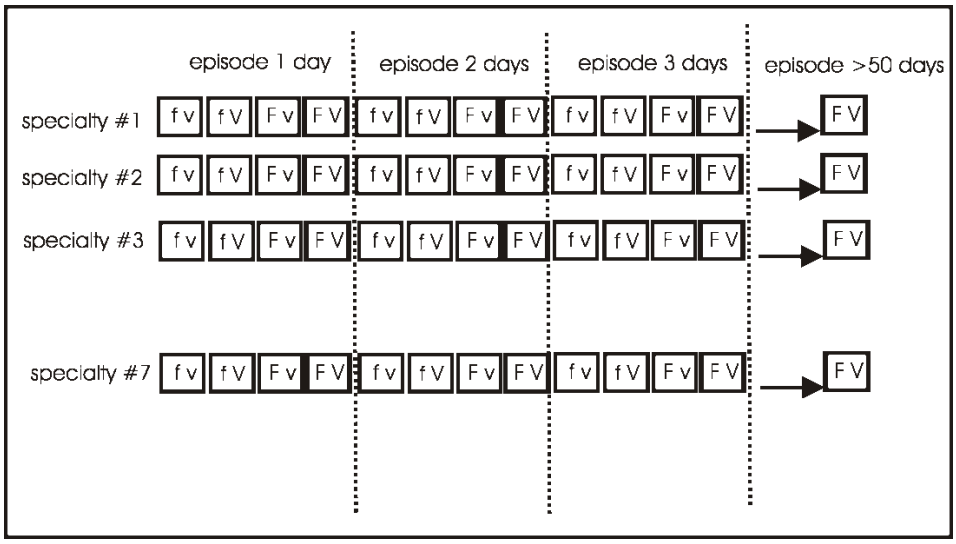

Figure 4.18. Array structure of TISS data where specialties 1 to 7 occupy separate rows and relative frequency of occurrence by episode length in days is written across columns. Within a component describing a given TISS component of a given length of episode, fv = TISS not present + not ventilated, fV = TISS not present and ventilated, Fv = TISS present and not ventilated, FV = TISS present and ventilated.

For episodes which have an active TISS parameter, the relative frequency of activity of a given TISS element is structured by relative frequency by day element within a sequence of days. Thus for a given episode of say 5 days, the frequency within day #1, day #2, day #3, day #4 and day #5 is identified for day elements which have or have not ventilated activity for each day. This is indicated in figure 4.19.

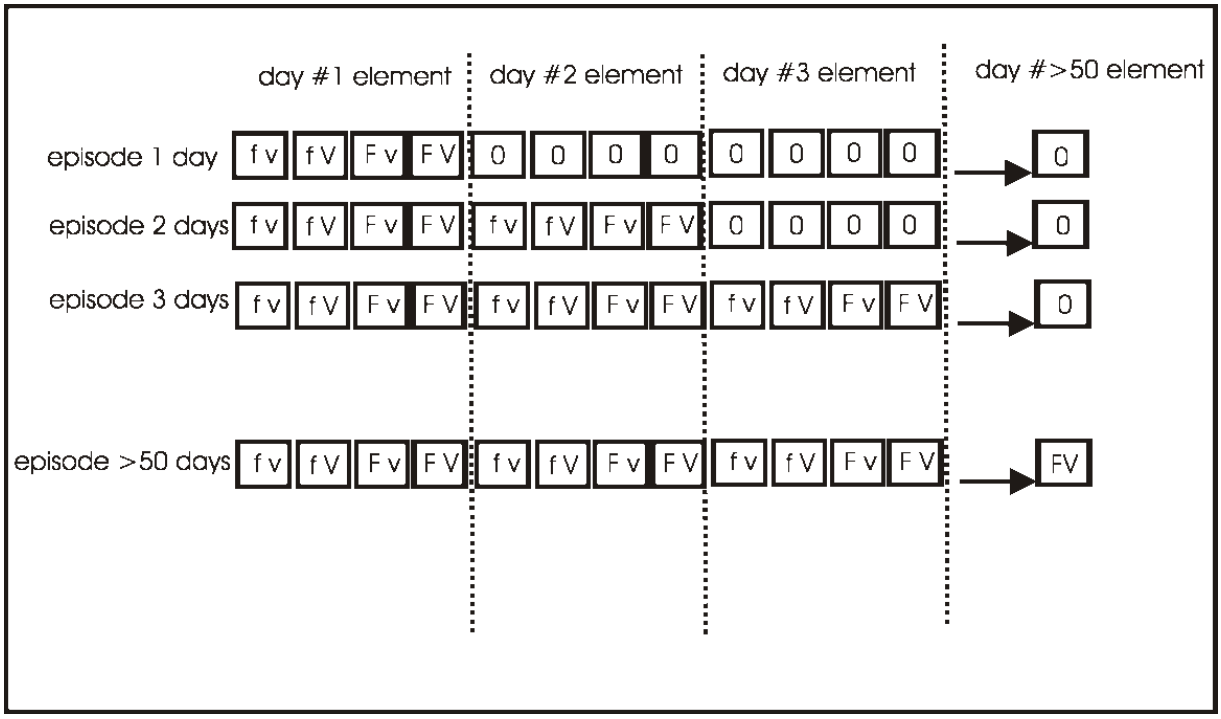

Figure 4.19. Data representation of specific TISS element activity for a given specialty and for episode of given duration and day element within a specific episode. Data is written in blocks of columns per specific specialty - e.g. columns 1 to 200 relate to specialty #1 and specialty #2 relates to column entries 201 to 400 etc.

In addition a separate mode of data analysis, a separate data file for each TISS parameter is created based on the frequency of number of occurrences of a specific parameter within a specific episode length as indicated in figure 4.20.

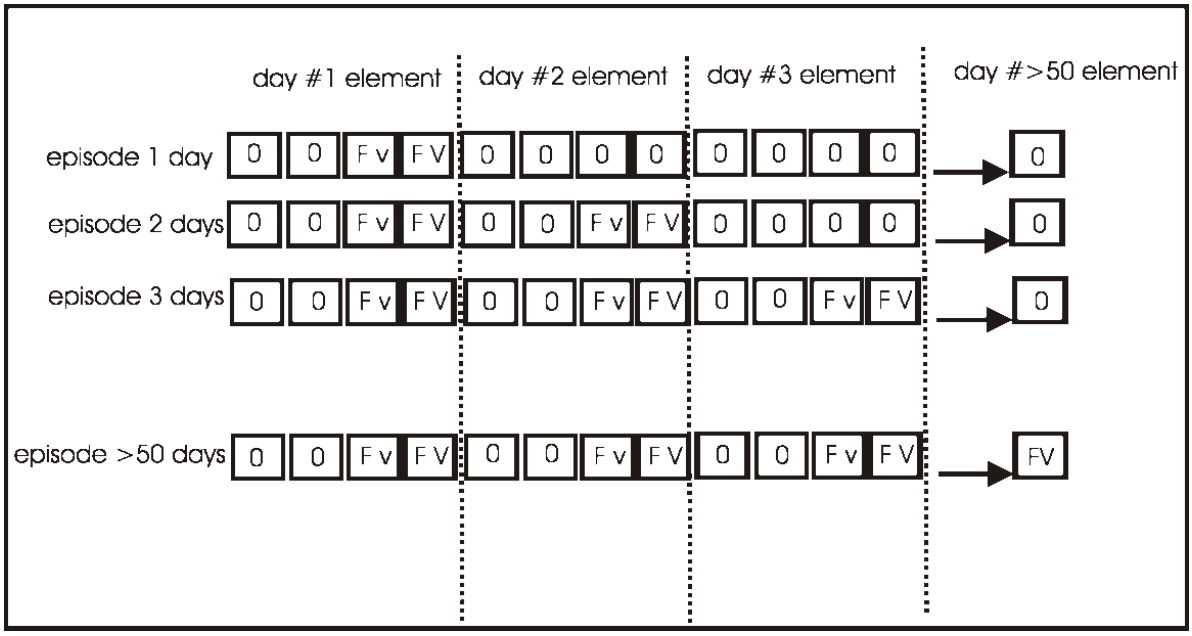

Figure 4.20. Structure of data format of file to represent relative frequency of TISS activity – where element Fv in day element #n, is the number of times the TISS element is present (non ventilated episode) and FV is the corresponding number for a ventilated episode. In this context, a ventilated episode is one where at least one day is ventilated.

The identification of TISS activity and associated general clinical activity allows 'interventions' to be written into the patient clinical activity record which is structured to contain 288 slots per day, each of a nominal 5 minute duration, as indicated in table 4.5. A separate Matlab ® programme for every active TISS parameter is used to produce these array parameters and with data being stored within a corresponding data file.

Episode	Time	TISS Reference	Activity
73	06:00	11	hourly observations
74	06:05	0	
75	06:10	0	
76	06:15	0	
77	06:20	0	
78	06:25	0	
79	06:30	0	
80	06:35	833	Respond ventilation alarm
81	06:40	0	
82	06:45	0	
83	06:50	0	
84	06:55	0	
85	07:00	11	hourly observations
86	07:05	0	
87	07:10	832	ventilatory care:suction
88	07:15	0	
89	07:20	0	
90	07:25	0	
91	07:30	1011	Handover ON shift
92	07:35	833	Respond ventilation alarm
93	07:40	1012	Handover OFF shift

Table 4.5. Structure of TISS activity within admission/discharge episode – indicating how elements of activity are expressed within the patient episode.

The maximum episode set for such simulated patient activity is 50 days, corresponding to a maximum of 14400 interventions. Within a specific episode, key components associated with admission are included as a 'bundle' of discrete interventions as indicated in table 4.6. The number of interventions per day per patient will vary as a function of specialty, ventilation status of patient and derived level of 'severity' of condition of patient. Additional interventions tend to be undertaken at patient admission and discharge.

Episode	Time	TISS Reference	Activity
46	03:45	1211	review admission notes
47	03:50	1091	general admission
48	03:55	352	collect non specialist sample (mic)
49	04:00	1171	initiate basic monitoring
50	04:05	1151	structure care plan
51	04:10	1101	initiate QS record
52	04:15	1111	weigh patient
53	04:20	1161	communicate care plan
54	04:25	151	Urine catheter (female)
55	04:30	271	assess bed requirement
56	04:35	101	Establish arterial line (arm)
57	04:40	322	routine blood sample
58	04:45	381	urine analysis
59	04:50	355	microbiology screen

Table 4.6. Core elements of clinical activity on admission with elements written within 5 minute ‘slots’ within the active day.

Hourly observations are then written into the activity matrix, followed by additional TISS/intervention components and followed at the close of the episode by standard discharge elements as indicated in figure 4.21.

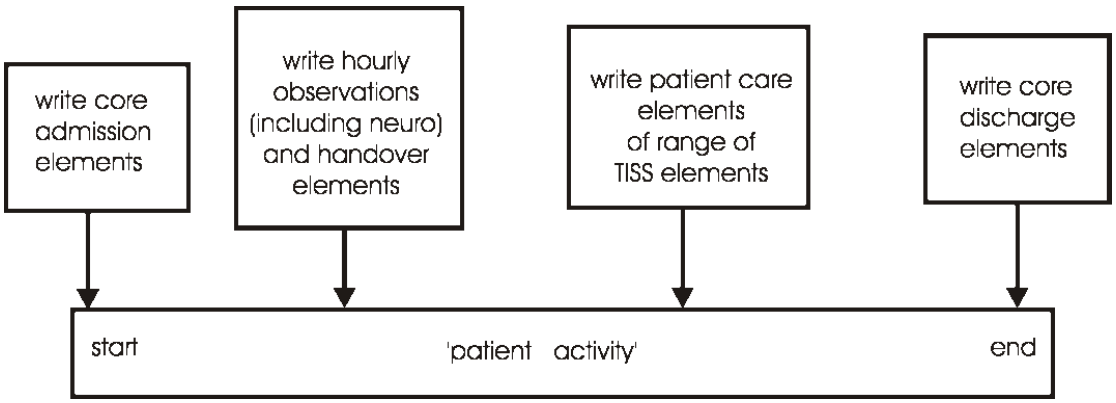

Figure 4.21. Summary of derivation of patient activity using key elements of TISS activity.

4.7 Structuring of Sequences of Simulated Interventions

An initial test sequence of simulated interventions was derived using this technique for validation of the risk simulation model described in subsequent chapters. Figure 4.22 indicates a normalised distribution of frequency of nursing interventions of a year's simulated activity where the intervention reference relates to the sequence number of the entry within the main intervention description file. Within this initial data set, around 52% of the indicated interventions are blank, indicating that the complex process of simulating interventions required further development.

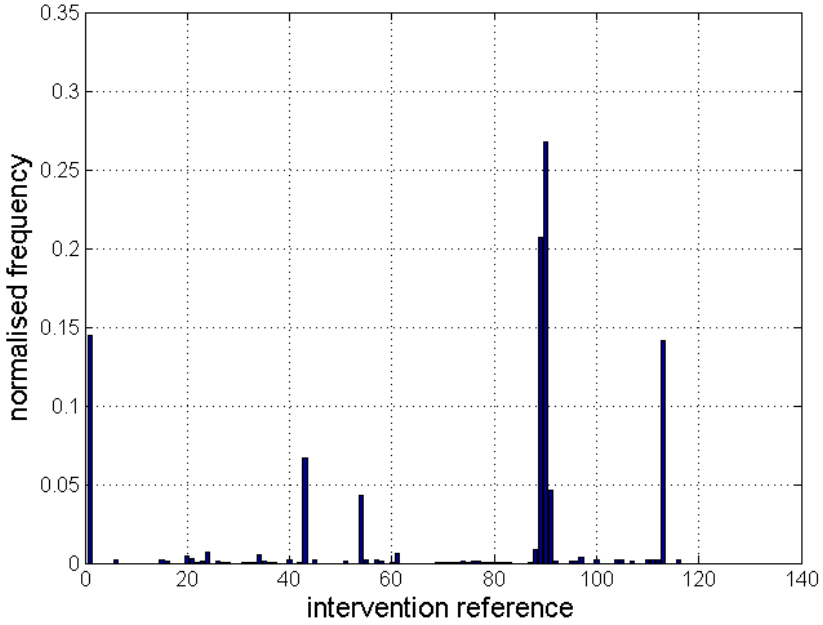

Figure 4.22. Normalised frequency distribution of interventions within set #1 of simulated interventions used for initial validation of risk simulation model.

Table 4.7 indicates the seven interventions recorded at highest frequency level.

Sequence	**Reference**	**Intervention Description**	**Frequency**
90	833	Respond to ventilator alarm	0.2672
89	832	Establish appropriate patient ventilation	0.2071
1	11	TISS hourly vital signs	0.1445
13	1172	Establish basic monitoring alarms	0.1413
43	274	Bed sore management	0.0664
91	834	Routine suction ventilated patient/airway	0.0467
54	323	Request clotting factor	0.0429

Table 4.7. Details of interventions referenced in figure 4.20 at highest frequency level.

The structuring and simulation of clinical interventions within the Critical Care Unit is identified as the most time consuming and complex stage of the development of the whole risk simulation process. The initial set of simulated interventions was identified as requiring revision due to 'missing' interventions though at this stage in the overall project it was considered relevant not to delay development of the main risk simulation module. The initial set of simulated interventions was, however, considered adequate to validate the function of the main risk simulation module.

4.8 Multiple Repeat Interventions

The indication of intervention activity levels is also used to determine the degree of 'busyness' associated with a patient. For some activities, such as 'chest x-ray', this is an intervention which is relatively of short duration. For other activities, such as ventilation, an episode is initiated with a marker element and terminated with a corresponding 'end ventilation' marker to indicate when the episode completed. During a specific period of patient ventilation, for example, there is a finite probability for suction of airways. The model also identifies a finite probability in each 5 minute 'slot' for the requirement of this intervention. Similar probability functions are implemented to reflect activity of attention to ventilator alarm or infusion device alarm. This is a characteristic of clinical activity which requires an on-going level of nursing/clinical care and attention. The number of interventions created in this way is highly dependent on the values of relative probability associated with such activities. These types of intervention will tend to dominate the 'intervention' activity pattern.

4.9 Summary

This chapter describes the mechanisms for simulating patient admission/discharge episodes and also the population of such episodes with clinical interventions/activity. The following chapter describes how a sub structure is identified with each clinical intervention, where elements of linked competency and adverse effect are identified.

Chapter 5: Structuring Clinical Interventions as Competency/Risk Data Sets and Review of Adverse Events in Critical Care Medicine

5.1 Introduction

The chapter describes how clinical interventions can be expressed as a series of linked 'competencies/adverse effects' and 'preventive measures'. This represents the level of activity at which evaluation of risk is subsequently undertaken. In addition, sub structures relating to task complexity, team involvement and supervision mode are identified within competencies/adverse effects to alter the mode of function of risk evaluation. The chapter also focuses on clinical studies in the Critical Care environment which identify features and trends related to adverse clinical incidents and general risk causation. The review of such studies is also used to identify how key parameters such as supervision, distraction and competency mismatch can be identified as input functions for a 'risk engine' to estimate the level of risk associated with the adverse effect.

The identification of the interventions experienced by patients in the Critical Care environment is a necessary part of the process of analysis of associated adverse effects. Further, it is identified that an 'intervention' undertaken by an individual can be described as a subset of competencies possessed by the individual, as indicated in figure 5.1. Each sub task is associated with a required level of related competency.

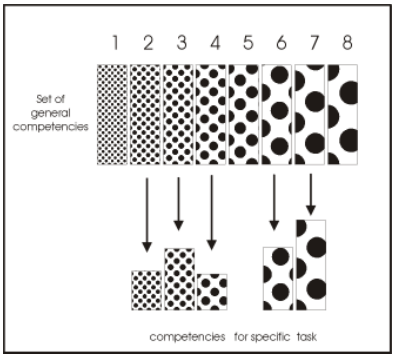

Figure 5.1. Schematic representation of an intervention as a subset of individual competencies. With identification of eight general competencies, a specific task identified in the figure requires input from five of these at varying levels of competence.

The expression of an 'intervention' as a 'basket' of competencies of varying types and levels as referenced in equation 5.2 and figure 5.2 provides an increased level of 'quantisation' of skill description and measurement and is the basis for all subsequent work described in the Thesis.

The main set of competencies associated with an individual within a specific clinical staff group can be described as:

$$C_{individual} = \sum_{k=1,n} a_k C_k \qquad (5.1)$$

where a_k = value assigned for an individual for the specific identified competency C_k. The set of competencies C_k is therefore the entire set used for undertaking clinical duties. These identified 'competencies' are differentiated from 'tasks' which can be considered as requiring a 'basket' of identified competencies. In the model subsequently developed, the number of 'competencies' required for a specific 'task' can vary from one to as many as seven. This value of a_k is notionally identified as unity value at the highest competency level. A summary of staff groups and associated grades are indicated in Appendix 5.

The competencies required with a specific task C_{task} are a subset of the main set of competencies.

$$C_{task} = b_l C_{l.} + b_m C_m + b_n C_n + b_o C_o + b_p C_p + b_q C_q + b_r C_r \qquad (5.2)$$

where values b_l to b_r are the required levels of associated competence for competencies C_l to C_r. Figure 5.2 essentially shows levels of competency required for a specific task and competency levels available from a specific individual. Increased risk is associated with increased lack of matching of required levels of competency.

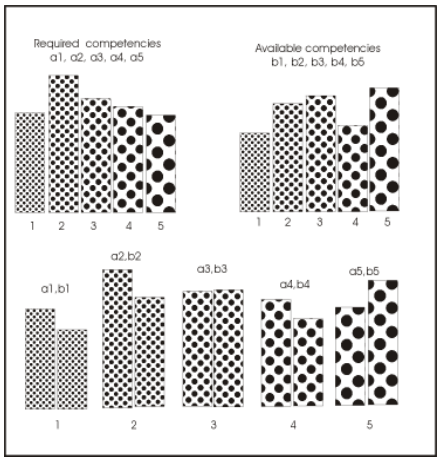

Figure 5.2. Comparison of required levels of competency for a specific task and available levels of competency of specific individual.

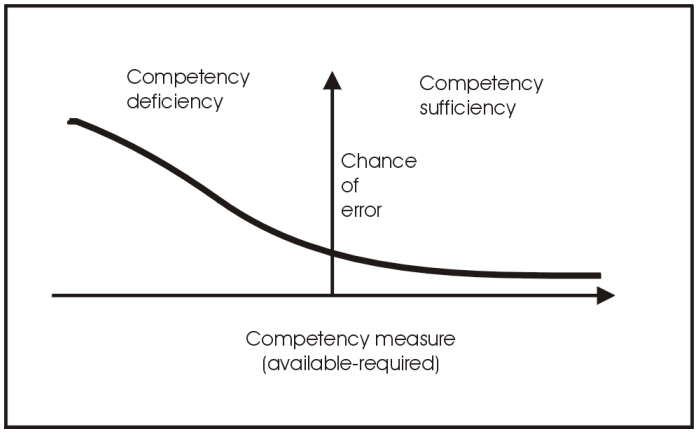

Figure 5.3. Concept of risk arising out of mismatch of required competency and available competency for specific task.

The simulation model subsequently develops the notion of 'competency mismatch' as the parameter which is used in risk estimations involving individual competency. This is developed in chapter 6 within the structure of Fuzzy Logic functions (section 6.4). In structuring a set of competencies required to carry out a specific clinical procedure, basic competencies are 'paired' with 'Linked Adverse Effect' – as indicated in table 5.1.

Competency	**Linked Adverse Effect**
Observe sterile procedure	Infection at cannulae site
Insert cannulae Appropriately	Tissue injury at needle entry site
Set up dialysis unit Correctly (filter, cannulae, infuscate)	Dialysis does not proceed at indicated Treatment rate
Interpret patient condition in the context of dialysis treatment	Patient metabolism is not maintained at optimum level
Communicate observations where appropriate to more senior staff	Patient condition not managed appropriately

Table 5.1 Example of set of listed competencies with linked adverse effect relating to set up of a dialysis system.

Table 5.2 outlines comparable competencies/adverse effect for arterial blood sample analysis.

Competency	Linked Adverse Effect
Observe sterile procedures	Infection at cannula site
Sample blood from arterial line using correct sample	Blood clots in system due to unheparinised sample
Enter patient ID into analyser system	Wrong patient ID entered
Load sample into analyser system	Blood can be sprayed onto individual
Evaluate blood gas parameters	Misinterpret patient blood gas parameters
Communicate findings where appropriate to more senior staff	Patient condition not managed appropriately

Table 5.2 . Example of set of listed competencies with linked adverse effect relating to blood gas analysis of arterial sample.

Thus there is not a 'single' competency relating to correct use of a blood gas system. Such 'adverse effects' can present a direct and high risk to the patient or present a condition which has the potential when combined with another factor to cause actual harm. The process of structuring the 'competency / adverse effect' details for a single intervention is not inherently difficult but requires careful cross reference with relevant clinical staff. Issues of complexity arise due to the sheer number of interventions identified. Herein lies the complexity of clinical risk.

Based on all identified TISS and associated activity, it is possible to establish a master file of all competencies associated with specific staff groups. An extract from this file is indicated in table 5.3.

Competency Description	Reference number	Level complexity	Supervision flag	Ability to ask flag
Validate QS parameters (hourly TISS)	2	2	1	1
Check progress of all infusions (hourly TISS)	3	2	1	1
Determine/monitor fluid balance of patient (Hourly TISS)	4	2	1	1
Notes of patient are written up appropriately (hourly TISS)	5	2	1	1
Determine patient neurological status (Hourly TISS)	6	2	0	0
Determine net intake and output volume (nurse)	7	2	1	1
Interpret fluid balance (nurse)	8	1	1	1
Interpret fluid balance (medic)	9	1	0	1
Alter patient fluid balance (nurse)	10	1	1	1

Table 5.3. Extract of identified nursing competencies.

Specific attributes are introduced at the level of the individual competency. The level of complexity ranges over a scale of 1 to 3 to describe a level associated with carrying out the specific competency and where 1 is the least complex and 3 is the most complex. This factor is subsequently utilised in the functionality of the 'risk engine' as described in figure 6.1. In addition, the 'Supervision flag' identifies if a specific competency is moderated by supervision of other staff (Supervision flag = 1) and if the competency is moderated by competency sharing (Ability to ask flag =1).

A subset of adverse effects is outlined in table 5.4.

Description	Ref
Patient QS data is unavailable/unreliable (hourly vital signs)	2
Error in prescribed infused drug delivery (hourly vital signs)	3
Patient fluid balance is less than optimal (hourly vital signs)	4
Patient notes contain missing or incorrect data (hourly vital signs)	5
Patient neurological status is incorrectly determined (hourly vital signs)	6
Error in fluid balance measurement:Patient fluid balance not optimised (nurse)	7
Error interpretation of fluid balance:Incorrect fluid management (nurse)	8
Error in fluid input adjustment: patient fluid balance less than optimal (nurse)	9
Error in interpretation of fluid balance: Incorrect fluid management (medic)	10
Fluid balance inappropriately modified (nurse)	11
Incorrect items used (peripheral IVs – nurse)	12
Infection at peripheral IV site (nurse)	13
Inappropriate peripheral IV site selected (nurse)	14
Problem at peripheral IV site on insertion (nurse)	15
Incorrect items used (peripheral IVs - medic)	16

Table 5.4. Subset of entries describing Adverse Effects. A total of 521 adverse effects are currently identified for specific set of patient interventions.

Table 5.5 indicates a form used to structure competency factors, competency text and adverse effect associated with a specific intervention.

Intervention Number	91	Staff Group	2 (medic)
Description	Establish CVP line (medic)		

Physical Effort	3
Emotional/stress effort	7
Intellectual effort	4

Competency factor #1	0.8	Table entry
Competency (text/code)	Identify/organise correct components CVP line (medic)	7
Adverse outcome(text/code)	Delay in undertaking CVP procedure - medic	21

Competency factor #2	0.8	Table entry
Competency (text/code)	Observe sterile precautions CVP site (medic)	8
Adverse outcome (text/code)	Infection at CVP site - medic	22

Competency factor #3	0.8	Table entry
Competency (text/code)	Insert CVP line (medic)	9
Adverse outcome (text/code)	Inappropriate CVP placement : waveforms inappropriate	23

Competency factor #4	0.8	Table entry
Competency (text/code)	Insert CVP line (medic)	9
Adverse outcome (text/code)	Tissue damage at entry site : CVP line	24

Competency factor #5	0.8	Table entry
Competency (text/code)	Insertion CVP line (medic)	9
Adverse outcome (text/code)	Adverse patient reaction : CVP insertion	25

Table 5.5. Structure of an intervention as a series of elements linked to identified competencies and adverse effects. The values under 'Table Entry' are the specific entries in the identified staff group competency table and the global adverse effect table.

The staff group identifies which table of competencies to access. Interventions can be subsequently represented as a series of numeric arrays, with separate description of competency factors, identified competency and associated adverse effect, as indicated in table 5.6 where up to five components are indicated.

No	Description	SG	Ph	Em	Me	CF1	C1	A1	CF2	C2	A2	CF3	C3	A3	CF4	C4	A4	CF5	C5	A5
11	Tiss hourly vital signs	1	4	3	6	0.8	2	2	0.8	3	3	0.8	4	4	0.8	5	5	0.8	6	6
21	Tiss hourly vital signs plus neuro	1	4	3	6	0.8	2	2	0.8	3	3	0.8	4	4	0.8	5	5	0	6	6
71	Measure/record /manage fluid balance (nurse)	1	1	1	2	0.8	7	7	0.8	8	8	0.8	10	9	0	0	0	0	0	0
72	Interpret Fluid balance (nurse)	1	0	1	2	0.8	8	8	0	0	0	0	0	0	0	0	0	0	0	0
73	Interpret fluid balance (medic)	2	0	1	2	0.8	2	10	0	0	0	0	0	0	0	0	0	0	0	0
74	Alter patient fluid balance (nurse)	1	1	1	2	0.8	10	11	0	0	0	0	0	0	0	0	0	0	0	0
82	Peripheral line establish/replace (nurse)	1	3	3	3	0.8	11	12	0.8	12	13	0.8	13	14	0.8	14	15	0	0	0
83	Peripheral line establish/replace (medic)	2	3	3	3	0.8	3	16	0.8	4	17	0.8	5	18	0.8	6	19	0	0	0
87	Remove peripheral IV line (nurse)	1	2	2	2	0.8	12	13	0.8	16	20	0.8	17	13	0	0	0	0	0	0
91	Establish CVP line (medic)	2	4	5	5	0.8	7	21	0.8	8	22	0.8	9	23	0.8	9	24	0.8	9	25
93	Positional check CVP line with x-ray	2	1	2	4	0.8	10	26	0.8	11	27	0.8	12	28	0	0	0	0	0	0
95	Remove CVP line (medic)	2	2	4	4	0.8	8	29	0.8	13	30	0	0	0	0	0	0	0	0	0
101	Establish/replace arterial line arm (medic)	2	3	5	5	0.8	14	31	0.8	15	32	0.8	16	33	0.8	17	34	0	0	0
105	Remove arterial line/end activity	1	2	3	3	0.8	12	38	0.8	18	39	0.8	19	40	0	0	0	0	0	0
121	Maintenance mode epidural	1	3	3	3	0.8	20	41	0.8	20	42	0	0	0	0	0	0	0	0	0
122	Replacement drug reservoir epidural	1	3	4	4	0.8	21	43	0.8	12	44	0.8	22	45	0	0	0	0	0	0
123	Removal epidural catheter	1	4	4	4	0.8	12	46	0.8	24	47	0.8	24	48	0	0	0	0	0	0
132	Establish PCA	1	3	3	3	0.8	24	49	0.8	25	50	0.8	26	51	0.8	27	52	0.8	28	53
133	Replace PCA	1	3	3	3	0.8	12	55	0.8	30	56	0.8	25	57	0.8	26	58	0.8	28	53

Table 5.6. Structure of intervention array, indicating level of required competency CFi, referenced competency (Ci) and associated adverse effect (Ai) ; i=1,5. No is intervention reference, SG is reference for staff group. Ph, Em and Me are physical effort, emotional/stress effort and intellectual effort components as percentage values of reduction from pre-existing values.

Additional codes have been identified with adverse effects. These include a specific 'intrinsic risk' code which identifies an adverse effect whose likelihood is essentially independent of the skill/competency level of the responsible staff. A description is included of the 'reversibility' of the adverse effect and also of its relative severity. Components of these codes are summarised in table 5.7.

Code	**Values**	**Description**
Intrinsic Risk	0 & 1	1 indicates that the outcome is intervention independent
Reversibility	1 to 5	1 easily reversed ;5 almost irreversible - see table 5.8
Severity	1 to 5	1 insignificant ; 5 immediate risk to patient – see table 5.9
Type event	1 to 43	See table 5.10

Table 5.7. Details of additional codes linked with adverse effects.

Additional details of codes for severity and reversibility are outlined in tables 5.8 and 5.9. These codes are relevant for additional modes of analysis of derived values of adverse effects.

Code element	Description
1	Very easily to reverse
2	Relatively easy to reverse
3	Moderately difficult to reverse
4	Significantly difficult to reverse
5	Almost impossible to reverse

Table 5.8. Levels of reversibility associated with adverse effect.

Code element	Description
1	Insignificant risk to patient
2	Relatively low level of risk to patient
3	Moderate level of risk to patient
4	Relatively high level of risk to patient
5	Very high risk to patient

Table 5.9. Levels of severity associated with adverse effect.

There is, however, a structural difference between the nature of 'adverse events' referenced in the literature and the nature of 'adverse effects' identified within the risk simulation system being described. Based on the nature of the associated reporting system, 'adverse events' tend to relate to instances where there is tangible evidence of either patient harm or a near miss such as accidental ventilator disconnection or medication error. An adverse effect associated with ventilation could relate to an event of lesser significance such as 'tracheotomy tapes not made secure' which indicates the potential for development of a more serious incident.

Table 5.10 identifies a structure of classification of 'types' of adverse effect which is broadly based on classification systems subsequently referenced in this chapter (Giraud *et al.* (1993), Bracco *et al.* (2003), Rothschild *et al.* (2005)). The classification of type of adverse effect provides a comparative measure for checking outputs of simulated sets of data with such referenced sets.

Code	Description		Code	Description
1	Medication		23	Central lines
2	Nutrition		24	Arterial lines
3	Monitoring		25	epidurals
4	Airway		26	analgesia
5	Communication to team		27	Patient involvement
6	Communication patient/rel		28	Intra cranial pressure
7	Acquired infection		29	Chest drains
8	Handover processes		30	EVDs
9	IV infusions		31	Lower digestive tract
10	Patient records & ident.		32	Patient/bed restraints
11	QS system		33	Renal function
12	Logistics of supply		34	Lumbar puncture
13	Pathology/patient samples		35	Dermatological support
14	Blood products		36	Cardioversion
15	Radiology		37	Defibrillation
16	Tissue viability		38	Traction
17	Fluid balance		39	TPN
18	Use of consumables		40	Basic patient care
19	Patient observations		41	Staff injury
20	Catheters		42	Unit disruption
21	Wound management		43	Patient pathway
22	Enteral feeding			

Table 5.10 Types of adverse effects identified.

This set of types of adverse effects has been derived for the specific set of interventions relevant within the Critical Care Unit at University Hospital, Coventry. There will be finite differences in coding between similar units in other healthcare facilities. Significantly different sets of types of adverse effects would be in evidence for different clinical environments such as Accident and Emergency and Cardiothoracic Intensive Care.

Subsequent analysis describes distributions of frequency of types of adverse events for simulated sets of patient activity. Such analysis can also include distributions weighted by individual likelihood

of component adverse effects, so that the resultant distribution reflects patterns of simulated risk. Table 5.11 outlines details of previously described codes associated with specific adverse effects.

Description	Ref	Intr.	Revers.	Severity	Type
Patient QS data is unavailable/unreliable (hourly vital signs)	2	0	1	2	3
Error in prescribed infused drug delivery (hourly vital signs)	3	0	1	3	9
Patient fluid balance is less than optimal (hourly vital signs)	4	0	1	2	17
Patient notes contain missing or incorrect data (hourly vital signs)	5	0	1	3	10
Patient neurological status is incorrectly determined (hourly vital signs)	6	0	1	3	19

Table 5.11. Example of codes assigned to specific adverse effects. 'Intr.' Indicates status of 'intrinsic' risk of the specific sub task (table 5.7).

5.2 Representation of Levels of Staffing Competency

At the level of the greatest detail, the competencies available within a Critical Care Unit would be described at the level of the individual, where specific competencies related to the set of identified competencies are established for each individual staff member. For nursing staff at the Critical Care Unit at University Hospital Coventry, this would correspond to a core nursing group of around 150 staff members. A simplification of this model which preserves the element of variation in levels of competency is to establish available competencies according to 'sub bands' within the nursing grade structures as outlined in the 'Agenda for Change' agreement (Department of Health 2004c). Table 5.12 identifies how for each of the main nursing grades a series of 5 sub grades of competency description are assigned.

competency	5a	5b	5c	5d	5e	6a	6b	6c	6d	6e	7a	7b	7c	7d	7e
1	0.8	0.8	0.8	0.8	0.8	0.82	0.82	0.82	0.82	0.82	0.85	0.85	0.85	0.85	0.85
2	0.8	0.8	0.8	0.8	0.8	0.82	0.82	0.82	0.82	0.82	0.85	0.85	0.85	0.85	0.85
3	0.8	0.8	0.8	0.8	0.8	0.82	0.82	0.82	0.82	0.82	0.85	0.85	0.85	0.85	0.85
4	0.8	0.8	0.8	0.8	0.8	0.82	0.82	0.82	0.82	0.82	0.85	0.85	0.85	0.85	0.85
5	0.75	0.76	0.77	0.78	0.79	0.8	0.81	0.82	0.83	0.84	0.85	0.86	0.87	0.88	0.89
6	0.75	0.76	0.77	0.78	0.79	0.8	0.81	0.82	0.83	0.84	0.85	0.86	0.87	0.88	0.89
7	0.8	0.8	0.8	0.8	0.8	0.82	0.82	0.82	0.82	0.82	0.85	0.85	0.85	0.85	0.85
8	0.75	0.76	0.77	0.78	0.79	0.8	0.81	0.82	0.83	0.84	0.85	0.86	0.87	0.88	0.89
9	0.75	0.76	0.77	0.78	0.79	0.8	0.81	0.82	0.83	0.84	0.85	0.86	0.87	0.88	0.89
10	0.75	0.76	0.77	0.78	0.79	0.8	0.81	0.82	0.83	0.84	0.85	0.86	0.87	0.88	0.89
11	0.75	0.76	0.77	0.78	0.79	0.8	0.81	0.82	0.83	0.84	0.85	0.86	0.87	0.88	0.89
12	0.8	0.8	0.8	0.8	0.8	0.82	0.82	0.82	0.82	0.82	0.85	0.85	0.85	0.85	0.85
13	0.75	0.76	0.77	0.78	0.79	0.8	0.81	0.82	0.83	0.84	0.85	0.86	0.87	0.88	0.89
14	0.7	0.71	0.72	0.73	0.74	0.75	0.76	0.78	0.8	0.81	0.82	0.83	0.84	0.85	0.86
15	0.8	0.8	0.8	0.8	0.8	0.82	0.82	0.82	0.82	0.82	0.85	0.85	0.85	0.85	0.85
16	0.75	0.76	0.77	0.78	0.79	0.8	0.81	0.82	0.83	0.84	0.85	0.86	0.87	0.88	0.89
17	0.75	0.76	0.77	0.78	0.79	0.8	0.81	0.82	0.83	0.84	0.85	0.86	0.87	0.88	0.89
18	0.75	0.76	0.77	0.78	0.79	0.8	0.81	0.82	0.83	0.84	0.85	0.86	0.87	0.88	0.89
19	0.8	0.8	0.8	0.8	0.8	0.82	0.82	0.82	0.82	0.82	0.85	0.85	0.85	0.85	0.85
20	0.8	0.8	0.8	0.8	0.8	0.82	0.82	0.82	0.82	0.82	0.85	0.85	0.85	0.85	0.85
21	0.75	0.76	0.77	0.78	0.79	0.8	0.81	0.82	0.83	0.84	0.85	0.86	0.87	0.88	0.89
22	0.7	0.71	0.72	0.73	0.74	0.75	0.76	0.78	0.8	0.81	0.82	0.83	0.84	0.85	0.86
23	0.75	0.76	0.77	0.78	0.79	0.8	0.81	0.82	0.83	0.84	0.85	0.86	0.87	0.88	0.89
24	0.65	0.67	0.69	0.71	0.75	0.8	0.81	0.82	0.83	0.84	0.85	0.86	0.87	0.88	0.89

Table 5.12. Schematic representation of assigned competency levels for nursing co-workers within designated grade structures linked with specific identified competency.

These assigned values of competency are essentially the levels of competency associated with specific individuals on the basis of sub grading and where for basic tasks the lowest staff grade (band 5a) is empirically set at the required competency level of value 0.8. For more complex tasks the required competency level of 0.8 is set at higher grading levels. In this simplified model, all staff of the same sub grading level have the same competency for any referenced sub task. Levels of competency required for specific sub tasks are separately determined (see table 5.6) and the difference between the assigned level of competency for a specific sub task to an individual on a specific sub grade and that identified to undertake a specific sub task is the basis for calculation potential competency mismatch.

In practice the levels of competency within a staff group will be a dynamic quantity, as staff leave, new staff are recruited and on going processes of staff training are implemented. Also, various types of activity will reinforce competency by practice. Less frequently undertaken procedures may suffer a reduction in available competency though the risk model currently does not support this mode of dynamic skill monitoring.

5.3 Preventive Measures

Interventions have been structured as a series of linked sub competencies and adverse effects with up to seven such pairings being incorporated into a specific intervention. The value of seven has been found to be sufficient for identified clinical activity though could readily be expanded if considered necessary. At the same level of description of competency and risk, it is also possible to identify ‘preventive measures’ which can be described as factors which would tend to reduce the likelihood of the adverse effect taking place.

Table 5.13 outlines a generic example where ‘preventive measures’ relate to changing a tyre on a vehicle. This indicates the role of ‘preventive measures’ in identifying positive actions to reduce risk.

Sub competency	adverse effect	Preventive measure
Select a safe place to work	Collision with moving traffic	Availability of warning signs to alert oncoming traffic.
Ensure car is immobile prior to jacking up of car	Car may move when jack is applied	Availability of instruction for safe operation on jack.
Obtain suitable spare tyre	Spare tyre may be under inflated	Availability of air pump.
Jack up car appropriately	Car may collapse if process inappropriate or jack faulty	Availability of material to insert under car to prevent car falling.
Replace tyre and tighten nuts	Uneven torque may cause incorrect tyre location	Availability of checklist for tyre replacement.

Table 5.13. Indication of set of preventive measure linked with specific pairings of sub competency and adverse effect for 'generic' task.

In the context of clinical interventions, it is identified that preventive measures can also be linked to specific 'sub competency/adverse effect' items as indicated in table 5.14. It is also identified that more than one preventive measure may be linked to a specific 'sub competency/adverse effect'.

Competency	Linked Adverse Effect	Preventive Measures
Observe sterile procedures	Infection at cannula site	Hand wash prior to taking blood sample.
Sample blood from arterial line using correct sample	Blood clots in system due to unheparinised sample	Provision of syringes which are pre-heparinised. Local control to ensure correct syringes are available.
Enter patient ID into analyser system	Wrong patient ID entered	Reduce risk of ID error by means of bar code system using patient ID.
Load sample into analyser system	Blood can be sprayed onto individual	Wear gloves while handling sample. Ensure all equipment users are appropriately trained. Restrict machine access to staff who have been trained on equipment.
Evaluate blood gas parameters	Misinterpret patient blood gas parameters	Provide update training on blood gas parameter interpretation. Evaluate skill level of team of assessment of blood gas parameters.
Communicate findings where appropriate to more senior staff	Patient condition not managed appropriately	Encourage team communication. Highlight findings in patient notes.

Table 5.14. Indication of set of preventive measures linked with specific pairings of sub competency and adverse effect for specific clinical task of taking and processing an arterial blood gas sample.

Figure 5.4 outlines the structure of how such preventive measures are linked from a master file of individual preventive measures.

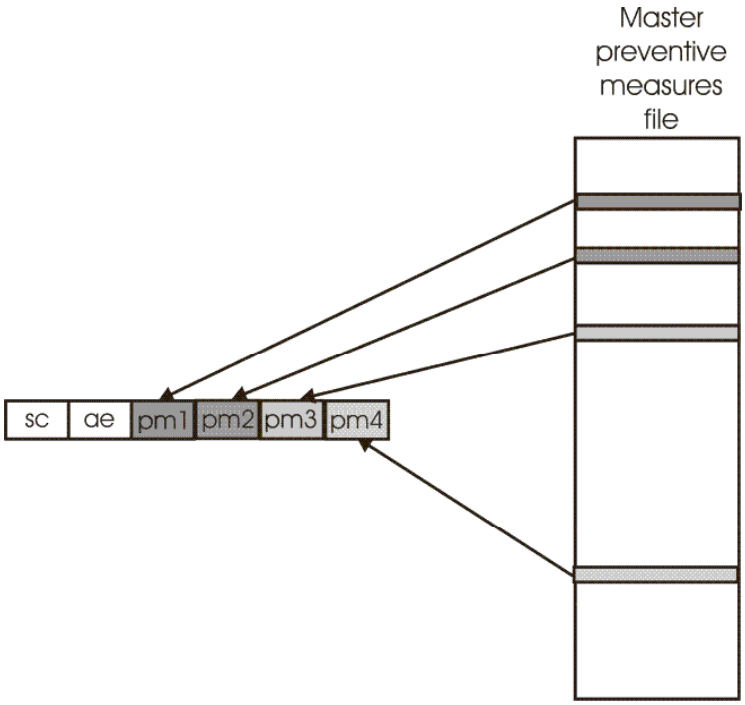

Figure 5.4. Incorporation of preventive measures pm1, pm2, pm3 and pm4 into a specific linked sub competency (sc) and adverse effect (ae).

Thus where a set of 'competency sub task/adverse effects' are processed and a finite probability value associated with each adverse effect, these probability values can be linked with the sub set of identified preventive measure. This allows preventive measures to be evaluated on the basis of identified risk values across the given range of clinical activities and allowing a targeted risk reduction strategy within the clinical area. Elements of analysis of preventive measures can relate to a specific sub task process, a specific intervention of several such items or extend across the entire set of structured interventions. It is also relevant to review preventive measure distribution by type of adverse effect.

The incorporation of details of preventive measures into the intervention array is therefore achieved by the incorporation of four additional columns per specific 'sub competency/adverse effect'. Thus a specific sub task for a specific sub group is referenced by the set level of competency, the competency reference, the adverse effect reference and four references to relevant preventive measures. This represents an expansion of the structure previously indicated in table 5.6.

This process is then providing a derived focus on preventive measures to reduce the incidence levels of clinical risk. This is identified as a novel process which has the potential to target risk prevention. Processes of creation of the generic preventive measure file, the revised intervention array and modification of the main risk simulation module accordingly to weight preventive measures with risk are outlined in the context of further work in chapter 8.

5.4 Review of Adverse Events in Critical Care Medicine

It is certainly necessary to extract as much relevant information as possible from available literature relating to adverse events in Critical Care medicine in the development of risk causation models. The general nature, however, of contributions from the literature is to provide insights into these factors within the context of a specific Critical Care Unit and which relates to a specific subset of data within the unit. Definitions of what constitutes an adverse event will also vary subtly. In addition, the reporting of the relative frequency of events can be described as 'events per 1000 patient days' which does not provide useful information, for example, relating to the chance of a medication error per specific administration of medication to a specific patient. Such an analysis of available literature, however, provides an essential framework within which models of risk causation can be developed.

Sinopoli *et al.* (2007) describe a study comparing the relative incidence of 'safety incidents' between patients in ITUs predominantly containing 'medical' patients and also 'surgical' patients, with the initial assumption that such 'different' sets of patients would have separately identifiable patterns of such 'safety incidents'. In fact no such 'differentiation' was observed between the set of 646 events from medical patients and 707 events from surgical patients. The study, however, provides a useful analysis of causative factors identified with identified 'safety incidents' as outlined in table 5.15 and where a specific incident can have more than one causative factor.

	Medical (N=646)	**Surgical (N=707)**
Training	50	48
Team	38	32
Patient	33	25
Provider	25	16
Management	22	19
Organisational	16	17
Task	11	13

Table 5.15 Distribution of factors contributing to safety incidents - after Sinopoli *et al.* (2007)

The specific classification of type of safety incident reported by the authors is reproduced in table 5.16.

	Medical (N=646)	Surgical (N=707)
Communication	60	56
Clinical management	53	56
ICU management	51	54
Therapeutic	46	42
Hospital management	23	19
Equipment/devices	14	19
CPOE	13	6
Line, tube, drain	8	13
Diagnostic testing	8	6
Airway	7	7
Skin breakdown	6	5

Table 5.16. Distribution of types of safety incident - after Sinopoli *et al.* (2007).

The conclusion of the authors from a risk perspective was that there was little to be gained by 'separating' medical and surgical cases within physically separate ITU facilities. Also, the two most important causative factors relate to 'training' and 'team'. Cullen *et al.* (1997) describe in detail the typical framework within which adverse drug events take place as part of a general study comparing intensive care and also general care facilities. Initial expectations anticipated that incidents of such adverse drug events would be associated with periods of above average stress levels or elevated levels of work activity. As part of the study, detailed 'debriefing' of staff associated with the adverse drug event was undertaken where a total of 28 factors within groupings which included Team Status, System Factors, Patient Status and Prevailing Circumstances were recorded on a 1 to 5 analogue scale. It was identified, however, that the majority of such incidents were associated with staff who were working within a 'normal' work environment within which there were no significant issues of stress or workload. This would seem to imply that a component of error is originating from deficiencies in how 'medication' tasks are structured.

The number of preventable adverse drug events and potential adverse drug events within ITUs was at a level of 29 and 77 respectively for a total of 5574 patient days, providing a value of 19 such events per 1000 patient days. With an average of 15 drugs administered within a 24 hour period, this indicates an absolute adverse drug event probability of 0.0013. Also, when comparisons were made with levels of incidence within general hospital units, results showed similar levels to those within ITUs where allowance was made for the relative rate of drug prescribing within both areas.

In order to determine outcomes within ITUs as a possible function of level of throughput, Durairaj *et al.* (2005) describes a review of 196,097 consecutive admissions within 29 hospitals in Northwest Ohio between March 1991 to March 1997. The study found no significant differences with level of

activity for pulmonary and neurologic diagnoses but did identify lower mortality in high volume units for patients with gastro-intestinal diagnoses. The study has somewhat greater significance in the USA, where greater options exist for selection of hospital care and where larger units would potentially attract higher levels of referrals if a link between improved outcome and level of patient throughput was established. The authors conclude that a much more significant effect would be to improve the level of 'intensivist' participation/involvement within ITUs, after the analysis of Young (2000), which indicates that implementation of the Leagfrog Group recommendations could possibly save 53,850 lives a year in the USA.

The evaluation of risk within the critical care environment relates not only to the risk of procedures that are undertaken, but also to the risk of procedures that are either delayed or not undertaken. A classic study by Kollef *et al.* (1999) to determine the significance of inadequate antimicrobial treatment of infections determined that the risk of hospital mortality was four times as great among infected patients receiving inadequate antimicrobial treatment compared with patients not exposed to this risk. This identifies, therefore, that for this specific component of patient management, delay or inappropriate antimicrobial treatment is a risk factor which is significantly influenced by ITU clinical management policy.

The study of Giraud *et al.* (1993) into adverse effects in ITUs highlights some effects which remain valid and others which have been modified to some extent by changes in prevailing clinical practice, such as more intensive patient monitoring and which would reduce the dependence on direct clinical observations. The patient group comprised 382 patients corresponding to 400 consecutive patient admissions. A total of 124 adverse effects were identified (31%) and with 107 of these identified as 'major', with three leading to death. Drug related adverse events were excluded from the study.

Intervention	Total	Major	Intervention	Total	Major
Mechanical ventilation	130	64	Nursing	9	2
Intubation, oxygenation	16	14	Haemodialysis	6	5
Extubation	13	11	Bronchoscopy	4	3
Drugs	30	17	Equipment	14	42
Transfusion, nutrition	8	1	Peripheral venous catheter	36	4
Central venous cath.	12	5	Central venous catheter	13	8
Venous, arterial puncture	11	-	Arterial catheter	4	1
Pleural drainage	4	2	ET tube	33	11
Urinary, gastric drainage	3	-	Ventilator (equipment)	3	-
Drainage material	23	2	Syringe pump	15	13
Haemodialyser,mattress	6	9	Iv catheter/other pump	8	3

Table 5.17. Distribution of adverse events after Giraud *et al.* (1993)

What the study and similar types do not derive is the relative probability per specific patient intervention. The number of events detected is important to assess overall risk but comparisons between units is made difficult due to the different nature of clinical protocols undertaken. A summary of identified associated factors is shown in table 5.18.

Identified associated factors	Total	Major
Insufficient surveillance (sum)	68	33
- Nurses	54	27
Junior physicians	4	3
Senior physicians	7	2
Others	3	1
Inadequate experience (sum)	33	9
- Nurses	12	4
- Junior physicians	16	3
- Senior physicians	4	1
- Others	1	1
Equipment malfunction (sum)	29	14
- Venous catheters and IV catheters	15	7
- ET tubes	5	4
- Syringe pumps	2	2
- Others	1	1
Inadequate equipment (sum)	9	7
- Syringe pumps	7	7
- Mattresses	2	0

Table 5.18. Summary of associated factors with identified adverse incidents after Giraud *et al.* (1993

Subsequent development of patient monitoring technology has significantly changed some of the risk

factors identified in this study, with continuous monitoring of an extended range of patient parameters now identifying deterioration of patient condition more rapidly. Also, in the study, a high incidence of bed sores is identified but not matched to specific causes. The authors compare their rate of adverse events of 13% with a contemporary value of 9% in the USA after the study by Steel *et al.* (1981).

A more recent Swiss study undertaken by Bracco *et al.* (2003), reviewed the incidence of adverse clinical events and related causation of a set of data relating to 1024 patients in a prospective organisational study. In addition, the consequence of adverse effects was graded using a derived scale. Table 5.19 identifies summary findings, with type of error linked with cause of error.

Type of error	**Planning**	**Execution**	**Surveillance**	**Total (n (%))**
Venous lines and catheters	2	29	24	**55 (23)**
Respiratory system	15	14	18	**47 (20)**
Cardiovascular system	14	14	11	**39 (16)**
Drugs-related complication	8	19	3	**30 (12)**
Neurological system	11	5	6	**22 (9)**
Urinary system	1	4	2	**7 (3)**
Gastrointestinal system	4	0	2	**6 (2)**
Skin and muscular system	0	0	2	**2 (1)**
Management complications	20	3	10	**33 (14)**
total	**75**	**88**	**78**	**241 (100)**

Table 5.19. Summary details of type of error and cause of error after Bracco *et al.* (2003) identified as due to human factors.

The authors conclude that the causes of error were evenly distributed between planning, execution and surveillance. A significant component of 'planning' related to the initial diagnosis of patient condition. Table 5.20 summarises the resulting severity of consequences of adverse outcomes.

Classification	**Number**	**%**
Without consequences	38	16
Adding minor morbidity	138	57
Prolonging ITU stay	62	26
Permanent sequelae	2	0.8
Death	1	0.4

Table 5.20 Summary of severity of consequences after Bracco *et al.* (2003).

In general, more severe outcomes of adverse incidents were associated with the errors linked with planning. The result of adverse effects was in general to prolong the stay of patients in the ITU. This

was considered equivalent to 15% of the total patient stay time within the period of the study. Although these effects certainly adversely affect the mortality results of the ITU unit, the effect of prolonging bed stay implies that patients who could have been treated within the ITU unit (e.g. emergency cases) were in fact not treated or experienced a delay in treatment if transferred to an ITU in another hospital. A significant review of safety within the ITU environment has been provided by Valentin and Bion (2007) in which key topics such as error causation, error prevention, standardisation, work environment and safety climate are reviewed. This provides a focused summary of concerns and remedial approaches to risk reduction within Critical Care Units in the UK.

A review by Rothchild *et al.* (2005) analysed levels of error corresponding to 391 patients within 1490 patient days. Within their study, an 'adverse event' is identified as any injury due to medical management, rather than the 'underlying disease' and 'serious medical error' is identified as 'a medical error that causes harm (or injury) or has the potential to cause harm'. The study found a level of 'adverse event' of 120 in 79 patients for 1490 patient days, indicating a level of 80.5 per 1000 patient days. The comparable level for 'serious medical errors' was 149.7 per 1000 patient days. The study in particular provides details of relative frequency of occurrence within the specific classification of serious medical errors. Table 5.21 summarises prevention/diagnostic errors and treatment and procedure errors.

Clinical Activity: System factors	**All serious medical events**	**Clinical Activity**	**All serious medical events**
Prevention and diagnostic errors		**Treatment and Procedure errors**	
Failure to take precautions or follow protocol to prevent accidental injury	30	Medication error in ordering or execution of treatment	170
-Medication related	13	-Wrong dosage	62
-Premature self extubations	3	-Duplicate order	21
Avoidable delays in diagnosis	13	-wrong medication	15
Failure to use indicated test or act on test results	10	-Failure to discontinue a medication order	14
Inadequate patient assessment	8	-Wrong rate or frequency	12
Other prevention or diagnostic error	6	-Wrong route	8
Total (Prevention and diagnostic errors)	67	-Omitted medication	8
		-Wrong patient	8
		-Other medication error	22

Table 5.21 Summary of all serious medical errors for categories of Prevention and diagnostic errors (left columns) and Medication Errors (right columns) after Rothschild *et al.* (2005). (Note: More than one factor may be indicated for a given serious medical error.)

A striking observation from table 5.21 is the relatively high level of serious medical errors arising from lapses in medication protocols.

Clinical Activity: System factors	**All serious errors**
Treatment and procedure errors - continued	
Failure to take precautions or follow protocol to prevent accidental injury	22
Preventable hospital acquired infection	0
Inadequate training or supervision	5
Inadequate reporting or communication	5
Avoidable treatment delay	3
Failure to check equipment or defective equipment	1
Other treatment or procedure error	1
Total (Treatment and procedures)	207
Monitoring and reporting errors	
Inadequate monitoring system	17
Medication related	14
Inadequate reporting/communication	38
Wrong patient	8
Do-not-resuscitate order did not match true code status	8
Test result	5
Total (Monitoring and reporting errors)	55

Table 5.22 Details of Other Treatment and procedure errors and Monitoring and Reporting errors, after Rothschild *et al.* (2005).

This study highlights the advantage of an increased level of description of system factors associated with medical errors. Such studies, however, tend to provide a distribution of effects which relate to prevailing condition of patient workload and illness severity and the internal processes of running such units. They still, however, provide valuable insight into cause and effect of risk within the critical care environment.

In order to identify factors that have commonality between different units, the SEE (Sentinel Events Evaluation) study, Valentin *et al.* (2006), was structured by the European Critical Care Network. Within the study, a 'sentinel event' was defined as 'an occurrence that harmed or could have harmed the patient'. A total of 220 ITUs worldwide participated with 'measurement' taking place within a 24 hour period on January 21st 2004. The contributing ITUs were mainly European. Such a study has the advantage of number of Critical Care Units taking part but the disadvantage of variation in key areas such as staff shift patterns, case mix, clinical protocols and staffing ratios. For a total of

1913 patients a total of 584 sentinel events were identified affecting 391 patients. A summary of the observed rates of such events within identified categories is indicated in table 5.23.

Category of event	**Events per 100 patient days (%)**
Lines, catheters, drains	14.5 (37.4)
Medication (prescription)	5.7 (14.7)
Medication (administration)	4.8 (12.4)
Equipment	9.2 (23.7)
Airway	3.3 (8.5)
Alarms	1.3 (3.4)
Total	38.8 (100)

Table 5.23. Observed rates of sentinel events - after Valentin *et al.* (2006).

The main conclusion of the authors of the SEE study is that results are broadly in line with previous findings undertaken for longer studies within specific ITUs. The study, however, did not seek to assign underlying cause of such levels of activity such as in planning or communication which would have added to the value of the study. The authors in particular identify the urgent need to reduce errors associated with lines, catheters and drains and also activities related to medication, which account for around 64% of reported sentinel events. The implication is that procedures need to be revised in order to reduce the identified effects and or training issues need to be revisited. The incidence of airway events is somewhat lower than reported in other studies, such as that of Bracco *et al.* (2003) and Giraud *et al.* (1993). A more detailed analysis of sentinel events relating to lines, catheters and drains is outlined in table 5.24.

Item	**Total number of patients**	**Unplanned dislodgement Number patients (%)**	**Inappropriate disconnection Number patients (%)**
Arterial line	1214	27 (2.2)	12 (0.9)
Central venous line	1368	19 (1.4)	12 (0.9)
Pulmonary artery catheter	105	4 (3.8)	0
Dialysis catheter	159	6 (3.8)	3 (1.9)
Foley catheter	1579	24 (1.5)	13 (0.8)
Enteral nutrition probe	1050	47 (4.5)	11 (1.0)
Intracranial probe (drain)	67	1 (1.5)	0
Chest drain	264	4 (1.5)	4 (1.5)
Others	455	12 (2.6)	9 (2.0)

Table 5.24. Analysis of sentinel events associated with lines, catheters and drains - after Valentin *et al.* (2006)

For this set of observations, it is not clear what is causing the levels of dislodgement or disconnections of lines. Possible causes include inappropriate initial insertion, patient movement/involvement, accidental contact (clinical staff), unauthorised removal (due to poor communication) or failure of the line (blockage). This indicates that a risk model based on specific interventions at specific times of day will be able to estimate the risk of adverse events based on the scope of the specific intervention, such as if a line was inserted correctly or not. If at a later stage, a 'satisfactory' line is accidently disconnected, then this adverse event is essentially unrelated to the circumstances of its initial insertion. The SEE study also provided a summary of chronological distribution of sentinel events. This provides therefore a time line averaged over activity cycles for the 220 units participating in the study. The peaks at around 9.00 am and 11.00 am are considered to co-incide with the period of nursing shift changeover and peak levels of activity generally. This effect was initially observed by Donchin *et al.* (1995). The SEE study, though limited by the scope of its data set, identifies a strong prevailing interest within ITUs to identify and reduce/eliminate levels of such sentinel events.

The study by Kern and Kox (1999) describes the effect of implementation of standard procedures within an ITU dealing primarily with patients undergoing cardiac surgery. In general, the structure of procedures associated with cardiac intensive care is less diverse than that of a medical/surgical ITU. Once it was identified that there was a requirement to reduce levels of overall mortality rates, clinical procedures were restructured to improve the consistency and quality of received care according to identified clinical needs. Table 5.25 summarises the changed patient mortality in patient groups for a series of three six month periods and where improved procedures were put in place after the first six month period. The mortality rate of 6.6% is essentially identified as a baseline level.

Time interval	**Apache II**	**Risk of Death**	**Mortality %**	**Total patients in study period**
6/96-12/96	10.8	8.5	6.6	541
1/97-6/97	10.7	8.6	4.3	456
7/97-12/97	11.9	10.9	4.8	414

Table 5.25. Variation in patient group information for consecutive six month intervals – Kern and Kox (1999). (Standards implemented at end of first six month interval.)

Table 5.25 indicates an improvement in patient outcomes with implementation of set standards designed to provide a greater level of consistency in patient management and care. The index of severity of patient condition described using the Apache II score and associated 'risk of death' factor indicate comparable levels in the first two 6 month intervals and a higher level of severity of condition in the third six month period. Standardised procedures were grouped into organisational structure, post operative care and Intensive care in long term ITU patients. Aspects of post operative intensive

care management implemented within the revised framework of increased standardisation are identified in table 5.26.

Safety of patients' transportation using on-line monitoring
Standard procedures on admission at the ICU
Standardised sedation regimen using sedatives and α_2 antagonist separately
Time schedule for in-unit medical staff
Standard hygienic procedures
Maintenance of safety standards
Standard procedures with regard to patients' relatives and Ethical standards

Table 5.26. Structure of procedures for post operative care – after Kern and Kox (1999)

Legislation was passed in 1999 in California to mandate a minimum patient-to-nurse ratio of 6:1 for medical and surgical patients by July 2003. A study by Aiken *et al.* (2002) reviewed the patient discharge data from hospitals in Pennsylvania and matched these to both details of corresponding patient-to-nurse staffing ratios and also nurse satisfaction surveys. An odds ratio analysis determined that an increase of one patient per nurse to a hospital's workload would increase burnout and job dissatisfaction by factors of 23% and 15% respectively. Similarly, for an increase of one patient per nurse to a hospital's workload would increase mortality by 7%. Thus comparing a system with a patient-to-nurse ratio of 4:1 and 8:1, this would result in an increase in mortality of 31%. While this study relates largely to non-ITU environments, it indicates a general characteristic of nursing staffing profiles. Also, the significantly increased complexity and mortality within ITUs would tend to reinforce the effects identified by this study.

A relatively recent study undertaken in Germany by Graf *et al.* (2005) determined the incidence of adverse events within a 64 day period, during which a total of 50 errors were identified involving 32 patients and based on a total patient set of 216. The level of incidents per eligible patient day was determined to be 0.07 per day. The authors also indicate that there probably was an element of under recording of events. For some reason, incidents were most likely to occur on Wednesdays and Thursdays. Graf *et al.* (2005) describe a summary of 'human failures' - as listed in table 5.27.

Type of Error	Number (%)
Staff-related	**59 (73)**
Disregard of standards, rules and orders	13
Communication insufficiency, misunderstanding	11
Wrong, incomplete or delayed ecg assessment	7
Delayed intervention	7
Overwork, lack of time	7
Lack of experience	6
Wrong, incomplete or delayed ecg assessment	3
Wrong diagnosis	3
Order illegible	2
Drug-related errors	**17(21%)**
Drug given but not prescribed	10
Wrong dose	7
Various	**5(6%)**
Equipment error	3
Very ill/complex patient	2
Total	**81(100%)**

Table 5.27. Summary of human failures - after Graf *et al.* (2005).

After identification by the study of Graf *et al.* (2005) of high levels of 'disregard of standards, rules and orders', the clinical group subsequently implemented processes to provide greater clarity within designated procedures and also improved specific levels of staff and team communication. The results of this tightening of procedures are not reported. The authors conclude, however, that the focus of error and incident monitoring is to determine how such incidents arise and why the relevant precautions failed. The emergence of a culture of 'practice review' is identified by Levy (2006) as the way towards reduction of adverse outcomes which has less emphasis on aspects of reporting outcomes.

The omission of specific recommended treatments and therapies is often identified as an indicator of less than optimal care. Several studies have shown that while set treatment/diagnostic processes are recommended/advocated, it is often the case that such processes are not included in the care of the patient. In a detailed study, McMullin *et al.* (2006) describes the change in levels of compliance relating to administration of heparin for prevention of venous emboli. In an initial phase, normal practice was identified. In phase 2, a process of education, prompting and performance feedback relating to heparin administration was implemented which was followed by a third phase which retained computer prompts. The rates of adherence to thromboprophylaxis within phases 1, 2 and 3 were 60%, 90.9% and 100% respectively. The main conclusion of the study was that basic functional elements of clinical practice can be altered when a specific focus is provided to initiate and direct

change. While monitoring of level of venous thromboembolism and deep vein thrombosis was undertaken using ultrasound, the rates on incidence was identified to be similar in phases 1, 2 and 3.

The study by Schuerer *et al.* (2006) relating to implementation of a local hospital adverse incident reporting system (SAFE) provides a focus relating to management and implementation of the scheme and also some of the basic findings of the study. Initially an on-line system provided a level of uptake of around 20 responses per 1000 patient days. This increased to a maximum of around 50 responses per 1000 patient days with the introduction of a locally managed card system which indicated that the level of reporting of incidents was dependent on human factors. Table 5.28 summarises the findings of a sequence of 230 completed reports using the SAFE system.

Event Type	**Events**	**Caused harm**
Medication error	89 (38.7)	15 (17)
Test/treatment/episode	57 (24.8)	22 (30)
IV complications	13 (5.7)	7 (54)
Laboratory	12 (5.2)	2 (17)
Equipment/product	11 (4.8)	3 (27)
Fall	8 (3.5)	1 (13)
Blood products	5 (2.2)	0 (0)
Behavioral/psychiatric	4 (1.7)	3(75)
Surgery	3 (1.3)	0 (0)
Other	28 (12.2)	8 (29)
Total	230 (100)	61 (27)

Table 5.28. Summary of report types and percentage (brackets) that resulted in patient harm, after Schuerer *et al.* (2006).

This study indicates that the rate of detection of adverse events per patient is typically in the mid range of values compared with other studies. It also reinforces the importance of issues relating to 'disregard of standards, rules and orders'. In the context of work by Kanji *et al.* (2004) and McMullin *et al.* (2006), this factor is probably due to a collective lack of awareness of indicated practice rather than intentional disregard to follow set guidelines. The keynote of determining and implementing procedural policy, however, comes from the clinical director of the specific Critical Care Unit. This implies that the clinical director has a key role not just in managing the care of specific individual patients but for setting goals and improving generic levels of practice throughout such a unit.

Aspects of time of admission into the Critical Care environment and the resulting clinical outcome has been studied by Sheu *et al.* (2007) in which patients admitted during 'office hours' (08.00 am -06.00 pm on weekdays) and 'non office hours' (06.00 pm -08.00 am on weekdays and all times on weekends) were examined for differences in levels of mortality. It was determined that 39.1% of

patients (239) were admitted during 'office hours' and 60.1% of patients (372) during 'non-office' hours with the ICU mortality rate for the two groups being 27.2% and 27.4%. The differences between the two groups are not significant and was attributed to the provision of a consistent level of clinical management. This result is contrasted with the studies reported by Wunsch *et al.* (2004) and Ensminger *et al.* (2004).

A review of factors influencing events associated with airways as part of the Intensive Care Unit Safety Reporting Study (ICUSRS) as reported by Needham *et al.* (2004) is outlined in table 5.29.

Main Factor	**Sub factors**
Patient Factors: Clinical or social characteristics of a patient that contribute to adverse event	Medical condition and complexity
	Language and communication
	Personality and social factors
Provider factors: Characteristics or state of a clinician that contributes to adverse event	Knowledge skills and competence
	Fatigue
	Motivation and attitude
	Physical or mental health
	Failure to follow established protocol
Team factors: Characteristics of the team that contribute to adverse event	Verbal/written communication during handover
	Verbal/written communication during routine care
	Verbal/written communication during crisis
	Supervision and seeking help
	Team structure and leadership
Training factors: Characteristics of staff training (or lack thereof) that contribute to adverse event	Knowledge, skills and competence
	Failure to follow established protocol
	Supervision and seeking help
Task factors: Characteristics of a specific task that contribute to adverse event	Availability of protocols
	Availability of test results
	Accuracy of test results
Management factors : Characteristics of the work environment that contribute to adverse event staffing	Staffing levels
	Skill mix
	Workload
	Equipment availability or maintenance
	Administrative and management support
	Physical environment
Organisational factors: Decision (or indecision) by management that contributes to adverse event	Financial resources
	Time pressures

Table 5.29. Set of principal factors and associated sub factors identified by the ICUSRS for characterisation of adverse medical events, after Needham *et al.* (2004).

Univariable analysis was used to evaluate relationships within the data set for airway and non-airway reports based on 78 airway events and 763 non airway events. This identified that the impact of such events could be reduced by appropriate staffing and personnel factors, including assistance from appropriately trained colleagues. In particular, the study identified additional risk for airway events for ages less than one year which reflected the logistic and technical difficulties of establishing and managing airways in the very young. The specific review of resultant patient harm is outlined in table 5.30 for airway and non-airway events.

Patient harm	**Airway (n=78)**	**Non-airway (n=763)**
Death	1	0.7
Physiologic change	54	30
Discomfort	38	78
Psychological distress	39	16
Dissatisfaction of relatives	38	20
Physical injury	22	21
Prolonged hospital length of stay – anticipated or actual	*19*	*14*

Table 5.30 Summary of patient harm for initial set of data after Needham *et al.* (2004).

Thus although airway events are fewer in number than non-airway types, they contribute more significantly to measures of resultant patient harm and presumably to extended length of stay within the unit. The study does indicate, however, the importance of appropriate airway management in order to minimise the level overall severity and level of incidence of adverse events in the ITU. This reinforces the concept of adverse effects being associated with an impact on patient mortality.

The requirement for increased objectivity in use of point-of-care systems (and indeed in terms of all diagnostic equipment) is outlined by Corstjens *et al.* (2006) in respect of blood glucose analysis systems in the critical care environment. Comparisons were made between the hospital reference laboratory and measurements on the Critical Care blood gas system (ABL715), a point-of care meter (Precision PCx) and continuous sampling system (CGMS Gold). The correlation with the ABL715 was good though results were consistently 18% higher than laboratory values. At a clinical level, it was identified that where accepted 'normal' ranges are identified, the accuracy of the indicated system has to be determined to be consistent with device specifications. In terms of calibration of specific systems, the ABL715 is described as being regularly calibrated by the hospital laboratory service, the CGMS system is calibrated at least four times a day and with the accuracy of the Precision PCx system relying inherently on the consistency of manufacture of each reagent strip. This identifies possible classification of risk associated with use of medical equipment based on the stability/accuracy of monitoring/treatment facility.

Jain *et al.* (2006) describes the effect of introduction of a process of quality improvement upon acquired infections and adverse events. The specific improvements added included:

- Multidisciplinary rounds
- Hand hygiene protocol
- Ventilator 'bundles'
- Urinary tract infection 'bundles'
- Central line 'bundles'
- Bed flow meetings
- Culture change - non 'vertical'

where a 'bundle' is a set of protocols to define specific procedures to be followed for a specific intervention. The level of daily adverse events was observed to fall from around 25 per day to under 5 per day. Table 5.31 summarises resultant changes in levels of hospital acquired infections. This shows significant reductions in levels of acquired infections with implementation of the quality package. In addition, the rolling average length of stay per patient fell from 5.92 days to 4.71 days over the study period (2001- 2004).

	Baseline (2001-2)	**2003**
Ventilator days	3471	2180
VAP per 1000 days	7.5	3.2
Central line days	6773	4576
Infections per 1000 line days	5.9	3.1
Foley catheter days	7691	5780
UTI per 1000 catheter days	3.8	2.4
Mortality	8.7	8.9

Table 5.31. Change in levels of hospital acquired infections (VAP = ventilator acquired infection; UTI – urinary tract infection) after Jain *et al.* (2006).

It is appropriate to reflect on the impact of staffing structures/staff and moral with the successful implementation of more structured procedures to reduce the level of infection. This will tend to reduce some components of stress related to patients acquiring infections but potentially increase others due to the increased level of adherence to protocols. Also, with the patient length of stay decreasing, this will tend to lead to higher patient throughput.

Binnekade *et al.* (2001) describes a system of relating potential risk to nurse staffing. An initial 'Critical Care Nursing Situation Index' (CNSI) was developed which comprised a series of 84 'gaps' in patient care and which was sub divided into groups of factors. These 'gaps' were identified as having

the potential to cause harm rather than having given rise to an adverse event. A specific observation was made by identifying 'true' items and 'false' items and with the sum of 'true' and 'false' elements constituting the number of 'items at risk'. Nursing time availability was characterised as less than or equal to thirty minutes or greater than thirty minutes per hour per patient. The study found that there were significantly more critical situations for the group with less than 30 minutes per nurse where a level of 30 minutes per hour per patient indicates a nurse/patient ratio of 1:2. Summary findings are indicated in table 5.32.

	Nursing time ≤ 30 min		*Nursing time □ 30 min*	
	Critical situations	*Items at risk*	*Critical situations*	*Items at risk*
Basic nursing care	*282*	*1082*	*147*	*846*
Care of mechanical ventilation	*231*	*1512*	*213*	*1277*
Care of intravenous lines	*151*	*983*	*86*	*756*
Administration of fluids	*27*	*366*	*13*	*280*
Monitoring of cardiac rhythm and circulation	*123*	*844*	*91*	*637*
Administration of medication	*54*	*821*	*20*	*647*
Care of enteral nutrition	*59*	*346*	*32*	*290*
Hygienic care and control of devices	*80*	*906*	*35*	*688*
Total	*1007*	*6860*	*637*	*5421*

Table 5.32. Summary of findings of Critical situations after Binnekade *et al.* (2001) and items at risk related to available nursing time per patient.

The study by Reader *et al.* (2007) describes a specific process of evaluation of interdisciplinary communication within four ITU units in Scotland. Use was made of a modified questionnaire developed initially in the USA by Shortell *et al.* (1994). Based on the sample of 48 doctors and 136 nurses, nurses reported lower levels of communication openness between doctors and nurses. Trainee doctors tended to report lower levels of communication with more senior doctors. In addition, the extent to which openness was identified between ITU team members tended to predict how well patient care goals were understood. Factors were scored using a 1 to 5 visual analogue scale. The specific categories of survey scale adopted were identified as:

- Communication openness between nurses and doctors
- Communication openness within groups
- Communication accuracy between nurses and doctors
- Communication accuracy between groups
- Shift communication between groups
- Shift communication within groups
- Unit communication timeliness
- Satisfaction with nurse and doctor communication
- Satisfaction with communication within groups

- Doctor leadership
- Nursing leadership
- Perceived unit effectiveness

The risks and dangers associated with mechanical ventilation are identified in several studies as warranting specific investigation. The study by Auriant *et al.* (2002) reviewed the nature and origin of clinical incidents due to mechanical ventilation within a three month observational period involving 137 patients in two ITUs. For activities associated with intubation, events were categorised as 'immediately life threatening' or 'secondary life threatening' depending on severity of impact of the clinical incident. For the 'monitoring' phase of ventilation, a category of 'non life threatening' was added. For the intubation phase, the total number of 'ILT' and 'SLT' events were 36 and 14 respectively. For the ventilation phase, the number of 'ILT, 'SLT' and 'NLT' events 67, 138 and 223 respectively. A summary of identification of cause is outlined in table 5.33.

	ILT clinical incidents	SLT clinical incidents	NLT clinical incidents
Human error and failure to follow rules	60.9	50.2	50.6
Patient	45.7	36.2	4.4
Equipment	14.2	13	46.5
Preventable	66.6	57.3	98.2
Physician involvement	31.5	0.03	33.6
Nurse involvement	31.5	62.3	55.6

Table 5.33. Summary of findings related to mechanical ventilation - after Auriant *et al.* (2002).

In addition, a total of 62 types of clinical incident were identified to describe all events identified. Analysis of data identified a level of clinical incident associated with mechanical ventilation of 0.004 per patient per ventilated day. This could be further analysed to separate intubation from the surveillance mode with a level of 0.365 clinical incidents per patient intubation and a level of 0.0029 per patient per ventilated day. The authors indicate that little objective evidence is available to compare values between different ITUs. Such studies, however, are important for determining base line levels of adverse incidents for comparison with simulations of such events.

Aspects of shift patterns are discussed by Donchin and Seagull (2002) where comparison is made between 'short' or 'long' rotations where short rotations involve a scheduled set of around three night shifts in a row and long rotations involving periods of between 4 to 6 weeks. In the context of short rotations, the individual is never properly adjusted to the normal circadian rhythm though it has been identified that the impact of such short term disturbances to normal sleep pattern can be minimised by a day shift followed by an evening shift followed by night shifts. In addition, the authors emphasise the elements of human factor engineering within critical care as a potential factor influencing the level of incidence of risk based on such ergonomic factors and which will contribute towards the level of

adverse events. Few if any studies, however, have listed 'human factor engineering' as a key causal factor within adverse events within the Critical Care environment.

Systems of evaluation of severity of patient illness and nursing workload find significant application within Critical Care Medicine. The review by Miranda *et al.* (1996) of the development and current significance of the TISS (Therapeutic Intervention Scoring System) highlights specific issues within Critical Care of the use of such scales. More importantly, within the context of simulating clinical activity within the Critical Care Unit, the TISS-28 items provide a useful indication of range of core nursing activities as outlined in table 5.34. This version of TISS was devised from the structure of TISS-76 which utilises a total of 76 input factors. This study relates the TISS score system to actual nursing time where each point is equivalent to 10.8 minutes.

TISS Number	Activity	Points
	BASIC ACTIVITIES	
1	Standard monitoring: Hourly vital signs, regular registration, review fluid balance	5
2	Laboratory. Biochemical and microbiological investigations	1
3	Single medication: Intravenously, intramuscularly, subcutaneously and/or orally	2
4	Multiple intravenous medication. More than one drug, single shots or continuously	3
5	Routine dressing changes: Care and prevention of bed sores, daily dressing change	1
6	Frequent dressing change: Frequent dressing change (at least one time per shift) and/or extensive wound care	1
7	Care of drains. All (except gastric tube)	3
	VENTILATORY SUPPORT	
8	Mechanical ventilation. Any form of mechanical ventilation/assisted ventilation with or without PEEP, with or without muscle relaxants: spontaneous breathing with PEEP	5
9	Supplementary ventilatoty support: Breathing spontaneously through ET tube without PEEP, supplementary oxygen any method if 8) applies.	2
10	Care of artificial airways. ET tube or tracheostomy	1
11	Treatment for improving lung function: Thoraxphysiotherapy, incentive spirometry inhalation therapy, intra-tracheal suctioning	1
	CARDIO-VASCULAR SUPPORT	
12	Single vaso-active medication. Any vaso active drug.	3
13	Multiple vaso-active medication. More than one vaso active drug, disregarded type and dose.	4
14	IV replacement of large fluid losses. Fluid administration> 3 L/m2/day, disregarded type of fluid administered.	4
15	Peripheral artery line	5
16	Left atrium monitoring. Swan Ganz catheter with or without cardiac output measurement	8
17	Central venous line	2
18	Cardiopulmonary resuscitation after arrest. In the past 24 hours (single precordial percussion not included)	3
	RENAL SUPPORT	
19	Haemofiltration techniques. All.	3
20	Qualitative urinary output measurement eg by urinary catheter	2
21	Active diuresis eg Furosemide >0.5 mg/Kg/day for overload	3
	NEUROLOGICAL SUPPORT	
22	Measurement Intracranial Pressure	4
	METABOLIC SUPPORT	
23	Treatment of complicated metabolic acidosis/alkalosis	4
24	Intravenous hyperalimentation	3
25	Enteral feeding. Through gastric tube or other GI route (eg jejunostomy)	2
	SPECIFIC INTERVENTIONS	
26	Single specific intervention in the ICU. Eg naso or orotrachael intubation, introduction of pacemaker, cardioversion, endoscopes, emergency surgery in the past 24 hours, gastric lavage - (X-rays ultrasound, ecg, dressings, introduction of venous or arterial lines are not included)	3
27	Multiple specific interventions in the ICU. More than one as described in item 26	5
28	Specific interventions outside the ICU - eg surgery or diagnostic procedures	5

Table 5.34. Description of TISS 28 scoring system - after Miranda, de Rijk, and Schaufeli (1996)

The review by Shortell *et al.* (1994) into the role of good management in the operation and performance of a Critical Care environment identifies specific factors which are likely to have an effect on outcomes of such units. Specific factors identified as inputs to the system include:

- Technological availability
- Task diversity (diagnostic diversity)
- Nurse staffing
- Caregiver interaction (culture, leadership, communication, co-ordination, problem solving, conflict management

The study identifies not just communication within a specific Critical Care unit but the communication of the unit to all relevant services within the core hospital unit. Within the data collecting element of the study, information was collected on 17,440 patients from 1691 hospitals in the USA with findings summarised in table 5.35.

	Risk Adjusted mortality	Risk adjusted ICU length of stay	Nurse Turnover	technical quality of care	ability to meet family member needs
Technological availability	-0.42	-0.03	-0.25	0.11	-0.26
Diagnostic diversity	0.46	0.06	-0.07	0.03	0.15
Nurse/patient staffing ratio	0.14	0.06	-0.04	0.1	0.11
Caregiver interaction	0.09	-0.34	-0.36	0.81	0.74

Table 5.35. Ordinary least squares regression results (standardised coefficient) of variables, after Shortell *et al.* (1994).

Two significant findings relate to the relationships of technological availability and diagnostic diversity to the risk adjusted mortality. Thus with increased technological availability, risk adjusted mortality falls while with increased diagnostic diversity, risk adjusted mortality increases. The negative correlation between technological availability and ability to meet family member needs is noteworthy, indicating that the use of increased technology offsets development of intrapersonal skills. The negative correlation between caregiver interaction and risk adjusted ICU length of stay implies a mechanism through more carefully implemented/monitored levels of care.

For any model specifically developed to simulate input factors of care and output measures of risk, one evaluation of its performance would be to evaluate equivalent regression coefficients.

A review of errors within the paediatric intensive care unit (PICU) environment by Tibby *et al.* (2004) links the level of incidence of adverse events on a range of factors. Data for the one year study was abstracted from information data sets routinely used for patient management and where adverse incidents had been identified since 1993. A specific series of potential risk factors leading to the occurrence of an adverse event were identified. These included temporal factors of day (08.00 am to 08.00 pm), night shift, weekend/bank and holiday staffing compared with the day shift activity. Factors related to patient activity included the bed occupancy at the start of a shift, the number of admissions and discharges during a shift and the level of patient dependency within a shift. Such patient dependencies were based on the recommendations of the UK Paediatric Intensive Care Society (2001). One factor related to nursing staff mix was the percentage of F grade and G grade nurses on duty within a specific shift. A factor related to composition identified the percentage of staff working as permanent rostered staff and permanent staff working as either rostered and non rostered staff. This factor was included to identify the role of staff who may have been fatigued by working additional shifts.

In addition, a supervision factor was included to verify if the nurse in charge of a shift was a G grade (most senior). A 'difficulty' scale was also devised to measure occurrences (e.g. death of a patient) which may compromise the ability of the supervising nurse to carry out his/her duties.

It was identified that a total of 284 adverse events took place on 220 of 730 shifts. Of these 103 were identified as being unit related and 181 patient related, with these occurring at a rate of 6.0 per 100 patient days. These were subsequently broken down to drug error (55), intravenous /arterial line (37), equipment (32), patient injury (26), patient care (21) and accidental extubation (10). With incidents being coded as serious/moderate and actual/near miss, there were 83 serious adverse incidents (actual 49, near miss 34) and 98 moderate adverse events (actual 85, near miss 13).

A statistical analysis of the study data identified some obvious effects related to generic activity but also some important observations for evaluation of nursing supervision. With increased percentage of F and G grades on duty, there was a reduction in number of total adverse events. With an increase in the percentage of shifts with an F grade in charge there was a reduction in level of serious adverse events. This is presumably mainly a supervisory effect. With an increase in the level of permanent rostered staff, there was a decrease in level of actual adverse events. This implies that staff undertaking additional shifts may not be as effective as rostered staff due, for example, to sleep deprivation or fatigue effects. There was not a direct link with the number of admissions/discharges during a specific shift and in fact the odds ratio fell. It may have been relevant to separate these two factors, since additional work may be associated with admissions compared with discharges. Also, in relation to new medical residents, the level of adverse events actually fell with their deployment. This suggests that such staff may have had higher levels of supervision during their initial deployment. There was identified also that the incidence of adverse events associated with equipment reduced

with the G grade nurse in charge, indicating that training factors in the use of equipment may be involved. The expected effect of increased level of events with increased patient dependency was also identified. In general, the study identifies several key factors that would be expected to relate to levels of adverse events within Critical Care units within the UK and provides useful insight for development of a simulation model of risk within this environment.

A separate multivariate analysis further differentiated effects on adverse events by pairing sub categories of variable. This confirmed effects of bed occupancy with patient dependency and level of rostering with levels of F and G grades on duty. It is highly relevant, however, to relate reporting structures of simulated adverse effects within the Critical Care environment to peer reviewed medical literature of the Critical Care environment. What has been previously identified, however, is the non standard way in which such incidents are defined and the relative frequency of such incidents described. Table 7.14 summarises some key characteristics of relevant studies previously referenced, including classification of incidents and frequency of occurrence reference.

5.5 Review of Classification of Incidents and Frequency Reference

Table 5.36 confirms the diverse processes of categorisation of adverse incidents associated with Critical Care activity as reported in the literature. Studies with relatively high numbers of classifications include Rothschild *et al.* (2005) (31) and Giraud *et al.* (1993) (22). Studies with relatively low numbers of classifications include Tibby *et al.* (2004) (6) and Binnekade *et al.* (2001) (8). This confirms the set of 'types of adverse effects' structured in this research, as outlined in table 5.10, as being greater than that typically used in such studies. It is identified, however, that this set of 'types of adverse effects' originates from an in depth analysis of interventions undertaken within the Critical Care environment while the listed studies derive classifications from evidence of Clinical Adverse Events. Thus activity which does not result in clinical adverse events would tend not to be reported. The adoption of a set of types of adverse effects with 43 classifications is therefore considered justified.

Study	Classification of incidents	Frequency Reference
Sinopoli *et al.* (2007).	11 classifications, no specific reference medication errors and ventilator components	Number of safety incidents per group of medical (N=646) or surgical patients (N=707)
Giraud *et al.* 1993	22 classifications based largely on high risk interventions such as arterial catheter, pleural drainage etc.	Described as number of incidents (Major and Total) within study period.
Bracco *et al.* (2003)	Summary of 9 general classifications such as respiratory system, venous lines and catheters etc.	Referenced as components of planning, execution and surveillance incidents within study period
Rothschild *et al.* (2005).	Listing of 7 general categories, 10 categories relating to medication errors and additional 14 categories	Referenced as number of events within study period
Valentin *et al.* (2006)	Total of 6 generalised categories such as airway, alarms and equipment.	Events referenced as number per 100 patient days.
Valentin *et al.* (2006)	Sub division of sentinel events associated with lines, catheters and drains within 9 groups.	Referenced events as numbers per group and total patients per group
Graf *et al.* (2005).	15 summary of human failures 3 main groupings of human error staff related, drug and various with total of 13 sub divisions	Number of events in study
Schuerer *et al.* (2006)	Total of 10 report types such as medication error, blood products with	number of detected events and number which caused harm
Jain *et al.* (2006).	Infection rates VAP, central lines and catheters	Expressed as events per 1000 days of placement
Binnekade *et al.* (2001)	Identification of 8 main categories such as enteral nutrition, fluid administration	Descriptions of number risk situations and number critical situations
Tibby *et al.* (2004)	6 main categories such as equipment drug error	Rate referenced as number events per 100 patient days.

Table 5.36. Summary of key characteristics of relevant studies previously referenced, including classification of incidents and frequency of occurrence reference.

5.6 Clinical Review of Interventions

Clinical medicine is in a continual process of reviewing and revising procedures for patient benefit. These are often some of the more basic procedures undertaken. The study by Corwin, Parsonnet and Gettinger (1995) reviewed the intrinsic reasons for providing blood transfusions. In a study of 609 patients, a subset of 142 patients had a length of stay greater than one week and where 121 of these patients received a blood transfusion. One factor relating to the level of blood transfusion is the volume of blood lost to blood sampling which in the study undertaken is typically around 40 ml per day or higher. Approximately 30% of this is accounted for via phlebobomy. Analysis of administration of blood transfusion within the study group, however, indicated that no formal indication was identified for 29% of infusions. The study identified that proper evaluation of the need to provide a blood transfusion can probably reduce the requirement to provide such infusions. Also, a reduction in the level of blood taken due to phlebotomy will also contribute towards lower levels of transfusion and with reduction in levels of associated adverse events.

The level of caution in use of blood transfusions is justified according to the review of Walker (1987) where an extensive range of transfusion risks are identified. The analysis of adverse effects is characterised as 'serious adverse effects' with a probability of 1 in 190 and 'troublesome adverse effects' with a probability of 1 in 5. The greatest clinical risk was identified as viral hepatitis though subsequently this factor has been significantly reduced due to improved screening processes. This study is an excellent example of levels of risk of a specific clinical intervention being quantified based on processes of clinical audit from a wide range of medical investigators.

5.7 Analysis of Adverse Incidents: Causation and Prevention Factors

While most of the clinical studies relating to adverse incidents are seeking to identify the effects of such incidents, there is also a trend for developing processes to examine risk causation and prevention in greater detail. The review by Stockwell (2006) provides a detailed scoping of techniques for analysis of errors as part of a 'safety toolbox'. Specific modes already in wide clinical use are incident reporting, morbidity and mortality conferences and peer review. Less widely used techniques in healthcare but which find wider application in engineering sectors include Root Cause Analysis (RCA), failure mode and effects analysis (FMEA), probabilistic risk assessment (PRA) and Six Sigma. Root Cause Analysis has been developed within the healthcare community in the UK as a process for in depth analysis of significant clinical adverse events. This tends to take the form of an intense team based analysis. Such detailed analysis of incidents, however, does not provide a systematic review of procedures/protocols on a preventive basis. A key observation is that the level of reported 'adverse events' is likely to be the 'tip of the iceberg' in relation

to the actual number of incidents that take place. The incident reports in themselves, are however useful markers of trends.

In the UK, the National Patient Safety Agency supports an e-learning tool related to root cause analysis of adverse events. This is designed essentially for in depth review of specific adverse clinical events rather than for studies to review sequences of adverse events. The review by Stockwell and Slonim (2006) also indicates that it tends to be the more serious events which occur which will be reviewed on the basis of root cause analysis and it may be more appropriate to monitor parameters which are indicative of procedures beginning to fail rather than wait for a serious failure of a process to occur. This is in many ways analogous with Quality Systems such as ISO9001:2008 (British Standards Institution, 2008) where routine monitoring of key performance indicators provides controlling feedback about identified performance levels.

Within the system described by Reason (1995), types of human error are identified as skill based, rule based and knowledge based. In addition specific 'violations' of procedure are identified as routine, reasoned and reckless. Specific contributory factors are identified as Patient, Individual, Task, Communication, Team and Social, Education and Training, Equipment and Resources, Work Conditions and Organisation and Strategy. So called barriers to occurrence of adverse events include Physical, Natural (e.g. time, distance), Human action and Administration. Where the Root Cause Analysis leads to review of processes and procedures, an analysis of such barriers can often lead to error reduction. Within the information gathering exercise, differentiation is made between an 'influencing contributory factor' and a 'causal contributory factor' where the former may influence the likelihood of an adverse event but the causal factor was the one which led to the event taking place. The subsequent in depth review of issues relating to adverse incidents has itself a structured framework to arrive at the relevant root causes of the adverse event. Usually such analysis will involve a focused team approach.

The wider relevance of Failure Mode and Effects Analysis within healthcare is further discussed by Stockwell and Slonim (2006) where the focused use of the tool in specific instances is identified as being able to reduce risk of specific interventions such as endotracheal tube placement. While, however, the tool is considered of somewhat limited value, its use within a range of error reduction techniques is still relevant. Stockwell and Slonin (2006) references also Probabilistic Risk Analysis with use of fault tree analysis (NASA 2002, Krouwer 2004) to indicate causation of a specific risk outcome. Fault tree analysis is of course widely employed as component of Probabilistic Risk Analysis to reduce the intrinsic failure rate of complex engineering systems such as nuclear power stations and space launch systems.

The report by Baldwin *et al.* (1998) describes the necessary organisational framework for implementation of local forums for exchange of information and general development of team communication. This is within the context of Intensive Care units in Australia. A key requirement identified relates to appropriate planning/structuring of such events and with also the collation and wider dissemination.

5.8 Summary

Interventions are described as a sequence of sub tasks which have pairings of 'sub competency and adverse effect' and which can be linked to a series of 'preventive measures'. The distribution of 'adverse effects' is used to structure a standard set of types of 'adverse effects' against which comparisons are made with clinical adverse events associated with patient care in the literature (chapter 7). Details are also described of sub structures of staff competency and type of adverse effects. A review of clinical studies describing incidence of adverse events within the Critical Care environment is used to identify causal factors for the development of risk simulation mechanisms. These concepts are subsequently used in chapter 6 to develop a 'risk engine' mechanism based on implementation of Fuzzy Logic techniques.

A key component of this review identified a specific series of classifications of types of adverse events, their relative distribution and causation (Giraud *et al.* (1993); Bracco *et al.* (2003); Rothchild *et al.* (2005); Valentin *et al.* (2006); Graf *et al.* (2005); Schuerer *et al.* (2006); Needham *et al.* (2004)). This identified both a diverse series of such classifications and a general lack of a standardised approach. Consideration of the literature also revealed variation in setting of 'thresholds' for identification of such 'adverse effects'. Aspects of standardisation of systems for classification of clinical adverse events are further discussed in chapter 8.

The set of referenced clinical studies in chapter 5 has provided an insight into aspects of development of the 'risk engine' in section 6.2, in particular with identification of role of available competency, level of supervision, level of distraction, and level of individual effectiveness. The literature has also identified a range of more subtle factors such as team planning, awareness of procedures and team communication. The role of these parameters in 'risk engine' functionality is also reviewed in section 6.2. In general the set of referenced clinical studies in chapter 5 do not propose models of risk causation based on identified parameters. This reflects generally the lack of development of such risk causation models in healthcare.

Chapter 6: Deriving Models of Clinical Risk

6.1 Introduction

This chapter describes how the structure of the 'risk engine' is implemented using a specific implementation of Fuzzy Logic, where linguistic interpretation of input parameters drives the output values of the functions. Fuzzy Logic has been applied in a wide range of applications where other methods of control/analysis result in complex systems of control/simulation with discontinuities of function.

The core of the chapter describes the specific implementation of a five state Mamdani fuzzy function for both input and output states. The specific 'Fuzzy Functions' are effectively lookup functions of form Z = f(X,Y) where in the specific implementation values of X, Y and Z are in range 0 to 10. A key element of the 'risk engine' is a component to translate a linear value of 'likelihood' to a probability function in range 0 to 1. In addition, additional structure is defined for functions such as supervision, distraction and team competency to develop the 'risk engine' to the stage where it can process sequences of previously simulated clinical activity. The utilisation of the Fuzzy Logic approach requires that every parameter related to the risk simulation process is expressed as a numeric quantity.

6.2 Describing a 'Risk Engine'

The formal literature within the Critical Care community provides much valuable material for developing models of risk. A key component of the research is the derivation of output values of risk associated with patient interventions and where the system of simulated patient activity modifies a subset of active input parameters which are assumed in turn to modify the output values of risk as shown in figure 6.1.

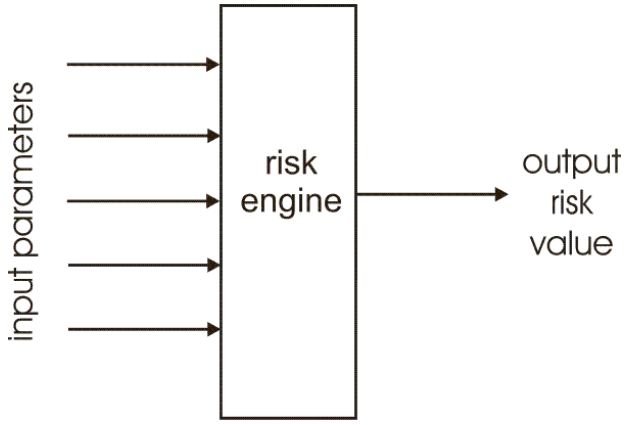

Figure 6.1. Schematic of generic 'risk engine'.

Within the context of risk in the clinical environment, various core parameters are self evident for this role of 'input parameters'. These are referenced in table 6.1 which also includes relevant references which confirm the role of such parameters as factors relating to clinical risk.

Parameters influencing risk	**Confirming References**
Competency available	Giraud *et al.* 1993; Needham *et al.* (2004).
Level of supervision	Aiken (2002) ; Binnekade *et al.* (2001) ; Tibby *et al.* (2004)
Level of distraction	Gurses and Carayon (2007); Donchin and Seagull (2002)
Level of individual effectiveness based on elements of fatigue, stress, shift patterns etc.	van Dongen *et al.,* (2003) ; Dorrian *et al.* (2006) Christensen, Levinson and Dunn, (1992) Koszalka and Skworcow (2003) **;**Jones *et al.* (1988); Barger *et al.* (2006) ;Elfering, Semmer and Grebner (2006) Fischer *et al.* (2006) ; Sallinen *et al.* (2004) Budnick *et al.* (1994) ; Iacovides *et al.* (2003)

Table 6.1. Set of core factors influencing levels of incidence of adverse clinical events within the Critical Care environment and with confirming literature references.

Various studies, however, also demonstrate the relevance of associated factors which can act to alter the relative incidence of adverse effects within the Critical Care environment. A clear component is that of communication of awareness of clinical policies and procedures. While many studies describe 'failure to follow procedures' as a key factor in manifestation of adverse clinical incidents, this is generally interpreted as a lack of awareness of procedures rather than deliberate intent not to follow them. There is also identified a factor relating to the optimisation of policies and procedures, where a specific policy, even if followed through to the letter, may not lead to an optimum outcome for the patient. The challenge within the Critical Care environment and within healthcare in general is to establish and maintain a set of appropriately written protocols to ensure implementation of best practice. There is also a possible link with the use of medical equipment related to interventions

which are linked to patient management and where there is an intrinsic component of risk associated with the reliability/maintainability of the equipment item and indeed the ability of the clinical user to operate it appropriately. It is also identified that team communication and patient planning are important for providing clarity in both determining and communicating elements of patient care. These strands with relevant supporting clinical references are described in table 6.2.

Related parameters influencing risk	**Confirming References**
Awareness of policies and procedures	Rothschild *et al.* (2005) ; Kern and Kox (1999) Needham *et al.* (2004); Jain *et al.* (2006) Auriant *et al.* (2002); McMullin *et al.* (2006) Graf *et al.* (2005)
Optimisation of policies	Kern and Kox (1999) McMullin *et al.* (2006)
Use of medical equipment	Corstjens *et al.* (2006) Valentin *et al.* (2006)
Team communication	Graf *et al.* (2005) Needham *et al.* (2004) Jain *et al.* (2006) McFetridge *et al.* (2007); Currie (2002). Rothschild *et al.* (2005).
Patient planning	Sinopoli *et al.* (2007) ; Needham *et al.* (2004)

Table 6.2. Related parameters influencing levels of incidence of adverse clinical events and with confirming literature references.

The method selected to define the relationships within the 'risk engine' is that of Fuzzy Logic, where the approach allows function mapping based on linguistic interpretation of identified variables. In line with the approach of linguistic interpretation, input parameters are 'paired' by means of implementation of two-input single-output Mamdani fuzzy function functions (Mamdani and Assilian,1975). Figure 6.2 indicates a 'risk engine' which implements both the core and related parameters referenced in tables 6.1 and 6.2.

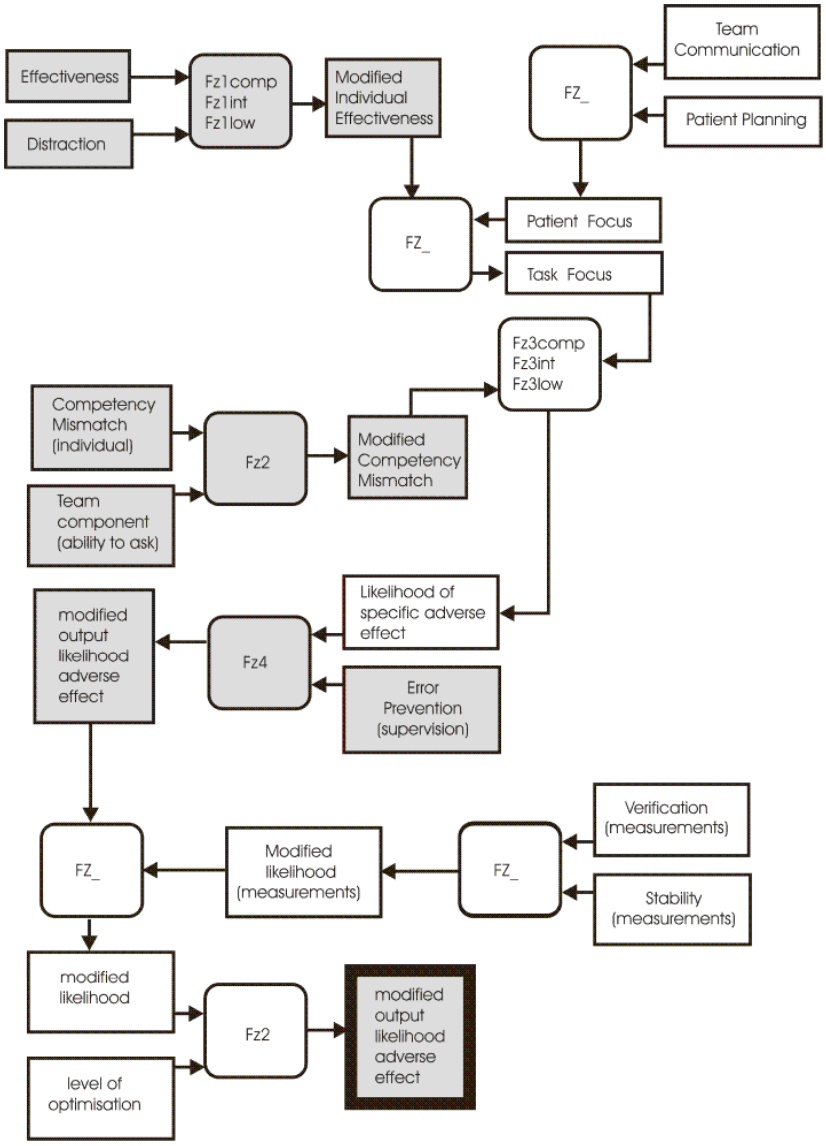

Figure 6.2. Complex model of system interactions using Mamdani Fuzzy functions. Highlighted elements relate to 'core' elements of model – non highlighted elements relate to 'related' elements of model.

Figure 6.2 is identified as the 'complex' 'risk engine' model and utilises nine fuzzy logic functions as indicated by rounded boxes. The mode of operation of the 'risk engine' has the flexibility to skip function elements that are not relevant for the specific evaluation of risk of an identified adverse effect. Thus a routine nursing task may not be linked to 'team communication' or 'patient planning' and may not involve use of medical equipment and may not be an identified procedure what is related to a specific specialized clinical protocol.

Within this framework, the component pairings of ‘Effectiveness/Distraction’, ‘Competency Mismatch(individual)/Competency Mismatch (Team)’ and ‘Supervision/Likelihood of adverse effect’ relate to the implementation of ‘core’ elements of the model. The pairing of ‘effectiveness/distraction’ provides a balancing effect of these two factors that can be linguistically interpreted within a standard Mamdani Fuzzy logic function. Similarly the components of competency mismatch provide another set of balanced effects which can be linguistically interpreted within a standard Mamdani Fuzzy logic function. The component of ‘Supervision’ is also identified as a moderating factor on a derived value of likelihood of adverse effect and for which linguistic interpretation is readily identified.

For specific components associated with the ‘related’ factors, the derived property of ‘patient focus’ from interaction of team communication and patient planning is justified by specific references which identify the importance of these factors. The output of patient focus is then combined with that of modified individual effectiveness to create the parameter of ‘Task Focus’. Modification of output likelihood is then related to the potential influence of the role of measurement uncertainty which is modified by effects of the level of verification of measurement equipment (maintenance) and the degree of stability of measurements. Finally the output is modified by the degree of optimisation of the associated technique being processed.

It was considered, however, relevant to implement a ‘risk engine’ primarily consistent with the operation of the core elements of risk evaluation as referenced in Table 6.1. In terms of medical equipment, while this is a parameter which is associated with risk, the relative occurrence of adverse events related to equipment failure/inaccuracy is relative low. In addition, specific adverse effects and competency issues can be separately identified within the simulation model. The linked items of ‘team communication’, ‘patient planning’ with output of ‘patient focus’ are identified as having a relevant role, though have not been implemented within the ‘core set’ due to the identified requirement to validate a simplified set implementation of the ‘risk engine’. For a similar reason, the ‘optimisation’ mode parameter is not implemented.

Figure 6.3 indicates the ‘core’ configuration of the ‘risk engine’ that has been adopted within the current research. From the viewpoint of computational speed and programming implementation, however, additional complexity of ‘risk engine’ design does not significantly complicate the programming implementation of the risk simulation system or degrade the speed of processing within the module.

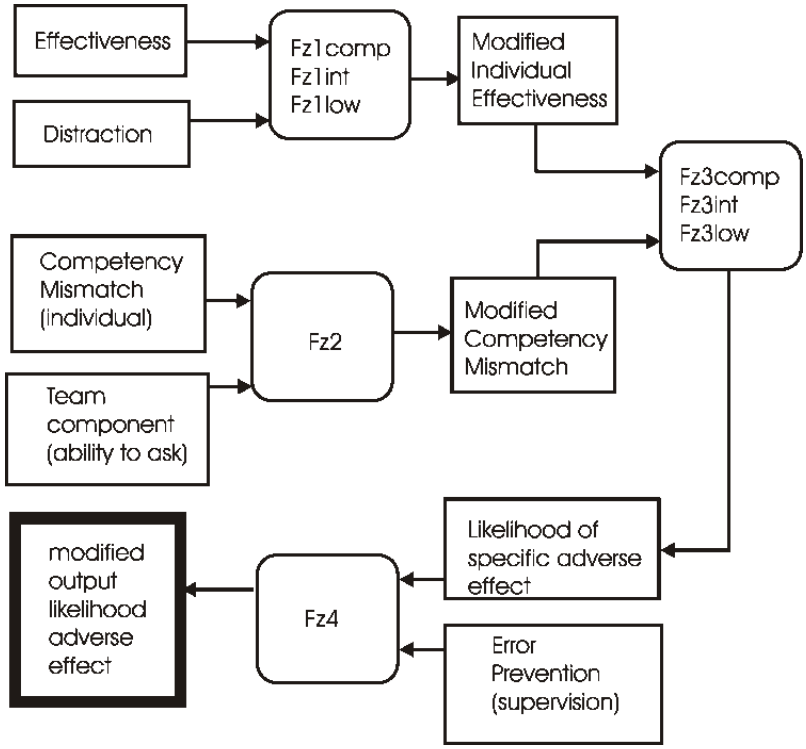

Figure 6.3. Structure of 'core' of 'risk engine' .

Figure 6.3 indicates how 'Effectiveness' is combined with 'Distraction' to create 'Modified Effectiveness' and 'Competency Mismatch (individual)' combined with 'Team Component Competency' to create 'Modified Competency Mismatch' as inputs to determine likelihood of specific adverse outcome which is in turn modified by 'supervision' factor to create 'modified likelihood' output. Also, specific flags can be set e.g. to enable/disable implementation of the supervision factor. Also, specific functions can relate to various grades of task complexity.

In using the technique of fuzzy logic, it is appreciated that almost an infinitely large set of membership functions could have been utilized for both input and output parameters. The functions Fz1, Fz2 etc. are therefore a specific member of a much larger set of possible functions. The attractiveness of the fuzzy approach is that with input of the basic understanding of how input and output states interact as described in the rule system, no further analytical review of the model is required to derive output functions.

With the development of the research and the active demonstration of the operation of the 'risk engine' on simulated sets of patient interventions, the role of Preventive Measures within the context of the risk evaluation has become identified and is further described in section 8.0. This relates to identification of factors which are identified as having a potential impact on likelihood and severity of output adverse effects. Where probability weightings are linked with identified adverse effects,

preventive measure provides an indication of factors/dependencies which are influencing the likelihood of such adverse effects. This provides a mechanism to highlight factors such as 'team communication' and 'patient planning' which have been excluded from the current implementation of the 'risk engine'.

The process of developing the underlying concepts as depicted in figure 6.3 has occupied a significant element of time of the research. The implementation of a specific 'risk engine', is however, relatively straightforward once the basic tools for deriving the fuzzy functions are available. Also, as a specific function in Matlab ®, the programming component of the 'risk engine' is minimal. With each of these applications involving the 'fuzzy engine', however, an essential component is to identify the intrinsic links between the direct inputs and the intermediate derived parameter values.

The function of the 'risk engine' indicated in figure 6.3 will vary according to values of 'ability to ask flag' and 'supervision flag' and also the level of complexity of the task (three levels). It was previously identified that when specific sub tasks were being undertaken, very basic tasks would be undertaken without any component of team competency being available (table 5.3). Also, it was identified that the fuzzy logic rule systems linking 'effectiveness and distraction', 'modified individual effectiveness' and 'modified competency mismatch' would be influenced by the complexity of sub tasks being undertaken. Separate rule systems are defined for low, intermediate and high complexity tasks.

The functions Fzn indicated in figure 6.3 are functions which have initially been derived using Fuzzy Logic techniques, which translate, for example, input values X and Y in range 0 to 10, to a single output value function in range 0 to 10. In the model simulation, where all relevant entries have a valid numerical representation, this allows rapid determination of probability of a given adverse outcome. While Fuzzy Logic techniques have been utilised to provide this functional mapping within a 'risk engine', it is identified that functions driven by other mathematical techniques may be at least of equivalent value. These have not been investigated at this stage.

6.3 Components of Fuzzy Logic Modelling

The initial theory of fuzzy sets as initially outlined by Zadeh (1965) has been subsequently developed as a sub set of mathematics and has been applied in a wide range of problem areas. In particular for the current application, use has been made of the widely employed two-input single-output (Mamdani and Assilian 1975) fuzzy inference system though other systems such as described by Sugeno and Kang (1988) and Tsukamoto (1979) have also been considered. Relevant material has also been reviewed within Jang, Sun and Mizutani (1997). Four separate Mamdani two-input single-output functions are employed to implement the 'risk engine' identified in figure 6.3.

A wide range of membership functions have been identified within the context of problem implementation within fuzzy sets. Specific types include triangular, trapezoidal, Gaussian and generalised Bell. In the context of the current application use was made of a five level trapezoidal function for both input and output functions as indicated in figure 6.4.

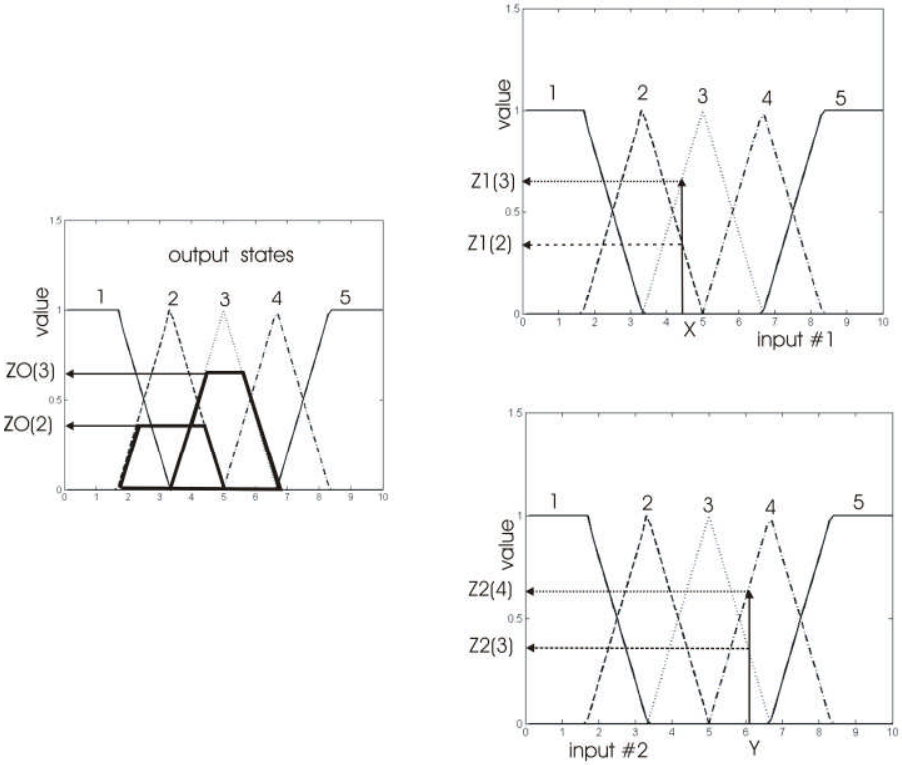

Figure 6.4. Illustration of a Mamdani system where independent input values X for input #1 and Y for input #2 intersect the five level trapezoidal membership functions.

Table 6.3 summarises the functioning of the Fuzzy function indicted in figure 6.4. The value Z1(3) indicates the value of intercept of input value X (input #1) with membership state 3 and correspondingly the value Z2(4) indicates the intercept of value Y (input #2) with membership state 4. With the application of identified fuzzy rules based on 'linguistic' relationships between the variables, values of the corresponding output functions can be identified as indicated in table 6.1 where, for example, rule 1 indicates 'if input #1 is state 2 and input #2 is state 3 then output is state 2'.

Rule number	1	2	3	4
State input #1	2	3	2	3
State input #2	3	3	4	4
Output rule	2	3	2	3
Rule Function	Min (Z1(2),Z2(3))	Min (Z1(3),Z2(3))	Min(Z1(2),Z2(4))	Min(Z1(3),Z2(4))

Table 6.3. Details of notional output rules based on input states with inclusion of rule function of the minimum value of intercepts.

In this example, the maximum number of rules that would fire for a single (X,Y) determination is 4. The specific functionality of figure 6.3 can be implemented by means of series of Mamdani fuzzy functions where specific rules structures are defined for the inputs functions and the specified output function. In terms of implementing the fuzzy logic model within Matlab®, the generic function identified in equation 6.3 is represented in figure 6.5.

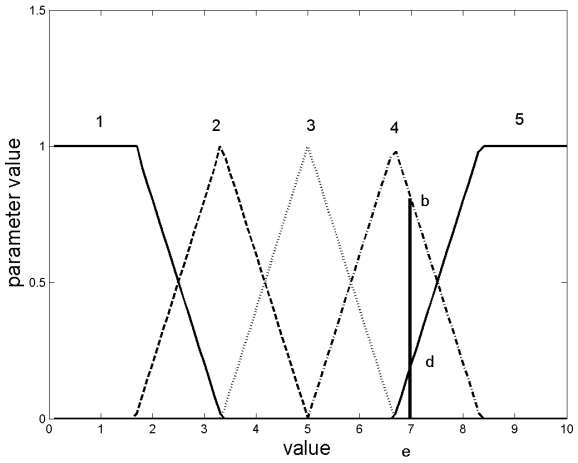

Figure 6.5. Details of main fuzzy function used for both input and output characterisation (a=4, b=0.8, c=5, d=0.2 as in example above).

The first stage of the process is implemented by means of a locally developed Matlab® function 'Fuzzy_5_level' with argument structure:

[a, b, c, d]=Fuzzy_5_level(e) (6.1)

where (*a, b*) is one set of intersection values of input rule and corresponding value and (*c, d*) is the second set of intersection value of input rule and corresponding intersection value and *e* is input parameter. Values of *a* and *c* correspond to the value of identified component membership function. Values of *b* and *d* are the specific function values which are intersected. Thus one pair (*a, b)* is

always defined as at least one membership function is 'hit'. The pair (*c, d)* may not always be defined, for example when *e*<1.667 or *e*>8.333 in the example shown.

The membership function of a specific output rule is generated by the function '*build_mf*' as outlined in equation 6.2 where *s* is the output rule which 'fires' and *y* is the value of intersection function.

[mf] = build_mf(s,y) (6.2)

Figure 6.6 indicates specific membership functions generated relating to parameters identified in table 6.3.

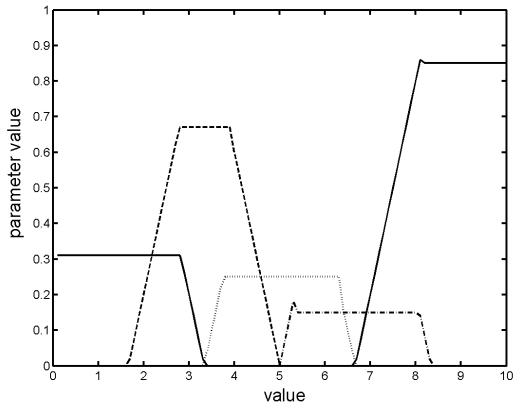

Figure 6.6. Indication of separate output membership functions corresponding to discrete values within equation 6.2 for intersection values of 0.31, 0.67, 0.26, 0.15 and 0.83.

Figure 6.7 indicates the resultant 'combined' membership function produced by taking the maximum value of all component entries across the separate five output membership functions.

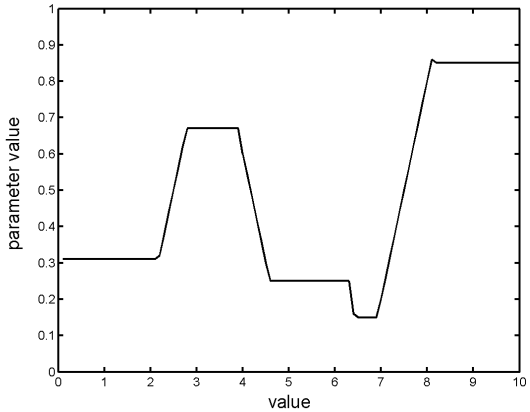

Figure: 6.7. Resultant output membership function produced from deriving maximum value of each component membership function referenced in figure 6.6.

Normally a maximum of four such membership functions would be generated. A set of five are included to indicate the process of structuring membership functions prior to defuzzification.

Defuzzification is undertaken using the standard centroid method using function indicated in equation 6.3.

$$Output_{cent} = defuzz(tx,maxv,'centroid') \quad (6.3)$$

Where *tx* is the output x range and *maxv* is the output *y* function expressed as the maximum value of any components within a given output state as indicated in figure 6.5. The process of defuziffication is designed to derive a 'weight' or 'effective measure' of the values of the values of the membership functions. The *'centroid'* method derives effectively the x axis value about which the area under the graph would balance. Functions 6.1 and 6.2 are written using locally developed Matlab® code while 6.3 utilises the Matlab® fuzzy toolkit. A specific derived Matlab module was developed to produce effectively a tool to derive an output Z parameter value for a set of input #1 and input #2 values in range 0 to 10 with variable steps of 0.1. A total of 25 rules as outlined in table 6.4 were used to structure the array of look up values. The module writes the 100x100 array to disc for later use by the programme which determines the output probability of specific adverse effects.

Rule Number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**
Input #1	5	5	5	5	5	4	4	4	4	4	3	3	3	3	3	2	2	2	2	2	1	1	1	1	1
Input #2	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Output rule	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?	?

Table 6.4. Indication of the 25 rules associated with the basic Mamdani function where each input can exist in any of five states and the output state indicated as '?' can be one of five output states.

A basic outline of characteristics of Mamdani fuzzy functions is outlined in Appendix 6.

6.4 Quantifying Competency Mismatch

A key element of risk simulation relates to derivation of a 'competency mismatch' function for use within the 'risk engine' for calculation of adverse effects. Equation 6.4 identifies the value of CM, competency mismatch, as a function of available competency *(avail_compet)* and required competency (*req_compet)* and where M1 is a constant.

$$CM = 5 - M1.(avail\_compet - req\_compet) \quad (6.4)$$

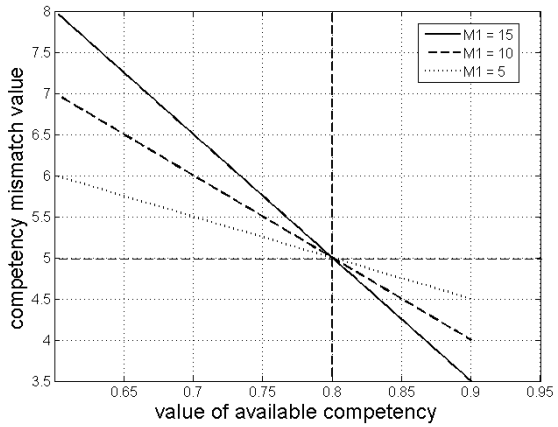

Figure 6.8. Value of competency mismatch as a function of available competency and value of M1 for value of required competency of 0.8.

Figure 6.8 indicates the significance of value of *M1* for driving values of output competency mismatch. Where the value of M1 is too low, then competency mismatch values will vary within too restrictive a value limit. Conversely, when the value of *M1* is too high the range of competency mismatch value will be excessive and not conform to structures identified within the fuzzy model relationships. Subsequently a value of M1 of 15 is adopted.

6.5 Examples of Implementation

Table 6.5 outlines typical rule based system for inputs and output relating competency mismatch of the individual (#1) with element of additional competency (#2). This is derived based on 'linguistic reasoning' of interpretation of defined states of inputs and outputs.

Rule Number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**
Competency	5	5	5	5	5	4	4	4	4	4	3	3	3	3	3	2	2	2	2	2	1	1	1	1	1
Mismatch #1																									
Competency	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Mismatch #2																									
Competency	5	5	4	3	3	4	4	4	3	2	3	3	3	3	2	2	2	2	2	2	1	1	1	1	1
Mismatch Modified																									

Table 6.5. Detail of rule system for modification of competency mismatch of staff member #1 with competency mismatch of assisting member of staff member #2. (5 = very high negative; 4 = high negative; 3 = intermediate; 2 = high positive, 1 = very high positive).

The derived three dimensional surface plot based on this rule set is indicated in figure 6.9.

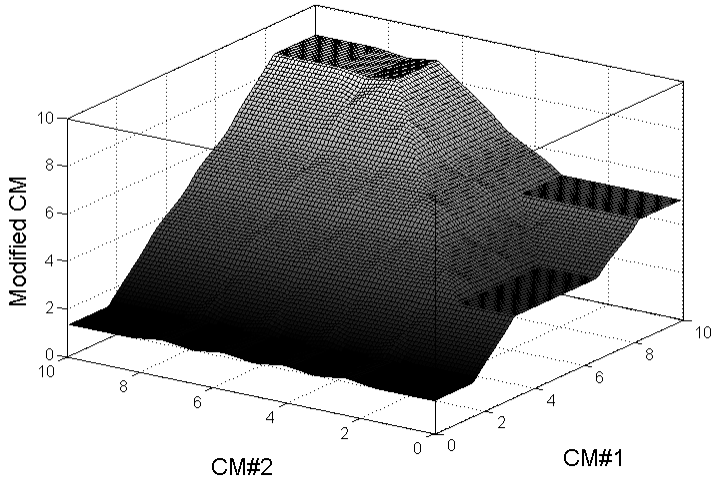

Figure 6.9. Interaction of input components of competency mismatch to provide combined output: CM#1 = competency mismatch staff member #1: CM#2 = competency mismatch of staff member #2.

This indicates the way in which fuzzy logic rule based systems effectively define a mapping function within the various stages of derivation of the 'risk engine'. In a similar way, it is appropriate to identify the rule functions for effectiveness and distraction using the three levels of task complexity where is it assumed that distraction will be a more significant factor in more complex tasks. It is appropriate, however, to define the states of distraction as it applies to degradation of ability to complete tasks effectively.

Rule State	**Description**
Very high (5)	Likely to cause loss of effectiveness during complex or moderately complex or simple tasks
High (4)	Likely to cause loss of effectiveness during complex or moderately complex tasks
Intermediate (3)	Likely to cause loss of effectiveness during complex tasks
Low (2)	Possible effect on some work
Very low (1)	No effect on level of effectiveness

Table 6.6. Description of level of distraction and ability to influence individual effectiveness.

In this rule set, distraction is combined with effectiveness. Effectiveness is more significantly degraded with degree of distraction.

Rule Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Effectiveness	5	5	5	5	5	4	4	4	4	4	3	3	3	3	3	2	2	2	2	2	1	1	1	1	1
Distraction	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Modified Effectiveness (complex)	3	4	4	5	5	2	3	3	4	4	2	2	2	3	3	1	1	2	2	2	1	1	1	1	1
Modified Effectiveness (intermediate)	4	4	5	5	5	3	3	3	4	4	2	2	3	3	3	1	2	2	2	2	1	1	1	1	1
Modified Effectiveness (low)	4	5	5	5	5	3	4	4	4	4	2	3	3	3	3	1	2	2	2	2	1	1	1	1	1

Table 6.7. Rule description for derivation of modified effectiveness based on levels of distraction and for level of task complexity (low, intermediate and complex).

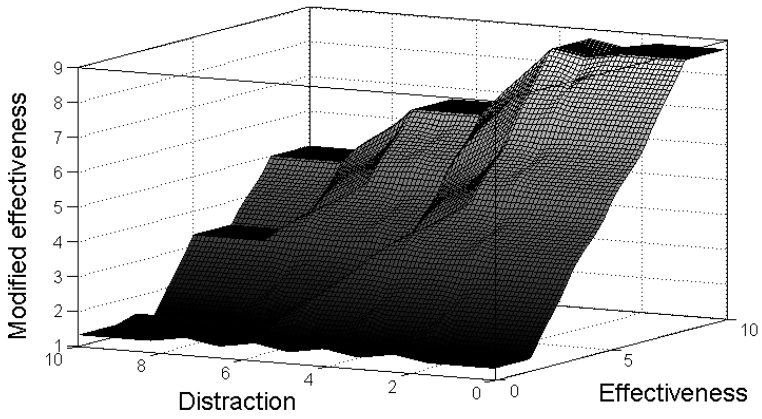

Figure 6.10. Combination of Effectiveness and Distraction for complex tasks (Fz1comp).

Thus the 'risk engine' identified in figure 6.3 can be designed and implemented using the 'two input one output' Mamdani fuzzy model and where the numerical functions are essentially defined by the identified set of rules for such functions. A summary of the various fuzzy logic functions are summarised in table 6.8.

Rule 1 input	5	5	5	5	5	4	4	4	4	4	3	3	3	3	3	2	2	2	2	2	1	1	1	1	1
Rule 2 input	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Fz1comp input	3	4	4	5	5	2	3	3	4	4	2	2	2	3	3	1	1	2	2	2	1	1	1	2	1
Fz1int input	4	4	5	5	5	3	3	3	4	4	2	2	3	3	3	1	2	2	2	2	1	1	1	1	1
Fz1low input	4	5	5	5	5	5	3	4	4	4	4	3	3	3	3	1	2	2	2	2	1	1	1	1	1
Fz2 output	5	5	4	3	3	4	4	3	2	3	3	3	3	3	2	2	2	2	2	2	1	1	1	1	1
Fz3comp output	5	5	5	5	5	4	4	5	5	3	3	3	3	4	5	2	2	2	3	4	1	1	1	1	3
Fz3int output	5	5	5	5	5	4	4	5	5	3	3	3	3	4	4	2	2	2	3	3	1	1	1	1	2
Fz3low output	4	5	5	5	5	3	3	4	5	2	3	3	3	3	4	1	2	2	2	3	1	1	1	1	1
Fz4 output	3	4	5	5	5	3	4	4	4	2	3	2	3	3	3	1	2	2	2	2	1	1	1	1	1

Table 6.8. Summary of input and output rule structures utilised in the structure of figure 6.1.

6.6 Mapping from Output Linear Value to Event Probability

The values of likelihood of adverse events within a linear scale between 0 and 10 require to be equated to an actual likelihood of occurrence in the range of 0 to 1 value through a separate mapping function. Table 6.9 indicates a typical process of mapping of probability and time frame that is routinely applied within risk assessments in the NHS (SAI Global 2004). Where, for example, a risk event is likely to occur on a daily basis, with nominal probability of unity, then the relative probability of events within other time frames can be derived as indicated in table 6.9.

Description of likelihood of adverse event	**Implied time frame**	**Relative derived numeric value**	**Scale value likelihood**
Very likely	Every day	1	8.3333
Likely	Once a week	0.1429	6.667
Occasional	Once every 3 months	0.01111	5
Rarely	Once a year	1/365	3.333
Very rarely	Once in five years	1/(365*5)	1.667

Table 6.9. Description of frequency and probability factors for event occurrence, where 'scale value likelihood' is linear output value of the 'risk engine'.

Figure 6.11 indicates the general variation of output probability with value of output likelihood using the step interval of 1.66667 between values of output likelihood. This indicates the characteristic maximum

value at output likelihood value of 8.3333 followed by step wise reduction to the minimum value at 1.6667.

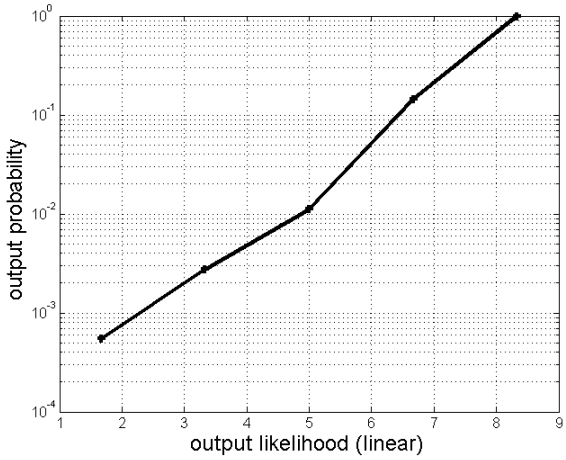

Figure 6.11. Variation of relative probability with output likelihood and based on values in table 6.9.

Assuming a linear log function of relative probability as a function of linear output likelihood, this has a generic function outlined in equation 6.5.

$$Y = Ao \,/\, Grad^{((8.3333-OutAE)/Step)} \quad (6.5)$$

where *Ao* is the maximum function value at *OutAE*=8.333*, OutAE* is the (linear) value of output likelihood from the 'risk engine', Step is the interval value of output likelihood (set at 1.66667) and *Grad* is a scaling factor.

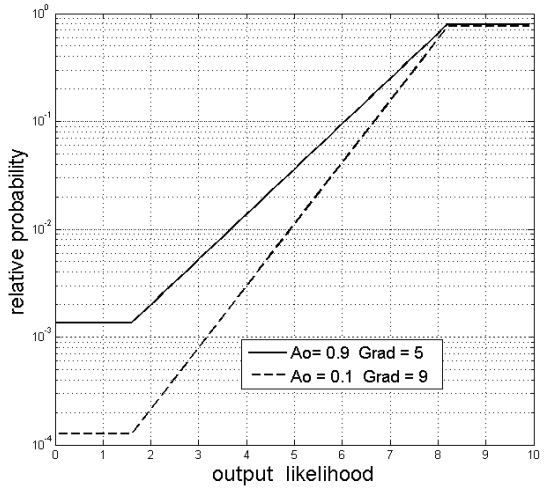

Figure 6.12. Variation of relative probability as function of output likelihood for specific values of *Ao* and *Grad.*

Where specific values of output risk are derived as a result of simulation using random number generation, a normalized event space of output likelihood values can be generated which requires to be translated to corresponding values of probability. Figure 6.13 indicates how specific values of constants used in equation 6.4 produce differences in values of cumulative normalized probability.

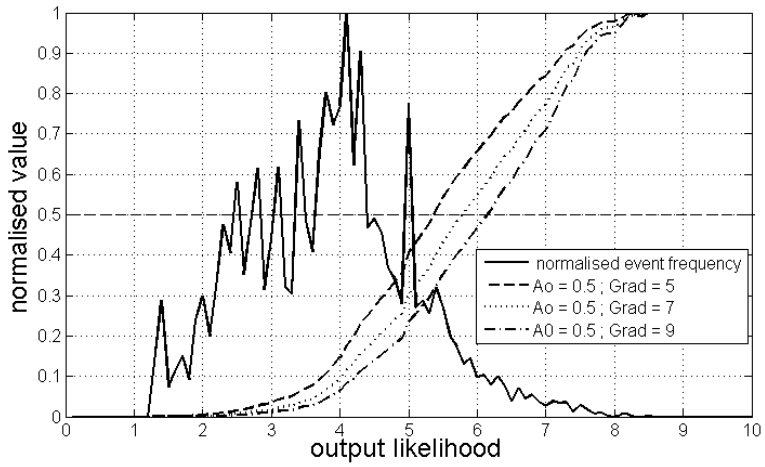

Figure 6.13. Variation of three separate cumulative probability functions with normalized event frequency for higher risk states. Corresponding values of average probability are 0.0122, 0.0068 and 0.0046.

More extensive analysis of the probability mapping function with test sets of simulated risk values is outlined in section 7.7.

6.7 Driving the Model: Working with Interventions

While the specific components of the inputs to the 'risk engine' have been defined, additional structure and definition is required to implement a working model. As previously described, interventions are identified as a key element of the risk model. Figure 6.14 indicates how interventions with linked competencies/adverse effects provide the basic structure for evaluation of risk effects. In the example the competencies are looked up in the nursing competency table at the appropriate grade of staff and the adverse effects in the corresponding (global) adverse effects table. Interventions for other staff groups reference the relevant competency table. Figure 6.15 describes the complex process of structuring input values to the 'risk engine' as part of the process of evaluation of probabilities of adverse effects.

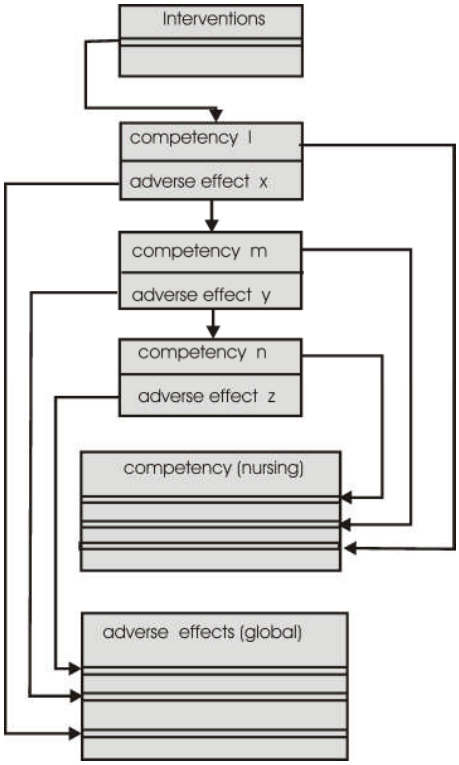

Figure 6.14. Structure of look up function of an intervention with three components of competency/adverse effect.

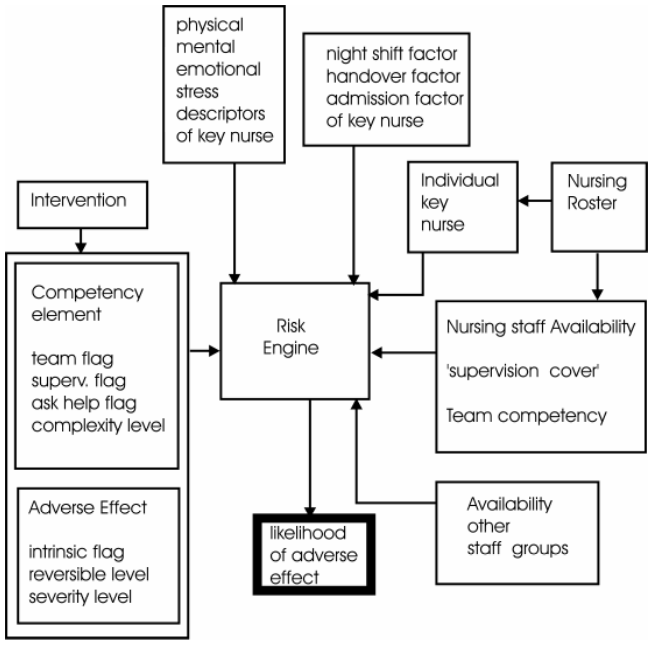

Figure 6.15. Summary of inputs to the 'risk engine' (figure 6.3) to determine probability of adverse effects associated with a specific component of competency within an identified intervention.

The code flags set within the competency element (supervision flag and ask help flag) determine specific modes of operation of the risk engine. The elements of physical, intellectual, emotional/stress descriptors influence the effectiveness of an individual as interventions are undertaken. The element of supervision is more highly defined for sets of nursing based interventions.

6.8 Staff Roster Processes

A key component of operating a Critical Care Unit is the allocation of nursing staff to individual patients. Previously, table 5.12 identified a sub banding structure within the ranges of bands 5 to 7. Nursing staff are identified to form a 'rostered' pool of staff consisting of staff of various grades and sub grades. The specific Critical Care Unit at University Hospital, Coventry, operates three 'teams' of staff based on bed groupings of 8, 8 and 10 beds. These teams essentially work 'autonomously' based on the physical layout of work environment and where the beds in each cluster form a cohesive team unit for communication of priorities, sharing of skills and local management of patient care. For this set of ten beds, staffing of these beds is undertaken on a staff roster basis. Table 6.10 identifies a typical analysis of relative staff grades within an identified sub unit of ten beds with utilisation of the sub grading structures of table 5.12.

Staff Grade	Number of allocated staff (example)
5a	0
5b	0
5c	2
5d	2
5e	2
6a	1
6b	0
6c	1
6d	1
6e	0
7a	0
7b	0
7c	1
7d	0
7e	0

Table 6.10. Example of allocation of nursing staff per notional 10 bed unit.

Each nurse 'team' will include at least one band 7 nurse allocated to the role of lead nurse.

For nursing staff of a specific band, such as band 5, specific details of individual staff are maintained in the format indicated in table 6.11.

Staff Ref	Competency description	Ability to Ask level	Supervision Coefficient	Handover Grade	Physical reserve grade	Emotional & stress Grade	Intell. reserve grade
1	5b	0.8	0.67	3	3	3	3
2	5b	0.8	0.67	3	3	3	3
3	5b	0.8	0.67	3	3	3	3
4	5b	0.8	0.67	3	3	3	3
5	5b	0.8	0.67	3	3	3	3
6	5b	0.8	0.67	3	3	3	3
7	5b	0.8	0.67	3	3	3	3
8	5b	0.8	0.67	3	3	3	3

Table 6.11. Variables associated with individual nursing staff with identification of competency description (as applied to all competencies), 'Ability to Ask' factor for team competency sharing, handover/admission function and physical, emotional/stress and intellectual reserve grades.

It is also possible to structure a specific 'Supervision coefficient', in range 0 to 1, to reflect the degree of supervisory ability of the individual. Thus each individual nurse with a unique staff reference will have a characteristic profile based on the sub code describing competency within the identified band (eg 5a, 5b etc.) and the other identified factors. The 'ability to ask' parameter is a measure of the relative probability that the staff member will ask for help in undertaking tasks. This acknowledges that the potential availability of additional competency within the group of nursing co-workers does not necessarily imply that it is taken up.

Details of nurse allocation within a specific time period is contained in a matrix of structure (beds,shift_number) where 'beds' is the number of active beds and 'shift_number' is the shift number that has been allocated and where the specific values of the matrix are the unique identifier of an identified staff member. Staff are allocated to patients on the basis of clinical need, where the more ill patients would be treated by the more experienced nursing staff. In the module which calculates likelihood of probability of adverse effects, the staff available for duty at the start of each shift are automatically matched to the patients by level of severity of patient condition. Table 6.12 indicates the basic roster structure used for risk simulations and was derived by a specially developed roster generation module which accessed a core set of 100 nurses with characteristic distribution of competency grades.

	nurse 1	nurse 2	nurse 3	nurse 4	nurse 5	nurse 6	nurse 7	nurse 8	nurse 9	nurse 10
day#1	12	27	29	42	44	48	64	73	77	89
night#1	13	16	30	33	45	49	65	69	75	85
day#2	12	27	29	42	44	48	64	73	77	89
night#2	13	16	30	33	45	49	65	69	75	85
day#3	12	27	29	42	44	48	64	73	77	89
night#3	13	16	30	33	45	49	65	69	75	85
day#4	12	27	29	42	44	48	64	73	77	89
night#4	13	16	30	33	45	49	65	69	75	85
day#5	14	28	31	43	46	50	66	74	78	90
night#5	15	17	32	34	47	51	67	70	76	86
day#6	14	28	31	43	46	50	66	74	78	90
night#6	15	17	32	34	47	51	67	70	76	86
day#7	14	28	31	43	46	50	66	74	78	90
night#7	15	17	32	34	47	51	67	70	76	86
day#8	12	27	29	42	44	48	64	73	77	89
night#8	13	16	30	33	45	49	65	69	75	85
day#9	12	27	29	42	44	48	64	73	77	89
night#9	13	16	30	33	45	49	65	69	75	85
day#10	12	27	29	42	44	48	64	73	77	89
night#10	13	16	30	33	45	49	65	69	75	85
day#11	14	28	31	43	46	50	66	74	78	90
night#11	15	17	32	34	47	51	67	70	76	86
day#12	14	28	31	43	46	50	66	74	78	90
night#12	15	17	32	34	47	51	67	70	76	86
day#13	14	28	31	43	46	50	66	74	78	90
night#13	15	17	32	34	47	51	67	70	76	86
day#14	14	28	31	43	46	50	66	74	78	90
night#14	15	17	32	34	47	51	67	70	76	86

Table 6.12. Summary of simplified roster used in risk simulations where numeric entries reference specific nursing co-workers.

For the group of 10 active beds, in the region of a minimum of 50 nursing staff are required to provide sufficient roster structure and including elements of annual leave and sickness. This is assuming 4 consecutive shifts ‘ON’ and three equivalent shifts ‘OFF’. The training profile of staff, however, will change dynamically as new staff are recruited and where staff in post develop their specific levels of competence. The model has the potential to simulate contributions from dynamic changes to the competency level of individual staff.

The nursing roster system within the Critical Care Unit at University Hospital, Coventry is generally similar, except that additional scope is required to roster staff due to sick leave, study leave and annual leave. Band 7 nursing staff tend not to work a full set of ‘duty’ shifts per week. A limited number of staff will work 8 hour shifts but are not included in the roster model.

6.9 Team Competency Cover

One of the key perceptions of work within the Critical Care environment is that of competency sharing within a team environment especially for nursing staff. Specific factors which relate to this mode are outlined in table 6.13.

Factor	**Issues**
Staff availability	Who is physically present in the area at a given point in time?
Staff proximity	Who is sufficiently close to a specific staff member to provide effective support?
Ability to provide additional competence	Can staff bridge identified competency gap?

Table 6.13. Issues relating to providing nursing competency cover.

A notional physical layout of the active 10 bed sub-unit within the Critical Care unit is indicated in figure 6.16. This shows specific bed numbers, an indicated bed (bed number #3) and pointers to beds where staff of higher competency are physically present at the time when a staff member at bed number #3 is undertaking an intervention. Parameters D1, D2 etc. are distance vectors to identified beds.

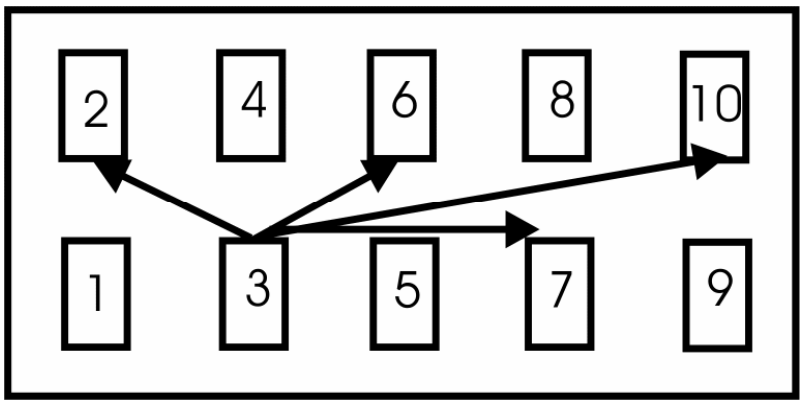

Figure 6.16. Representation of active ten bed sub unit where nursing staff in beds 2, 6, 7 and 10 are actually present and can contribute a higher competency for the individual at bed 3.

In the process of identification of maximum potentially available competency to a staff nursing member, probability functions are identified with each 'bed-to-bed' link which relate to the availability of staff member (present/not present and identified as *Attend(i))* and the effect of separation between individuals which is identified as *Sep_comp(i,j)* in equation 6.6. Where this probability is zero, the component of potential additional competency is ignored. These factors indicate that levels of 'team' competency will be degraded by senior staff who have to spend significant periods of time outside the immediate clinical area or where the physical layout of the unit prevents effective team communication and contact.

In addition, the model identifies an 'Ability to Ask' function *Fask(j),* which influences the process of seeking additional competency. Set typically as a probability value of 0.8, this factor can affect the level of additional competency which is potentially available but perhaps not taken up by the individual in question. The maximum available team competency for staff member j relative to a specific sub competency is identified as:

*Team_Max_Comp(j)= Fask(j). Max[Comp(i). Attend(i).Sep_comp(i,j)] i=i,10 i#*j (6.6)

Where *Comp(i)* is the competency level of nurse at bed i.

The *Sep_comp(i,j)* function introduces a factor to reduce the team interaction at increased distance between nursing co-workers. Table 6.14. describes the interactions between an active bed (rows) and linked beds (columns).

	Link 1	Link 2	Link 3	Link 4	Link 5	Link 6	Link 7	Link 8	Link 9
Bed 1	2	3	4	5	6	7	8	9	10
Bed 2	1	3	4	5	6	7	8	9	10
Bed 3	1	2	4	5	6	7	8	9	10
Bed 4	1	2	3	5	6	7	8	9	10
Bed 5	1	2	3	4	6	7	8	9	10
Bed 6	1	2	3	4	5	7	8	9	10
Bed 7	1	2	3	4	5	6	8	9	10
Bed 8	1	2	3	4	5	6	7	9	10
Bed 9	1	2	3	4	5	6	7	8	10
Bed 10	1	2	3	4	5	6	7	8	9

Table 6.14. Matrix of links of active bed and linked beds: For example active bed #1 links with beds 2,3 4,5 6,7,8,9 and 10 and active bed #8 links with beds 1,2,3,4,5,6,7,9 and 10.

Table 6.15 describes the values of probability of interaction using the rule outlined in figure 6.15.

	Link 1	Link 2	Link 3	Link 4	Link 5	Link 6	Link 7	Link 8	Link 9
Bed 1	1	1	1	1	1	0.8333	0.8333	0.6777	0.6777
Bed 2	1	1	1	1	1	0.8333	0.8333	0.6777	0.6777
Bed 3	1	1	1	1	1	1	1	0.8333	0.8333
Bed 4	1	1	1	1	1	1	1	0.8333	0.8333
Bed 5	1	1	1	1	1	1	1	1	1
Bed 6	0.8333	0.8333	1	1	1	1	1	1	1
Bed 7	0.8333	0.8333	1	1	1	1	1	1	1
Bed 8	0.8333	0.8333	1	1	1	1	1	1	1
Bed 9	0.6777	0.6777	0.8333	0.8333	1	1	1	1	1
Bed 10	0.6777	0.6777	0.8333	0.8333	1	1	1	1	1

Table 6.15. Values of probability of 'action at a distance' based on interaction rule as referenced *Sep_comp(i,j)* in equation 6.6.

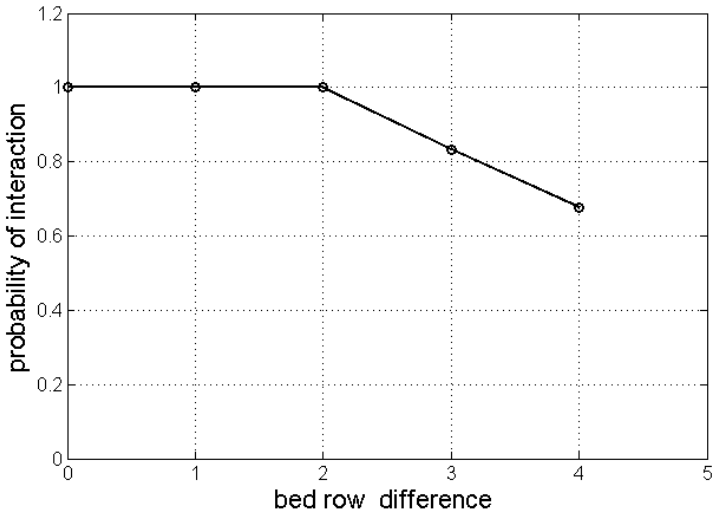

Figure 6.17. Rule function describing probability of competency sharing as a function of row difference between beds. More remote beds are likely to have less interaction.

Thus in the example of link from bed 3 to bed 10 in figure 6.17, this is a difference of 3 rows, which is associated with a probability value of 0.8333. This value is associated with element (Bed 3, Link9) of table 6.14.

This model of competency sharing identifies the relative probabilities of supporting individual competency from the team. For a number of reasons, such as fetching of consumable items/drugs, answering the telephone, etc. allocated nursing staff are not always present at the position of the allocated nursing station. At specific instants in time, the available 'team competency' will be most affected by the availability of the 'team leader' who is assumed to have most competency across the

range of patient interventions. The value of probability of attendance can be considered to be influenced by physical design/layout factors such as proximity of stock rooms/drug stores to the clinical area and general logistical planning. This approach indicates how logistical layout can influence risk factors associated with patient care.

It is also relevant to point out that the physical distribution of patients by severity grade can also influence the level of team competency sharing.

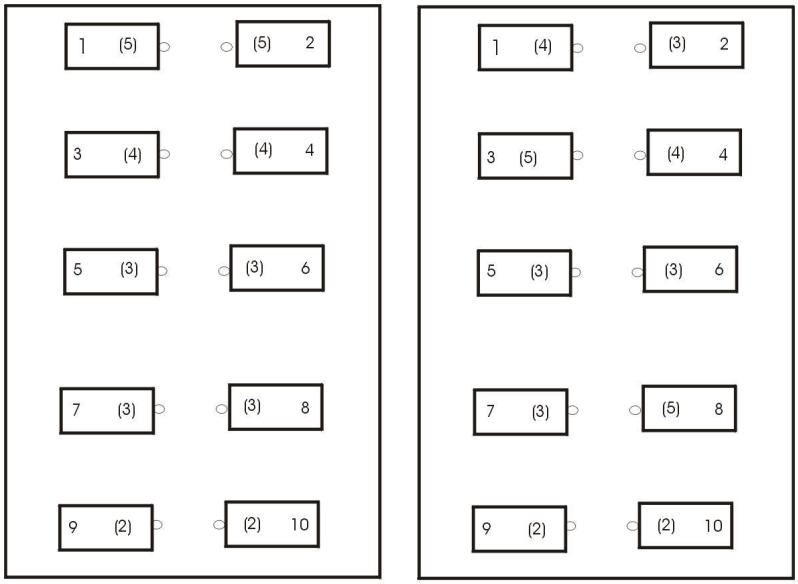

Figure 6.18. Indication of how distribution of patients by severity within the active sub unit (where numbers in brackets indicate level of severity of patient condition) will influence the sharing of competency as more highly trained staff are associated with patients of greater severity grade. In configuration A, most of the severely ill patients are in beds 1 to 4 which could restrict competency sharing while in configuration B, they are more widely distributed within the unit which would tend to enhance competency sharing.

6.10 Structuring Supervision

Supervision of nursing staff can be considered to have one component related to operational supervision by nursing co-workers in a specific sub unit (notionally ten bed model) and another component by other clinical co-workers such non-operational nursing staff (of senior grade) and other staff including doctors, pharmacists and dieticians.

Where a supervision parameter used with the fuzzy risk model has a range of value of 0 to 10, for nursing co-worker j, this can be considered to be of format:

$$Sv(j) = c_{ncw}.Sncw(j) + c_{oc}.So \quad (6.7)$$

Where *Sv(j)* is the combined supervision value for nursing staff member j, *Sncw(j)* is the component from other nursing co-workers and *So* is the combination for other clinical staff. Parameters c_{ncw} and c_{oc} are coefficients <1 to identify the mix of supervision between nursing co-workers and other clinical staff. Initial values of c_{ncw} and c_{oc} are identified as 0.9 and 0.1 and So as value 8.0 for dayshift and 4.0 for nightshift. This indicates the dominance of supervision due to nursing co-workers.

The value of *Sncw(j)* for nursing co-worker j can be identified as:

$$Sncw(j)=\Sigma\ (Sf(i)\ .\ \ t(i).\ \ Sep\_sup(i,j))\ i=1,10\ i\#j \quad (6.8)$$

Where *Sf(i)* is a supervision factor associated with a specific staff grade as indicated in figure 7.10, *t(i)* is 0 or 1 depending on whether bed is active/non active or if the staff member is present/not present and *Sep_sup(i,j)* is a probability of interaction function between beds related to supervisory role and with similar function to *Sep_comp(i,j)* utilised in equation 6.6. It is identified that the parameters of *Sep_comp(i,j)* and *Sep_sup(i,j)* are essentially equivalent, where the influence of physical layout will tend to influence both competency sharing and level of supervision. Section 6.14 outlines a systematic approach for generating values of *Sep_comp(i,j)* and *Sep_sup(i,j).* A key element identified in the evaluation of the supervision coefficient Sep_sup(i,j) is the awareness of patient condition between bed areas. In subsequent simulations using subsets of test data in chapter 7, *Sep_comp(i,j)* and *Sep_sup(i,j)* can be set to separate values if required.

Equation 6.9 describes the relationship between the supervision factor associated with a specific staff grade and the corresponding nursing co-worker, as indicated in figure 6.19.

$$Sf(i) = 0.053571.Subg(j) + 0.7321 \quad (6.9)$$

Within this model, the factor of ‘action at a distance’ is assumed to be similar for competency sharing and also for additive supervision.

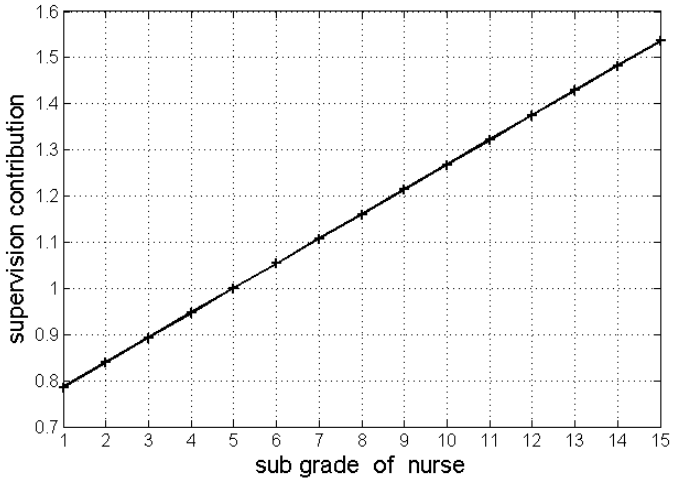

Figure 6.19. Variation of supervision component Sf(i) as a function of sub grade of nurse (1 to 5: band 5: 6 to 10 band 6 and 10 to 15 band 7).

6.11 Structuring Distraction

Distraction factors were previously referenced in section 6.2 where the level of bed occupancy was related to a notional distraction factor in the range 0 to 10 which could be used as an input to the fuzzy model. Subsequently, with the identification of a 'severity' parameter in range 1 to 5, the 'distraction' function is seen to be influenced by both the bed occupancy status and the corresponding level of severity of patient condition. Specific distraction weightings are empirically applied as indicated in table 6.16 to reflect the typical differences in levels of activity associated with each 'severity' level identified.

	Severity level 1	Severity level 2	Severity level 3	Severity level 4	Severity level 5
Distraction Coefficient Dc(j)	0.65	0.75	1	1.25	1.5

Table 6.16. Distraction coefficients used to determine distraction function within the 10 bed model critical care unit.

The value of distraction parameter, Dist(j) for nursing co-worker j is given by:

$$Dist\_ncw(j)=\Sigma(Dc(i).bedoc(i)\ Sep\_dist(i,j))\ i=1,10\ i\#j \qquad (6.10)$$

Where *Dc(i)* is the distraction coefficient as indicated in table 6.16, *bedoc(i)* is value 0 or 1 depending on the bed occupation status and *Sep_dist(i,j)* is a parameter weighting the distractive effect of function of bed separation. The function of *Sep_dist(i,j)* is similar to that of *Sep_comp(i,j)* and *Sep_sup(i,j).* Table 6.17 indicates a derived set of distraction coefficients derived in section 6.14. This numeric structure takes account of 'line of sight' in functions describing visual contact, verbal contact and awareness of patient condition.

	Link 1	Link 2	Link 3	Link 4	Link 5	Link 6	Link 7	Link 8	Link 9
Bed 1	1	1	1	0.719	0.898	0.573	0.573	0.468	0.468
Bed 2	1	1	1	0.898	0.719	0.573	0.573	0.468	0.468
Bed 3	1	1	1	1	1	0.719	0.898	0.573	0.573
Bed 4	1	1	1	1	1	0.898	0.719	0.573	0.573
Bed 5	0.719	0.898	1	1	1	1	1	0.719	0.898
Bed 6	0.898	0.719	1	1	1	1	1	0.898	0.719
Bed 7	0.573	0.573	0.719	0.898	1	1	1	1	1
Bed 8	0.573	0.573	0.898	0.719	1	1	1	1	1
Bed 9	0.468	0.468	0.573	0.573	0.719	0.898	1	1	1
Bed 10	0.468	0.468	0.573	0.573	0.898	0.719	1	1	1

Table 6.17. Derived set of distraction coefficients.

6.12 Outcome of Model Development: Physical Factors

A significant feature of the model development has been identification of sub structures and dependencies within derived values of key parameters such as competency, supervision and distraction as expressed within equations 6.8, 6.9 and 6.10 and relating to specific parameter values of *Sep_comp(i,j), Sep_sup(i,j)* and *Sep_dist(i,j).* These parameters can be described as strongly coupled where there is a significant reduction in coefficient values as a function of bed separation and conversely weakly coupled where the reduction in values with bed separation is less significant.

It remains a valid observation, however, that physical factors that encourage good competency sharing and good levels of supervision will also tend to increase factors of distraction within a team of nursing co-workers. The scope for further review and analysis of interaction of factors relating to competency sharing, levels of supervision and distraction is outlined in chapter 8.

6.13 Operation of the Risk Estimation Engine

At this stage, all of the essential definitions of the structure of the origin of data sets and how they interact within the information flows of the 'risk engine' have been defined. Subsequently the operation of specific elements of this calculation process are identified. In particular, the detail of the specific 'risk engine'.

In many ways the core function of the analysis process is the 'risk engine' itself, which within MatLab ®, is implemented as a function with numerous inputs and a single output value of relative risk of an adverse effect. Table 6.18 summarises the set of 'fuzzy' look up functions used in implementation of the 'risk engine'.

Function Reference	Function combined	Complexity level
F1zlow	Effectiveness & Distraction	low
F1zint	Effectiveness & Distraction	intermediate
F1zcomp	Effectiveness & Distraction	high
Fz2	Individual competence & team competence mismatch	-
Fz3low	Modified effectiveness & modified competency mismatch	low
Fz3int	Modified effectiveness & modified competency mismatch	intermediate
Fz3comp	Modified effectiveness & modified competency mismatch	high
Fz4	Likelihood of specific adverse effect & supervision	-

Table 6.18. Identification of fuzzy functions used to evaluate adverse risk effect values.

Figure 6.20 summarises the derivation of input arguments to the main function of the 'risk engine'.

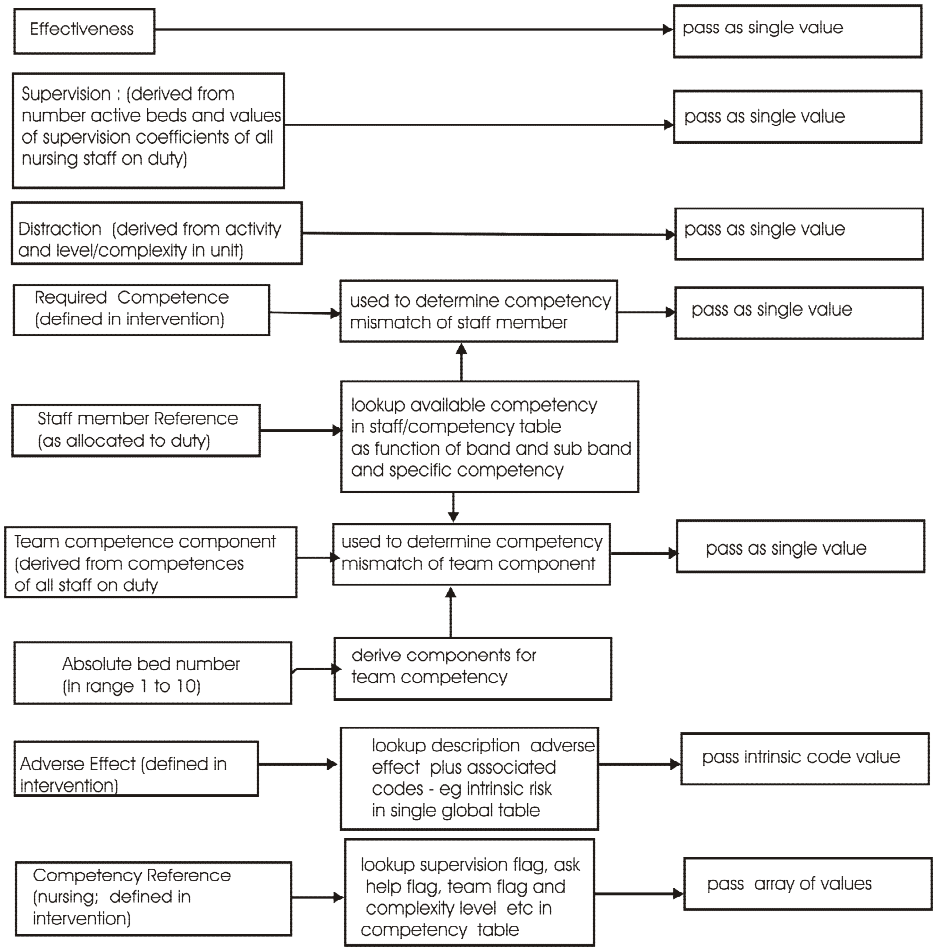

Figure 6.20. Derivation of input arguments to the main 'risk engine' function.

The specific syntax of the associated function is identified as:

[OutAE,Stat] =
NCW_Risk_Engine_09a [Eff, Sup, Dist, CMI, CMT, Intr, CmCd, F1zlow, F1zint, F1zcomp, Fz2 ,Fz3low, Fz3int, Fz3comp, Fz4] (6.11)

Where *OutAE* is the output likelihood (linear value), *Stat* is an internally derived status value, *Eff* is individual effectiveness, *Sup* is supervision, *Dist* is distraction factor, *CMI* is individual competency mismatch, *CMT* is team competency mismatch, *Intr* is value of code describing adverse effect and *CmCd* describes codes such as supervision flag, ability to ask flag and complexity level. The function NCW_Risk_Engine utilises the fuzzy functions previously referenced and which are shown in table 6.6.

Figure 6.21 indicates the structure of data required to be assimilated into the main risk engine module.

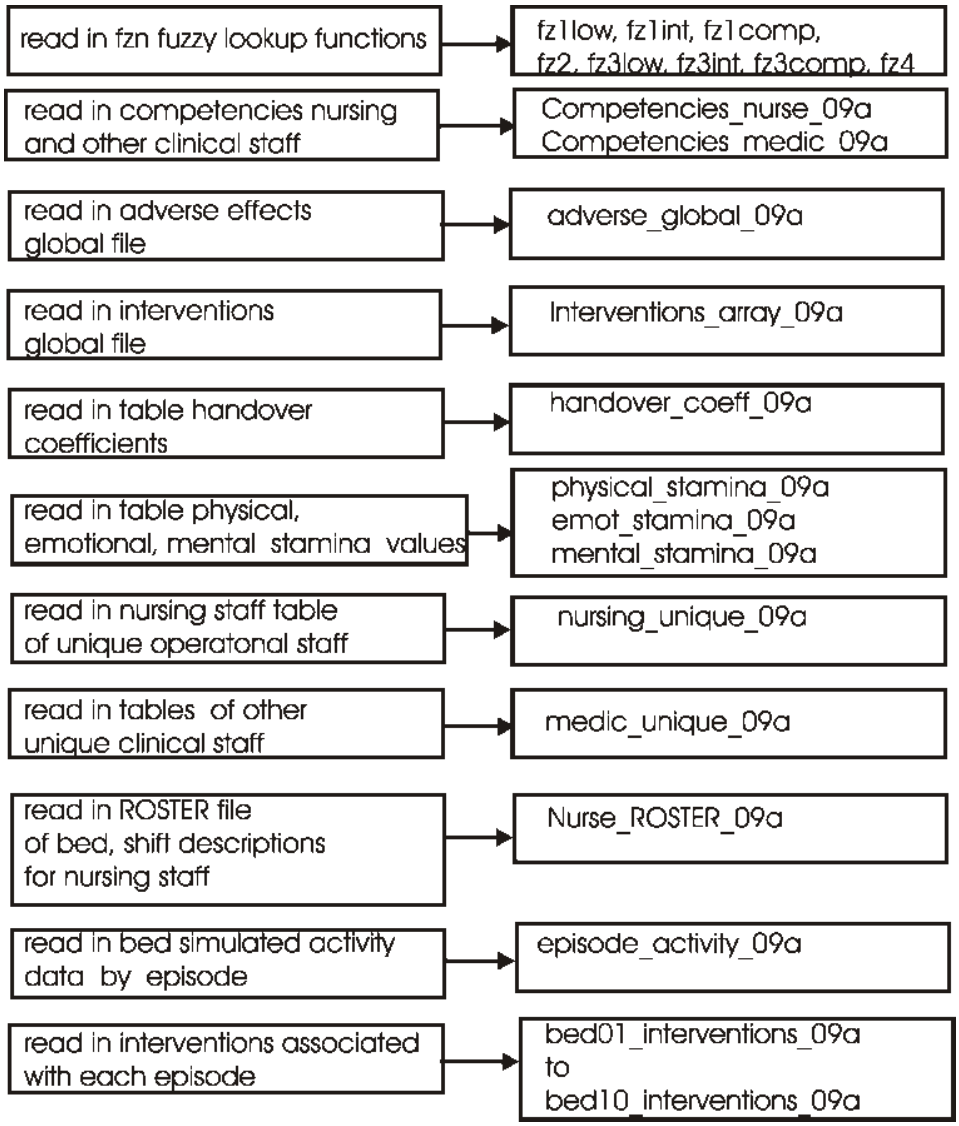

Figure 6.21. Structure of main data entries required for evaluation of risk values in main ‘risk engine’ module.

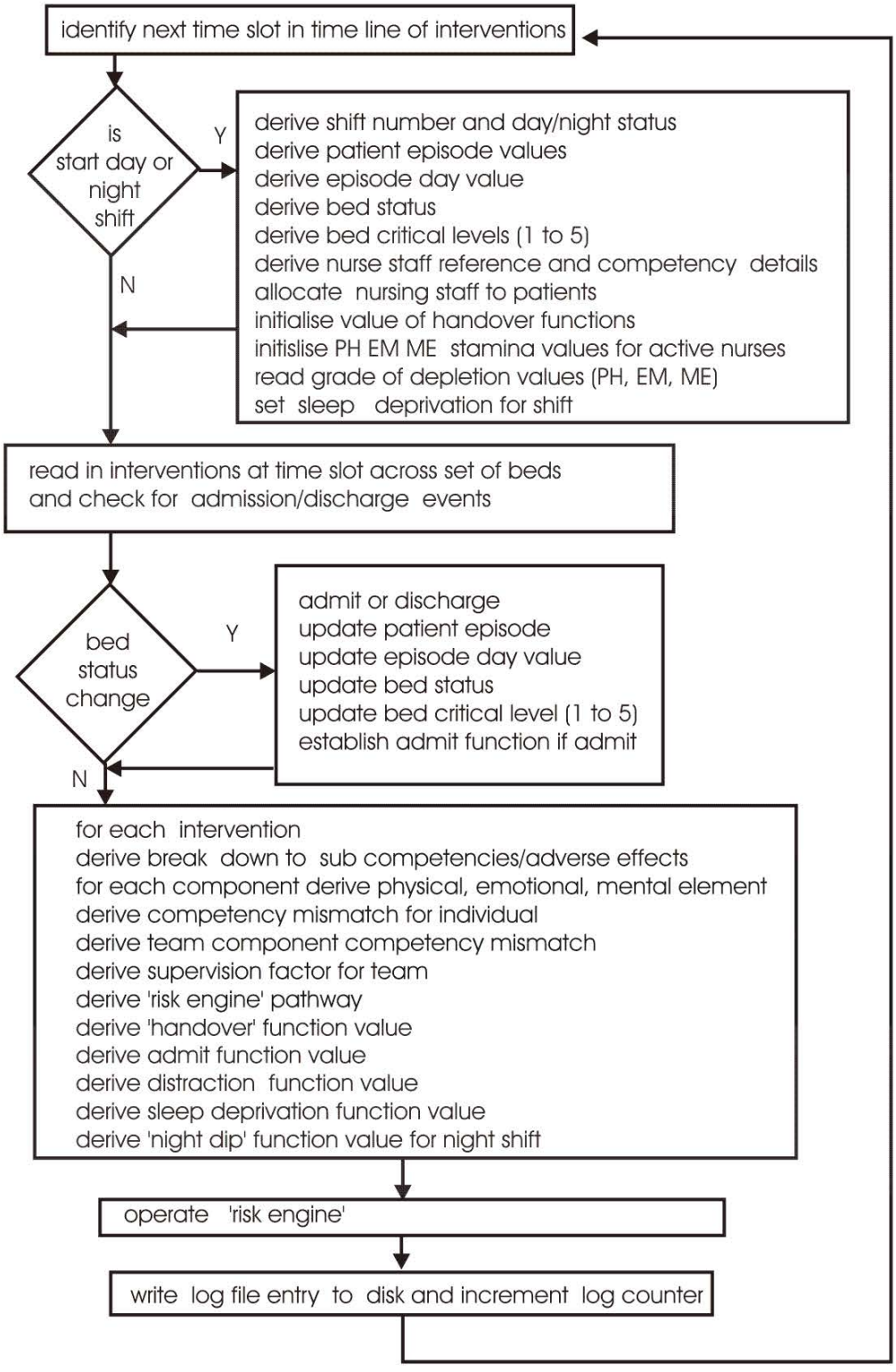

Figure 6.22. Overview of processing of intervention data within module evaluating competency/risk processing of simulated intervention data.

Figure 6.23 summarises the processing structure for calculation of probability of adverse effects of simulated interventions. Typically the active module will take 34 hours to process interventions associated with 9 months of activity. Processes of testing/validating the risk engine typically use smaller simulation data sets.

6.14 : Determination of Effect of Physical Aspects of Work Environment on Risk Factors

Development of the risk simulation system in sections 6.9 to 6.11 has identified characteristics of the physical work environment within Critical Care which impact on levels of risk associated with clinical activity. These relationships are summarised in table 6.19.

Parameter	Function	Equation
Sep_comp(i,j)	Value of probability of interaction between staff member j (seeking assistance) and staff member i (providing additional competency)	6.6
Sep_sup(i,j)	Value of probability of interaction between staff member j (obtaining supervision) and staff member i (providing supervision)	6.8
Sep_dist(i,j)	Value of probability of interaction between bed j (perceived component of distraction) and bed i (contributing component of distraction)	6.10

Table 6.19. Summary of identified parameters linking characteristics of the physical work environment within Critical Care and levels of risk associated with clinical activity.

These factors have been incorporated into the risk simulation system and with confirmation of the expected variation in simulated output risk with specific variation in parameter values. It is identified that further consideration is required for evaluation of the specific values of parameters outlined in table 6.19 to identify appropriate values for identified configurations of the physical work environment.

Within the context of identification of parameters outlined in table 6.19, table 6.20 outlines details of parameters identified as associated with each parameter.

Parameters	**Associated factors**
Sep_comp(i,j) Competency sharing	Visual contact (staff j to staff i) Verbal contact (staff j to staff i) Proximity (staff j to staff i) Mobility (staff j)
Srep_sup(i,j) Supervision	Visual contact (staff i to staff j) Verbal contact (staff i to staff j) Proximity (staff i to staff j) Mobility (staff j) Awareness patient condition (bed i to bed j)
Sep_dist(i,j) Distraction	Visual contact (staff j to staff i) Verbal contact (staff j to staff i) Proximity (staff j to staff i) Awareness patient condition (bed j to bed i)

Table 6.20. Associated factors linked to parameters of competency sharing, supervision and distraction and where j references the bed for which these coefficients relate.

It is identified that one option for deriving values of the parameter coefficients is to create a Fuzzy logic implementation for each parameter using appropriate linguistic structures as outlined in figures 6.23, 6.24 and 6.25.

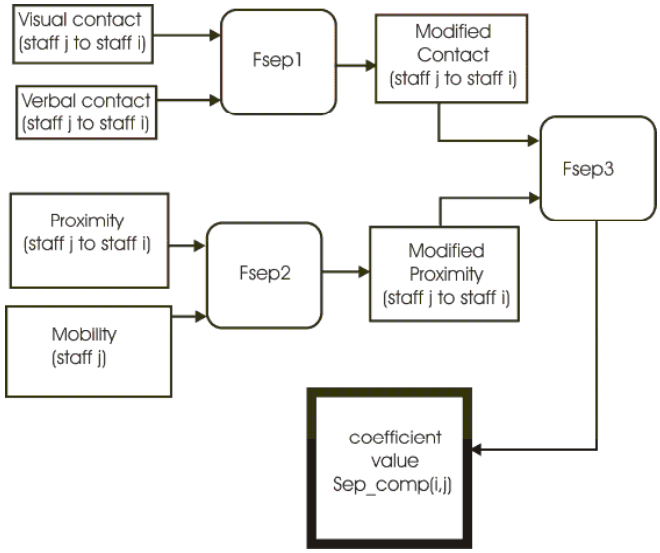

Figure 6.23. Use of Fuzzy Logic for derivation of coefficients for determination of Sep_comp(i,j).

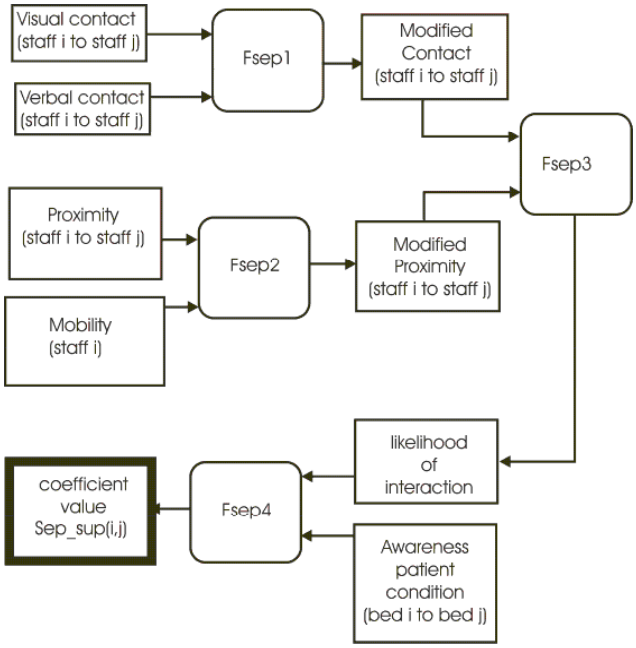

Figure 6.24. Use of Fuzzy Logic for derivation of coefficients for determination of Sep_sup(i,j).

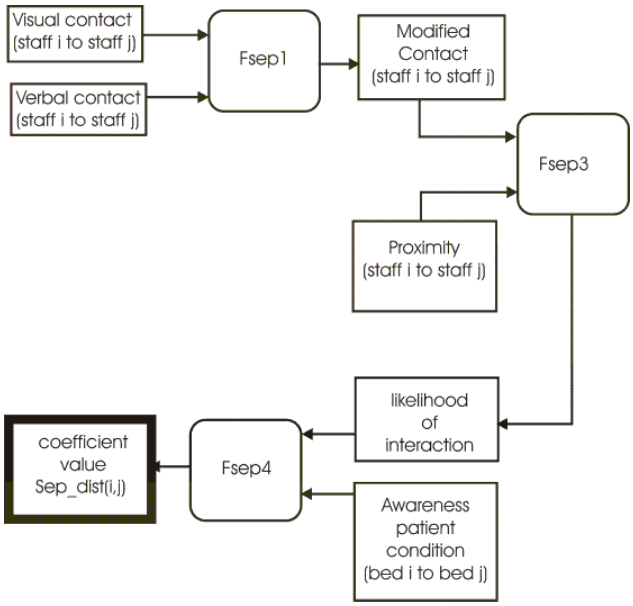

Figure 6.25 Use of Fuzzy Logic for derivation of coefficients for determination of Sep_dist(i,j).

Figure 6.26 describes the linguistic description of input parameter functions referenced in figures 6.23 to 6.25. Output function values have a comparable state description.

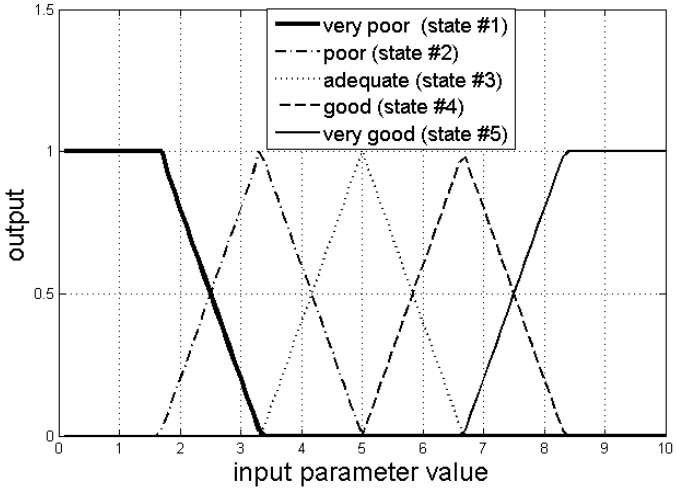

Figure 6.26 .Linguistic description of input parameters for determination of spatial coefficients of interaction.

Rule Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Visual contact	5	5	5	5	5	4	4	4	4	4	3	3	3	3	3	2	2	2	2	2	1	1	1	1	1
Verbal contact	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Modified contact	5	5	4	4	3	5	4	4	3	3	5	4	3	3	3	5	4	3	2	2	4	3	2	2	1

Table 6.21. Function assignment ‘Fsep1’: Input parameters: visual contact, and verbal contact : Output parameter : Modified Contact.

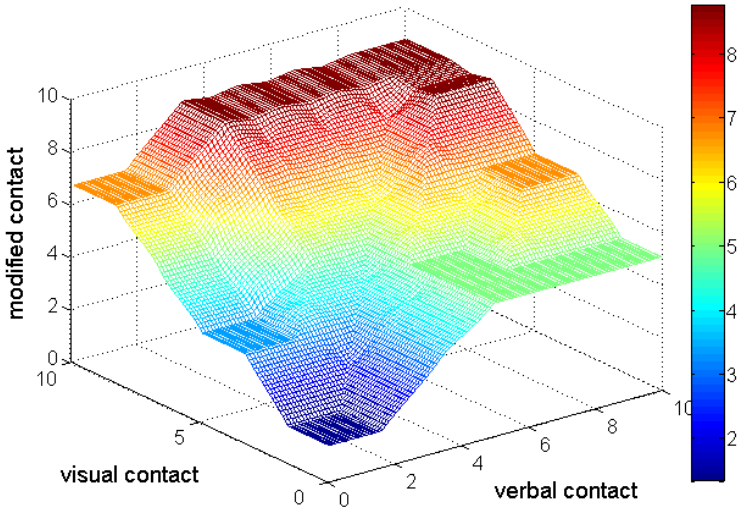

Figure 6.27. Surface plot of Fuzzy function Fsep1 as outlined in table 6.21.

Rule Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Proximity	5	5	5	5	5	4	4	4	4	4	3	3	3	3	3	2	2	2	2	2	1	1	1	1	1
Mobility	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Modified Proximity	5	5	5	5	5	5	4	4	4	4	4	4	3	3	3	4	4	3	2	2	3	3	2	1	1

Table 6.22. Function assignment ‘Fsep2’: Input parameters: Proximity and Mobility : Output parameter : Modified Proximity.

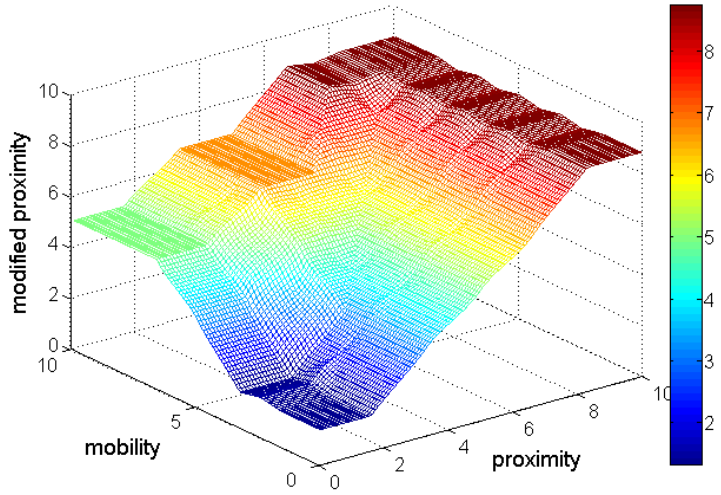

Figure 6.28. Surface plot of Fuzzy function Fsep2 as outlined in table 6.22.

Rule Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Modified contact	5	5	5	5	5	4	4	4	4	4	3	3	3	3	3	2	2	2	2	2	1	1	1	1	1
Modified Proximity	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Likelihood of interaction	5	5	5	5	4	5	4	4	3	3	5	4	3	3	3	5	4	3	2	2	4	4	3	2	1

Table 6.23. Function assignment: Input parameters ‘Fsep3’: Modified contact and Modified proximity : Output parameter : Likelihood of interaction – Sep_comp(i,j)

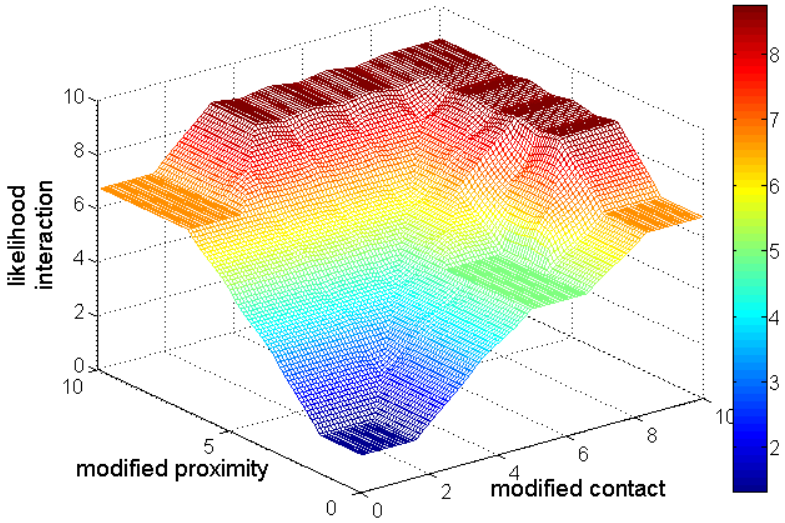

Figure 6.29. Surface plot of Fuzzy function Fsep3 as outlined in table 6.23.

Rule Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Likelihood of interaction	5	5	5	5	5	4	4	4	4	4	3	3	3	3	3	2	2	2	2	2	1	1	1	1	1
Awareness of patient condition	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Output coefficient	5	5	4	3	3	5	4	4	3	3	4	4	3	3	3	3	3	3	2	2	3	3	2	1	1

Table 6.24. Function assignment: Input parameters ‘Fsep4’: Likelihood of Interaction and Modified proximity : Output parameter : Likelihood of interaction.

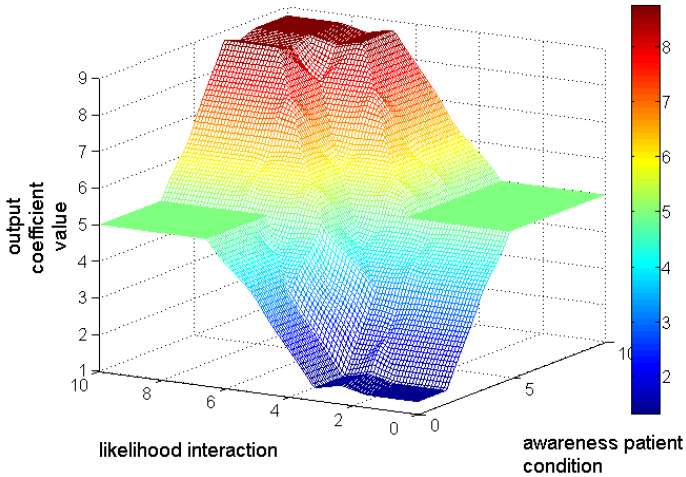

Figure 6.30. Surface plot of Fuzzy function Fsep4 as outlined in table 6.24.

Look up fuzzy functions have been configured using previously developed tools to derive look up table values.

This illustrates the further use of Fuzzy logic to derive values of coefficients as outlined in table 6.19. This therefore defines a process for determination of these coefficients for specific spatial configurations of Critical Care areas and for determination of specific values appropriate to the local configuration modelled on a bed value of ten.

A series of values for Sep_comp were derived for a standard ten bed configuration as referenced previously in figure 6.14. Values of visual contact, verbal contact, proximity and mobility were identified with bed to bed interactions as indicated in table 6.25 (bed 1) and table 6.26 (bed 5).

Bed link	Visual contact	Verbal contact	Proximity	Mobility
1-2	9	9	9	6.5
1-3	9	9	9	6.5
1-4	8.5	8.5	8.5	6.5
1-5	6	6	6.5	6.5
1-6	7.2	6.5	6	6.5
1-7	4.5	4	5	6.5
1-8	5	4.5	5	6.5
1-9	3	4	3.5	6.5
1-10	3.5	4	3.5	6.5

Table 6.25. Details of values of input parameters associated with bed 1 within the ten bed unit.

Bed link	Visual contact	Verbal contact	Proximity	Mobility
5-1	6	6	6.5	6.5
5-2	7.2	6.5	6	6.5
5-3	9	9	9	6.5
5-4	8.5	8.5	8.5	6.5
5-6	9	9	9	6.5
5-7	9	9	9	6.5
5-8	8.5	8.5	8.5	6.5
5-9	6	6	6.5	6.5
5-10	7.2	6.5	6	6.5

Table 6.26. Details of values of input parameters associated with bed 5 within the ten bed unit.

Values of calculated coefficients of Sup_comp are indicated in table 6.27.

	Link 1	Link 2	Link 3	Link 4	Link 5	Link 6	Link 7	Link 8	Link 9
bed 1	8.7293	8.7293	8.7293	6.288	7.6124	6.2979	6.3325	6.288	6.288
bed 2	8.7293	8.7293	8.7293	7.6124	6.288	6.3325	6.2979	6.288	6.288
bed 3	8.7293	8.7293	8.7293	8.7293	8.7293	6.288	7.6124	6.2979	6.3325
bed 4	8.7293	8.7293	8.7293	8.7293	8.7293	7.6124	6.288	6.3325	6.2979
bed 5	6.288	7.6124	8.7293	8.7293	8.7293	8.7293	8.7293	6.288	7.6124
bed 6	7.6124	6.288	8.7293	8.7293	8.7293	8.7293	8.7293	7.6124	6.288
bed 7	6.2979	6.3325	6.288	7.6124	8.7293	8.7293	8.7293	8.7293	8.7293
bed 8	6.3325	6.2979	7.6124	6.288	8.7293	8.7293	8.7293	8.7293	8.7293
bed 9	6.288	6.288	6.2979	6.3325	6.288	7.6124	8.7293	8.7293	8.7293
bed 10	6.288	6.288	6.3325	6.2979	7.6124	6.288	8.7293	8.7293	8.7293

Table 6.27. Values of calculated coefficients of Sup_comp (x10).

These are also represented in figure 6.29. This closely resembles the structure previously identified in table 6.15 and figure 6.15 where the key component was row difference between beds. In the more detailed Fuzzy Logic implementation, the component of line of sight can be incorporated in estimations, where, for example, bed 1 to bed 6 has higher visual contact than bed 1 to bed 5, even though they have the same row difference.

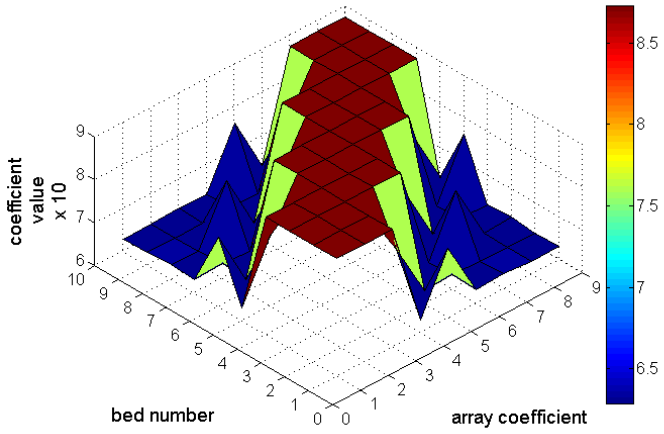

Figure 6.31. Surface plot of competency sharing coefficients for specific implementation of fuzzy logic implementation of figure 6.23.

The process of analysis is also relevant for determination of coefficients Sep_sup (tables 6.28 and figure 6.32) and Sep_dist (table 6.29 and figure 6.33).

	Link 1	Link 2	Link 3	Link 4	Link 5	Link 6	Link 7	Link 8	Link 9
bed 1	8.7293	8.7293	8.7293	6.1861	7.8427	5.2288	6.2316	5	5
bed 2	8.7293	8.7293	8.7293	7.8427	6.1861	6.2316	5.2288	5	5
bed 3	8.7293	8.7293	8.7293	8.7293	8.7293	6.1861	7.8427	5.2288	6.2316
bed 4	8.7293	8.7293	8.7293	8.7293	8.7293	7.8427	6.1861	6.2316	5.2288
bed 5	6.1861	7.8427	8.7293	8.7293	8.7293	8.7293	8.7293	6.1861	7.8427
bed 6	7.8427	6.1861	8.7293	8.7293	8.7293	8.7293	8.7293	7.8427	6.1861
bed 7	5.2288	6.2316	6.1861	7.8427	8.7293	8.7293	8.7293	8.7293	8.7293
bed 8	6.2316	5.2288	7.8427	6.1861	8.7293	8.7293	8.7293	8.7293	8.7293
bed 9	5	5	5.2288	6.2316	6.1861	7.8427	8.7293	8.7293	8.7293
bed 10	5	5	6.2316	5.2288	7.8427	6.1861	8.7293	8.7293	8.7293

Table 6.28. Values of calculated coefficients of Sep_sup (x10).

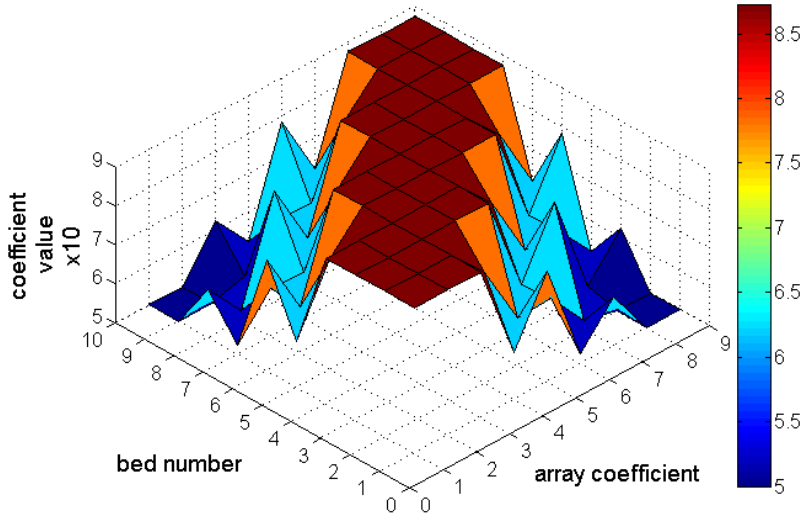

Figure 6.32. Surface plot of supervision coefficients for specific implementation of fuzzy logic implementation of figure 6.24.

This indicates a more marked effect of bed distance/separation on the corresponding coefficients of supervision. Modifications to bed arrangements such as the inclusion of pillars within the ten bed area would modify the values of the supervision coefficients.

	Link 1	Link 2	Link 3	Link 4	Link 5	Link 6	Link 7	Link 8	Link 9
bed 1	8.7293	8.7293	8.7293	6.288	7.8427	5	5	4.0872	4.0329
bed 2	8.7293	8.7293	8.7293	7.8427	6.288	5	5	4.0329	4.0872
bed 3	8.7293	8.7293	8.7293	8.7293	8.7293	6.288	7.8427	5	5
bed 4	8.7293	8.7293	8.7293	8.7293	8.7293	7.8427	6.288	5	5
bed 5	6.288	7.8427	8.7293	8.7293	8.7293	8.7293	8.7293	6.288	7.8427
bed 6	7.8427	6.288	8.7293	8.7293	8.7293	8.7293	8.7293	7.8427	6.288
bed 7	5	5	6.288	7.8427	8.7293	8.7293	8.7293	8.7293	8.7293
bed 8	5	5	7.8427	6.288	8.7293	8.7293	8.7293	8.7293	8.7293
bed 9	4.0872	4.0329	5	5	6.288	7.8427	8.7293	8.7293	8.7293
bed 10	4.0329	4.0872	5	5	7.8427	6.288	8.7293	8.7293	8.7293

Table 6.29. Values of calculated coefficients of Sep_dist (x10).

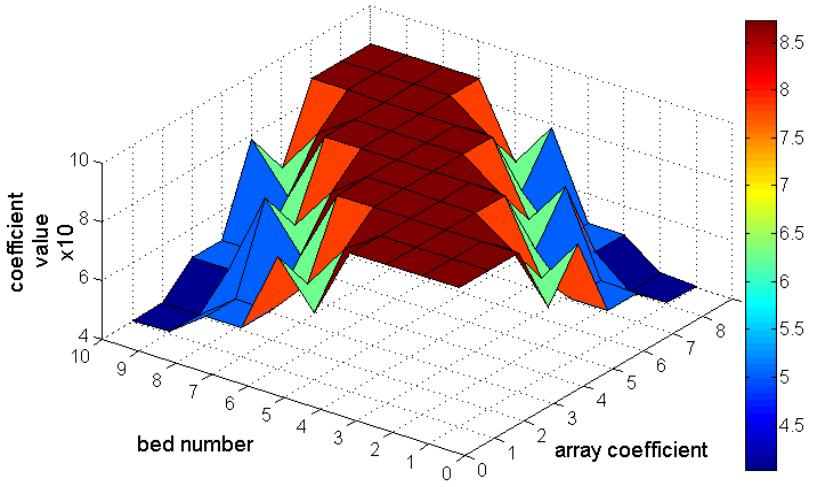

Figure 6.33. Surface plot of distraction coefficients for specific implementation of fuzzy logic implementation of figure 6.25.

This section has developed the concept of factors relating to competency sharing, supervision and distraction within a specific ten bed unit of standard bed layout. A model using Fuzzy logic has been developed and used to determine coefficient values relating to competency sharing, supervision and distraction as previously outlined in sections 6.9 to 6.12. This has identified refinements to the structure initially assigned to these coefficients and provided justification for use of specific values of these coefficient values.

6.15 Derivation of Single Effectiveness Factor from Multiple Effectiveness Functions

The formalisation of models of Fuzzy logic within the current chapter has been applied also to aspects of effectiveness functions previously introduced in chapter 3 in the context of determination of a single parameter value of individual effectiveness. A specific set of effectiveness parameters have been identified in relation to factors that have the potential to influence patterns of individual performance in the context of undertaking clinical activity. The set of parameters are replicated as table 6.30.

Term	Description
E_{ns}	Circadian rhythm day shift and night shift working
E_{ph}	Fatigue, based on physical exertion and based on task activities over a shift cycle
E_{em}	Fatigue, based on emotional/stress 'exertion' and based on task activities over a shift cycle
E_{me}	Fatigue, based on intellectual 'exertion' and based on task activities over a shift cycle
E_{h}	Effects related to handover at the start of a 12 hour shift
E_{adm}	Effects related to admission of a new patient
E_{sd}	Effect due to sleep deficit
E_{lt}	Long term effectiveness

Table 6.30. Summary of individual effectiveness factors.

It is appropriate to structure the specific effectiveness factors according to effect on functions which could relate to undertaking clinical interventions, as indicated in table 6.31.

Term	Concentration	Decision making	Attention to detail	Energy	Follow protocols	Communication
E_{ns}	x	x		x		
E_{ph}				x		x
E_{em}	x	x	x	x	x	x
E_{me}	x	x				
E_{h}		x	x			
E_{adm}		x	x			
E_{sd}	x	x		x		
E_{lt}	x	x	x	x	x	x

Table 6.31. Summary of functions potentially influenced by effectiveness factors.

Table 6.28 outlines details of key functions affected by specific effectiveness factors. This identifies similarities between E_{lt} and E_{em}, E_{adm} and E_h and E_{ns} and E_{sd} and provides the key linguistic interpretation structures for implementation within a Fuzzy Logic structure as indicated in figure 6.34.

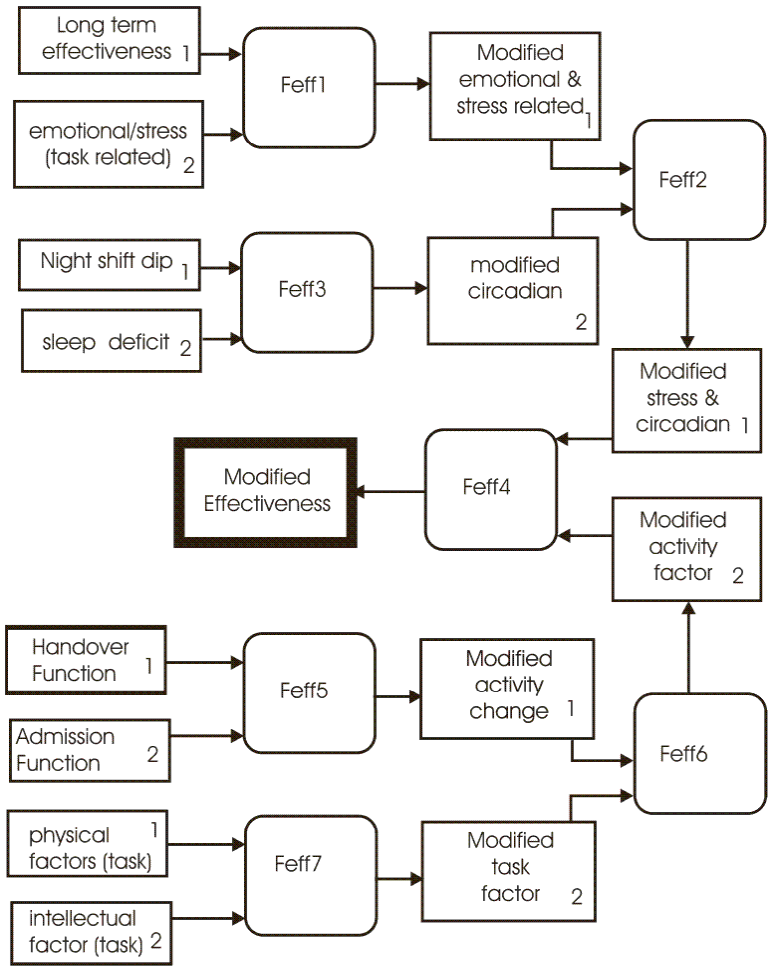

Figure 6.34. Relationship structure for fuzzy logic rule implementation of effectiveness factors.

This specific function requires a total of seven fuzzy functions for its implementation, indicating an increased level of activity compared with the core function of the 'risk engine' which required four distinct fuzzy functions. Input parameters to fuzzy functions are identified as '1' and '2' for subsequent use in table 6.29.

Rule number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Rule #1 input	5	5	5	5	5	4	4	4	4	4	3	3	3	3	3	2	2	2	2	2	1	1	1	1	1
Rule #2 input	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Feff1	5	4	3	2	1	4	4	3	2	1	3	3	3	2	1	2	2	2	2	1	1	1	1	1	1
Feff2	5	4	3	2	1	4	4	3	2	1	3	3	3	2	1	2	2	2	2	1	1	1	1	1	1
Feff3	5	4	3	2	1	4	4	3	2	1	3	3	3	2	1	2	2	2	2	2	1	1	1	1	1
Feff4	5	4	3	2	1	4	4	3	2	1	3	3	3	2	1	2	2	2	2	2	1	1	1	1	1
Feff5	5	4	3	2	1	4	4	3	2	1	3	3	3	2	1	2	2	2	2	1	1	1	1	1	1
Feff6	5	5	4	3	3	4	4	4	3	3	3	3	3	3	2	2	2	2	2	2	1	1	1	1	1
Feff7	5	4	4	3	2	4	4	4	3	3	4	3	3	2	2	3	3	2	2	1	3	3	2	1	1

Table 6.32. Fuzzy logic rules set relating to figure 6.32.

Functions Feff1, Feff2, Feff3, Feff4 and Feff5 are identical as derived from including the minimum value of effectiveness contribution from specific input contributions. Identification of '1' and '2' for 'rule #1 input' and 'rule #2 input' is structured in figure 6.34.

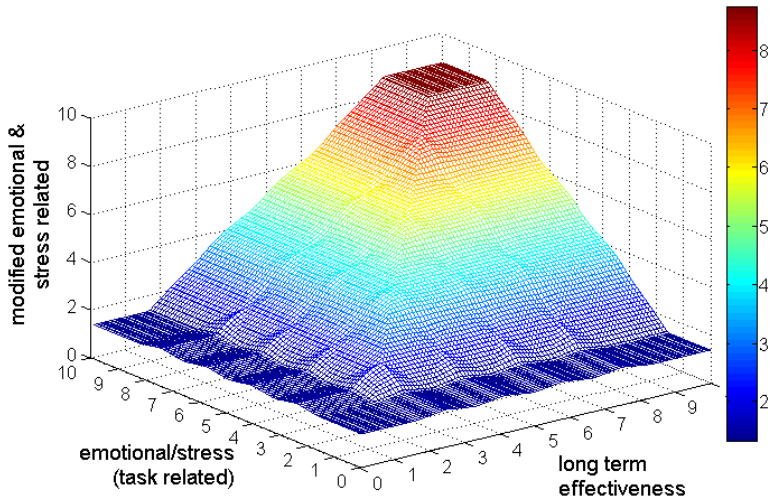

Figure 6.35. Fuzzy function Feff1 based on minimum value of effectiveness contribution from input values. Functions Feff1 through to Feff5 have identical characteristics.

The development of this function of combined effectiveness makes available to the main 'risk engine' the option to include the minimum value function or the combined function. Based on the complexities of the seven component fuzzy function, however, detailed analysis of the performance of the combined function would be a complex undertaking. An initial comparison of the characteristics of the two functions was undertaken by random simulation of values of input functions as indicated in table 6.33 where rand(1) indicates a random number value in range 0 to 1.

Parameter	Function value
E_{lt}	5.6 + 2.3.rand(1)
E_{em}	5.5 + 3.4.rand(1)
E_{ns}	5.4 + 3.3.rand(1)
E_{sd}	5.9 + 2.0.rand(1)
E_{h}	6.7 + 1.2.rand(1)
E_{ad}	4.2 + 2.6.rand(1)
E_{ph}	5.1 + 1.2.rand(1)
E_{me}	5.9 + 2.0.rand(1)

Table 6.33. Test sequence of random values for comparison of 'minimum function' and 'combined effectiveness' functions. See table 6.30 for parameter descriptions.

An extract from the sequence of values is indicated in figure 6.36, indicating general correspondence between the two functions.

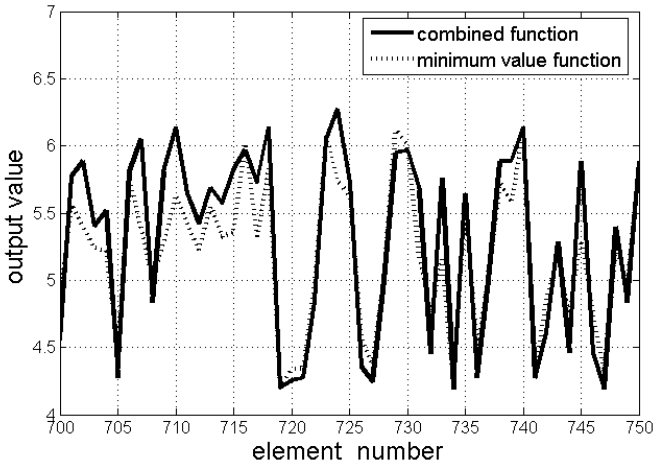

Figure 6.36. Extract of simulated sequence indicating values of 'combined function' and 'minimum value function'.

Fractional distribution of values of percentage difference between combined function and minimum function expressed relative to minimum function are outlined in figure 6.37. This indicates the trend for values of combined function to be greater in value than the minimum function.

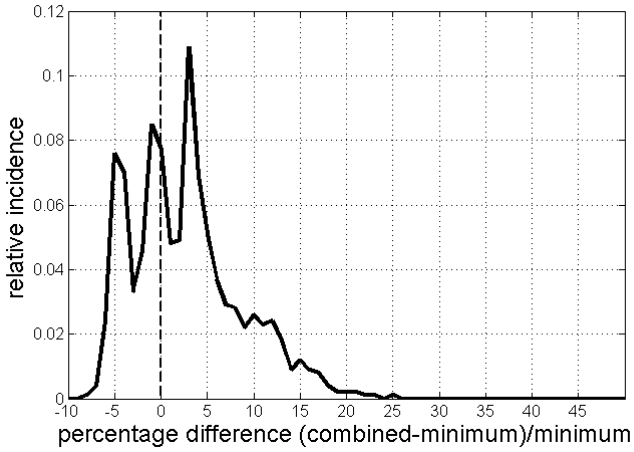

Figure 6.37. Fractional distribution of values of percentage difference between combined function and minimum function expressed relative to minimum function value and based on 1000 random values derived from mechanism referenced in table 6.30.

6.16 General Observations

The approach of the research has been to identify the requirements for simulation of clinical risk using the identified model and then implement the various components of the model as appropriate. One of the consequences of seeking to simulate clinical activity and its 'associated risk' is the number of components of such a model which have to be 'invented' since references in conventional medical literature to such models are almost entirely lacking.

The 'risk engine' system has been implemented as a specific fuzzy logic implementation in the form of a five level input/output trapezoidal function. At this stage in the description of the research, the use of this specific implementation is essentially identifying a mechanism to implement the concepts identified in the research and is not identifying an optimised 'risk engine'.

Within this context, the simulation of clinical activity as a series of discrete interventions has been the most demanding of resources. This is due to the inherent complexities relating to patient care within the Critical Care environment. The structuring of interventions has also involved extensive periods of observation/staff interview and also significant analysis of data within patient data sets within the QS data base system.

It is anticipated that subsequent phases of the research where the specific modules interact to generate output levels of adverse effects will provide additional relevant fine tuning and monitoring/verification of their function.

The development of the risk model, however, has identified elements of local infrastructure which are shown to influence levels of adverse effects. These include components of physical bed layout, location of storage facilities such as drugs and consumables and distribution of patients by severity of condition. This in turn identifies the scope for optimisation techniques for design of Critical Care units where the performance factors of different states can be identified with evaluations of risk with clinical activity.

6.17 Summary

The chapter has described how the dynamics of the 'risk engine' can be implemented by means of a series of linked functions incorporating Mamdani Fuzzy Logic. This together with structuring of input functions such as supervision, distraction, individual and team competency and the core function of the 'risk engine' develops the project to the stage of being able to evaluate risk associated with sequences of clinical interventions created by the previously referenced processes of simulation of clinical activity. The operation of the 'risk engine' to 'tune' its function and process sequences of simulated clinical interventions is outlined in chapter 7.

Chapter 7: Operation of Risk Simulation System

7.1 Overview

In this chapter the 'risk engine' is initially exercised on subsets of values of test input parameters in order to validate its performance. An example of this is the variation of output probability of adverse effects with variation in input values of individual effectiveness and distraction while other input parameters are held constant. Subsequently the characteristics of the risk simulation system are described where sets of simulated patient activity are processed by the risk simulation system. This is initially to check the qualitative performance of the risk simulation system with variation of specific parameters referenced in the risk simulation system and expressed in sets of equations introduced in chapter 6. Such parameters include level of nurse attendance (relating to supervision), level of requesting competency support, probability transfer function, level of sleep deprivation, level of nursing staff competency within rostered teams, nurse handover responses, level of interaction between beds based on physical separation and level of individual effectiveness based on Circadian (night shift) functions. Options for review of data relating to root cause analysis are identified. In addition, simulated risk values relating to a 9 month period of simulated clinical activity are expressed using 'type' of adverse effect codes and compared with local adverse clinical incident reporting information. Analysis is also undertaken of activity within a 'normalised' single day time frame and compared with results of the SEE study (Valentin *et al.* 2006). In addition, the relative distribution of risk according to sub grade of nursing staff is simulated for a range of skill mix levels within rostered nursing groups. Modes of reporting frequency of adverse clinical events are reviewed from the literature in order to establish appropriate comparison modes with the risk simulation system.

7.2 Validation Processes

The process of validation and 'tuning' of the module to determine values of probability of adverse effects identifies the following components:

a) Verification of implementation of defined model and component interactions
b) Verification of use of appropriate components of model data
c) Verification of output values of risk engine as a function of input values (supervision, distraction, effectiveness, competency mismatch of individual and competency mismatch of team)

Validation processes are facilitated by the generation of an array of (N,98) elements where N is the number of adverse effects calculated and the 98 elements allow verification of a wide range of derived parameter with also the data elements being written to disc as a 'reference' file. Stage b) relates to structuring parameters which equate as far as possible to anticipated parameter values within the structures being simulated. Stage c) relates to identification of how values of key functions such as supervision, distraction and effectiveness interact in the active model. A significant element of this validation stage is associated with determining the dynamic range of these functions as inputs to the 'risk engine'.

A sub set of core set of elements within this log file (total 98 elements) are identified in table 7.1.

Log file of adverse effect details	**Additional Details**
Episode number	as in main simulation sequence
Bed number	In range 1 to 10
Intervention slot	Sequence value of 5 minute 'slot'
Staff Group	01, 02 etc
Type adverse effect	As per defined categories
Distraction value	Component individual effectiveness
Physical component effectiveness	Component individual effectiveness
Emotional/stress component effectiveness	Component individual effectiveness
Intellectual component effectiveness	Component individual effectiveness
Sleep Deprivation component effectiveness	Component individual effectiveness
Night dip component effectiveness	Component individual effectiveness
Derived Individual Effectiveness value	As input to 'risk engine' estimation
Supervision value	As input to 'risk engine' estimation
Adverse effect reference – global	In range 1 to 524
Competency reference within staff group	eg. band 5d, 6c for nursing
Linear value adverse effect	In range 0 to 10
Probability value adverse effect	In range 0 to 1
Probability look up table element	Defined value of Ao, Grad and Step

Table 7.1. Core set of values retained in log file.

Initial evaluation of the module which determines probabilities of adverse effects was undertaken with an initial subset of a 9 month simulated set of clinical interventions (simulation set #1). This initial evaluation process was essentially used to validate the functionality of the module in deriving values of probability of adverse effects.

One of the significant elements of the data model is the option to exclude the contribution of supervision in determination of output probability value based on the nature of the specific competency being modelled. This is intended to take account of sub competencies/tasks which are essentially undertaken without supervision. The 'risk engine' will calculate different risk levels for sub tasks which have or do not have associated components of supervision. The distraction component is identified as increasing with both bed occupancy and the level of severity of patients. The level of supervision is identified to also potentially increase with increased numbers of staff on duty who may be available to prevent adverse effects taking place. One of the effects identified in the model structure is the effect on supervision factors of physical location of beds and the distribution of patients by level of complexity within the available bed space. In addition, the model takes account of the 'availability' factor of other nursing staff in the active clinical area, where staff may not be in a position to provide supervision if they are undertaking duties elsewhere.

Detailed information generated by the main routine which determines the probability level of adverse effects is stored at the end of each analysis run. A range of 'review' modules are available to interpret details of each set of data as indicated in figure 7.1.

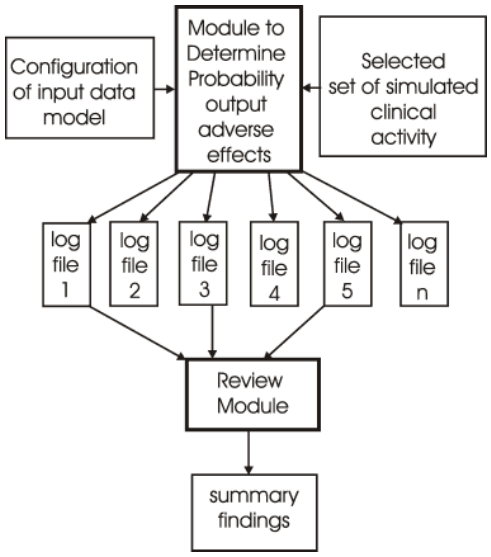

Figure 7.1. Twin stage process of analysis of data where 'Configuration of Input Data Model' can relate to both the set of data files read into the system or a specific configuration of the module to determine probability of adverse effects.

The module in figure 7.1 can review data from a single log file or determine an analysis based on a series of such files. This is used, for example, to identify correlations between input model parameters and output values. Within the log file, each entry is approximately 330 bytes, with an analysis of 347393 risk estimations occupying a file of size of approximately 115 Mbytes and corresponding to around 9 months of simulated clinical activity.

A more detailed analysis of elements relating to competency sharing, supervision and distraction has been previously outlined in section 6.14, where these factors are modified by elements of the physical work environment. This approach identifies a separate fuzzy 'engine' for determination of coefficients relating to competency sharing, supervision and distraction and where any specific 'bed to bed' interaction is referenced by values of visual contact, verbal contact, proximity and mobility. The method employed is essentially that used to derive the functioning of the 'risk engine' as described in section 6.3.

7.3 Validation of Risk Engine

A key component of the validation process of the module which determines the probability of specific adverse effects is the validation of the risk engine component referenced in equation 6.10. Table 7.2 indicates specific modes of checking of the 'risk engine' where a pair of identified variables ('Variable pair') range from 0 to 10 and remaining parameters ('Value other variables') are set at indicated default values.

Variable pair	Levels complexity	Supervision flag	Ability to ask flag	Value other variables
Eff, Dist	Low, medium, high	0 and 1	0 and 1	5
Eff, CMI	Low, medium, high	0 and 1	0 and 1	5
Eff,CMT	Low, medium, high	0 and 1	0 and 1	5
Eff,Sup	Low, medium, high	0 and 1	0 and 1	5
Dist, CMI	Low, medium, high	0 and 1	0 and 1	5
Dist,CMT	Low, medium, high	0 and 1	0 and 1	5
Dist,Sup	Low, medium, high	0 and 1	0 and 1	5
CMI,CMT	Low, medium, high	0 and 1	0 and 1	5
CMI,Sup	Low, medium, high	0 and 1	0 and 1	5

Table 7.2. Indication of sets of functions of 'risk engine' visually verified. Eff = Individual effectiveness; Dist = Distraction; CMI = Competency Mismatch Individual ; CMT = Competency Mismatch Team; Sup = Supervision. In example of 'Variable pair' of Eff and Dist, 'other' variables would be CMI, CMT and Sup.

Representation of the states of the simulated values can be undertaken using either values of linear output or be converted to a probability value through the use of the function described in equation 6.24. The probability function gives both indication of the general relationship between the two input parameters and an assessment of the associated level of probability values.

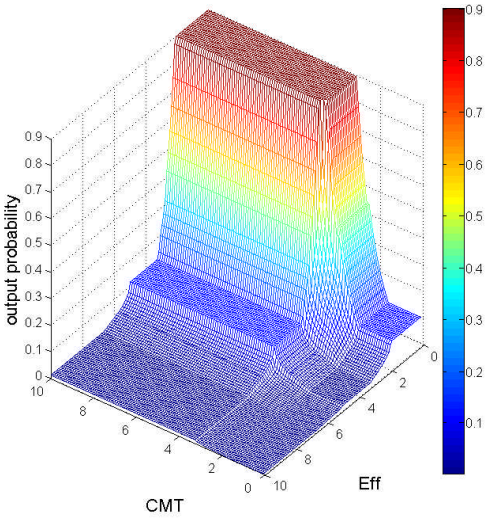

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Figure 7.2. Output mapping of rule system using probability mapping display for Individual Effectiveness (Eff) and Competency Mismatch Team (CMT) and other inputs = 5.0: Supervision flag = 0: Ability to ask flag=1: Level complexity =3; Probability lookup table value = 4.

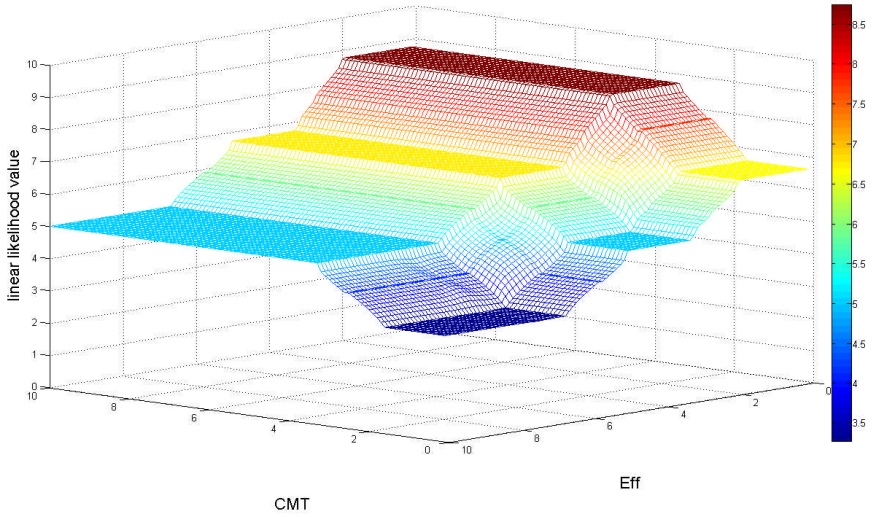

Figure 7.3. Output mapping of rule system of figure 7.2 with corresponding linear output shown for comparison. The probability mapping provides more direct indication of performance of the 'risk engine'.

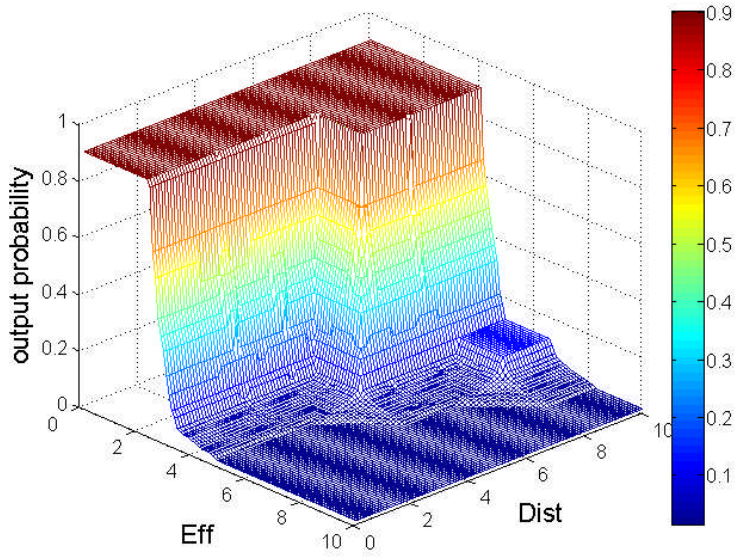

Figure 7.4: Output mapping of rule system using probability mapping display for Individual Effectiveness (Eff) and Distraction (Dist) and other inputs = 5.0 :Supervision flag = 1: Ability to ask flag=1: Level complexity =3: Probability lookup table value = 4.

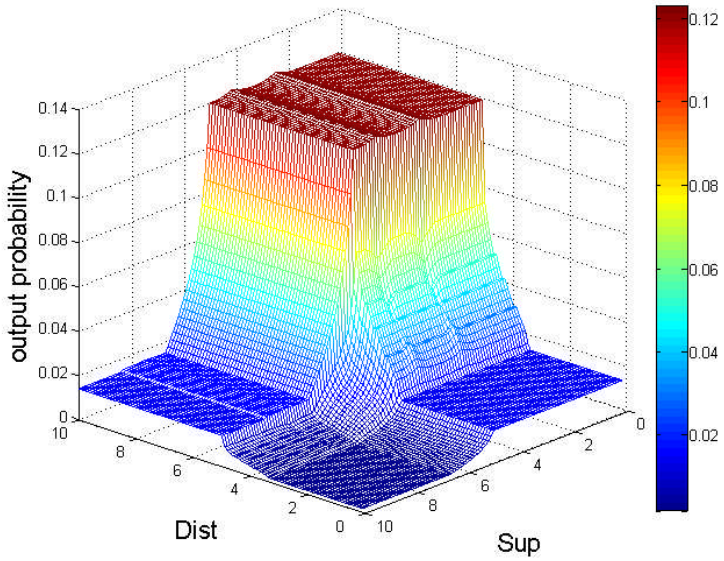

Figure 7.5. Output mapping of rule system using probability mapping display for Supervision (Sup) and Distraction (Dist) for other inputs = 5.0 :Supervision flag = 1: Ability to ask flag=1: Level complexity =3: Probability lookup table value = 4.

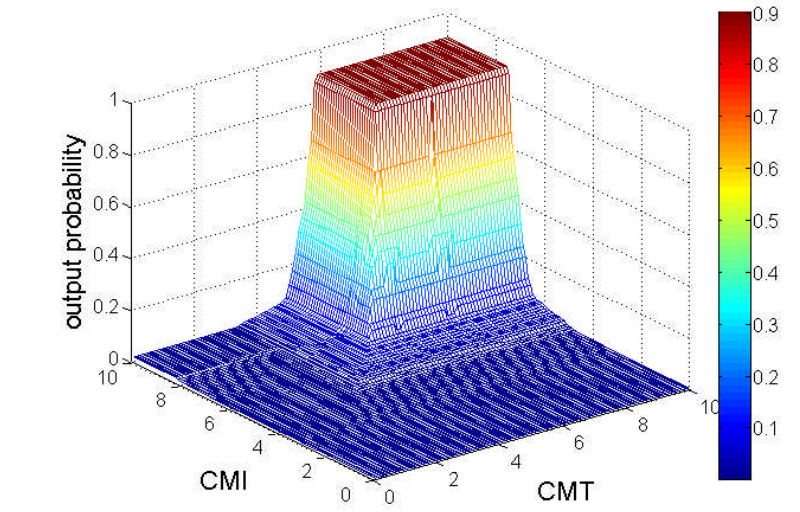

Figure 7.6. Output mapping of rule system using probability mapping display for Individual Effectiveness (Eff) and Distraction (Dist) for other inputs = 5.0:Supervision flag = 1: Ability to ask flag=1: Level complexity =2.

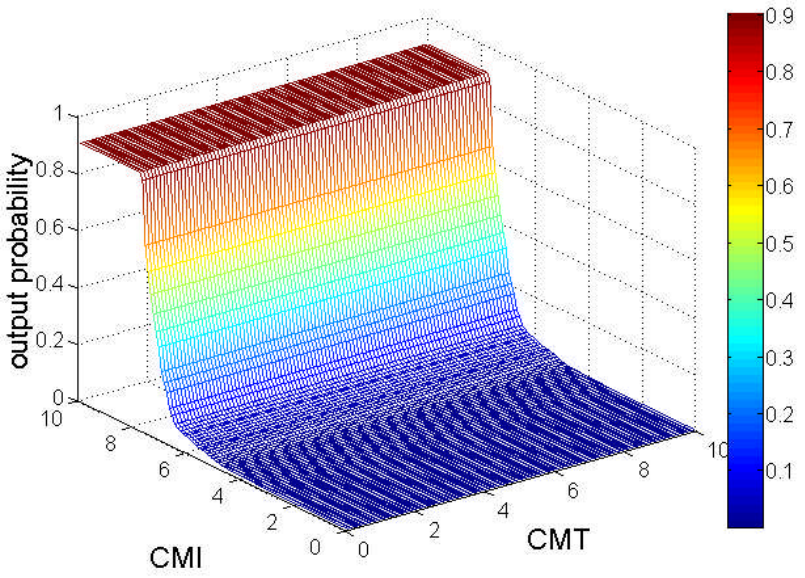

Figure 7.7. Output mapping of rule system using probability mapping display for Individual Effectiveness (Eff) and Distraction (Dist) for other inputs = 5.0: Supervision flag = 1: Ability to ask flag=0: Level complexity =2.

Figures 7.4 to 7.7 are included to indicate the general modes of interaction of specific input parameters for specific values of other input parameters and for specific values of codes for supervision flag, ability to ask flag and a level of complexity of task (1 = low: 2 = intermediate and 3 = complex). Where a specific input parameter is excluded from the calculation in the risk engine, such

as when supervision flag or ability to ask flag is zero, then the 'risk engine' appropriately modifies the output response, as indicated in figure 7.7 where the exclusion of Competency Mismatch (Team) does not control the contribution of increasing Competency Mismatch (Individual). Also, where both functions are excluded in the mapping of Supervision and Competency Mismatch (Team), then a flat surface is appropriately displayed.

The specific details of function surfaces are identified with the specific characteristics of the fuzzy function previously selected. The surfaces indicated relate to default values of 5 of the non varying input parameter values. There are therefore innumerable surface functions where the non varying input parameter values can be allocated a range of fixed values.

The simulation of the risk engine at specific levels of task complexity indicates the significant contribution that task complexity plays in determining levels of output probability. Figures 7.8, 7.9 and 7.10 indicate the simulation outputs for corresponding complexity levels of 1 (low), 2 (intermediate) and 3 (complex). There is significant difference between figure 7.8 and 7.9 (complex and intermediate) though the difference between 7.9 and 7.10 (intermediate and low) typically affects only low levels of output probability relating to high levels of individual effectiveness. This is further indication of the high importance of the process of classification of activity within these three grades of difficulty. It raises the question, also, about the sufficiency of using a three level classification system for task complexity.

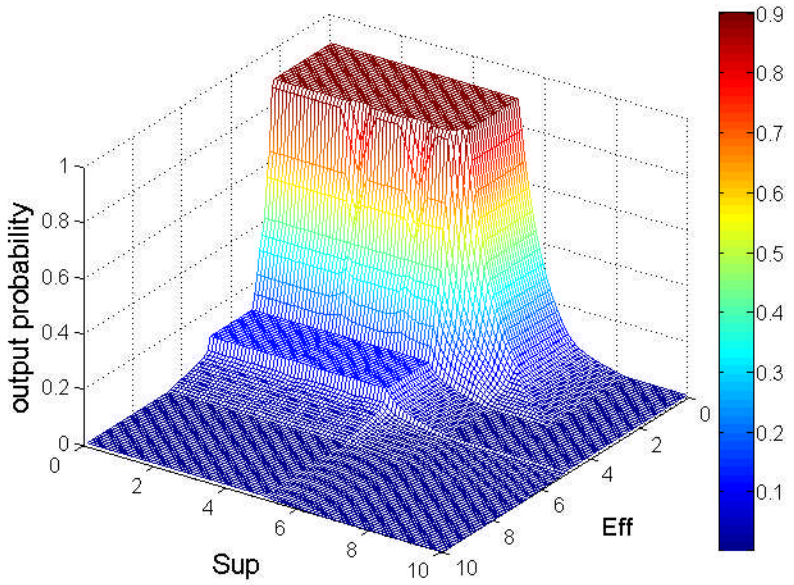

Figure 7.8. Output mapping of rule system using probability mapping display for Individual Effectiveness (Eff) and Supervision (Sup) and other inputs = 5.0 :Supervision flag = 1: Ability to ask flag=1: Level complexity =3: Probability lookup table value = 4.

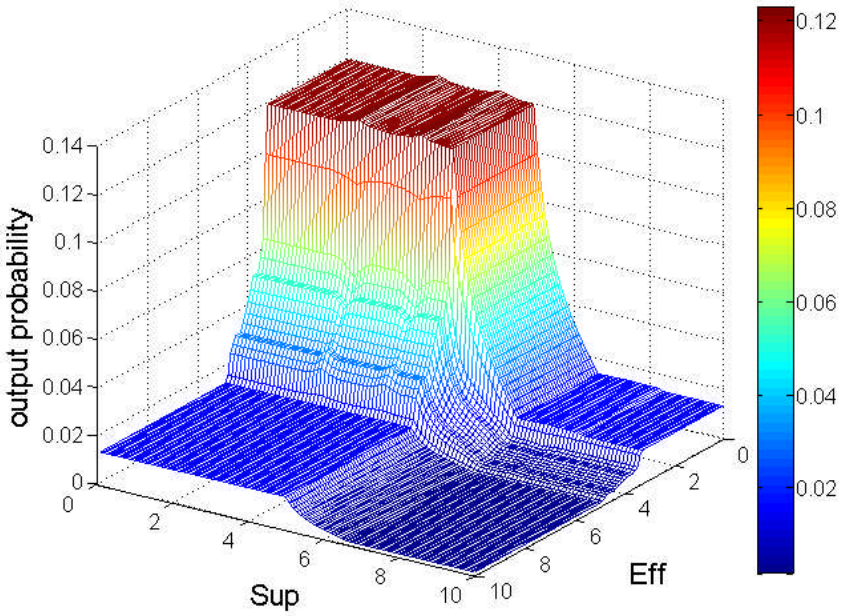

Figure 7.9. Output mapping of rule system using probability mapping display for Individual Effectiveness (Eff) and Supervision (Sup) and other inputs = 5.0 :Supervision flag = 1: Ability to ask flag=1: Level complexity =2: Probability lookup table value = 4.

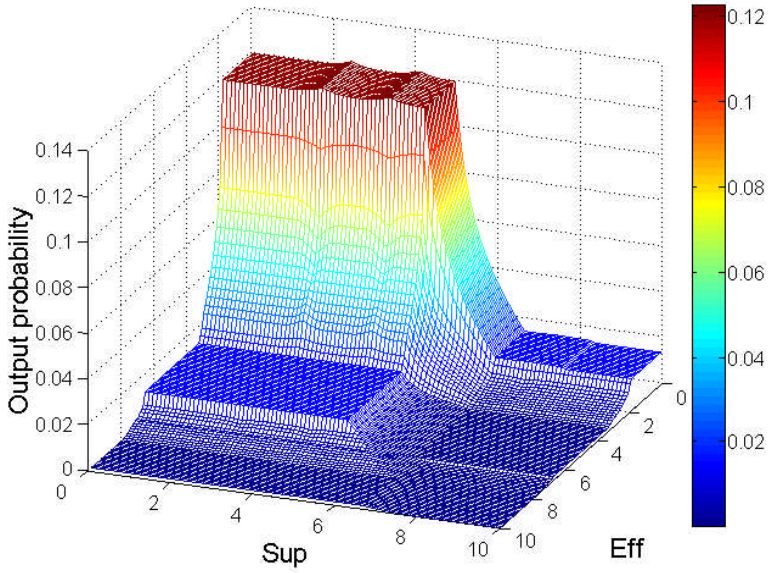

Figure 7.10. Output mapping of rule system using probability mapping display for Individual Effectiveness (Eff) and Supervision (Sup) and other inputs = 5.0 :Supervision flag = 1: Ability to ask flag=1: Level complexity =1: Probability lookup table value = 4.

7.4 Review of Distribution of Input Parameters and Associated Output Probability

Figure 7.11 indicates a series of sequential inputs (CMI, CMT, Dist, Sup and Eff) and output (Probability) of the risk engine for a sub set of values of a risk simulation process of adverse effects. This is a review mode using a specific 'review module' where parameters are read from a log file as indicated in figure 7.1. This facility is used initially to inspect the range of values presented to the risk engine and also the derived output probability values. The sets of input parameters can be grouped into:

- Competency mismatch values (Individual (CMI) and team (CMT))
- Distraction (Dist), supervision (Sup) (referenced to bed occupancy)
- Individual effectiveness (Eff)

This provides a means of fine tuning the model to ensure a necessary and sufficient range in input values to ensure that the 'risk engine' is appropriately driven. In figure 7.1, elements from the log file can be selected using a range of parameters values including bed number, staff member, grade of staff, competency reference of sub task, and adverse effect reference associated with sub task. In figure 7.11, the specific selected item is competency reference 13 (identify peripheral intra Venous site).

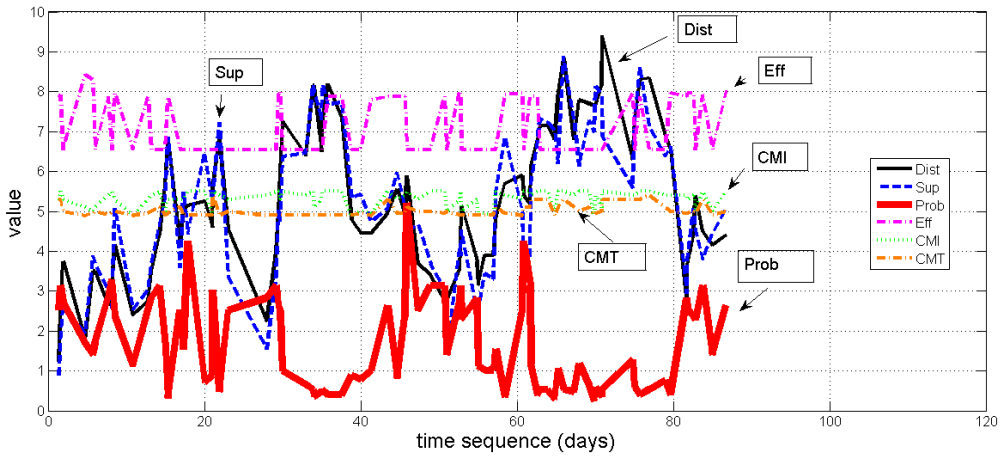

Figure 7.11. Input parameter values and output probability value (times 1000) for competency element 13 (identify peripheral intra venous site). Active codes for 'risk engine' are Supervision flag =1, Ability to ask flag = 0: Complexity code = 2: Probability lookup table value = 4.(Prob = Probability value of specific adverse effect).

Figure 7.12 indicates an expanded element of this output sequence between 60 and 87 elapsed days.

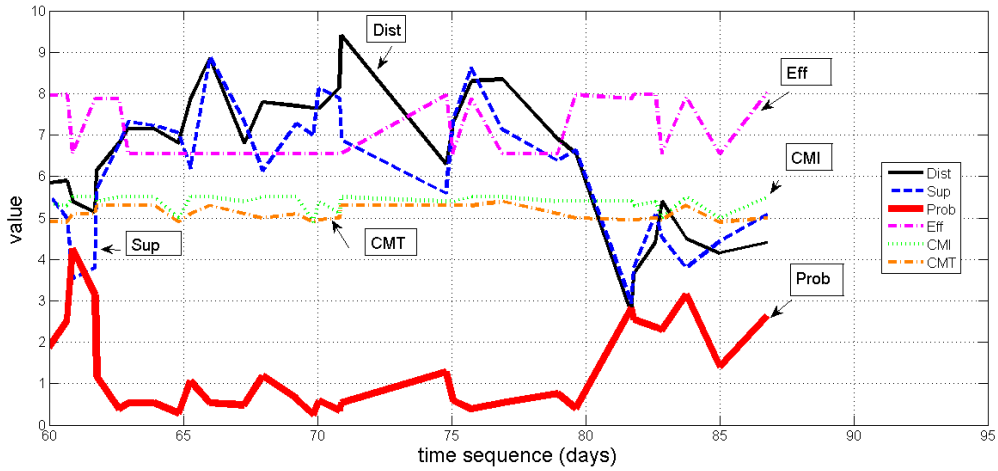

Figure 7.12. Input parameter values and output probability value (times 1000) for competency element 13 (identify peripheral intra venous site) for sequence between 60 and 85 days. Active codes for risk engine are Supervision flag =1: Ability to ask flag = 0: Complexity code = 2. Probability lookup table value = 4.

In terms of scaling distraction and supervision within the range of input values, the trend indicated in the above figure is for these two parameters to generally track each other. The local maximum of output probability at around 61 days is triggered by the reduction in level of supervision. The local maximum of output probability at around 82 days is triggered by the reduction in supervision level and where this is not apparently offset by the corresponding reduction in level of distraction.

7.5 'Two Dimensional' View of Simulation Process of Risk Engine

The characteristics of the risk engine can, however, be difficult to interpret in structure of figures 7.2 and 7.10. In addition to the three dimensional representation of variables, it is also possible to inspect a two dimensional simulation of variation of two parameters such as supervision and distraction as indicated in figure 7.13. This can be interpreted with reference to figure 7.5 to confirm the correspondence between the output values of probability indicated in figure 7.5 and those indicated in figure 7.13.

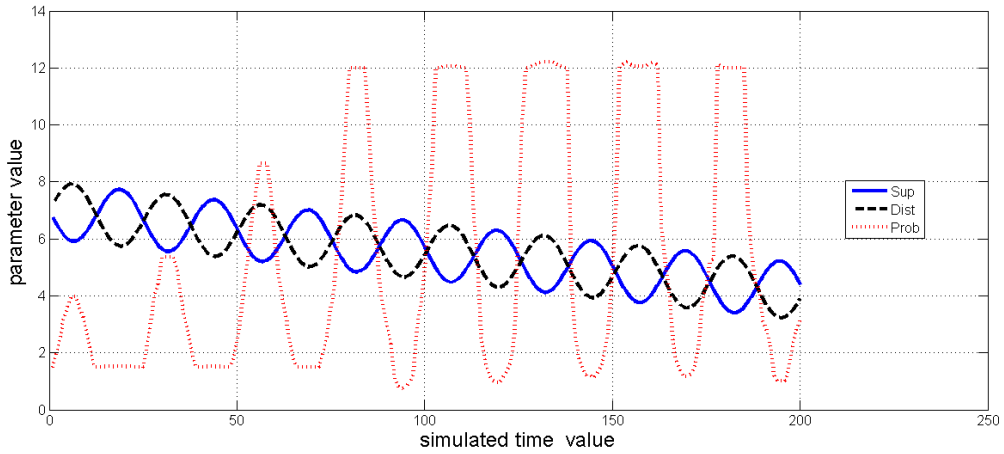

Figure 7.13. Simulated characteristics of output probability (x 100) (Prob) for simulated variations of Supervision (Sup) and Distraction (Dist) for Supervision flag =1: Ability to ask flag = 0: Complexity code = 3 and other input parameters =5.0.

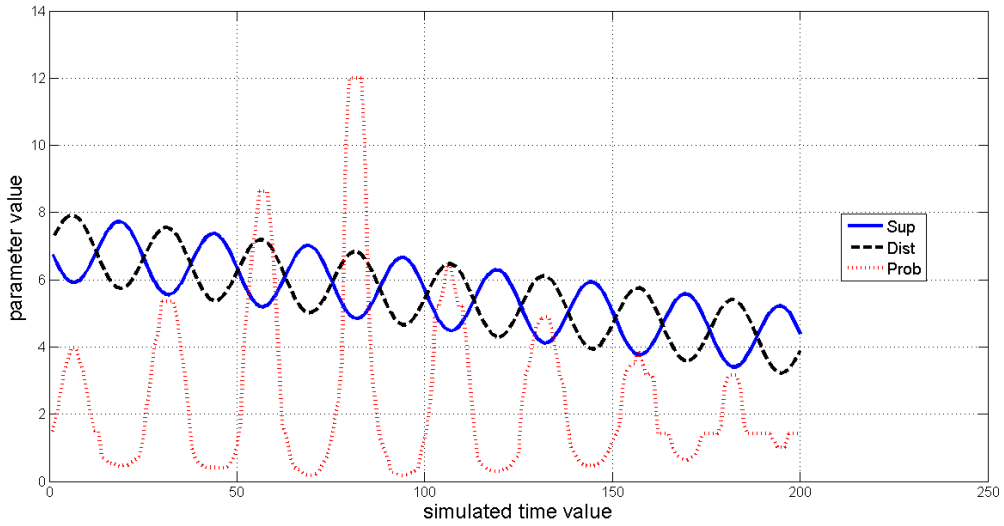

Figure 7.14. Simulated characteristics of output probability (x 100) (Prob) for simulated variations of Supervision (Sup) and Distraction (Dist) for Supervision flag =1: Ability to ask flag = 0: Complexity code = 2 and other input parameters = 5.0.

This two dimensional method of displaying input and output parameter values of figure 7.14 indicates in the example of input parameters Supervision and Distraction, the importance of level of complexity of task in deriving levels of output probability. The interaction between Distraction and Supervision is structured by the derivation of the distraction function and the supervision function based on bed occupancy level, patient severity and staff availability. Initial indications of behaviour of these two

functions indicates that they are typically balanced in their variations but that distraction can dominate when there may be a reduction in supervision due to non availability of staff in the clinical area.

Figure 7.15 indicates occurrences where supervision is likely to dominate distraction and establish low values of output probability – negative ordinate values. In addition, occurrences are identified where Distraction dominates and are likely to drive higher values of output probability, resulting in positive ordinate values. This indicates that the two functions are probably appropriately 'balanced' so that there is no trend for a specific parameter – Supervision or Distraction to dominate. This indicates the importance of scaling the input variables to the 'risk engine' appropriately.

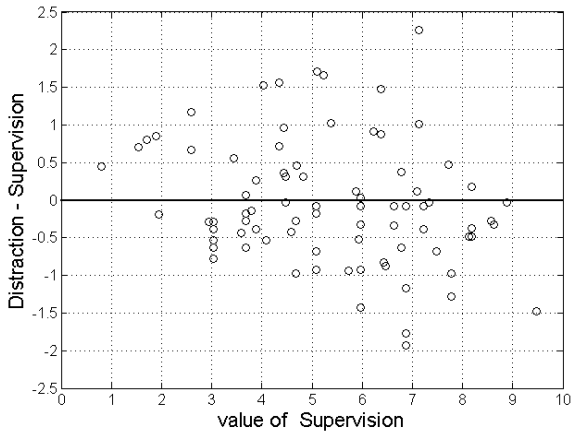

Figure 7.15. Detail of distribution of values of (Distraction-Supervision) as a function of value of supervision for the data set shown in figure 7.11 and where mean value of (Distraction –Supervision) is -0.0574; SD = 0.8149.

In optimising the module for derivation of probability of adverse effects, it is necessary to match the characteristic of the fuzzy function with the distribution of competency values associated with individuals and the equation that derives competency mismatch at the individual and team level.
Figures 7.16 and 7.17 indicate the effect of constraining function of CMT (competency mismatch – team) in deriving output probability values.

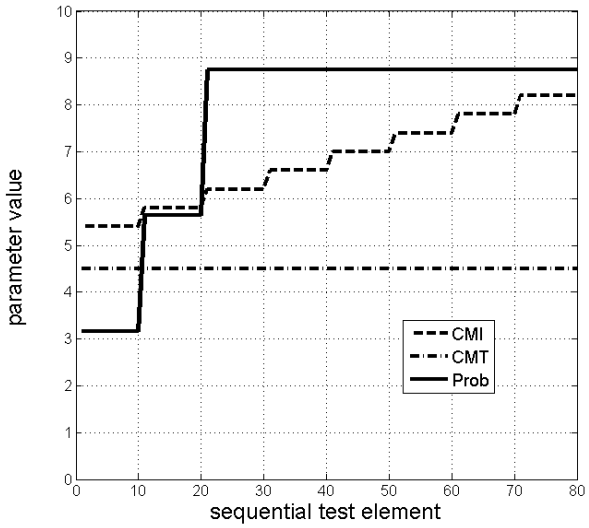

Figure 7.16. Example of sensitivity of output probability x 10 (Prob) to value of CMT (competency mismatch team) for variable value of CMI (competency mismatch individual) and fixed values of CMT, Distraction, Effectiveness and Supervision of 5.0. The value of CMT of 4.5 is not sufficient to offset the effect of increasing individual competency mismatch (CMI).

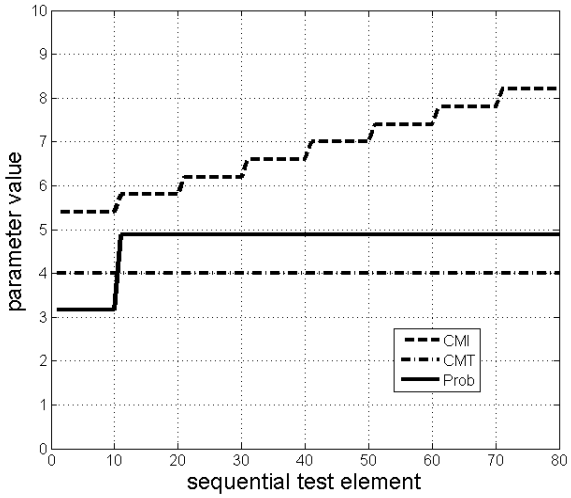

Figure 7.17. Example of sensitivity of output probability x 10 (Prob) to value of CMT (competency mismatch team) for variable value of CMI (competency mismatch individual) and fixed values of CMT, Distraction, Effectiveness and Supervision of 5.0. The value of CMT of 4.0 is able to offset the effect of increasing individual competency mismatch (CMI).

In terms of a scaling maximum and minimum competency values these are identified as 0.6 and 0.9 and where a value of 0.8 is identified as a level for required competency for the specific task. Values in excess of 0.8 are identified as indicating capacity for training other staff to undertake the specific task.

Based in the indicated range of values of competence and the identified level of required competency, the potential maximum and minimum value of *CMI* and *CMT* are indicated in table 7.3. This corresponds to a value of M1=15 in equation 6.4.

	CMI	CMT
Maximum	8	Note 1
Minimum	3.5	3.5

Table 7.3. Identified range of values of maximum and minimum values for CMI and CMT based on range of individual competency of 0.6 to 0.9 and for required competency level of 0.8. (Note 1: The maximum value of CMT derived from maximum available competency within a set of nursing co-workers.)

In allocating the values of competency with the set of nursing competencies, numerous competencies are standard generic competencies which are assigned the value of 0.8 as the required level for the lowest sub band of staff. Other competencies are allocated a starting competency of less than 0.8 to indicate practice which should be undertaken with some element of supervision by more senior staff. One variable element in moderation of individual competency mismatch by availability of supportive team competency is the term relating to 'ability to ask'. Where the value of this term is unity, the individual will always seek assistance from the team and can be set at variable levels to identify the influence of this factor on output probability of adverse effects.

7.6 Exercising the Model

In using the model to generate output values of risk associated with interventions and tasks, variations in the output values for the established model can be considered to relate to:

- Variations in the model in internal representation/calculation of variables
- Variations in parameters that are related to organisational structure, clinical activity and physical layout

Elements in the first category include:

- Probability mapping function
- Function to simulate handover response
- Sleep deprivation function
- Distraction coefficients

- Supervision relationships
- Function for competency mismatch (individual and team)
- Definition of level of intervention task complexity
- Components physical, emotional, intellectual depletion per intervention
- Recovery models physical, emotional, intellectual depletion per intervention
- Derivation of effectiveness function value based on all input parameters (physical, emotional, intellectual, handover, admission, night shift component, sleep deprivation)

Elements in the second category would include:

- Allocation of grades/sub grades of nursing staff within a specific rota
- Competencies allocated to specific grades of staff by grade/sub grade
- Level of sleep deprivation
- Levels of staff availability in clinical area
- Levels of 'ability to ask' in competency sharing
- Factors influencing bed to bed interaction (physical environment)

Subsequent exercising of the risk model can be identified with both categories. Activity with the first category assists in understanding the role and importance of various elements of design of the risk model, while in the second aspect, details are provided of changes in risk profile based on actual operational factors.

7.7 Probability Mapping Function

It is relevant to review the output probability mapping function which translates the linear output of the risk engine in range 0 to 10 to a specific probability value in the range between 0 and 1 as described in equation 6.5. Figure 7.18 indicates a specific series of simulated elements with a range of output probability values across the set of available tables outlined in table 7.4.

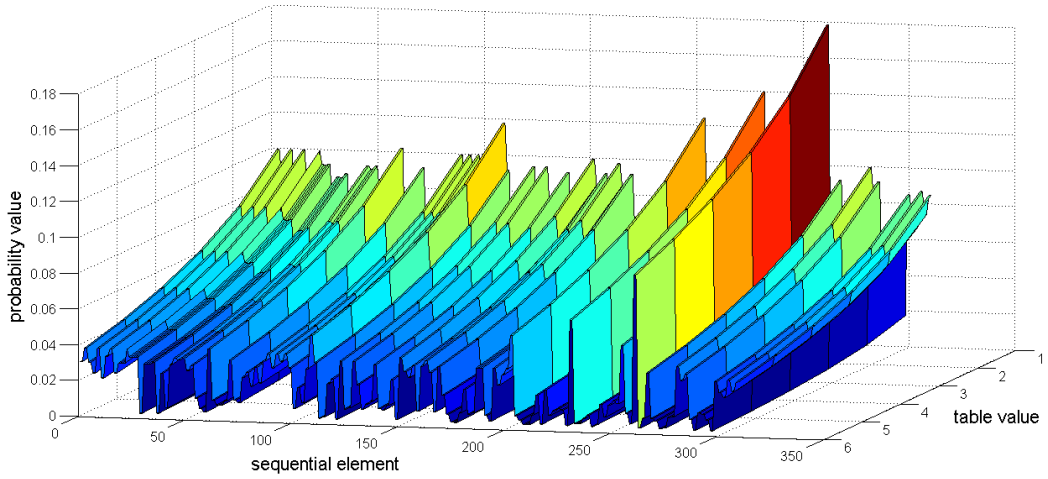

Figure 7.18. Variation in output probability values of adverse effects as a function of probability look up table values in range 1 to 6 associated with 310 elements associated with specific competency element 247 (review admission notes) using simulation set #1 and for table values indicated in table 7.4.

Table value	Ao	Grad	Step	Mean	Max	SD
1	0.9	5	1.6667	0.0616	0.1782	0.031
2	0.9	6	1.6667	0.0462	0.1483	0.0255
3	0.9	7	1.6667	0.0363	0.127	0.0215
4	0.9	8	1.6667	0.0295	0.111	0.0185
5	0.9	9	1.6667	0.0246	0.0986	0.0161
6	0.9	10	1.6667	0.0209	0.0887	0.0143

Table 7.4. Values of mean, maximum and standard deviation (SD) of a sequence of 310 values of probability of adverse effects as displayed in figure 7.18.

In subsequent estimations of simulated probability values, use is made of table 3 settings (Ao = 0.9; Grad = 7; Step = 1.6667). This is on account of the correspondence of this configuration with the basic risk analysis time frame/probability values identified in figure 6.8.

As part of a larger test series of 247222 discrete ‘competency/adverse effect’ pairs, figure 7.19 indicates the sum of all probabilities and percentage of total probability value greater than 0.1 as a function of table look up value in range 1 to 6. This shows the key role of the table value to derive output probability from the linear output of the risk engine. Reducing the sensitivity of this function reduces the value of sum of all probabilities and increases the percentage of contributions in range greater than 0.1. The ratio of sum of probabilities of table element #1 and table element #6 is 4.7.

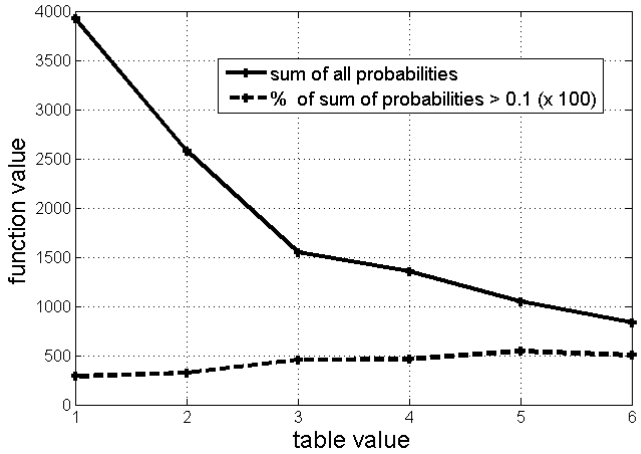

Figure 7.19. Variation of sum of all probabilities of adverse effects and percentage of individual values of probability of adverse effects in excess of 0.1 (scaled x 100) as a function of table took up value of probability transfer function referenced in figure 7.4.

7.8 Nurse Staff Attendance in Clinical Area

One basic component reviewed is the fraction of time staff spend within the unit, as a modifying factor for supervision. Changes in the mean output probability for a specific simulation profile are indicated in figure 7.20.

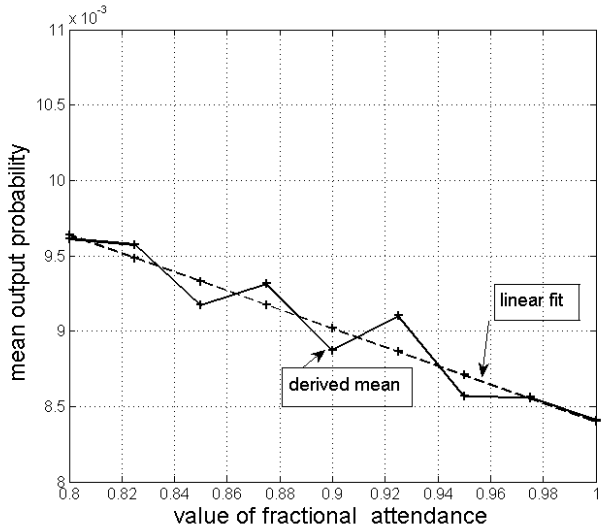

Figure 7.20. Variation of mean output probability derived from 27423 separate probability estimations for various values of fractional attendance of staff within a Critical Care Unit.

Assuming a linear regression applies to the data, the relevant equation is given by:

Prob _atn = - 0.0062. Fract + 0.0146

(7.1)

Where *Fract* is the fraction of time available to assist with supervision and *Prob_atn* is the mean probability value of all interventions as a function of value of *Fract*. For a reduction of staff attendance from value of 1.0 to 0.9, there is an associated increase in mean probability value of all adverse effects of approximately 7.3%.

Where a specific competency (element 247 - review admission notes) is selected from the set of all active competencies, an equivalent relationship is identified:

$$Prob\_atn = -0.0486.Fract + 0.0921 \quad (7.2)$$

For a reduction of staff attendance from value of 1.0 to 0.9, there is an associated increase in mean probability value of approximately 11.2%. This illustrates a general point that specific sub tasks will have levels of probability of adverse effect which are influenced by the level of assigned sub task complexity and whether such tasks are supervised or are part of team working.

7.9 Probability of Interaction Coefficients

The series of curves illustrated in figure 7.21 indicates a series of functions which describe levels of team interaction based on physical separation of nursing co-workers by bed row difference and with reference to bed layout structure indicated previously in figure 6.13.

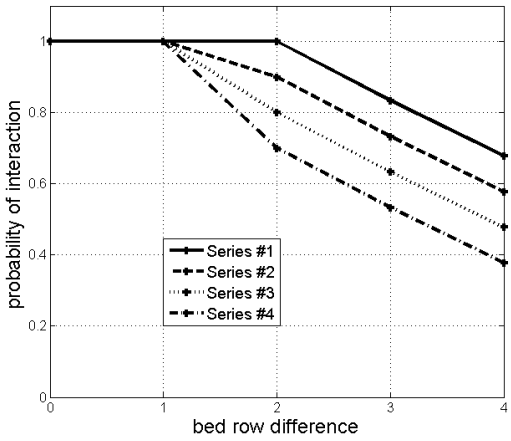

Figure 7.21. Identification of specific series of 'probability of interaction coefficients' used to determine changes in mean levels of output probability of test simulation.

The three curves series #2, series #3 and series #4 indicated in figure 7.21 are derived by decrementing values of series #1 by 0.1 for bed row differences of two and greater. Figure 7.22 describes the values of simulation probabilities for the series of values of probability for the set of parameters outlined in figure 7.21.

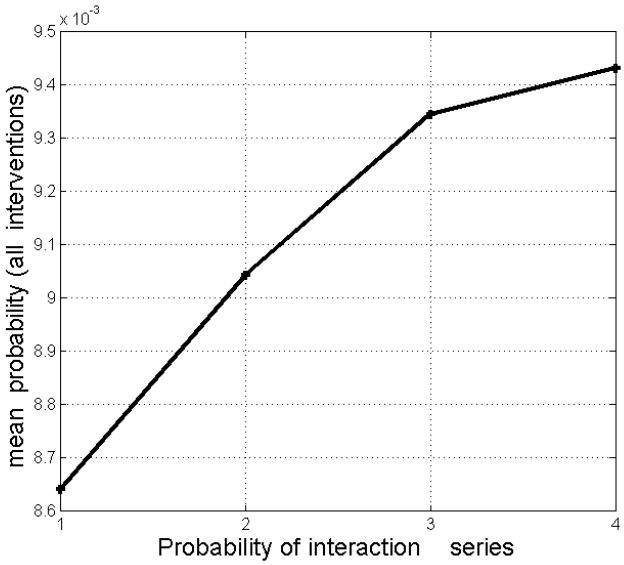

Figure 7.22. Value of mean output probability (all simulated interventions) for the set of interaction series identified in figure 7.21.

This confirms the trend to increase output likelihood of risk when there is reduced interaction between nursing co-workers on account of the effect of distance separation between beds in the work area. The difference in mean probability (all interventions) between series #4 and series #1 is equivalent to a percentage change of 9.16%. For this evaluation, a set of unity distraction coefficients was utilised and similar values were used for values of *Sep_comp(i,j)* and *Sep_sup(i,j).* This indicates the importance of ergonomic bed layout in the planning phase of Critical Care Units. As referenced previously, a systematic approach for determination of such interaction coefficients is outlined in section 6.14. This forms the basis of further work in finding optimised solutions of operational risk reduction within a specific clinical area based on bed layout.

7.10 Ability to Ask Parameter Value

Figure 7.23 indicates the variation of mean probability of simulated set #1 as a function of value of 'ability to ask parameter' as the probability that a nurse will ask for assistance where there is a competency shortfall and it is appropriate to ask for such assistance.

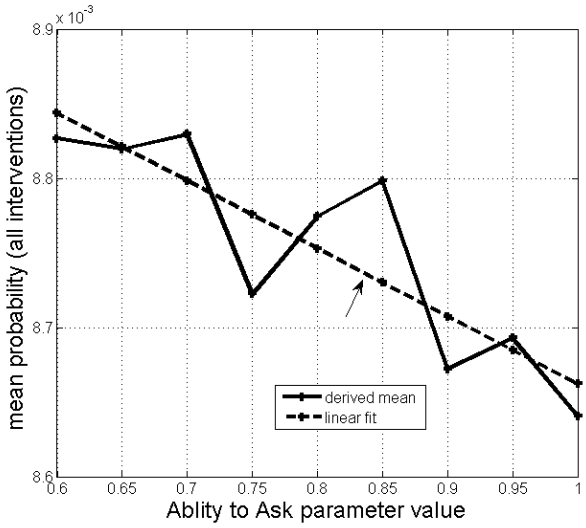

Figure 7.23. Value of mean output probability (all simulated interventions simulation set #1) for values of ability to ask parameter'.

This confirms the trend to increase output likelihood of risk when there is reduced likelihood that staff ask for help from the team of nursing co-workers. The relative change in mean probability (all interventions), from a parameter value of 1.0 to 0.6 is 2.1%.

7.11 Determination of Characteristics of Output Probability Distributions

For any process of operation of the 'risk engine' system, it is important to determine the distribution of probabilities within a given simulation set and also potential differences in distributions for specific configurations of simulated systems. Figure 7.24 indicates a specific method of inspection of distributions of probability values, where the normalised cumulative probability value Cum(pn) is given by:

$$Cum(p(n)) = \Sigma\, p(i) \,/ Cumsum\ i = 1,n \qquad (7.3)$$

Where *Cum(p(n)* is the cumulative sum of all components of probability from *p(1)* to *p(n)* and *Cumsum* is the sum of all contributions in the series. In this analysis, the probability space between 0 and 1 is sub divided into 1000 elements. The relative frequency of the distribution is indicated with the modal value normalised to unity.

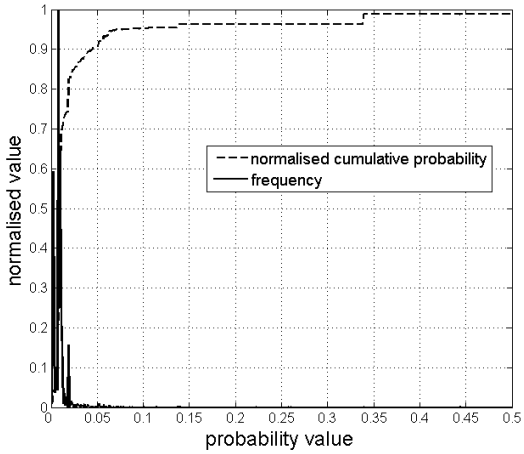

Figure 7.24. Details of normalised cumulative probability and normalised frequency of probability values for a specific simulation.

This indicates that approximately 95% of normalised cumulative probability values are achieved for probability values of less than 0.1. The modal probability is 0.008.

In addition, the method of analysis of normalised cumulative probability values can provide insight into comparisons of probability distributions resulting from specific configurations of the risk engine system. Figure 7.25 indicates the normalised cumulative difference between two specific risk estimations as a function of value of determined probability. This indicates that around 95% of differences in normalised cumulative probability appear to be accounted by probability values less than 0.1. This is an intrinsic characteristic of the functionality of the collective 'risk engine' modelled system. The distribution of probability values will also be influenced by the mapping function referenced in figure 6.10 which translates from linear output of the 'risk engine'.

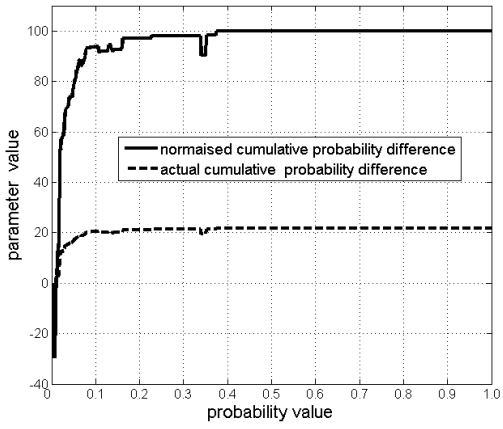

Figure 7.25. Normalised cumulative difference in probability values as a function of probability value where upper curve indicates percentage of total normalised cumulative difference value and lower curve indicates actual cumulative probability difference. (reference 15 and reference 24).

Figure 7.25 indicates that the change in parameters within the risk engine between higher risk and lower risk configurations are not producing a changed distribution of probability event space. Figure 7.26 indicates a comparison which results in a smaller difference in cumulative probability values – and where changes in levels of probability greater than 0.3 trigger more significant differences in the cumulative probability values.

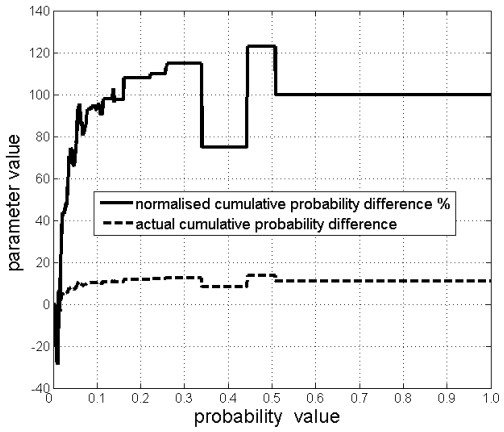

Figure 7.26. Cumulative difference in probability values as a function of probability value where upper curve indicates percentage of total cumulative difference value and lower curve indicates actual cumulative probability difference. (reference 15 and reference 22).

In considering the probability distributions of the output risk simulations, it is possible to identify the residual set of probabilities, say less than 0.1 which can be classified as 'safe practice', where the work activity is inherently safe. Probability values in excess of 0.1 can be described as 'inherently unsafe' and provide a more sensitive index of change of risk status of simulated clinical activity.

7.12 Configuration of Derivation of Competency Mismatch Components

The setting of 'sensitivity' to components of competency mismatch for both individual and team elements as outlined in equation 6.4 through the value of M1 is a key element of the risk simulation system. Risk simulations in sequence 1 to 5 were undertaken where a range of sensitivities to competency mismatch terms were included, and where values of M1 of 10, 12.5, 15, 17.5 and 20 were used. Analysis included review of simulated probabilities in excess of 0.1 as indicated in figure 7.27.

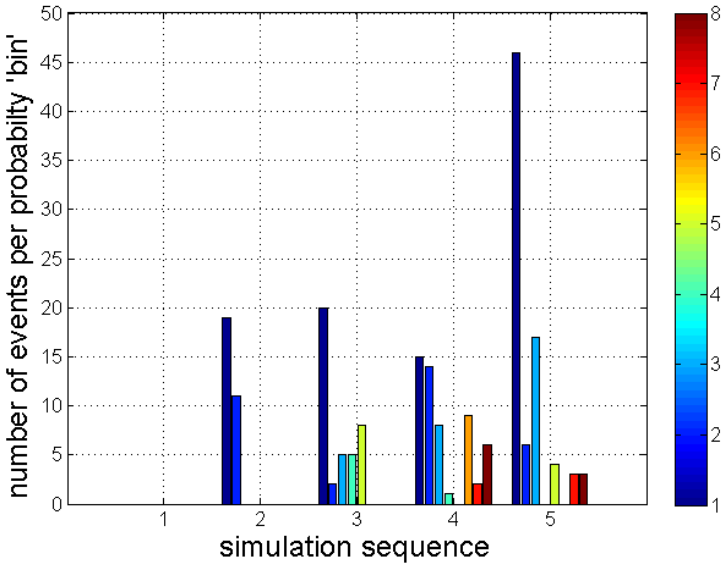

Figure 7.27: Colourmap indicates key to probability 'bins' where 1= 0.1 to 0.2, 2= 0.2 to 0.3 etc. In the first sequence, there are no probability values greater than 0.1. As the value of M1 is increased from 10 (simulation sequence #1) through to 20 (simulation sequence #5) to increase sensitivity to competency mismatch, there is a trend for increase in the number of 'probability events' within each sequence with values greater than 0.1.

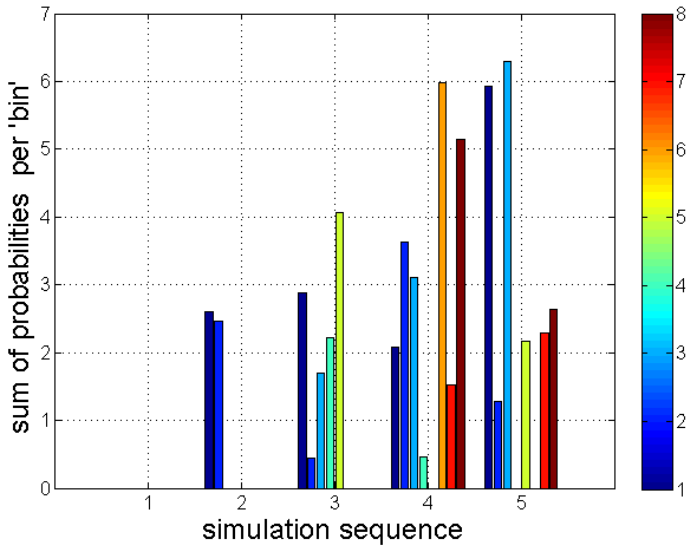

Figure 7.28. Colourmap indicates key to probability 'bins' where 1= 0.1 to 0.2, 2= 0.2 to 0.3 etc. In the first sequence, there are no probability values greater than 0.1. Corresponding values of sum of probabilities within each 'probability bin' references are indicated.

This indicates that as expected the value of M1 as referenced in equation 6.4 is an important indicator of sensitivity of simulation system to gaps in competency.

7.13 Sleep Deprivation Functions

Figure 7.29 indicates the variation of the sum of contributions of probabilities of adverse effects as a function of effectiveness factor introduced via sleep deprivation for day shift activity, night shift activity and combined shift activity. The series of day shift activity corresponds to variation of sleep deprivation in day shift with fixed night shift sleep deprivation of 5 hours and the night shift series corresponds to values of fixed day shift sleep deprivation of 5 hours and varying night shift sleep deprivation values. The trend for sum of all probabilities of adverse effect is similar for the sets of data. For the series with varying sleep deprivation in the night shift this corresponds to a 32 % increase in sum of all contributions in transition from a sleep deprivation value of 2 hours to 30 hours and a value of 65 % for the combined day and night shift. This indicates the sensitivity of output probability values to the value of individual effectiveness expressed through sleep deprivation factor. In the application of this factor, all staff within the indicated shift have the same level of sleep deprivation applied.

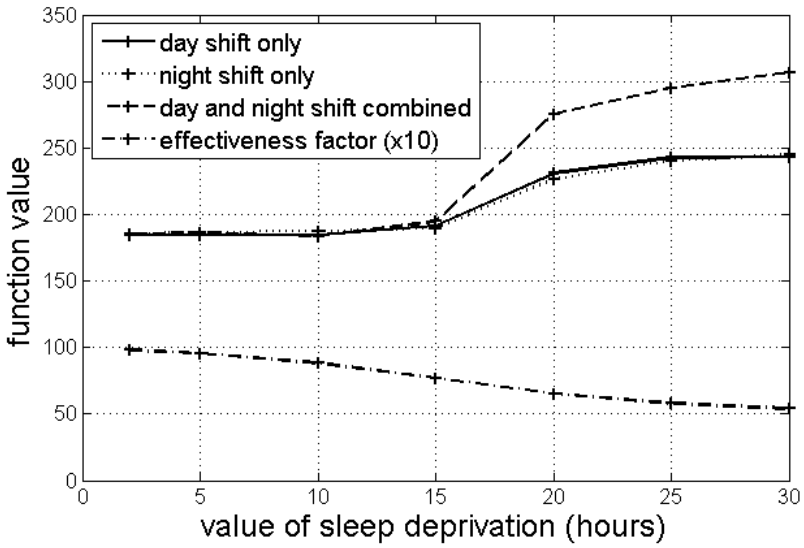

Figure 7.29. Variation of the sum of contributions to probability of adverse effects as a function of factor introduced via sleep deprivation effectiveness factor for day shift activity, night shift activity and combined shift activity and where values of sleep deprivation are set to 5 hours in the non varying shifts.

At high values of sleep deprivation the associated effectiveness factor introduced is dominating the individual effectiveness value. Sleep deprivation values will tend to be greater during night shift periods than day shift working on account of the anticipated dislocation of sleep patterns. This demonstrates the anticipated effect within the risk model of increasing value of sleep deprivation factors.

7.14 Simulations with Varying Levels of Team Competency

Table 7.5 outlines parameters used to simulate output levels of adverse effects as a function of competency within nursing group members of the established staff roster.

nurse ref	seq 1	seq 2	seq 3	seq 4	seq 5	seq 6	seq 7
12	2	2	3	3	3	4	4
27	2	3	3	4	4	4	5
29	3	3	3	4	4	4	5
42	3	3	4	5	5	5	6
44	3	3	4	5	5	6	8
48	3	4	4	5	5	8	10
64	4	4	5	7	8	9	10
73	5	6	6	8	8	9	10
77	6	7	8	9	10	10	12
89	9	10	10	10	13	14	15
Total	40	45	50	60	65	73	85
nurse ref	seq 1	seq 2	seq 3	seq 4	seq 5	seq 6	seq 7
13	2	2	2	3	3	3	4
16	2	2	3	3	3	4	5
30	2	2	4	4	4	4	5
33	4	4	4	4	5	6	7
45	4	4	5	5	5	6	7
49	5	5	5	5	6	8	9
65	6	6	6	7	7	9	9
69	6	6	6	7	7	10	10
75	7	7	8	8	8	10	11
85	10	10	10	10	9	11	14
Total	48	48	53	56	57	71	81
nurse ref	seq 1	seq 2	seq 3	seq 4	seq 5	seq 6	seq 7
14	2	2	3	3	3	4	4
28	2	3	3	4	5	5	5
31	2	3	3	4	4	5	6
43	3	4	4	5	5	6	6
46	4	4	5	5	5	6	6
50	5	5	5	5	6	7	8
66	6	7	7	7	8	9	9
74	6	7	7	8	9	10	10
78	8	8	8	9	9	10	12
90	9	10	10	10	13	14	15
	47	53	55	60	67	76	81
nurse ref	seq 1	seq 2	seq 3	seq 4	seq 5	seq 6	seq 7
15	2	2	3	3	3	4	4
17	2	2	3	3	4	4	4
32	2	3	3	4	4	5	5
34	3	4	4	4	5	6	6
47	4	4	5	5	6	6	7
51	4	4	5	5	7	8	8
67	6	6	7	7	8	9	10
70	6	7	8	8	8	10	11
76	8	8	8	9	10	11	12
86	9	9	10	10	11	12	14
	46	49	56	58	66	75	81
Global total	181	195	214	234	255	295	328

Table 7.5. Identification of sequence of levels of competency associated with sequences 1 to 7 of increasing individual competency. Sequence #5 is the default level of team competency.

Sequences #1 to #7 relate to increasing levels of competency within each nursing shift. This particular analysis has been identified to establish the basic sensitivity of the risk model to varying individual competency mismatch. Figure 7.30 indicates how the values of sum of individual probabilities and those >0.1 in value vary as a function the sum of all sub grades of each roster group.

In the structuring of this analysis, the staff references remain the same but a specific 'Nursing_unique' reference file is accessed with modified levels of nurse competency. This provides a flexible method of factoring in changes in competency within the simulation processes.

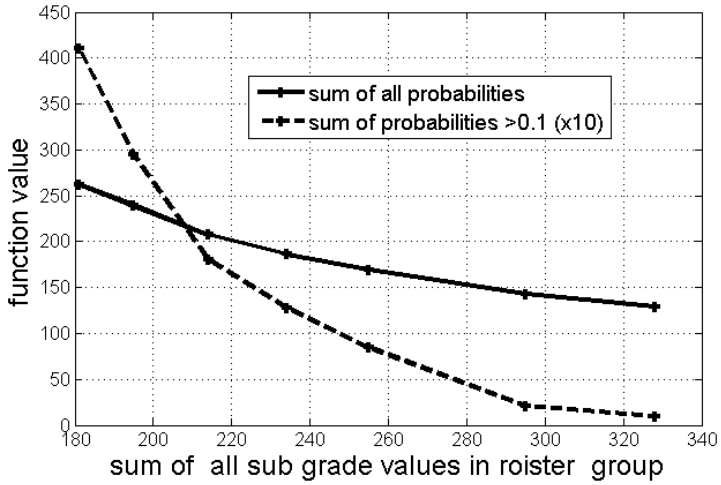

Figure 7.30. Outcome of simulated probability values of adverse effects (sum all probabilities and sum probabilities >0.1 (x10)) for the roster structures indicated in table 7.4 and which relate to sum of sub grade values of all staff within the roster group.

This shows an almost linear relationship between the sum of all probabilities and the corresponding sum of all sub grades in the roster group. There is however, increased sensitivity to probabilities greater than 0.1 with a reduction in value of the sum of the sub grade values for the rostered groups of nurses.

Figure 7.31 indicates details of events with derived probabilities greater than 0.1, indicating a higher percentage of such events for reduced levels of group competency.

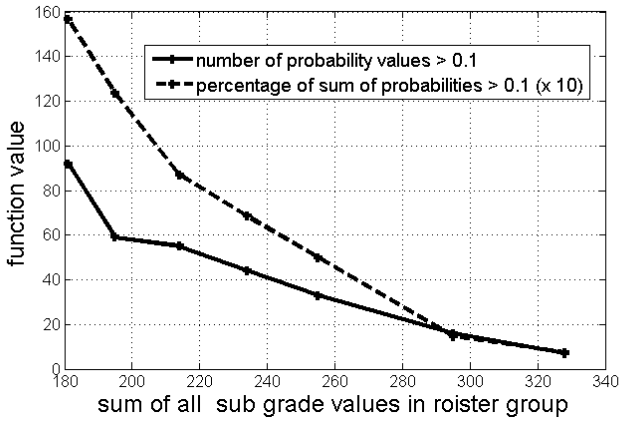

Figure 7.31. Variation in characteristics of probability distribution for varying values of sub grades within rostered groups for probability values less than 0.1. With decreasing values of competency in the sub groups, there is an increase in contributions of probability values greater than 0.1.

7.15 Simulation of Handover Response

The component of handover response is associated in the model with a reduction of individual effectiveness as referenced in equation 3.3. The default set of relationships of handover functions was previously outlined in table 3.5. A range of similar tables was created which introduced handover functions which coupled with increasing and decreasing effect on the handover response component of individual effectiveness. Table 7.6 indicates one set of parameters which described the most significant coupling to individual effectiveness and table 7.7 that table with the least significant coupling.

	A0	**A0**	**A0**	**hr**	**hr**	**hr**
	band 5	**band 6**	**band 7**	**band 5**	**band 6**	**band 7**
grade 1	0.45	0.4	0.35	5.5	4.5	4
grade 2	0.425	0.375	0.325	4	3.5	3.5
grade 3	0.4	0.35	0.3	3.5	3.25	3
grade 4	0.375	0.325	0.275	3	2.75	2.5
grade 5	0.35	0.3	0.25	2.5	2.25	2

Table 7.6. Details of assigned values of A0 and time to 50% recovery (hr - hours) for specific severity grade of patient and assigned nursing band: most significant coupling to individual effectiveness.

	A0 band 5	A0 band 6	A0 band 7	hr band 5	hr band 6	hr band 7
grade 1	0.25	0.2	0.15	3	2.5	2
grade 2	0.225	0.175	0.125	2	1.5	1.5
grade 3	0.2	0.15	0.1	1.5	1.25	1
grade 4	0.175	0.125	0.075	1	0.75	0.5
grade 5	0.15	0.1	0.05	0.5	0.25	0.5

Table 7.7. Details of assigned values of A0 and time to 50% recovery (hr - hours) for specific severity grade of patient and assigned nursing band: least significant coupling to individual effectiveness.

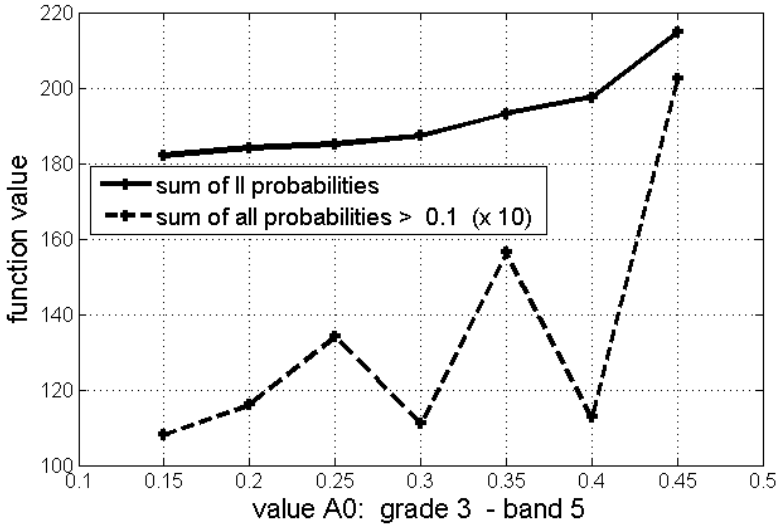

Figure 7.32. Variation of sum of output probabilities for test set as a function of value of A0 (grade 3: band 5) and where increasing values of A0 relate to increased effect on individual effectiveness at handover. Coupled with value of A0 is also the associated factor of recovery time associated with individual effectiveness.

With increasing value of A0, figure 7.32 indicates the sum of all probabilities increases as the handover effect has increasing influence on individual effectiveness.

7.16 Nurse Supervision Function

A linear relationship has been previously derived in section 6.10 between the sub grade level of a nurse and the corresponding component of supervision which is available to the set of nursing co-workers. This associated 'weight' of contribution as a function of sub grade is expressed as:

$$Nsup = 0.05357 . \quad Subg + 0.7321 \qquad (6.9)$$

Where *Nsup* is the contribution of a nursing co-worker to the group and *Subg* is the value of sub grade allocated to the specific nursing co worker. Values of *Subg* range from 1 to 15.

Figure 7.33 outlines the variation of sum of all probabilities and the sum of probabilities greater than 0.1 as a function of percentage change from default value of constant 0.7321 in equation 6.9.

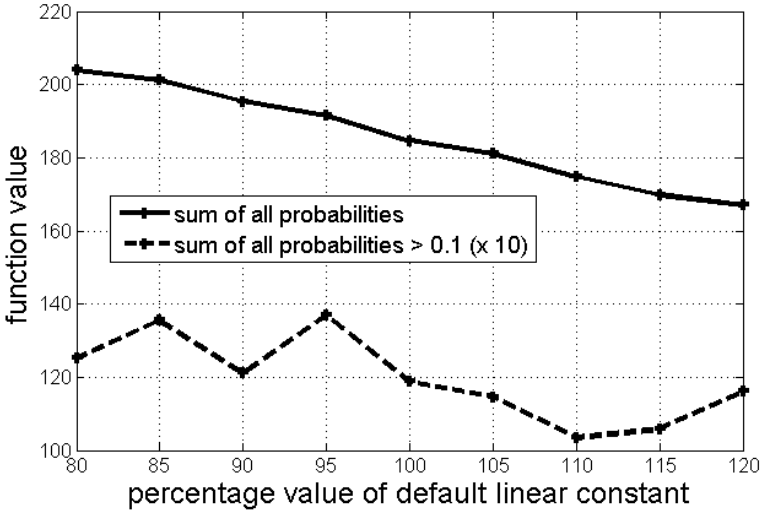

Figure 7.33. Variation of sum of all probabilities and the sum of probabilities greater than 0.1 as a function of percentage change from default value of constant 0.7321 in equation 7.7. Linear coefficients identified as (-0.9759,185.5756). Test set #1.

This confirms the anticipated response of the model to the change in indicated parameter, where an increased contribution to supervision is associated with a reduction in sum of probability values.

7.17 'Night Dip' Function

Based on consistent reporting of loss of individual effectiveness during night shift working, and with a local minimum of individual effectiveness, a specific function outlined in equation 3.5 was previously identified as an empirical match to the required effectiveness function. Figure 7.34 indicates how variations of this function influence the resulting probabilities of adverse effects. There is a general trend for increase in sum of all probabilities for reduction in value of minimum value at 03:30 am. The effect on probability values in excess of 0.1 is not apparent.

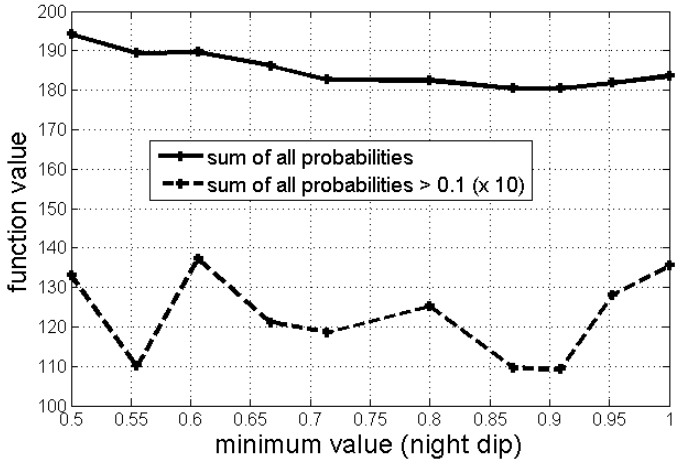

Figure 7.34. Variation of sum of probabilities and sum of probabilities >0.1 as a function of minimum value of night dip function.

7.18 Risk Structure within Competency Events

Each specific competency can be considered to have an associated risk factor, which would be modified by parameters of:

- Supervision flag
- Ability to ask (team)
- Level of task complexity

It is appropriate to review the specific contributions made to output risk based on the specific values of these parameters since they specifically influence the calculated values of risk of each adverse effect. Table 7.8 summarises values of simulation of a total of 347393 risk estimations where a total of 323941 relate to active supervision with team competency sharing.

	Low	**Intermediate**	**Complex**
Elements in simulation active	93431	204971	25539
Sum risk contributions	198.83	1409.88	274.75
Sum risk contributions >0.1	0	38.2	41.4

Table 7.8. Values of simulation of a total of 347393 risk estimations where a total of 323941 relate to active supervision with team competency sharing.

Figure 7.35 indicates the relative factors of contribution of level of task complexity towards sum of all risk contributions. Essentially complex tasks contribute approximately 5.05 times as much as tasks of low complexity while intermediate tasks contribute 1.56 times as much as tasks of low complexity. This confirms that the definition of task complexity is a key element in configuration of the risk simulation systems. Table 7.8 indicates that 52% of the sum of contributions greater that 0.1 is contributed from complex tasks which constitute only 7.9% of all the identified risk estimations. The mechanism for these changes is within the varying values of the fuzzy look up functions as referenced in table 6.6. Like for like comparisons are not referenced for codes relating to supervision and competency sharing.

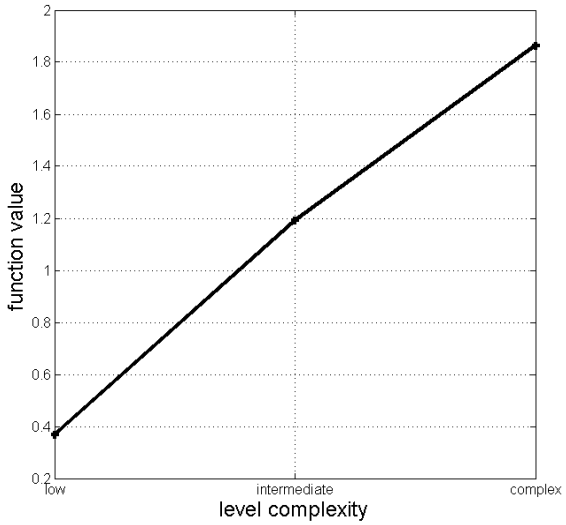

Figure 7.35. Relative factors of contribution of level of task complexity towards sum of all risk contributions.

7.19 Root Cause Analysis of Adverse Effects Occurring with Elevated Levels of Probability

The classical approach of Reason (1990) in explaining the causation of risk based events is the 'Swiss cheese' model where in given circumstances the combined effects of controls, surveillance and checks are not sufficient to balance the process of event causation. The risk simulation model provides a demonstrable framework where these effects can be replicated within a formal computational framework. The risk simulation model being described has therefore the potential to provide insight into why a specific adverse effect is triggered at a high probability value, based on analysis of specific events associated with key values of input parameters in the risk engine. This process is facilitated by review of the log file which is created with each cycle of risk simulation. Table 7.9 outlines the key fields reviewed by the root cause analysis review module used to analyse specific adverse effects which occur with high probability, as suggestive of unsafe practice. Probability values are typically reviewed in excess of a value of 0.05.

Parameters Value
Competency Mismatch (Individual)
Competency Mismatch (Team)
Team Involvement (Y/N)
Supervised (Y/N)
Distraction
Complexity
Supervision
Sleep Deprivation (a)
Handover (b)
Night Dip (c)
Admission function (d)
Physical effort (e)
Emotional effort (f)
Intellectual effort (g)
Individual Effectiveness (minimum value of (a) to (g))
Probability Value

Table 7.9. Core elements in review table for determination of root cause of occurrences of unsafe practice based on review of individual parameter values.

Recalled data can be analysed using graphical techniques of Matlab ® or Excel ® as indicated in figures 7.36 and figure 7.37 where data are displayed as a sequence of in descending order of value of output probability.

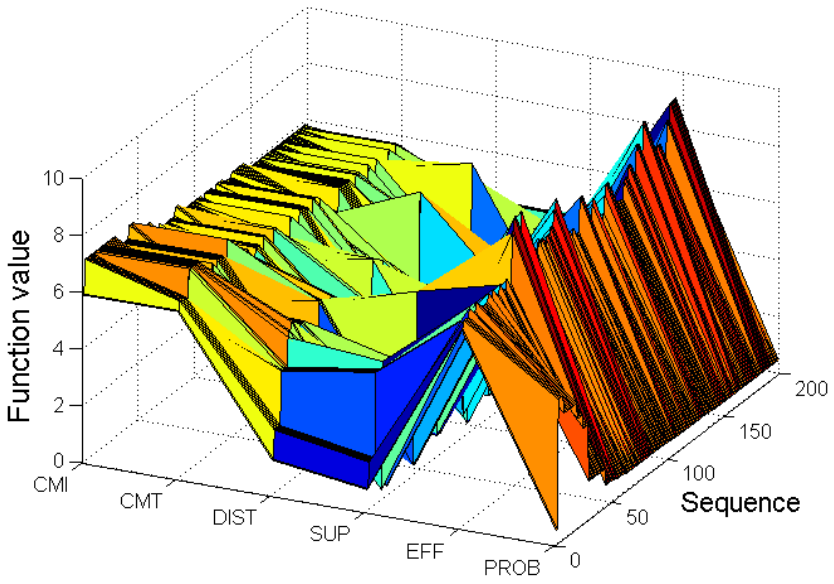

Figure 7.36. Graphical display of sequence of events with probability events greater than 0.05 indicating values of Competency Mismatch Individual (CMI); Competency Mismatch Team (CMT); Distraction (DIST); Supervision (SUP) and output probability (PROB). The sequence is sorted in descending order of probability value and with values of output probability scaled by a factor of 10.

The display mode in figure 7.36 can provide insight into the interactions between input factors. Figure 7.37 indicates details of data set with Excel ® analysis.

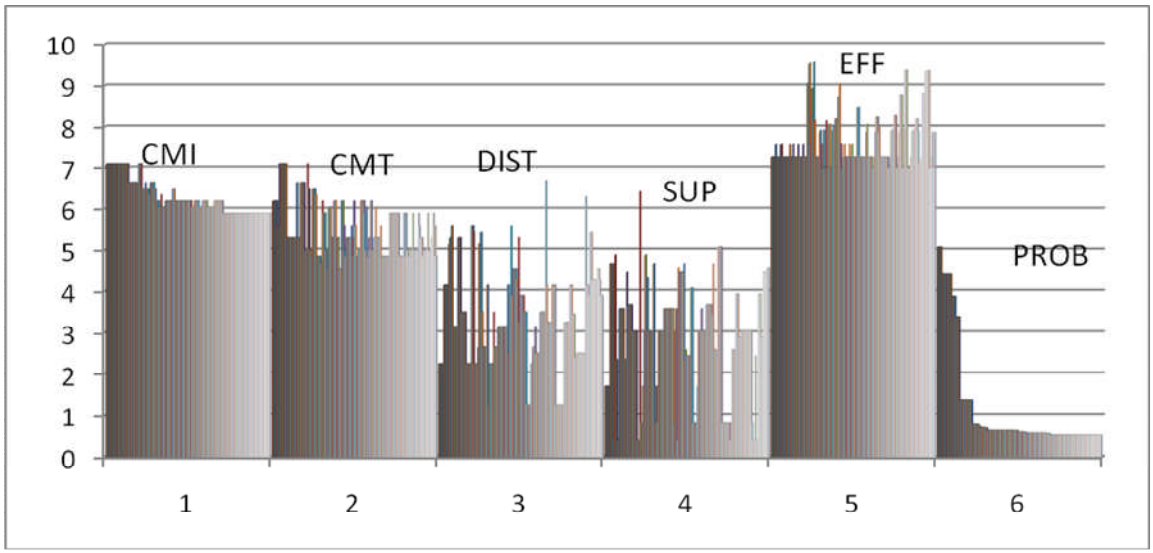

Figure 7.37 Graphical display using Excel® of sequence of events with probability events greater than 0.05 indicating values of Competency Mismatch Individual (CMI); Competency Mismatch Team (CMT); Distraction (DIST); Supervision (SUP) and output probability (PROB). Elements in each data set, e.g. nth element interact with corresponding elements in other data sets to produce the nth

element of output probability. The sequence is sorted in descending order of probability value and with values of output probability scales by a factor of 10.

The display mode in figure 7.37 provides a useful appreciation of how interactions between the various parameters produce the resulting range of output probability values. In this particular analysis, the dominant component producing the highest values of output probability appears to be the factor of competency mismatch of the individual. In addition, the relatively large values of effectiveness are possibly 'masking' the variations in values of distraction. A key feature of the risk simulation facility is identified as the relative ease with which 'root cause analysis' of adverse effects can be undertaken.

Additional levels of review can be included by extraction of additional variables which may influence the operation of specific risk evaluations. A key factor is also the level of complexity of the specific sub task being undertaken.

7.20 Type of Adverse Effects Distribution: Initial Test Data Set

Table 7.10 indicates the distribution of types of adverse effects for nursing interventions in relation to a simulated series of 9 months of test simulation data for normalised frequency of activation, weighted distribution and weighted probability per patient day stay. This confirms the initial assessment of figure 4.20 relating to gaps in series of interventions included in the initial test set.

Element Number	Type Adverse Effect	Normalised frequency	Normalised frequency (probability weighted)	Normalised probability per patient day
1	'Medication'	0.0026	0.0118	0.0182
2	'Nutrition'	0.0006	0.0087	0.0134
3	'Monitoring'	0.225	0.0745	0.1151
4	'Airway'	0.4475	0.4324	0.6679
5	'Communication to team'	0.0037	0.0065	0.01
6	'Communication patient/rel'	0	0	0
7	'Acquired infection'	0.0094	0.0091	0.0141
8	'Handover processes'	0.0064	0.0097	0.0149
9	'IV infusions'	0.0491	0.0731	0.1129
10	'Patient records & ident.'	0.0475	0.0712	0.11
11	'QS system'	0.0483	0.058	0.0897
12	'Logistics of supply'	0	0	0
13	'Pathology/patient samples'	0.02	0.0093	0.0144
14	'Blood products'	0.0005	0.0002	0.0002
15	'Radiology'	0	0	0
16	'Tissue viability '	0.022	0.029	0.0449
17	'Fluid balance'	0.0458	0.0543	0.0839
18	'Use of consumables'	0.0007	0.0005	0.0008
19	'Patient observations'	0.047	0.1144	0.1768
20	'catheters'	0	0	0
21	'Wound management '	0.0076	0.0058	0.009
22	'Enteral feeding'	0	0	0
23	'Central lines'	0	0	0
24	'Arterial lines'	0	0	0
25	'epidurals'	0	0	0
26	'analgesia'	0.0006	0.0085	0.0132
27	'Patient involvement'	0	0	0
28	'Intra cranial pressure'	0.0013	0.0005	0.0007
29	'Chest drains'	0.0041	0.003	0.0046
30	'evds'	0.0002	0.0001	0.0001
31	'Lower digestive tract'	0.0001	0	0.0001
32	'Patient/bed restraints'	0.0013	0.0095	0.0146
33	'Renal function'	0.0075	0.0056	0.0086
34	' Lumbar puncture'	0	0	0
35	'Dermatological support'	0	0	0
36	'cardioversion'	0	0	0
37	'defibrillation'	0	0	0
38	'traction'	0	0	0
39	'TPN'	0	0	0
40	'Basic patient care'	0	0	0
41	'Staff injury'	0	0	0
42	'Unit disruption'	0	0	0
43	'Patient pathway'	0.001	0.0043	0.0066

Table 7.10. Summary of distribution of types of adverse effects for nursing interventions for 9 months set of simulated data using initial test simulation sequence for normalised frequency of activation (347393 events), weighted distribution (sum of 2158.4) and weighted probability per patient day stay (total 1397.17 days).

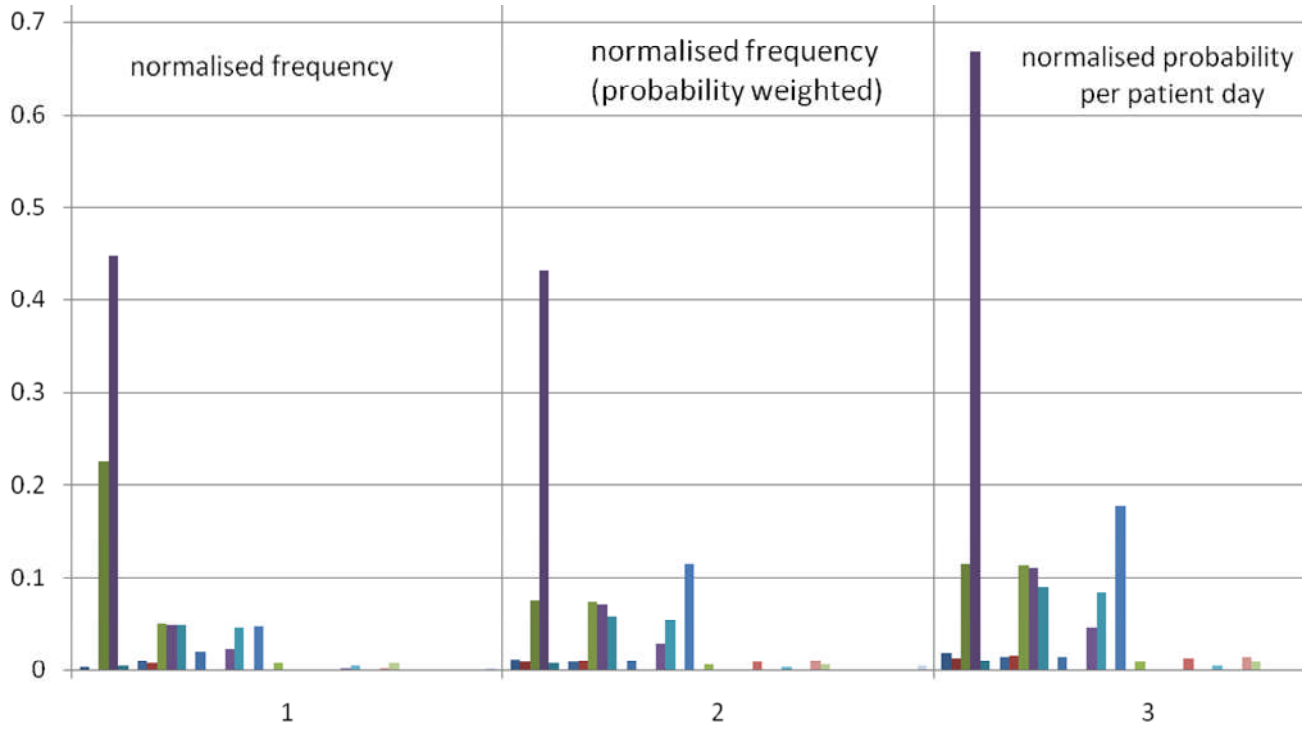

Figure 7.38. Graphical representation of data of table 7.10.

The analysis is grouping specific adverse effects together under a single ‘type’ of adverse effect reference. The more commonly referenced normalisation factor is that of ‘events per patient day’.

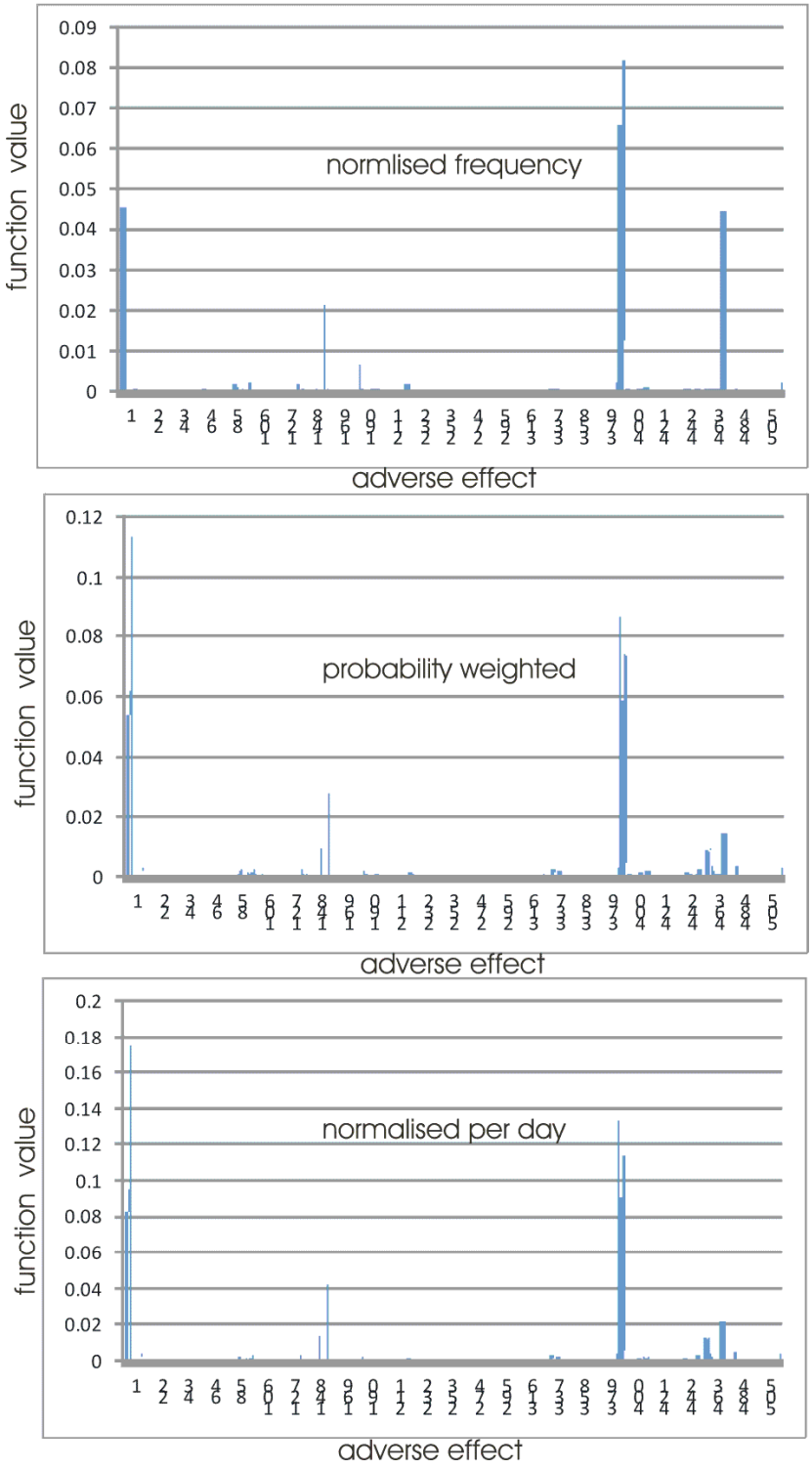

Figure 7.39. Representation of distributions of adverse effects for normalised frequency (top), normalised frequency probability weighted (middle) and normalised probability per patient day (bottom) and for data set described in table 7.10. The effect of the probability weighting is evident between distributions in top section compared with middle and bottom sections. The cluster of adverse effects around 380 relates primarily to patient ventilation.

7.21 Analysis of Risk of Adverse Effects as a Function of Time of Day

One means of investigating influence of time of day in the level of incidence of adverse effects is to display an indication of the relative risk within 5 minute 'slots' associated with 'sub competency/adverse effects'. Initially the normalised distribution of all 'sub competency/adverse effects' within the 288 time slots of a notional day is derived for a specific set of simulated clinical activity. In the second stage the normalised sum of probability values within the corresponding 288 time slots is derived for the same set of 'sub competency/adverse effects'. The ratio value is then derived of the normalised sum of probabilities divided by the corresponding normalised number of 'sub competency/adverse effects' for each time slot within the notional day. Lastly these values are normalised so that the sum of all 288 contributions within the notional day is unity.

Figure 7.40 indicates the results of this distribution for 9 months of simulated data. This indicates a local minimum of values around 11.00 am and a local maximum around 03.30 am.

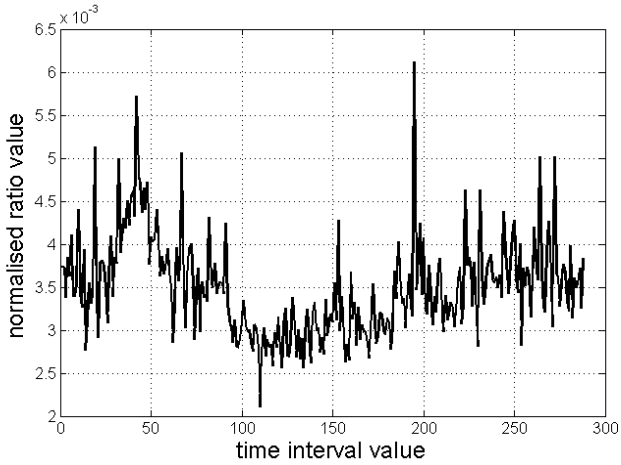

Figure 7.40. Details of measure of normalised risk as a function of time of day for all estimations of adverse effects structured within a single time of day episode and for a 9 month simulated period of interventions. (time interval value 144 = 12.00 noon).

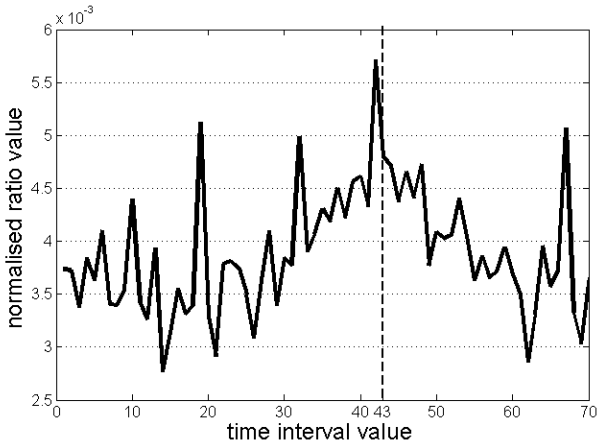

Figure 7.41. Distribution or normalised ratio values of probability of adverse effect around 03:30 am (time interval value 43).

The local maximum of values in figure 7.41 at around 03.30 am would appear to correspond with the minimum value of the 'night dip' function associated with night shift working previously referenced in section 3.10.

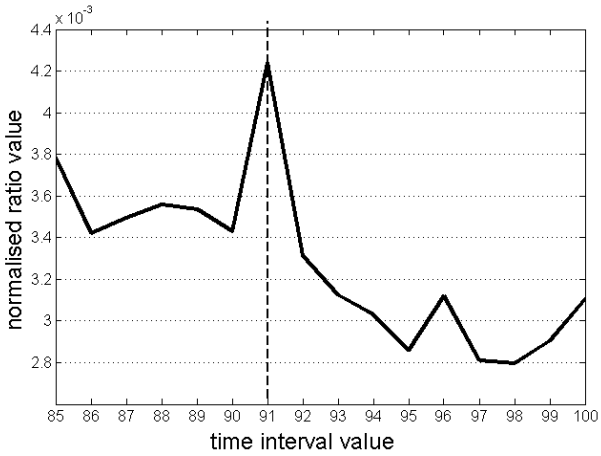

Figure 7.42. Distribution or normalised ratio values of probability of adverse effect around 07.30 am shift change (time interval value 91).

The local maximum value in figure 7.42 at around 07.30 am (time interval value 91) appears to be linked with the morning shift changeover though the effect would appear to be short lived.

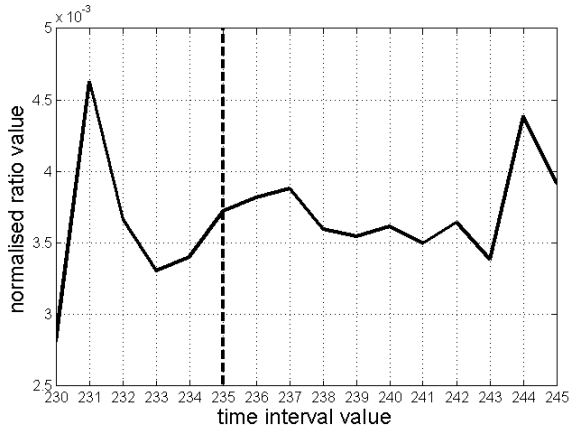

Figure 7.43. Distribution or normalised ratio values of probability of adverse effect around 07.30 pm shift change (time interval value 235).

In this data set the time of shift changeover at 07.30 pm (time element value 235) does not appear to contribute significantly to the normalised risk ratio value.

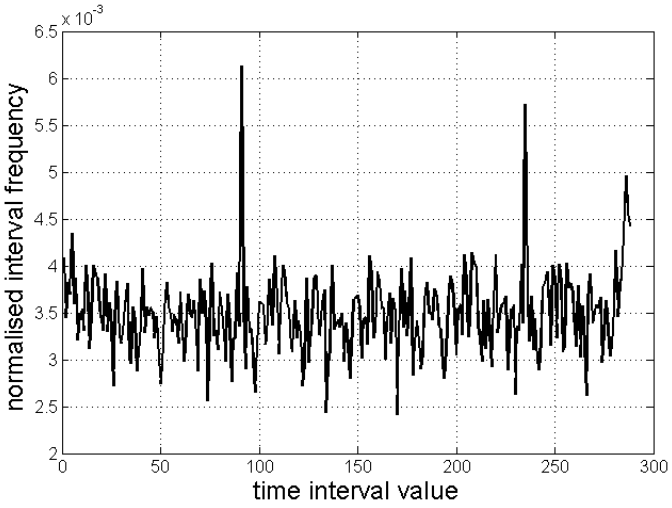

Figure 7.44. Variation of normalised frequency of 'sub competency/adverse effects' within 5 minute time intervals within generic single day time interval.

Figure 7.44 indicates a relatively similar pattern of activity of 'sub competency/adverse effects' within a generic single day time distribution. Additional activity associated with increased admission/discharges between 10.00 am and 04.00 pm (time interval values 120 and 192) as referenced in figure 4.4 would not appear to be present.

This mode of analysis of reviewing parameters within the time frame of a generic single day provides a relevant means of review of output distributions of adverse effects which are associated with parameters linked to structured time based activity such as shift handover episodes and interventions affected by 'night dip' effects of reduced individual effectiveness.

It is relevant to compare this derived distribution with the 'chronological distribution of sentinel events' derived as part of the SEE study (Valentin *et al.* 2006). Within this study, the time distribution of 584 events is referenced within the frame of time of day of occurrence. Peaks of sentinel events are reported at times which are linked with ward rounds and shift changeover, though the data is not sufficiently detailed to confirm with high levels of confidence. Interpretation of this international study requires some caution since it is the summed data from a series of 220 Critical Care Units.

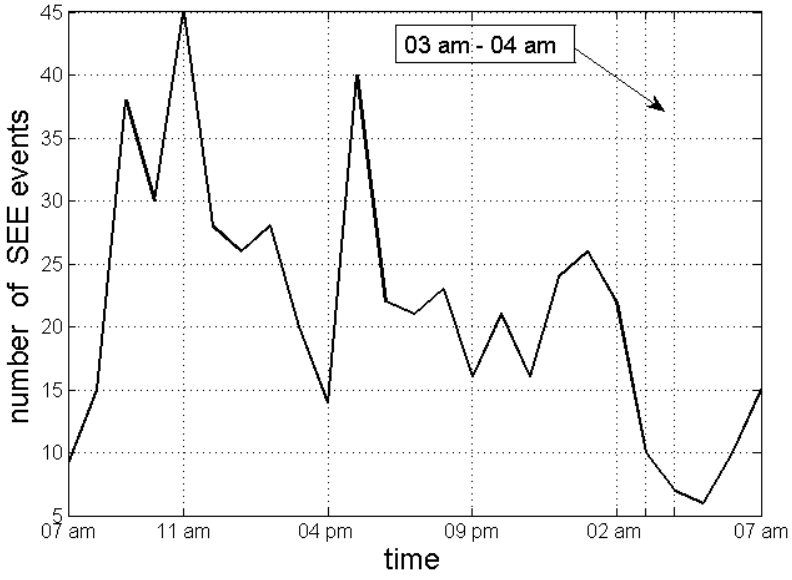

Figure 7.45. Chronological distribution of 'Sentinel events' within the SEE study after Valentin *et al.* (2006) in hour intervals.

The minimum level of SEE events appears to be coincident with the circadian 'night dip' at around 03.30 pm. It is likely, however, that this minimum of 'sentinel events' is also co-incident with minimum levels of activity and possibly minimum levels of staff supervision to report such 'sentinel events'. Figure 7.45 also requires to be interpreted in the context of general effectiveness of reporting mechanisms of 'sentinel events'.

7.22 Analysis of Relative Risk with Nurse Sub Grade Allocation

In the output log file created by the risk simulation process, the value of probability of adverse effect is associated with specific nursing co-worker sub grade value and where nursing sub-grade values as described previously in section 5.2 range from 1 to 15. A relevant output from this set of data is a normalised distribution of sub tasks as a function of sub grade of nursing co-worker as outlined in figure 7.46. This distribution is naturally highly dependent on the levels of staff selected within the roster structure of nursing co-workers and the allocation process of nursing co-workers to patients. There is no 'grade 13' within the sub grades of nursing staff within the specific staff roster used for the analysis.

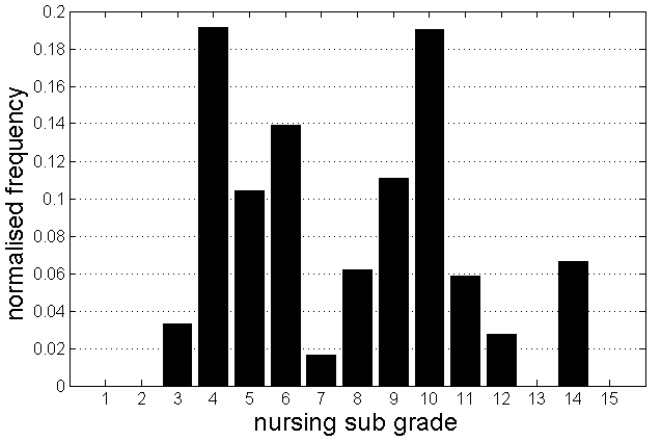

Figure 7.46. Normalised distribution of activity levels (numbers of sub tasks) as a function of sub grade of nursing co-workers for a specific roster configuration and set of simulated clinical activity (total adverse effects 63,769).

For a given simulated data set and for a specific structure of nursing competencies within a roster structure as previously referenced in table 7.5, details of normalised distribution of risk can be determined as a function of nursing sub grade. This is undertaken by determining separately for each nursing sub grade value the sum of total probabilities of adverse effects and the total number of adverse effects and deriving a relative value of probability per nursing sub group value. These values are then normalised so that the sum of all contributions over the total set of 15 possible contributions is unity.

Figure 7.47 indicates the associated distribution of normalised ratio values for the distribution referenced in figure 7.46. This indicates a reduction in ratio value for sub grades 3 to 8 consistent with competencies increasing through these sub grades. The distribution of figure 7.47 will also be influenced by the nature of tasks linked to specific sub levels, where the lowest sub bands will be allocated to least ill patients and with staff of increasing seniority more likely to be associated with interventions which are more complex and associated with higher competency requirements and higher levels of risk. This is suggested in the increase in ratio values for sub grades 9, 10 and 11. With further increase in competency, there is a trend in sub bands 12 and 14 to reduce normalised ratio values. The structure of figure 7.46 is closely dependent on the set of competencies for specific sub tasks allocated to specific nursing sub grades.

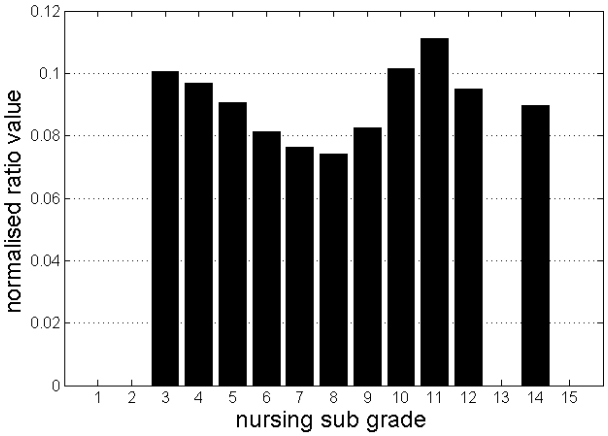

Figure 7.47. Values of normalised ratio value of probability of adverse effect as a function of nursing sub grade for specific nursing roster distribution (band 7 components included) and set of simulated clinical activity (total adverse effects 63,769).

This facility provides a means of review of relative risk of undertaking interventions as a function of nursing sub grade. The effect of competency sharing between nursing co-workers can be readily demonstrated using this mode of analysis to review distributions as a function of mix and distribution of nursing co-workers. Where there is a reduction in numbers of more senior staff, such as indicated in figure 7.48 then a 'flat' pattern of normalised ratio value is observed, indicating possibly a loss of supervisory function. There are no available clinical studies/sets of data which can be used to check against the findings of the model.

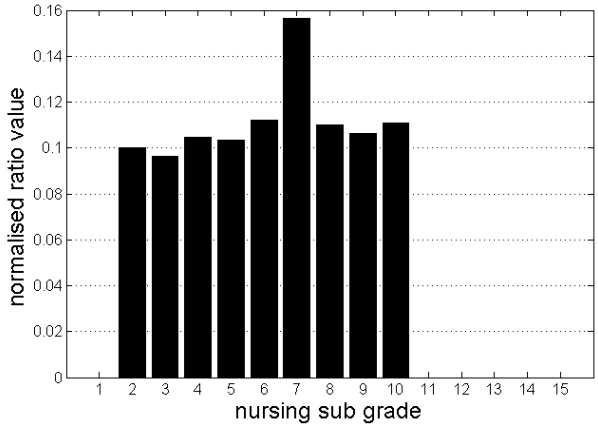

Figure 7.48. Values of normalised ratio value of probability of adverse effect as a function of nursing sub grade for specific nursing roster distribution (no band 7 components) and set of simulated clinical activity (total adverse effects 63,769).

7.23 Components of Competency Sharing, Supervision and Distraction

A framework for derivation of 'bed to bed' interactions associated with competency sharing, supervision and distraction as a function of physical bed layout has been described in section 6.14. This approach utilised fuzzy logic descriptions of key parameters of interaction and general techniques as incorporated in the construction of the 'risk engine' described in section 6.2. The risk simulation system is sensitive to variations in the values of these matrix elements which allows for minimisation of risk factors as a function of bed layout. This aspect of further work is referenced within chapter 8.

7.24 Review of Clinical Adverse Event Reporting: Critical Care Unit 2007-2009

UHCW NHS Trust monitors Clinical Adverse Events (CAEs) throughout its organisation as a means of reducing the incidence of such adverse events and generally improving patient care. A series of reports in Excel ® in time period January 2007 to July 2009 and related to patient care within the Critical Care Unit at University Hospital, Coventry was made available by the Clinical Governance Department. The specific CAE forms were not individually reviewed. The structure of these reports is listed in table 7.11.

Information Item	**Role/Description**
ID	Unique numeric CAE identifier
Incident date	Date of incident
Detail (coded)	Coded description of detail such as 'laboratory investigations', 'transfer' or 'Infection Control'
Adverse event (coded)	Coded description of type of adverse event, such as 'delay in administering medication', 'inappropriate transfer' or 'communication failure within the team'
Description	Free text description of details relating to CAE
Action taken	Free text description of action taken in relation to the CAE, including feedback from staff directly involved, issue resolution if action within CCU or action relating to other clinical groups such as Theatres and A&E.

Table 7.11. Structure of format of Clinical Adverse Event report.

Table 7.12 describes relative frequency of these events using the mapping to the set of types of adverse effects as listed previously in table 5.10 and where the relative frequency (Rel. Frq.) values indicate the number of events per 1000 patient days. Details of patient 'days' were derived from admission/discharge data for the period August 2006 to August 2008.

Code	Description	Rel. Frq.		Code	Description	Rel. Frq.
1	Medication	3.1		23	Central lines	0.31
2	Nutrition	0.21		24	Arterial lines	0.10
3	Monitoring	0.15		25	Epidurals	0.10
4	Airway	0.41		26	Analgesia	0.36
5	Communication to team	0.67		27	Patient involvement	1.03
6	Communication patient/rel	0.05		28	Intra cranial pressure	0
7	Acquired infection	0.67		29	Chest drains	0.05
8	Handover processes	0.87		30	EVDs	0.21
9	IV infusions	0.67		31	Lower digestive tract	0.0
10	Patient records & ident.	0.51		32	Patient/bed restraints	0.0
11	QS system	0.10		33	Renal function	0.0
12	Logistics of supply	0.36		34	Lumbar puncture	0.05
13	Pathology/patient samples	0.31		35	Dermatological support	0.0
14	Blood products	0.41		36	Cardioversion	0.0
15	Radiology	0.36		37	Defibrillation	0.05
16	Tissue viability	3.7		38	Traction	0.0
17	Fluid balance	0.10		39	TPN	0.05
18	Use of consumables	0.93		40	Basic patient care	2.36
19	Patient observations	0.0		41	Staff injury	0.05
20	Catheters	0.05		42	Unit disruption	0.05
21	Wound management	0		43	Patient pathway	3.39
22	Enteral feeding	0				

Table 7.12. Summary details of documented Clinical Adverse Events normalised to events per 1000 patient days of clinical activity in time period January 2007 to July 2009 and assuming an annual patient episode of 7531 days.

This indicates the dominance of effects of ‘Patient pathway’, ‘Basic patient care’, ‘Medication’ and ‘Tissue viability’. This mode of reporting of Clinical Adverse Events assigns the ‘originator’ department as the clinical department where the incident is reported. This results in a key percentage of reports arising from inappropriate actions outside the Critical Care Unit. Specific examples of this relating to ‘Patient pathway’ would include:

- Patient received directly from theatres and not from Recovery, with no CVP line or arterial line in place on admission to the Critical Care Unit.

- Lack of documentation from Neuro surgeons for patient with multiple neurosurgical injuries delays patient management in the Critical Care Unit.

- Unacceptable transfer of ill patient from Clinical Decisions Unit with no monitoring or nursing/medical escort.

Medication errors arising from outside the Critical Care Unit can also be identified based on inappropriate drugs administration, for example, in Theatres or in Recovery. Although the incidents relating to 'Airway' are few in number, these tend to equate to high levels of risk, such as the blocking of an ET tube by bronchial secretions or disconnection of a ventilator. The discipline applied to medication practice is strictly formal, where relatively minor deviations from accepted practice initiate the reporting of a CAE. Such minor deviations would include, for example, the identification of a missing single vial of Potassium Chloride in the Controlled Drug cabinet. Medication errors also include instances where prescribed medication is omitted.

The relatively large numbers of Clinical Adverse Events relating to tissue viability can also reflect instances where tissue viability issues are identified on admission from other hospitals or clinical areas within UHCW NHS Trust. The relatively large number of incidents reflects also the process of periodic patient review to identify instances of compromised patient tissue viability. It is also likely that there is a component of under reporting of Clinical Adverse Events within the Critical Care Unit.

7.25 Comparison of Data Relating to 'Adverse Effects' and 'Adverse Events'

There is a subtle difference between the two sets of data, where the distribution of adverse effects represents a distribution of probabilities where every specific adverse effect has a finite probability value between 0 and 1. By comparison, however, adverse events are either present (value 1) or absent (value 0).

The distribution of adverse effects is highly dependent on the initial mapping of interventions as part of the patient treatment process. It is also dependent on the sub structure of 'competency/adverse effect' incorporated within specific interventions. In addition, the current set of interventions are essentially those associated with nursing co-workers, so specific sets of interventions, for example associated with Radiology, would not be identified.

The comparison of the two sets of data, as outlined in figure 7.48 indicates a significant difference between the parameters values – see table 7.10 for specific adverse effect values per patient day.

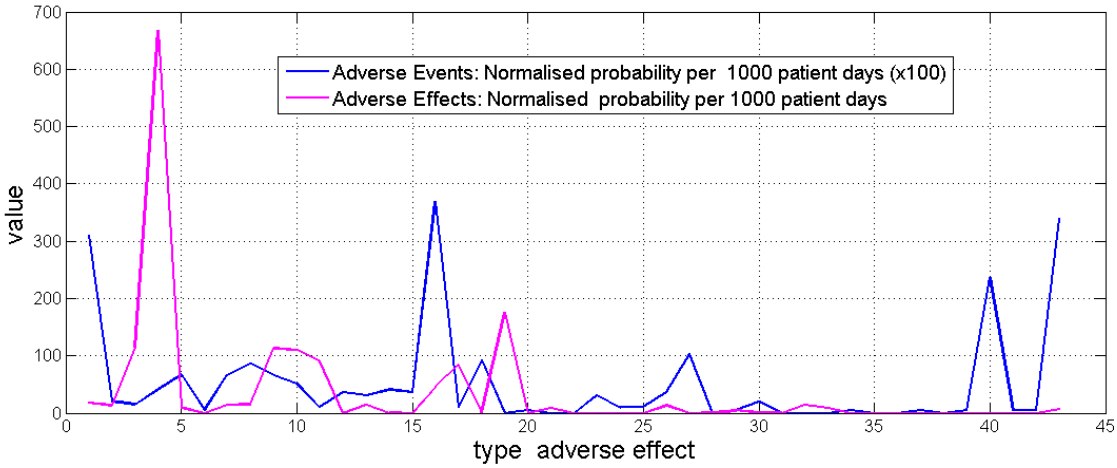

Figure 7.49. Details of values of clinical adverse events (x 100: blue) and adverse effects normalised (magenta) to activity per 1000 patient days and using classification of type of adverse effect.

The role of adverse effects is identified with quantification of risk factors within a risk modelling framework. The role of Clinical Adverse Event reporting relates to reporting based on agreed 'event characteristic' parameters and where subsequently relevant corrective and preventive measures are established to reduce likelihood of re-occurrence. It is also relevant to compare levels of Clinical Adverse Events with comparable levels reported by the SEE study (Valentin *et al.* 2006) as indicated in table 7.13.

Category	Events per 1000 patient days (SEE study)	CAEs per 1000 patient days, CCU, University Hospital, Coventry.	Adverse effect related per 1000 patient days (current research)
Lines, catheters and drains	145	0.46	5.4
Medication	105	3.1	18.2
Equipment	92	0.93	115.1
Airway	33	0.41	667.9
Alarms	13	0.15	-

Table 7.13. Approximate comparison of levels of Clinical Adverse Events with levels reported by the SEE study (Valentin *et al.* 2006) and referenced to level based on derived risk simulation of adverse effects (current research). No specific code match is indicated for 'Alarms'.

This confirms the low levels of CAE reporting relative to comparable clinical studies and the lack of value in using this information source to compare against the simulated risk sequences. Issues are also identified in reconciling the separate coding systems of the SEE study with the types of adverse effect created in the simulated risk analysis. Options also exist for selection of 'high' risk codes relating to adverse effects to indicate an event that could trigger a clinical adverse event using the

code definitions previously outlined in table 5.9. In addition comparison of measured and simulated risk patterns would benefit from mapping simulated adverse effects directly to the simplified code systems of studies such as the SEE study (Valentin 2006). This also highlights the need for standardisation in description of event criteria as referenced in the categories such as 'airway' and 'alarms' referenced in table 7.13.

A clearer verification of the risk simulation system is clearly focused on more effective means of simulating the clinical activity of patients passing through the Critical Care facility and would indicate refinement of the existing extensive software module which undertakes this function. This again emphasises the basic requirement of any risk simulation system to effectively reflect the patterns of associated clinical activity.

7.26 Observations

The process of operating the risk simulation system has allowed aspects of its characteristics to be determined, with variations in internal representation of functions within the model and also direct input of parameters such as staff competency producing specific effects on the levels of output probability of adverse effects. The general observed effects have essentially been consistent with qualitative expectations where single parameters have been altered.

The nature of the risk being determined by the risk simulation system is referenced at the level of 'adverse effects' which can relate to specific adverse clinical incidents or also be identified as the creation of a 'less satisfactory' level of patient condition which may have the potential when combined with other factors to lead to a Clinical Adverse Event. Adverse effects can also be considered as triggers which have the potential to result in Clinical Adverse Events.

Where active comparisons are made between the simulated adverse effects and frequency of occurrence of clinical incidents in the reported studies, it may be relevant to map codes directly between the adverse effects and the code structure of a specific study. In the example of the SEE study, for example, this would require a mapping to the limited set of categories referenced in table 7.13.

The more useful measure of level of incidence of incidents as referenced in table 7.13 is where activity is normalised to specific periods of clinical activity such as per 100 patient days (Valentin *et al.* (2006)) or per 1000 patient days (Jain *et al.* (2006)). A comparison of reporting frameworks has previously been described in table 5.35. The equivalent measure identified in this research is that of 'effects per patient day' as referenced in figure 7.38 and figure 7.39 where this can be in respect of a 'type of adverse effect' or a 'specific adverse effect'. In table 7.12, Clinical Adverse Events are referenced within a period of 1000 patient days. These factors can be identified using the total

number of patient days associated with a set period of simulated clinical activity. In addition, this factor will automatically take account of periods where specific beds are not occupied.

The intrinsic difference between 'adverse effects' and Clinical Adverse Events has been previously referenced. It is anticipated that the normalised frequency of 'adverse effects' will normally be greater than that of Clinical Adverse Events where the common reference framework of 'types of adverse effect' is utilised. This is based on the structuring of 'adverse effects' as being essentially contributory factors to 'adverse clinical incidents' as indicated in figure 7.50.

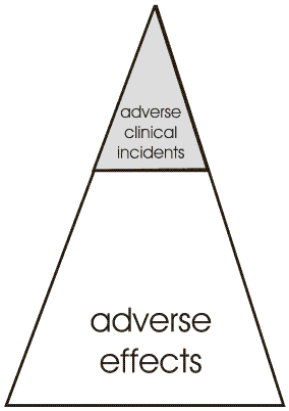

Figure 7.50. Implied relationship between adverse effects and adverse clinical incidents.

7.27 Summary

The exercising of the 'risk engine' based on subsets of values of test input parameters confirmed qualitatively the correct functioning of the risk simulation system. The specific three dimensional representations of probability functions essentially derived via the fuzzy logic functions were identified as a specific subset of a much larger set of possible functions. In addition, risk simulation results based on simulated patient activity qualitatively confirmed the expected behaviour of the model for specific parameters such as the level of nurse attendance (relating to supervision), level of requesting competency support, level of sleep deprivation, level of nursing staff competency within rostered teams, nurse handover responses, level of interaction between beds based on physical separation and level of individual effectiveness based on Circadian (night shift) functions.

The comparison between simulated risk values of a 9 month period of simulated clinical activity using 'type' of adverse effect codes and local adverse clinical incident reporting information over a two year period showed poor 'overlap' and also missing elements within the simulated set of clinical interventions. It was identified, however, that the local adverse clinical incident reporting system appears to be significantly underestimating the level of such adverse events when comparisons are

made with relevant clinical studies such as the SEE study. This confirms the essential difference between 'formal' clinical adverse events which may require extensive administrative management and resolution by senior nursing/medical staff and voluntary self reporting (no blame) schemes for reporting of more minor yet also relevant observations and for which there is little or no administrative overhead.

The analysis of activity derived from the 9 month period of simulated clinical activity and within a 'normalised' single day time frame confirmed the role of the 'night shift' effect and morning handover effect though the anticipated increase of activity between 10:00 am and 04:00 pm was not clearly evident. The analysis of activity derived from the 9 month period of simulated clinical activity and within a 'normalised' single day time frame as referenced with the results of the SEE study (Valentin *et al.* 2006) showed poor overlap which is identified as originating in part from the process of simulation of clinical interventions and possibly also reporting mechanisms within the SEE study.

This confirms the importance of mechanisms and processes to replicate as accurately as possible the level of patient activity within periods of simulated clinical activity. Possible methods to more accurately develop such techniques are referenced in chapter 8 within the context of further work.

There was some encouraging overlap between the simulated adverse effect levels and the summary categories of the SEE study through further work is required to improved clinical activity simulation, express the SEE output category codes directly from individual adverse effects and possibly utilise the level of risk structure to identify the more serious elements of adverse effects which would contribute towards clinical adverse events.

The relative distribution of risk according to rostered sub grade of nursing staff within the 9 month period of simulated clinical activity confirmed the anticipated role of more senior staff in reducing the relative risk of less experienced nursing team members though this was not validated against any established clinical study or equivalent local data set. It was identified that reporting the frequency of adverse clinical events as probability per day or per 1000 patient days provided a relevant means of comparison between the risk simulation system and the corresponding clinical literature. In the following and final chapter a further review of the research is undertaken and areas for further work are summarised.

Chapter 8: General Conclusions and Further Work

8.1 Summary and Justification of Major Contributions

The following key contributions (elements) described in this Thesis are identified as:

Element 1 The identification and implementation of the concept of expressing levels of clinical risk within a specific clinical environment with expression as finite probabilities of occurrence.

Justification: The reality of healthcare is that adverse clinical events all too readily can be expressed as probabilities of occurrence with reference to a base line level of activity - such as events per equivalent 1000 patient days. It was identified at an early stage within the research that systems for modelling clinical risk should also describe outcomes within a formal framework of determined probabilities. The remaining set of identified elements in this section describe essentially processes and mechanisms for implementation of this concept.

Element 2 Structure of patient care as a series of interventions and where interventions are described at the level of sub tasks which are associated with linked levels of competency, adverse effects and also preventive measures.

Justification: The description of interventions within the context of the role of sub tasks, linked levels of competency and preventive measures provides a structured generic framework for analysis of clinical activity. This approach is also the basis on which the method of risk simulation operates. It is identified that the method operates at a specific 'quantum' level of risk identification where the identified 'adverse effects' are at a level which cannot usefully be sub divided to other levels. This 'quantisation' of risk is identified as an approach which can also be applied within other areas of risk analysis and risk simulation. The approach of risk 'quantisation' has also made possible identification of characteristics associated with both 'sub tasks' and 'adverse effects'. In the context of 'sub tasks', for example, these can potentially be modified by competency sharing and also supervision and also described at specific levels of complexity. It is identified that the task of developing the structure of interventions is quite distinct from the practical processes of identifying specific interventions within a specific clinical setting. The identification of 'sub tasks' and 'adverse effects' confirms the reality that a single clinical intervention can be associated with more than one adverse clinical outcome.

Element 3 System for simulation of clinical activity based on admission/discharge data and analysis of clinical intervention data. This consists of two main components of admission/discharge details : date time admission and date time discharge, specialty etc. and interventions associated with specific patient admission/discharge episodes.

Justification: The process of simulation of clinical risk associated with clinical activity requires methods to create clinical interventions which closely reflect actual interventions experienced by patients. The component of simulation related to admission/discharge episodes has been adequately determined by detailed analysis of patient admission/discharge details. The component of simulation based on 'populating' patient admission/discharge episodes with appropriate interventions has been found more challenging and developed method within MathLab® programming language leads to over complex programming techniques which are highly specific to a given clinical specialty.

Element 4 Derivation of competency mismatch function to describe gap between available competence and required level of competence and implementation of concept of team competency levels.

Justification: The representation of competency levels associated with sub tasks using a linear scale and the identification of competency mismatch relative to a defined numeric level has provided a means of deriving an input parameter for operation of the 'risk engine' – as referenced in element 5. Linked with the concept of individual competency is that of 'group competency' where the maximum available competency potentially available to a team member is that of the most competent individual within the team. This allowed competency mismatch levels to be determined for each sub task within an intervention and also value of corresponding team competency mismatch as inputs to the 'risk engine'

Element 5 Development of empirical effectiveness functions to structure the 'individual effectiveness' value of clinical staff with component functions relating to circadian rhythm, physical exertion, intellectual exertion, stress, shift handover, influence of admission of patient and sleep deficit.

Justification: An extensive review of the literature relating to adverse clinical incidents in the Critical Care environment identified a range of factors influencing individual effectiveness but without any derivation of empirical functions that could be used to describe values associated with individual effectiveness. A series of empirical functions relating to circadian rhythm, physical exertion, intellectual exertion, stress, shift handover, influence of admission of patient and sleep deficit were created based on direct observations within the Critical Care environment and also with reference to the relevant literature.

Element 6 Development of ‘risk engine’ consisting of four Fuzzy transitions to calculate output probability of occurrence of specific adverse effect based on five input functions with individual effectiveness linked with distraction, individual competency mismatch linked with team competency mismatch and moderating effect of supervision

Justification: The development of the ‘risk engine’ is identified as the single most important contribution to the Thesis where in a novel implementation a finite value of probability is associated with each sub task within an intervention. The ‘risk engine’ represents an intuitive representation of interaction of parameters which reflects behavioural patterns referenced in the literature and also observed within the setting of clinical activity within the Critical Care Unit. In addition, the implementation of the ‘risk engine’ where fuzzy functions are essentially look up functions provides efficiency in processing time. The operation of the ‘risk engine’ is identified to be associated with processes of optimisation where ranges of parameters are required to be configured to lie within typical parameter ranges

Element 7 The introduction of ‘coefficients of interaction’ based on physical layout of Critical Care sub unit which identifies role of physical environment on influence of supervision, competency sharing and distraction

Justification: The identification of ‘coefficients of interaction’ based on physical layout of Critical Care sub unit which has led to the evaluation of role of physical environment on influence of supervision, competency sharing and distraction has been an unexpected but a significant outcome of the research. This confirms that the physical layout of the Critical Care Unit (and that of similar units) is contributing factors to level of clinical adverse incidents. In addition, the research has identified a method of determining such coefficients of interaction for these healthcare facilities.

Element 8 Integration of all elements into the risk simulation system listing all elements of the identified components and deriving levels of probability of adverse effects based on periods of simulated clinical activity.

Justification: While the identification of the component elements of the risk simulation system provides complexity within each element, the integration of all elements into the risk simulation system into a cohesive functioning model implemented in Matlab ® represents a significant contribution in the research and introduces associated challenges of verification of function of associated software.

8.2 General Conclusions

The research work described in this Thesis comprises the following phases:

- Development of risk model
- Determination of modes of clinical interventions/activity
- Implementation of risk model functionality
- Optimisation/tuning of characteristics of risk model functionality
- Simulation studies with the risk simulation system using simulated clinical activity
- Comparison of simulated risk with observed risk patterns
- Identification of 'preventive measures' analysis as a tool for risk reduction

A novel approach for simulation of risk in the clinical environment has been described in the Thesis with a specific focus related to risk within a Critical Care Unit, which provides a framework for clinical risk simulation based on detailed description of task activity. Such a risk simulation system is also identified as a mechanism for potentially reducing the risk of clinical systems as they are initially designed and configured, rather than operationally managed. The risk simulation model is also identified as having general applicability to other task/risk related environments.

In undertaking the various stages of the risk model development, both the challenge/benefits and difficulties/pitfalls associated with such a process have been encountered. On the plus side, for example, the simulation system can identify increased structure for elements which had previously been identified within conventional risk analysis within the clinical environment but without demonstrated linkage to clinical risk. An example of this would include the identification of team interaction, supervisory function and distraction level based on parameters linked to the design of the physical environment. Another positive outcome of such a process has been the structuring of role of preventive measures which are intrinsically linked to the structure of 'sub task/adverse effect' which is used as the foundation of the risk model. This component was intuitively identified during the process of risk model development and provides a generic supportive approach towards risk reduction strategies. It also provides the direct link between preventive measures and task activity which is not an identified method of risk reduction strategies in healthcare.

A process of risk analysis using the outlined approach in this research, coupled with appropriate determination of linked preventive measures has the potential to provide a consistent approach to risk reduction in the clinical environment. The structure of the identified risk model is also likely to be appropriate for risk reduction within other complex task/skill related work environments.

The relevant clinical literature identifies that clinical staff are only too aware of the restrictions which impact specific tasks, especially those restrictions which are apparently outside of their immediate control. Such limitations include the availability of services from other health professionals, availability of drugs/consumables, access to computerised reporting systems and effectiveness of pathology services. The inherent awareness of such factors allows them to be readily incorporated within the risk model, primarily in the context of adverse effects and preventive measures. While the risk simulation system has evolved from its core definitions, subsequent operation of the model confirms the overriding importance of the approach of structuring interventions at the level of 'sub-task/adverse effects' where the lowest level of risk components (sub competencies/adverse effects) and associated preventive measures can be identified.

The structure of the intrinsic 'risk engine' utilises fuzzy components with two parameter inputs. Where subjective parameters such as effectiveness, distraction and competency mismatch are being used as linguistic interpretations of level and degree, the linguistic sense of inputs with the fuzzy logic remains clear with two parameter inputs but would become confused with three or more inputs to derive logical relationships.

The research has indicated the requirement for effective processes to validate the functioning of programming elements within the 'risk engine' facility. This has largely been undertaken by operation of the 'risk engine' with selected input parameter values and internally held constants and with observations of sets of output values from the 'risk engine'. This has largely been derived empirically based on observations of how the model performs over a range of configurations. This is identified as an important component of any risk simulation system which uses the functionality of 'risk engine' to evaluate levels of risk of adverse effects.

The research has also identified the relevance of probability values of a specific adverse effect normalised to a specific period of patient stay such as per patient day or 1000 days. While this is a practical expression of relative probability, such a value will also tend to be relevant for the specific case mix (specialty and severity) used initially for simulation. Variants of such probability values can also be referenced for individual specialties.

While techniques for risk reduction in acute healthcare have consumed significant resources, errors continue to take place. The risk simulation approach outlined in this research is an example of another technique to improve the safety of the clinical environment. A specific focus of the technique is the engagement in detail with the clinical activity within the work environment which self identifies components of risk and preventive measures identified as contributing factors to reduce clinical risk. The research has undertaken the approach of a 'catch all' scenario where as much clinical activity as possible has been identified for inclusion within the model sequence. Less ambitious approaches of quantification of specific components of clinical activity such as medication, infusions and ventilator

support would also have been viable approaches and where published research describes the frequency of adverse outcomes within such specific areas of clinical activity. It is considered, however, that it is the development of systems of risk simulation for 'catch all' activity which presents most potential for risk reduction scenarios. The derivation of such systems, however, is complex though at a level of complexity that can be managed by currently available computer resources.

The process of risk estimation outlined within the research is potentially capable of transfer to other fields of activity. In the context of describing tasks at the levels of competency, adverse effect and preventive measure, the structure is clearly generally applicable. A relevant example is identified as rail track maintenance where interventions are described as sets of sub tasks with listed details of associated competency, adverse effect and preventive measures. Within identified work teams, a range of competencies would be identified and with the highest level associated with senior supervisory staff. Modification of individual competency mismatch would be structured by available supervisory structures. The analysis would be driven by task related activity which would be analogous to interventions structured at the clinical level. Comparable expressions for distraction and effectiveness would be derived from the nature of task activities. As with the requirement for observation within the clinical environment, appropriate simulation models would require to be developed based on analysis and observation of patterns of actual job activity. As with the structure of simulation of clinical activity, the time consuming component of the simulation process would be characterisation of the nature of activity and the time sequence of specific tasks within work teams. Within this context, the function of the 'risk engine' as structured in figure 6.1 and with the range of input/output parameter values would again seem appropriate. Effectiveness functions in the clinical applications relating to 'admission' and 'handover' would not be directly relevant though scope would exist to incorporate functions considered relevant and based on analysis of activity.

8.3 Further Work

Within the scope of derivation of the fuzzy logic look up functions that have been derived to provide the functionality of the risk simulation system, there exists the scope for significant levels of experimentation in evaluation of both variants of fuzzy logic functions and equivalent functions derived from a range of methods. It is identified that this is an area which would benefit from additional investigation and with initially variants of fuzzy logic functions providing equivalent and applicable solutions

The risk model has identified how activity within the Critical Care environment can be structured in a detailed way at the 'task' level of activity. Refinements of the identification and scheduling of clinical activity levels could, for example, be undertaken by a more focused time and motion study, either by self reporting of staff or by means of more detailed independent observer activity. There seems,

however, to be in inherent professional resistance to collect information at this level of detail. In addition, it is technically possible to identify 'person positioning information' based on RFID technology where the physical location of staff can be continuously monitored to identify percentage of time at the patient bedside. Again, there may be difficulties in obtaining ethical approval for research involving this level of personal information but it is identified that such information has the potential to significantly improve processes of simulation of staff utilisation.

A key achievement of the research has been to demonstrate the implementation of the model within a stable programming environment where complex information flows can be reliably processed. There is perhaps a differentiation between the level of complexity which a programming environment can reliably handle and a level of complexity at the human level which can be reliably designed, implemented and verified. With the implementation of a specific level of model complexity, this process has identified areas for further refinement of the model to increase its general level of flexibility. In terms of sleep deprivation, for example, it would be possible to include a level of sleep deprivation applied to specific individuals and which varied with the day sequence number of period of duty within a sequence of days of duty on dayshift or night shift. This would more effectively replicate the pattern of progressive sleep deprivation during active shift working.

The element of long term factors of individual effectiveness has been referenced but not specifically implemented in the risk model. Such functions would have correspondence with processes of individual burnout referenced by Iacovides *et al.* (2003). Based on the existing levels of complexity identified within the programming structures, it would be possible to implement this function where selected staff members are associated with a time varying function of individual effectiveness linked to long term stress factors within the period of simulation of clinical activity.

The research associates considerable importance with elements of physical environment related to factors of sharing of competency within a team, supervision levels and distraction. As increased physical separation decreases the interaction between beds, this will tend to reduce competency sharing and supervision as negative effects and also decrease distraction element which is a positive effect. For designers of Critical Care environments, the challenge is to structure these functions to minimise the identified associated risk components and maximise benefits of increased team sharing and supervision. In this context, a process is identified in section 6.14 to allow evaluation of associated matrix parameters as referenced in tables 6.13 and table 6.15. The structuring of these algorithms identifies specific areas of research for comparative evaluation of these parameters within the Critical Care community and also within the field of architectural design of hospitals. This matches with the growing awareness in health system of 'lean' systems where the physical environment is designed around work processes to optimise levels of work effectiveness and in consequence reduce levels of risk.

The risk simulation model has identified the role of physical environment in influencing relative factors of competency sharing, levels of supervision and distraction. In general factors which improve competency sharing and supervision will provide for increased distraction. This identifies that further work is appropriate to indentify factors which can be undertaken in physical layout designs to optimise the positive effects of competency sharing and supervision without proportional increase of distraction levels.

The research has identified individual effectiveness as a being influenced by a range of effectiveness functions, and where the default value presented to the 'risk engine' is that of the minimum value of the function values. Section 6.15 develops a structure using fuzzy logic to implement a linguistically consistent model for combination of the component functions to derive a single output risk factor. It is identified that further work at the level of operational research is required to review/validate the derivation of a single 'representative' value of effectiveness function and in general review/investigate the role of individual effectiveness functions.

Considerable effort has been directed to structuring patterns of interventions which correspond as closely as possible with actual work processes within the Critical Care unit. The results of current risk simulation studies confirms the internal resilience of the 'risk engine' design and structure but identifies further refinement is necessary in structuring of the referenced interventions with specific patient episodes. This is identified from observations of 'missing' interventions within the set of known clinical activity. This confirms the importance of deriving a sequence of simulated interventions which corresponds as closely as possible with the activity of the identified clinical area. The effective description of interventions relating to patient treatment also remains at the core of more general programmes of risk reduction within patient pathways.

The implantation of the risk model has involved the creation of a diverse set of data arrays, the majority of which have been implemented through the use of Excel ® spreadsheets. It is identified that a useful development in respect of further work would be to structure an information tool that would allow the creation a diverse set of data files to fully support the requirements of the risk engine system.

It is identified that the risk model described in the Thesis is one where 'primary' 'adverse effects' are described and which arise out of direct identification of possible outcomes. Further work is required to identify mechanisms where one or more 'primary' types of adverse effects combine to give rise to 'secondary' types of risk.

In addition, standardisation of system of classification of clinical adverse events would benefit further research in this area.

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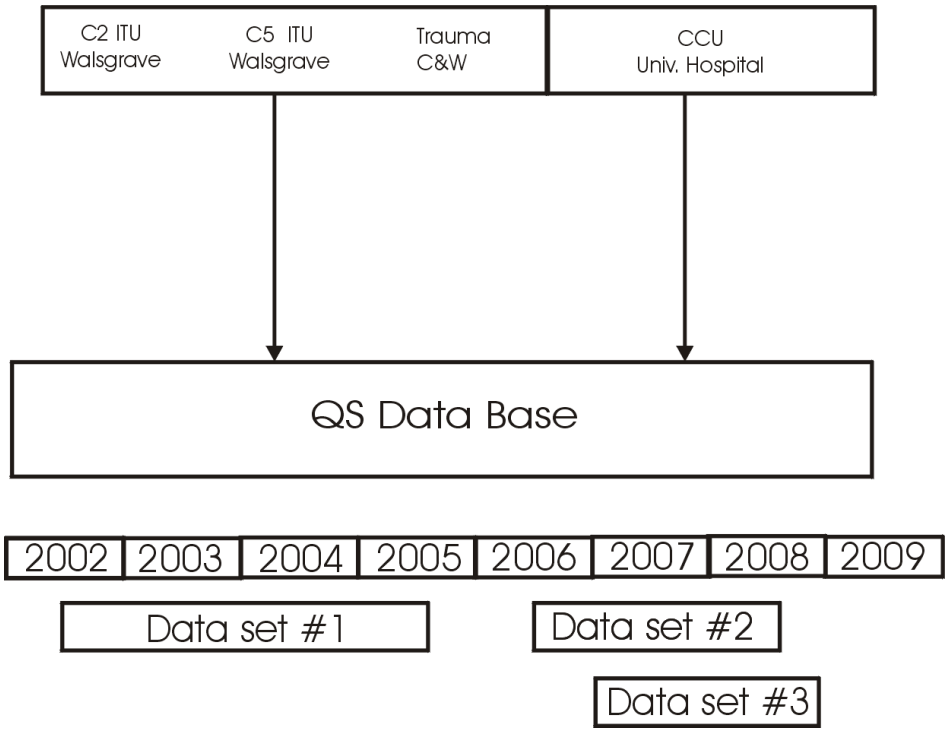
Appendix 1: Summary of Data Structures



Detail of sequences of data sets derived from the QS data base system. Data sets #1 and #2 contain summary details of individual patient discharge episodes – with inclusion of summary details of level of clinical care and associated interventions. Data set #3 contains a full set of TISS activity per patient episode.

Appendix 2: Core TISS Elements

Ref. No.	TISS Description	Ref. No.	TISS Description
1	TISS-Hourly Vital Signs	21	WTISS-excessive diarrhoea
2	TISS-Hourly Neuro Vital Signs	22	WTISS-stoma care
3	WTISS-less than hrly neuro obs	23	WTISS-routine dressings (wound)
4	TISS-ECG Monitoring	24	WTISS-multiple dressing changes
5	WTISS-oximetry	25	WTISS-wound irrigation/debride.
6	TISS-Measure Cardiac Output	26	WTISS-Tracheostomy care
7	WTISS-intake/output	27	WTISS-bed
8	TISS-Peripheral IVs	28	WTISS-patient restraints in situ
9	WTISS-triple/quad luman CVP line	29	WTISS-isolation of patient
10	TISS-Arterial Line	30	WTISS-pressure sore
11	TISS-Pulmonary Artery Catheter	31	WTISS-chest Xray
12	WTISS-epidural	32	WTISS-Routine blood specimens
13	WTISS-P.C.A.	33	WTISS-Multiple ABGS
14	TISS-Intracranial pres monitor	34	WTISS-Special Lab Tests
15	TISS-Urinary Catheter	35	WTISS-microbiology
16	TISS-Chest Tubes	36	WTISS-Ultrasound/echo/EEG
17	WTISS-drainage tubes -wound	37	WTISS-Diag. Proc. outside ITU
18	WTISS-change EVD	38	WTISS-urine analysis
19	WTISS-NG tube enteral feeds	39	WTISS-stable/unstable dialysis
20	WTISS-enema	40	WTISS-CVVH

Table A2.1 TISS data set - elements 1 to 40

Ref. No.	TISS Description
41	TISS-Peritoneal Dialysis
42	WTISS-op whilst on ITU
43	WTISS-Endoscop/Bronchoscopy
44	WTISS-New trach mini trach
45	WTISS-Pleural Tap
46	WTISS-Paracentesis
47	WTISS-Pericardial Tap
48	WTISS-Lumbar puncture
49	w CCMDS Liver support
50	w CCMDS Dermatological support
51	WTISS-Active AV Pacing
52	WTISS-Standby Pacemaker
53	TISS-Cardioversion-Arrhythmia
54	WTISS-Arrest/defib
55	w arrest record complete
56	TISS-Lavage of Acute GI Bleed
57	WTISS-induced hypothermia
58	TISS-Orthopedic Traction
59	WTISS-Continuous Drug Infusion
60	TISS-Antibiotics IV
61	WTISS-Intermittent IV drugs
62	WTISS-Stat IV drugs
63	TISS-Active Diuresis
64	WTISS-Renal dose dopamine
65	TISS-Vasoactive Drug Infusion
66	TISS-Anticoagulation
67	WTISS-Thrombolytic therapy
68	TISS-Acute Digitalization<48hrs
69	WTISS-Antiarrhythmia infusion
70	TISS-Concentrated K+ Infusion
71	WTISS-Metabolic imb. treatment
72	WTISS-Electrolyte imb. treatment
73	WTISS-Arterial Infusion
74	WTISS-Fluid replacement
75	TISS-Pres-activated Bld Infusion
76	TISS-Platelet Transfusions
77	WTISS->5units blood products
78	WTISS-Central TPN/vitrimix
79	WTISS-peripheral TPN/Intralipid
80	TISS-Rx Seizures/Meta Enceph
81	TISS-Nasal/Oral Intubation
82	WTISS-Nasopharyngeal suctioning
83	WTISS-CMV/SIMV/IMV
84	WTISS-spont/CPAP
85	WTISS-Oxygen
86	WTISS-Physiotherapy
87	WTISS-Nebulised drugs

Table A2.2 TISS elements in series 41 to 87

Appendix 3: Expanded TISS elements

TISS No.	TISS Description	Intervention Reference	Description/mode
1	TISS-Hourly Vital Signs only	11	Implement hourly
2	TISS-Hourly + Neuro Vital Signs	21	Implement as required
4	TISS-ECG Monitoring	41	Implement all patients
5	WTISS-oximetry	51	Implement all patients
6	TISS-Measure Cardiac Output	61	identify requirement (medic)
		62	implement procedure (ventilator type)
		63	Implement procedure (arterial waveforms)
		64	Observe and interpret waveforms
		65	end of activity
7	WTISS-intake/output	71	Measure/record/manage fluid balance (nurse)
		72	Interpret fluid balance (medic)
		73	Interpret fluid balance (nurse)
		74	Alteration patient fluid balance (nurse)
		74	End activity
8	TISS-Peripheral IVs	81	identify requirement
		82	peripheral line establish/replace (nurse)
		83	peripheral line establish /replace (medic)
		87	Remove IV site (nurse)
		88	End of activity
9	WTISS-triple/quad luman CVP line	91	Establish/replace CVP line (medic)
		93	Positional check x-ray CVP line
		96	Remove CVP line/End of activity
10	TISS-Arterial Line	101	establish arterial line arm (medic)
		102	Establish arterial line leg (medic)
		105	Remove arterial line / end activity
12	WTISS-epidural	121	maintenance mode
		122	Replace drug reservoir
		123	Removal catheter/end activity
13	WTISS-P.C.A.	131	identify requirement
		132	Establish PCA
		133	Replace PCA
		134	Remove PCA/end activity

Table A3.1. set of expanded TISS based interventions (group elements 1 – 13).

TISS No.	TISS Description	Intervention Reference	Description/mode
14	TISS-Intracranial pres monitor	141	Insert bolt (neurosurgeon/ccu medic)
		142	Observe IC pressure (nurse)
		143	Monitor condition sensor system
		144	Replace sensing element
		145	Remove bolt/end activity (medic)
15	TISS-Urinary Catheter	151	female insertion - (nursing)
		152	male insertion – (medical)
		155	female remove (nursing)/end activity
		156	male remove (medical) / end activity
16	TISS-Chest Tubes	161	identify requirement
		162	Insert chest drain (medic)
		164	Change bottle – chest drain (nurse)
		165	Observe drain chest tube
		166	Remove chest tubes/end of activity
17	WTISS-drainage tubes -wound	171	identify requirement wound drainage
		172	Insert wound drainage
		173	Observe condition wound drainage (hourly to 4 hourly)
		174	Replace wound drain bag
		175	Remove wound drain/end activity
18	WTISS-change EVD	181	identify requirement
		182	Initiate procedure (medic)
		183	Observe condition EVD hourly and record volume (nurse)
		184	Remove EVD/end activity
19	WTISS-NG tube enteral feeds	191	Initiate enteral feeding (nurse)
		192	x-ray confirmation NG placement
		193	Insert NG tube only (medic)
		194	Check pH of stomach sample
		196	Stop enteral feeding
		197	Remove NG tube/end activity (nurse)
20	WTISS-enema	201	identify requirement
		202	Undertake enema
		203	End activity

Table A3.2: set of expanded TISS based interventions (group elements 14-20).

TISS No.	TISS Description	Intervention Reference	Description/mode
21	WTISS-excessive diarrhoea	211	Manage excessive diarrhoea
		212	End activity
22	WTISS-stoma care	221	CCU nurse stoma management (once per 3 days)
		223	Observe condition (4 hourly)
		225	End activity
23	WTISS-routine dressings (wound)	231	Routine dressing change
		233	End activity
24	WTISS-multiple dressing changes	241	Multiple dressing change
		244	End activity
25	WTISS-wound irrigation/debride.	252	Wound irrigation
26	WTISS-Tracheostomy care	261	Tracheotomy care (daily)
		262	Suction care (variable frequency)
		267	End of activity
27	WTISS-bed	271	identify bed required
		272	set up bed normal
		273	set up bed specialist
		274	Move patient (4 hourly)
		275	remove bed specialist
28	WTISS-patient restraints in situ	281	identify need for patient restraint
		282	establish patient restraint
		284	End activity
29	WTISS-isolation of patient	291	identify need for isolation
		292	follow isolation protocol
30	WTISS-pressure sore	301	assess risk of pressure sore
		302	Observe at risk sites (daily)
		303	Dressing change - bed sores
		305	End activity
31	WTISS-chest Xray	312	radiographer component
		313	Clinical review x-ray
		314	Interpretation NG tube
		315	Interpretation of central line – x-ray
		316	Interpretation of trachy tube – x-ray
		316	End activity

Table A3.3 . set of expanded TISS based interventions (group elements 23-31).

TISS No.	TISS Description	Intervention Reference	Description/mode
32	WTISS-Routine blood specimens	321	Bloods (am screen & admission)
		322	Determine cross match
		323	Determine clotting factor
		324	Request liver function test
		325	End activity
33	WTISS-Multiple ABGS	331	Blood gases & interpret
34	WTISS-Special Lab Tests	341	to be expanded
35	WTISS-microbiology	355	Screen on admission MRSA/cleb
		356	Screen on discharge MRSA/cleb
		357	Screen on 7 days MRSA/cleb
		358	Prescribe antibiotic (medic)
		359	End activity
36	WTISS-Ultrasound/echo/EEG	361	radiologist ultrasound
		362	neurophysiologist EEG (neuro)
		363	clinical assessment (neuro)
37	WTISS-Diag. Proc. outside ITU	371	accompany patient CT/MRI
		372	End activity
38	WTISS-urine analysis	381	Test on admission
		382	End activity
40	WTISS-CVVH	402	Initiate CVVH procedure
		403	Monitor CVVH parameters
		404	End activity
43	WTISS-Endoscopy/Bronchoscopy	431	identify need for endoscopy/bronch
		432	undertake procedure (endoscopy)
		433	undertake procedure (bronchoscopy)
44	WTISS-New trach mini trach	442	Insertion external trachy - (medic)
		446	removal of trachy
		447	Insertion mini trach
		449	remove mini trach
45	WTISS-Pleural Tap	452	undertake procedure (Radiologist)
		453	undertake procedure (CCU medic)
		454	End activity
48	WTISS-Lumbar puncture	482	undertake lumbar puncture and interpret findings
		486	End activity

Table A3.4. set of expanded TISS based interventions (group elements 32-48).

TISS No.	TISS Description	Intervention Reference	Description/mode
50	w CCMDS Dermatological support	502	undertake procedure (Drmatologist)
		503	Monitor dermatological condition (nurse)
		504	End activity
51	Medication - focus	511	Review patient medication on admission (medic)
		512	Review patient medication on admission (Pharmacist)
		513	Review patient medication - routine (Pharmacist)
		514	Prescribe and administer drug
		515	Prescribe drug only
		516	Case review medication
		517	Review patient antibiotics (Microbiologists)
		518	End activity
52	Drug Round Activity	521	Identify Routine drug round activity
		522	Administration of drug within drug round (specific drug)
		523	Administration of IV infusion (syringe driver)
		524	Administration of IV infusion (volumetric)
		525	Administration of drug (immediate)
		526	Respond to infusion alarm (syringe driver)
		527	Respond to infusion alarm (volumetric)
		528	End activity
53	TISS-Cardioversion-Arrhythmia	532	undertake procedure cardiov.
		533	End activity
54	WTISS-Arrest/defib	541	undertake defibrillation
		542	End activity
57	WTISS-induced hypothermia	572	undertake procedure
		573	Observe core body temperature
		574	End activity
58	TISS-Orthopedic Traction	581	identify traction requirements (Orth)
		582	implement requirements (Nursing)
		583	Monitor traction process (nurse)
		584	End activity
59	WTISS-Continuous Drug Infusion	591	Initiate continuous drugs
		595	End activity
60	TISS-Antibiotics IV	601	Initiate antibiotic treatment
		606	End activity - antibiotics
61	WTISS-Intermittent IV drugs	611	Initiate int IV drugs
		616	End activity

Table A3.5. set of expanded TISS based interventions (group elements 50-61).

TISS No.	TISS Description	Intervention Reference	Description/mode
62	WTISS-Stat IV drugs	621	Initiate STAT IV drugs
		624	End activity STAT IV drugs
63	TISS-Active Diuresis	632	implement procedure
		633	End activity
65	TISS-Vasoactive Drug Infusion	652	Implement procedure vasoactive infusion
		653	End activity
66	TISS-Anticoagulation	662	implement procedure - anticoagulation
		663	Clotting screen (anticoagulation)
		664	End activity
67	WTISS-Thrombolytic therapy	672	Implement Clotting screen (thrombolytic)
		673	End activity thrombolytic therapy
69	WTISS-Antiarrhythmia infusion	691	implement Antiarrhythmia infusion
		693	End activity
70	TISS-Concentrated K+ Infusion	702	implement procedure conc K+ infusion
		703	K level monitor (K infusion conc)
		704	End activity
71	WTISS-Metabolic imb. treatment	712	implement procedure metab.imb.
		713	pH monitor (metabolic)
		714	End activity
72	WTISS-Electrolyte imb. treatment	721	identify requirement
		722	implement procedure
		723	Electrolyte monitor (elect imb)
		724	End activity
74	WTISS-Fluid replacement	741	identify requirement
		742	implement procedure
		743	End activity
75	TISS-Pres-activated Bld Infusion	752	Obtain cross match
		753	implement procedure bld transfusion – pres activated
		754	End activity
76	TISS-Platelet Transfusions	761	Evaluate requirement for platelet transfusion
		762	Implement procedure – platelet transfusion
		763	Obtain clotting screen
		764	End procedure

Table A3.6. set of expanded TISS based interventions (group elements 62-76).

TISS No.	TISS Description	Intervention Reference	Description/mode
77	WTISS->5units blood products	772	implement procedure
		773	Obtain cross match
		774	Monitor patient Hb
		775	End activity
78	WTISS-Central TPN/vitrimix	784	Prescribe TPN (Diet)
		785	Prescribe TPN (Medic)
		786	Review TPN (Diet))
		787	Implement TPN (nurse)
		788	Monitor TPN (nurse)
		789	End activity
81	TISS-Nasal/Oral Intubation	811	Intubate (oral)
		812	Intubate (nasal)
		815	End activity/remove (oral)
		816	End activity/remove (nasal)
82	WTISS-Nasopharyngeal suctioning	821	Initiate Nasoph. suctioning
		822	Routine suction episode
		823	End activity
83	WTISS-CMV/SIMV/IMV	832	implement procedure
		833	Respond ventilation alarm & observe
		834	Patient ventilation care (suct etc.)
		835	Cease ventilation episode
84	WTISS-spont/CPAP	841	identify requirement
		842	implement procedure
85	WTISS-Oxygen	852	implement procedure (ventilator)
		853	implement procedure (non-ventilator)
		854	Monitor /adjust O2 concentration & humidification
		855	End activity
86	WTISS-Physiotherapy	861	identify requirement
		862	implement procedure
		863	End activity
87	WTISS-Nebulised drugs	872	Implement nebulised drugs
		873	Monitor nebulised delivery
		874	End activity

Table A3.7. set of expanded TISS based interventions (group elements 77-87).

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Appendix 4: General Nursing Activity

Gen No.	General Description	No.
1	GEN_Nurse handover_ON_Shift	1011
2	GEN_Nurse handover_OFF_shift	1021
3	GEN_Pain_management_assess	1031
4	GEN_oral hygeine	1041
5	GEN_clean_down_bed_equipment	1051
6	GEN_assist_food_drink_patient	1061
7	GEN_bed_bath_patient	1071
8	GEN_cope_disruptive_patient	1081
9	GEN_Admit_patient_nursing	1091
10	GEN_Initiate_QS_record	1101
11	GEN_weigh_patient	1111
12	GEN_accompany_external_invest.	1121
13	GEN_discharge patient_survival	1131
14	GEN_discharge_patient_non_survival	1141
15	GEN_Structure_care _plan	1151
16	GEN_Communicate_care_plan	1161
17	GEN_basic_monitoring_establish	1171
18	GEN_patient_warming	1181
19	GEN_respond_to_vent_alarm	1191
20	GEN_respond_to_monitoring_alarm	1201
21	GEN_review_admission_notes	1211
22	GEN_update_patient_notes	1221
23	GEN_respond_infusion_alarm	1231
24	GEN_set_up_humidifier	1241
25	GEN_Aeseptic_technique	1251
26	GEN_Barrier_nursing	1261
27	GEN_Discharge_planning surv	1271
	GEN_Discharge_planning non surv	1272
28	GEN_Moving_Handling_Patient	1281
29	GEN_Nutritional_support	1291
30	GEN_Blood_Glucose_Management	1301

Appendix 5: Staff Tables

Staff Group	Grade Structure	Grade Code
Nursing:	Band 8b(Matron) Band 7 (sister) Band 6 (senior) Band 5 (Entry Grade)	1
Medical Staff	Consultant Registrar Senior House Officer	2
Radiographer	Staff Grade	3
Pharmacist	Senior Grade Staff Grade	4
Physiotherapist	Senior Grade Staff Grade	5
Dietician	Senior Grade Staff Grade	6
Microbiologist	Consultant Registrar Senior House Officer	7
Radiologist	Consultant Registrar Senior House Officer	8
Dermatologist	Consultant Registrar Senior House Officer	9
Orthopaedic	Consultant Registrar Senior House Officer	10

Table A5.1 Summary of staff types that can have involvement within a typical critical care environment.

Appendix 6: Internal Functioning of Mamdani Fuzzy Functions

1 Introduction

The process of risk estimation of adverse effects is identified as being derived using the Mamdani Fuzzy function (Mamdani and Assilian, 1975) outlined in chapter 6. The characteristics of this particular function were analysed in more detail in this appendix in order to identify specific factors that could have relevance for the use of the function within the identified 'risk engine'.

Values of Competency Mismatch and Effectiveness were assigned randomly as:

$$Cm(hh)=0.9+8.7.rand(1) \quad \text{(A6.1)}$$

$$Eff(hh)= 2.6+6.9.rand(1) \quad \text{(A6.2)}$$

Where Cm(hh) is Competency Mismatch of element hh, Eff(hh) is associated Individual Effectiveness and hh is in range 1,1000. A specific rule system as outlined in table A6.1 was used. No configuration of the MatLab® random number functions was undertaken.

Rule Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Competency Mismatch	5	5	5	5	5	4	4	4	4	4	3	3	3	3	3	2	2	2	2	2	1	1	1	1	1
Effectiveness	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Output	3	4	4	5	5	3	3	4	4	4	2	2	3	3	2	1	2	2	2	2	1	1	1	1	1

Table A6.1. Rule table for output rule firing based on Competency Mismatch and Individual Effectiveness.

Each pair of input values fires on average 3.2 states (3200 from 1000 input values).

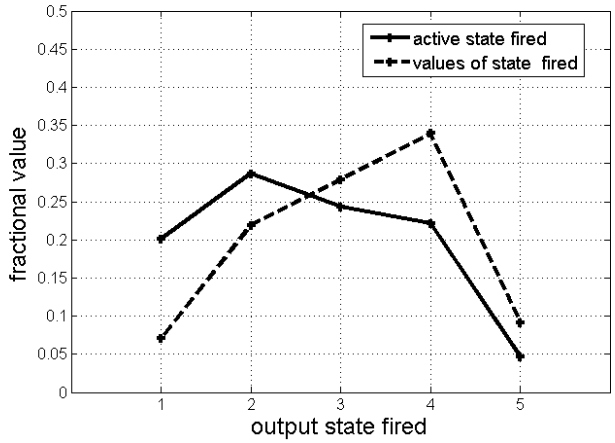

Figure A6.1. Summary distribution of relative frequency of output state derivation and also output defuzzified value for each state that fires.

Figure A6.1 outlines characteristics of output states selected as a function of input parameter values.

Figure A6.2 indicates the corresponding distribution of defuzzified values for each set of input values with interval value of 0.1.

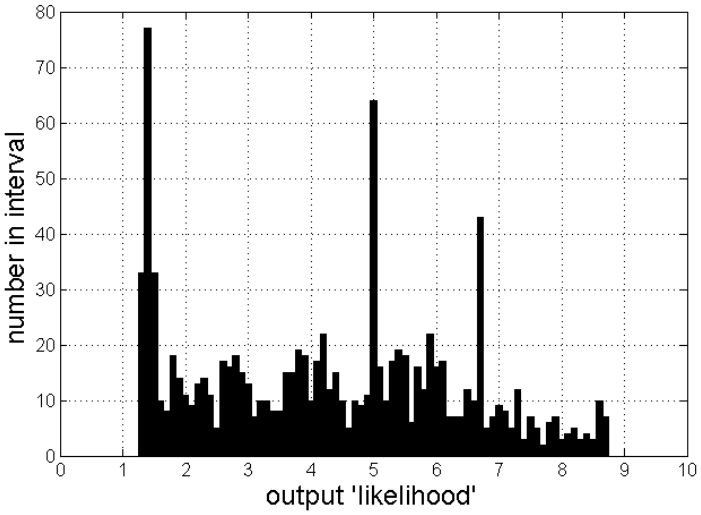

Figure A6.2. Corresponding distribution of defuzzified value for each set of input values with interval value of 0.1 for output ‘likelihood’.

The input space of variables is this example is set to activate all rules within the rule matrix. This indicates maximum and minimum values of output ‘likelihood’ determined by the structural nature of the Mamdani fuzzy function in its trapezoidal implementation.

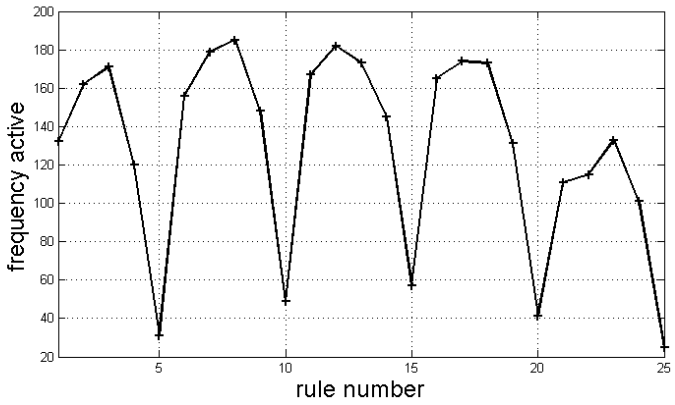

Figure A6.3 Corresponding frequency of rule activation for the identified data set in equation A6.1.

Figure A6.3 indicates the corresponding frequency of rule activation. This pattern is established by the overlap of random numbers generated the selectivity of states of the input fuzzy functions.

A modified set of input function data was also defined as:

Cm(hh)=1.0 + 5.4.rand(1) (A6:3)

Eff(hh)= 1.6 + 4.4.rand(1) (A6:4)

This created a more restricted set of input parameters values as indicated in figure A6:4.

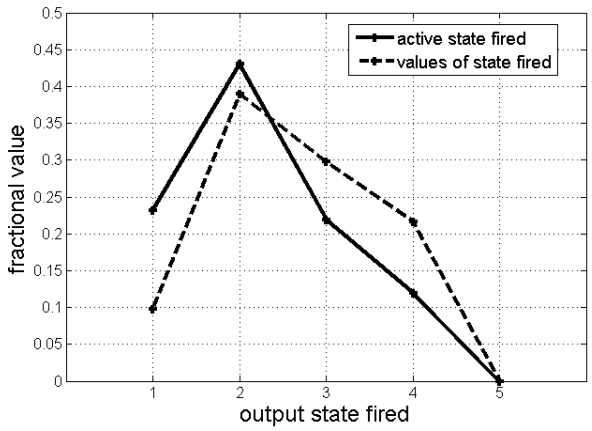

Figure A6.4. Summary distribution of relative frequency of output state derivation and also output defuzzified value for each state that fires for reduced range of values of input values.

Figure A6.5 indicates the corresponding range of values of output 'likelihood' based on set of input parameters of reduced value range. The maximum value of output likelihood is this thus reduced. This also corresponds with non-firing of rules 1 to 6 in figure A6.6.

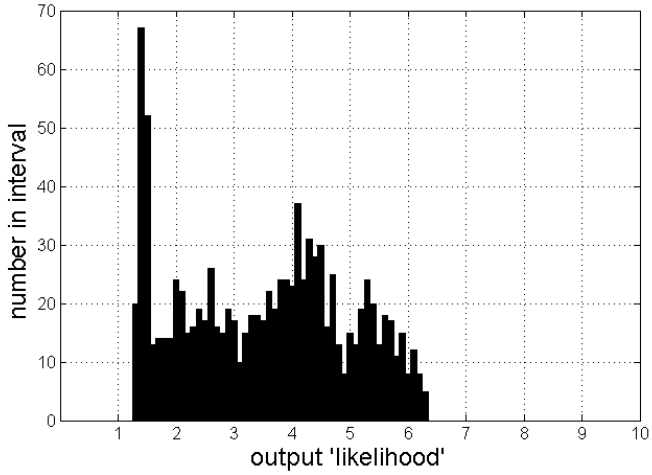

Figure A6.5. Corresponding distribution of defuzzified value for each input value of Cm(hh) and Eff(hh) for A reduced field of values.

Figure A6.6 identified corresponding frequency of rule firing for the reduced set of input values.

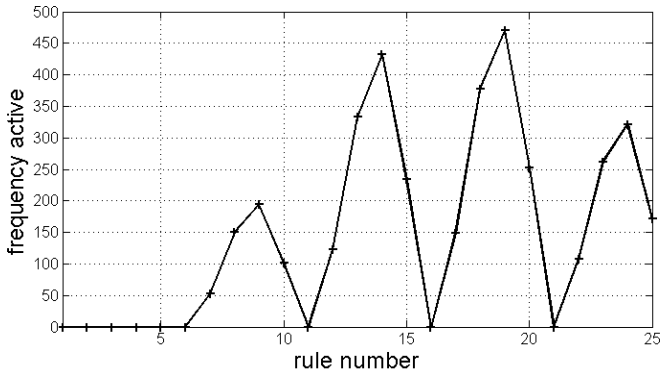

Figure A6.6. Rule distribution for data set for reduced range of input parameters.

These observations generally confirm the characteristics of the functioning of the Mamdani fuzzy function utilized for implementation of Fuzzy logic within the ‘risk engine’ structured in figure 6.3.

The complexity of the ‘risk engine’, however, is identified to relate to the utilisation of up to four of such functions to determine the output likelihood of adverse effects.

Appendix 7: Elements of Risk Simulation in Other Clinical Areas

1 Introduction

One of the areas identified for future work was that related to application of the risk model within other clinical areas. Specific summary overviews of a range of clinical areas are identified.

1.1 Accident and Emergency Department

The environment of the Critical Care Unit characterises relatively low levels of patient throughput but with a wide range of patient interventions in a multi-specialty environment. This is contrasted by activity within the Accident and Emergency department where there is a much higher patient throughput but typically a reduced level and number of patient interventions. In addition, the interventions are typically less complex and with a priority for screening patient condition and/or stabilising patient condition prior to referral elsewhere. The scope of risk simulation within this clinical environment is identified to be essentially similar with the requirement to identify the specific interventions with associated sub competencies and adverse effects as well as the basic sequence of patient led activity. Patient throughput within the Accident and Emergency Department of large acute hospitals is in the region of 75,000 per year - equivalent to in excess of 200 cases per day. Most patient episodes will be of less than 6 hours duration. Extensive records of patient activities are now typically available within patient record systems and the scope and extent of such records has evolved considerably since initial developments in information systems within the A&E environment (Clarkson *et al.* 1982).

In A&E, however, there is no permanent location for patients who progress through physical locations according to the stage of treatment. A simulation system would be required which would allocate patients to specific locations in accordance with the flow of patients within the unit. Superimposed on this flow of patients would be the identified interventions experienced by the patient. Functions of competency mismatch would require to be modulated by a function which took into account the likely availability of other staff within the immediate vicinity of the patient.

Similarly, functions of supervision would be modulated by local availability of senior staff. In addition, distraction would require a function modulated by levels of local clinical activity. It is likely that effectiveness functions which reflect levels of physical, emotional and intellectual ‘exertion’ would play a more prominent role with the determination of patterns of individual effectiveness.

The physical layout of the A&E unit would also play a key role in the risk simulation. While information on generic aspects of patient care such as registration date and time and discharge date and time, elements of patient work flows and time spent in specific activity zones would require to be

determined by prolonged periods of observation. There is increased focus within this model on the role of the doctor in managing the patient rather in the role of the nurse to provide care. Again, there is an intrinsic component of 'risk' within the physical design of such departments.

1.2 Cardiac Intensive Care

Within University Hospital, Coventry, Cardiac Surgery utilises dedicated high dependency facilities within a specific 16 bedded Cardiac Intensive Care. Typical case mix will include heart bypass and valve surgery of various types. The operation of this unit will reflect high throughput value with reduced length of stay where admissions are dominated by planned surgery streamed from a dedicated set of cardiac theatres. The scope of interventions will reflect a reduction in requirement of ventilated episodes and a narrower range of administered medications and nursing/clinical interventions. Within this facility at University Hospital, Coventry, there is no implementation of the QS system which is utilised within the main Critical Care unit, so characterisation of the model of admission/discharge episodes and the nature of interventions would require the employment of alternative methods.

1.3 Surgical Ward

While the same 'risk engine' system would be applicable, the internal representation of the model would reflect key structural changes in both the nature of interventions and the allocation of clinical staffing resources. Structuring risk clinical risk simulation in this environment would require extensive periods of direct observation to accumulate a representative series of patient care episodes which could in turn be used to simulate long time sequences of associated patient care. In general patients would be less intensively treated but with increased variations in the level of resources (e.g. clinical staffing) available. Elements of physical layout of clinical areas would also impact on risk factors relating to sharing of competency, supervision and levels of distraction. One of the complexities of the model simulation would be to actively locate clinical staff within the clinical area and identify interactions which took place between staff members. Processes of specific importance would include those of admission and discharge, where transfer and communication of key elements of patient information would have a significant effect on patient management.

1.4 Simulations of Models of Continuity of Care

This identification of the levels of complexity associated with this research indicate that further development of such research should be primarily focused within quantification of the clinical activity experienced by patients in order to more appropriately match the patterns of Clinical Adverse Events with the simulated patterns of adverse effects. This identifies an extension of the concept within the

discipline of clinical risk management of virtual patient simulation where initially simulation of activity relates to a specific 'micro environment' such as Critical Care or Accident and Emergency. In the wider scenario, however, it becomes relevant to simulate patient 'pathways' as a sequence of episodes across specific 'micro environments' as indicated in figure A7.1 and where specific interactions are also associated with entry to the care process, transitions between micro environments and the exist from the care process.

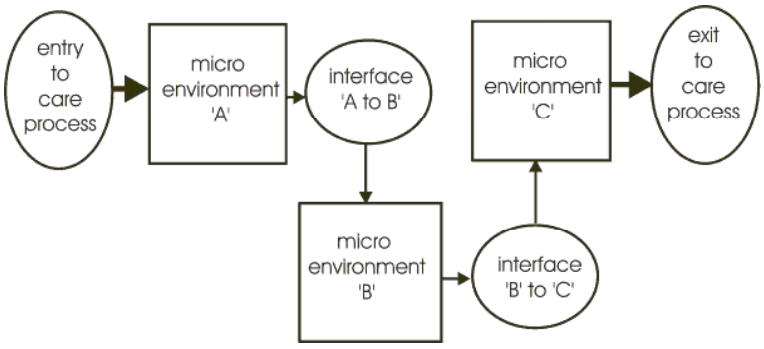

Figure A7.1. Structure of patient pathway which indicates linked sequences of care within 'micro environments'.

This current research describes risk simulation within a specific 'micro environment' of a Critical Care Unit, though a more comprehensive model would include entire patient care pathways. In such an expanded approach, each 'micro environment' would require structuring of its own specific risk simulation model. Such an expanded approach would also require extensive implementation of 'handover effects' within the patient journey.

In the context of the quality of care delivered within a health system, the trend has been to focus on the competence and training of the health professional 'at the cutting edge' of care. Examples would include the anaesthetist maintaining patient equilibrium during surgery, the surgeon undertaking surgery, the nurse in Critical Care administering intravenous infusions or the ophthalmologist treating a patient with a laser. It is all too obvious, however, that many of the risks within a healthcare system relate to processes which initiate, direct, manage and review the patient 'pathway' and which may not directly involve clinicians.

Such processes would structure the initial patient referral, review by a medic, identification of treatment, delivery of treatment and subsequent follow up. This process can be identified as a sequence of interventions within separate 'micro systems' which manage the patient treatment 'pathway' as indicated in figure A7.1 Failure within these facilitating functions, however, can result in introduction of significant inefficiencies and dislocations in patient treatment.

Appendix 8: Publications

Conference Proceedings

Clarkson D.M. and Haas O.C.L. (2006) 'Structuring a model of clinical risk based on fuzzy interpretation of large sequences of individual acute care interventions' In Burnham K.J. and Haas O.C.L. (ed.) *Proceedings of the eighteenth International Conference on Systems Engineering* (ICSE2006), Coventry, UK, Held September 5-7 2006 at Coventry University.

Clarkson D.M., Haas O.C.L. and Burnham K. J. (2009) 'Risk simulation modelling in acute healthcare' In Burnham K.J. and Haas O.C.L. (ed.) *Proceedings of the twentieth International Conference on Systems Engineering* (ICSE2009), Coventry, UK, Held September 8-10 2009 at Coventry University.

Risk Simulation in Critical Care Activity , D.McG.Clarkson and O.C.L. Haas (poster)
15th Annual International; Forum on Quality and Safety in Healthcare, Nice, France, 20-23 April, 2010.

Evaluating risk related factors of bed layout in a Critical Care Unit: A fuzzy modelling approach, Douglas McG..Clarkson and Olivier Haas, submitted to UKACC International Conference on Control (CONTROL 2010), 7-10 September, 2010.