TO INVESTIGATE THE FEASIBILITY OF PREDICTING, IDENTIFYING AND MITIGATING LATENT SYSTEM FAILURES IN A UK NHS PAEDIATRIC HOSPITAL

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Thesis Summary

The aim of this study was to investigate the feasibility of identifying latent system failures in a paediatric National Health Service hospital in the England (NHS). Medicine related errors affect up to 9% of all patients in NHS hospitals.

The theoretical basis included error causation theory, the functioning of short-term memory and how the brain manages multiple stimuli. The literature review covered error causation and prevention research, undertaken in healthcare settings and other high-risk industries. The study environment was the dispensary of Birmingham Children's Hospital (BCH) and a busy ward. The study instrument was non-participant, direct observation of routine dispensing and medicines administration tasks.

The first phase identified latent risks in a specific readily observable task set in a specialist paediatric hospital pharmacy department. Having identified a major latent risk, *interruption*, the investigation then established the significance that interruptions had on operatives. The second phase investigated the efficiency and effectiveness of the current Incident and error reporting system (IR1s) in supporting learning from incidents and changing practice.

The first phase identified "interruptions" as a latent error and demonstrated, for what appears to have been the first time in healthcare research, the impact these have on operatives. The second phase confirmed that a gap existed in healthcare error reduction strategies. From the outcomes of the first two phases a completely new strategy, to predict latent system errors and then to reduce them was devised. The strategy was then implemented in another area of the hospital, with different staff, on a high-risk task, IV medicine administration and was shown to reduce medicine errors.

Key Words and Phrases: Medicine Incidents; Checklists; Error Causation; Efficiency, Incident Reporting, Interruptions, Learning Organization, Latent System Failures, Quality Management Systems, Memory, Multitasking, Non-professionalism, Patient Safety, Paediatric Pharmacy, Professionalism, Risk Management.

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Dedication

To my dear friends and family who put up with much to make this possible, thank you.

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List of Abbreviations

ADC	Automated Dispensing Cabinets
ADR	Adverse drug event
AHRQ	Agency for Healthcare Research. U.S. Department of Health & Human Service
BBC	British Broadcasting Corporation
BCH	Birmingham Children's Hospital
BRFs	Basic Risk Factors
Datix	Incident collation and reporting software used by NHS organisations
DoH	Department of Health
FAR	Federal Aviation Authority
FCE	Finished Consultant Episode
FT	Foundation Trust
GEMS	Generic error-modeling system
GPhC	General Pharmaceutical Council
GPs	General Practitioners
HSE	Health and Safety Executive
IRIs	Incident reporting form used in the National health Service
I.V.	Intra Venous injection
LSM	Least squares means
NPSA	National Patient Safety Agency
Medmarx	Medication Error Orientation Manual
NHS	National Health Service in the United Kingdom
NICE	National Institute for Health and Clinical Excellence
NLRS	National Learning and Reporting Service
NCCMERP	National Coordinating Council for Medication Error Reporting and Prevention)
NMC	Nursing and Midwifery Council
PICU	Paediatric Intensive Care Unit
PICU ST	Paediatric Intensive Care Unit Safety Team

QMS	Quality management systems
RCA	Root cause analysis
SEM	Standard Error of the Mean
SERS	Safety Event Reporting System
SoP	Standard operating procedure
SSADM	Structured system and design methodology
WHO	World health Organisation
WUS	Wake Up Safe project

Chapter 1 Background and Introduction

Background

Adverse drug events have accounted for 16% of Hospital admissions in the UK according to the World Health Organization [1] who go on to say that some countries spend up to 15-20% of their hospital budget dealing with drug complications and in the National Health Service in England and Wales the costs have been estimated to be £530 million pounds a year[2]. The National Patient Safety Agency's (NPSA) National Reporting and Learning System (NRLS) data, a database of voluntary reported incidents, shows that the proportion of reported medication incidents that involve 0-4 years olds is higher than that for the population as a whole and it is recognized that children are a particularly vulnerable group when it comes to medication errors. Reasons for this have been attributed to a number of causes that include: medicines used for children are often used outside of their license or are simply just not licensed for children, dose calculations are complicated and medicines are used in ad hoc formulations and presentations.

These reasons, alone may not be adequate to account for the frequency of medicine errors that occur in paediatric pharmacy other factors may need to be considered? This study will investigate the feasibility of identifying errors in paediatric pharmacy prospectively and then go on to demonstrate that it is possible to reduce the frequency of their occurrence.

This study will look in detail at a single phase in the dispensing process of paediatric medicine, *the accuracy-checking phase*, and by applying error causation theory look for indicators of the existence of latent errors within the system. It will then attempt to determine whether these latent errors are inherent within the dispensing processes, workplace design or are of some other identifiable source. Finally, it will propose solutions to mitigate these latent errors.

Introduction

[1] WHO Organisation (2002). Safety of Medicines - A Guide to Detecting and Reporting Adverse Drug Reactions - Why Health Professionals Need to Take Action.

[2] NICE (2015). Costing statement: Medicines optimisation Implementing the NICE guideline on medicines optimisation (NG5).

A study [3]Pirmohamed, James et al. (2004) conducted from November 2001 to April 2002 in two NHS hospitals in Merseyside assessed 18,820 patients aged over 16 years of age admitted for cause of admission. It found that there were 1225 admissions related to an adverse drug event (ADR), giving a prevalence of 6.5%, with the ADR directly leading to the admission in 80% of cases. The median bed stay was eight days, accounting for 4% of the hospital bed capacity. In another study of ADRs in hospital inpatients it was thought that ADRs may be occurring in 9% of hospital inpatients , Davies [4](Davies, Green et al. 2009) .

The National Learning and Reporting System (NLRS) was created in 2003 as one of the outcomes of the report "An Organisations with as memory"[5], published by the department of Health following review chaired by the Chief Medical Officer for England, Professor Sir Liam Donaldson, DoH (2000) After the recent reorganization of the NHS, in 2014, the responsibility for patient safety passed from the National Patient Safety Organisation (NPSA) to NHS England (NHSE). Each NHS organisation and others providing healthcare such as General Practitioner Surgeries (GPs) and Community Pharmacies collect details of incidents, reporting each occurrence through completing an incident form, known as an IR1. This is achieved using IR1 reporting software such as Datix[6], although other systems also exist, which is passed onto the NLRS gateway and the data aggregated and analysed. The NLRS holds data on over 4 million incident reports submitted since its inception in 2003, with over 600,000 of these having been reported between October 2014 and March 2015 alone[7]

The National Reporting and Learning System data showed that in a 12-month period between October 2007 and September 2008 there were 910,089 incidents and, of these, 2% were found to relate to the care of neonates and 5% to the care of children. Medication incidents were the most commonly reported incident type for children accounting for 17% of all incidents NPSA (NLRS 2009)[8] . In another NPSA report, children aged up to four years were involved in 10.1 per cent (2,081) of all medication incident reported where age was

[3] Pirmohamed, M., et al. (2004). "Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients." BMJ 329(7456): 15-19.

[4] Davies, E.C., Green, C.F., Mottram, D.R., Pirmohamed, M.; Adverse drug reactions in hospital in-patients: a pilot Study Journal of Clinical Pharmacy and Therapeutics (2006) 31, 335-341

[5] Donaldson,L (Chair). An organisation with a memory; Department of Health (2000) <https://www.aagbi.org/sites/default/files/An%20organisation%20with%20a%20memory.pdf

[6] http://www.datix.co.uk/en/products/datixweb/incident-reporting <accessed August 2017>

[7] Organisation Patient Safety Incident Reports - data workbooks September 2015; < http://www.nrls.npsa.nhs.uk/resources/?entryid45=135465> accessed February 2016

[8] NLRS, NPSA.-. (2009). Review of Patient Safety for Children and younf people.

stated, NPSA [9](NHS 2007). One study found that the rate of potential adverse drug events or *near misses* (ADEs) was about 3 times higher in children than for adults Kaushal (2001) [10].

Types of errors that lead to adverse drug events are well documented. Error reduction strategies within the NHS are led by the NPSA and its *seven steps for all healthcare settings* approach NPSA [11] , which consists of a number of elements that include building a safety culture, risk management, incident reporting, communication, learning from errors and changing systems. Learning from errors is an outcome of the recommended investigation methodology, Root Cause Analysis (RCA). RCA and changing systems form a useful and effective error reducing strategy but are not without their limitations. RCA is dependent upon reconstructing the past in an attempt to understand error causation and thereby eliminate this error from occurring in the future. However, this approach is particularly susceptible to hindsight bias and counterfactual thought. Counterfactual thoughts express a past that is possible but untrue. Counterfactual theory helps to explain how inquiries may be subject to biases and errors of judgment that can manifest themselves in incorrect perceptions and the misallocation of blame, Reiss [12](Reiss 2001) . Hindsight bias is the tendency for people with outcome knowledge to believe falsely that they would have predicted the reported outcome of an event. Research suggests that it is impossible to reconstruct the past accurately, Fischhoff[13] Given knowledge of outcome, reviewers will tend to simplify the problem-solving situation that was actually faced by the practitioner. “The dilemmas, the uncertainties, the tradeoffs, the attentional demands, and double binds (two or more conflicting messages) faced by practitioners may be missed or under-emphasized when an incident is viewed in Hindsight. Possessing knowledge of the outcome, because of the hindsight bias, trivializes the situation confronting the practitioners and makes the correct choice seem crystal clear.” Woods (Woods, Johannesen et al. 1994)[14].

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[9] NHS, NPSA. (2007). Safety in doses: medication safety incidents in the NHS: P6; The fourth report from the Patient Safety Observatory.

[10] Kaushal, R., et al. (2001). "Medication errors and adverse drug events in pediatric inpatients." JAMA 285(16): 2114-2120.

[11] NPSA; 2004; Seven steps to patient safety; file:///Users/anthonysinclair/Downloads/NRLS-0034-seven-steps-pat-reference-2004-07-v1.pdf <accessed July 2009>

[12] Reiss, D. (2001). "Counterfactuals and inquiries after homicide." The Journal of Forensic Psychiatry 12(1): 169-181.

[13] Fischhoff B. For those condemned to study the past: heuristics and biases in hindsight. In: Kahneman D, Slovic P, Tversky A. Judgments under uncertainty: heuristics and biases. Cambridge: Cambridge University Press, 1982: 335–51

[14] Woods DD, Johannesen LJ, Cook RI, et al. Behind human error: cognitive systems, computers, and hindsight. Pp7-8; (CSERIAC SOAR 94-01) Wright-Patterson, AFB, OH: Crew Systems Ergonomics Information Analysis Center, 1991.

Two areas that merit research and the outcomes of which could potentially impact on the numbers of adverse drug events are an understanding of error causation in the *paediatric pharmacy* setting and an appreciation of associated processes. This study set out to identify latent errors and look for weaknesses, latent errors, in the existing system.

Error theory & causation

The two most commonly reported errors associated with dispensing of medicines, as reported to the National Reporting and Learning System (NRLS), are the wrong medicine or drug being supplied and the correct medicine being supplied but with an incorrect strength or dose or frequency, Warner [15] (Warner 2008). Dispensing the wrong medicine or the right medicine but with an incorrect strength or dose is the visible outcome of a particular error process. In other words, it was the error outcome *not* the error cause. Error outcomes, such as incorrect picking errors, that is selecting the wrong medicine or right medicine but incorrect strength, have been reduced successfully by a variety of simple but clever techniques that include not storing similarly named medicines next to each other. Also, changing packaging and using colour to good effect. The error cause can be repeated even though the error outcome will now be different. Atenolol 100mg tablets may no longer be picked incorrectly for a prescription requiring Allopurinol 100mg Tablets but another picking error might well occur. The questions that need to be addressed are what factor or factors caused the error to occur and so an unwanted outcome and end, more significantly, could these factors have been predicted and so prevented.

It is relevant to consider the definition of an error. The following description is largely based upon James Reason's book Human Error (1990) [16], chapter 3. "Errors are planned actions that fail to achieve their desired consequences without the intervention of some chance or unforeseen agency. Error types include slips and lapses, where the actions do not go according to plan and mistakes where the plan itself is inadequate to achieve its objectives". In addition to error types, which are performance related, there are error forms, which are evident at all levels of human performance and are a product of the cognitive processes of long-term memory. Reason's *Generic error modeling* system or GEMS, itself derived from

[15] Warner,B Reducing dispensing errors; (2008) ;
< http://www.thepharmacist.co.uk/clinical services/reducing-dispensing-errors> accessed July 2009.

[16] Reason,J. Human Error ;Cambridge University press;1990; P64

Rasmussen's skill-rule-knowledge classification of human performance, [17]Rasmussen (1983) presents an integrated picture of error mechanisms operating at the three levels of performance:-

1. Skill based performance is sensory-motor in nature, the ability to correlate visual stimuli, motor coordination with space and depth perception to carry out pre-determined tasks, that take place "without conscious control as smooth, automated and highly integrated patterns of behaviour" Rasmussen [18](Rasmussen 1986) . An example of this activity would be stacking shelves with medicine packs or the reverse activity of selecting a pack from a shelf in the dispensary. These are automated routine actions requiring little conscious attention,[19] Embrey (1990).

2. Rule based activities in the context of the dispensary would include accuracy checking dispensed medicines. The medicine has been assembled and labeled and finally requires an operative to check that the correct medicine has been dispensed for the selected patient. Appropriate labels and instructions have been selected. Rule based activities require some conscious cognitive activity and some automated behavior. It takes the form of, *if* this happens *then* take this action. *If* this medicine requires being stored below 8 degrees centigrade *then* attach a *store in the fridge* label.

3. Knowledge based activities have no routines or rules available for their solution and require active conscious thought to derive a solution. In the dispensary, this type of activity is typified by the Clinical pharmacy screening process.

   A diagrammatic representation follows taken from Reason (2002)

[17] "Skills, Rules and Knowledge;Signals,Signs ans Symbols and other distinctions in HUman performance Models." IEEE TRansaction Systems, Man and Cybernetics 13(3): 257- 266.

[18] Rasmussen, J. (1986). Information Processing and Human-Machine Interaction: An Approach to Cognitive Engineering, Elsevier Science Inc.

[19] Embrey, D. (1990). Understanding Human Error and Behaviour. Internet, Human Reliability Associates Ltd

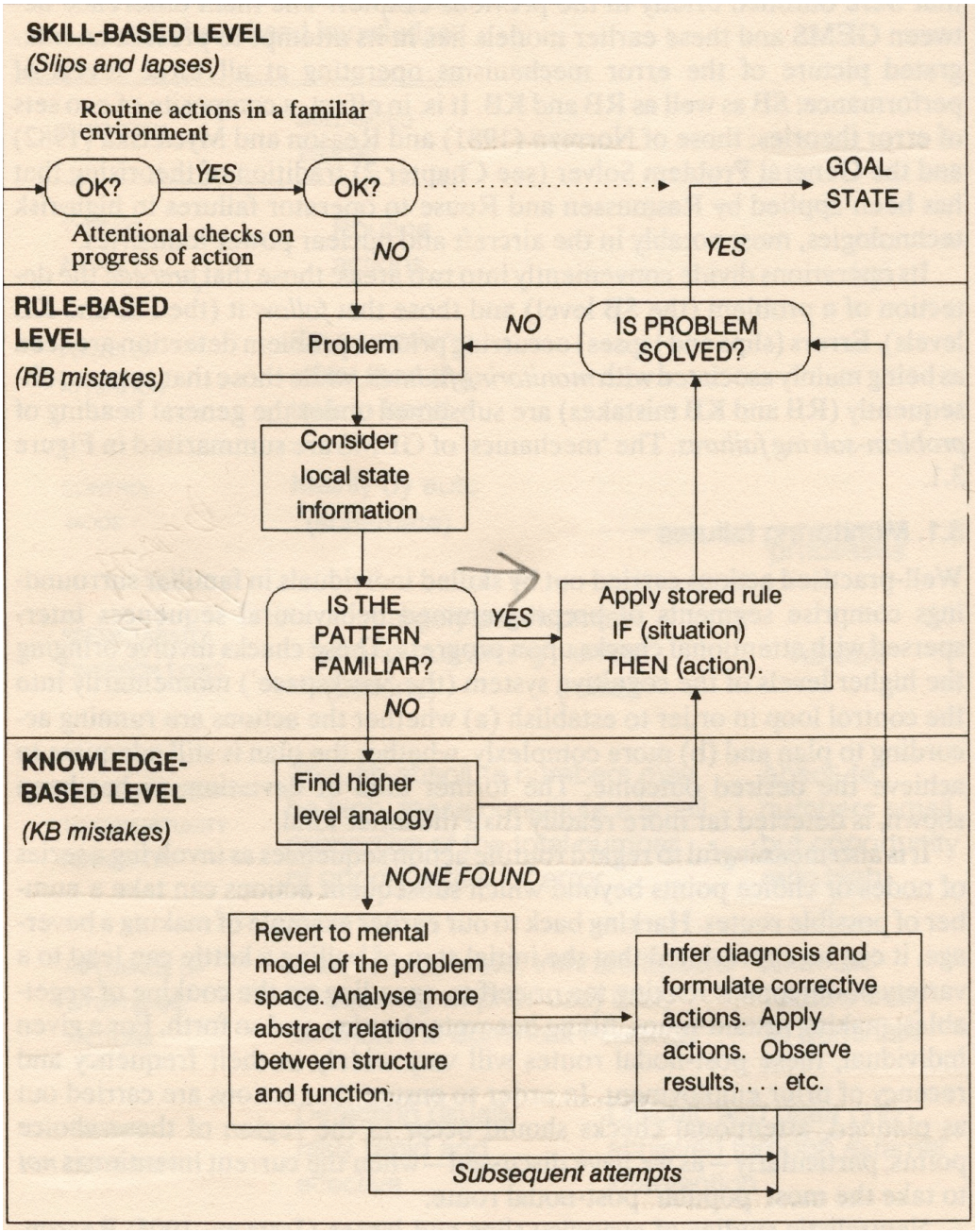

Figure 1 Outlining the dynamics of the generic error modelling system (Gems). Reason (1990)

Groeneweg's Groeneweg (2002) summary of the *Generic error-modeling system (*GEMS), three stages are traversed in order to bring about intentional actions. These are

1. Planning the action,
2. Mental storage of the action in the memory and
3. Execution of the action.

Errors can occur at each of these stages generating planning mistakes, storage lapses or execution slips. Groeneweg [20] Groeneweg (2002) goes on to explain that slips and lapses may occur as a result of a lack of attention, for example owing to an internal or external distraction, or because of over attention (too many or prolonged checks), which often occurs after a period of reduced attention and Double Capture slips, where the control of an action is captured by a stronger habitual sequence. Perceptual confusion errors often cause slips resulting in the correct action being carried out on the wrong but similar-looking object. Two other error types also have relevance and these are reduced intentionality, where there is a delay between formulation of an action and execution of the action as a result of a failure in prospective memory. Environmental capture refers to a situation where something in the surroundings distracts an operator from their intended task, for example a telephone ringing, resulting in the failure to carry out the intended action.

Errors at the skill-based level are mainly due to monitoring failures as a result of inattention to the task in hand. Rule based activities are solved by applying rules, that is an if…..then problem solving approach and errors arise from the application of *bad* rules or the *misapplication* of good rules. Knowledge based mistakes arise from the concept of *bounded rationality*, a term coined by Herbert Simon, Simon (1978)[21], that is the rationality of individuals is limited to the information they have at their disposal, the cognitive limitations of their minds and the time they have available to solve the problem. In particular, where knowledge available for the required cognitive processing is inadequate or missing it is known as cognitive under specification.

In addition to the three Error types, described above, Error forms occur at all performance levels and originate in all cognitive processes and are explained later in this paragraph, Reason (1990). Reason (1990) argued that the area in which cognitive functions are carried out in the brain is an area called the *working memory*. In order to function, the working memory draws knowledge from our long-term memory or knowledge base. To retrieve information appropriate to a particular problem-solving situation, two heuristics are employed. These are *similarity-matching,* using the degree of likeness between events or objects, and the second is known as *frequency gambling,* that is selecting events or objects that have occurred before; these are known as cognitive primitives and are thought to process information automatically without conscious effort. When cognitive operations are

[20] Groeneweg, J. (2002). Controlling the Controllable: Preventing Business Upsets, DSWO Press.

[21] http://innovbfa.viabloga.com/files/Herbert Simon theories of bounded rationality 1972.pdf <accessed August 8th, 2016)

underspecified, that is insufficient information is available to carry out a task, memory defaults to the most appropriate response that has occurred most often previously. A lack of attention to the task in hand, inadequate processes or failure to comply with existing processes, insufficient, incomplete or inadequate knowledge or information all contribute to error causation.

Error types and error forms are only part of the error causation picture. In the example of a pharmacy dispensary in which medicines are dispensed, an operator carrying out a skill based task, for example preparing a label for a tablet container, may momentarily lose concentration and generate an incorrect label. A mistake or *substandard* act has occurred. In the accident causation model known as the *Swiss Cheese* model developed by *Reason (1990)*, and used widely in the NHS, there is a chance that a barrier or defense in the dispensing process will identify the error before the medicine reaches the patient that it is intended for. There is also a chance that the substandard act won't be detected by the barrier and will pass through to cause an accident. The barrier in this context is the pharmacy operative tasked with accuracy checking dispensed items.

Figure 2 Swiss cheese model of accident causation (Reason 1990)

Each slice of cheese represents a barrier or defense put in place to prevent an accident from occurring. The holes represent weaknesses in each barrier.

An error type or error form have occurred that has led to a substandard act which in turn, if not prevented from doing so by a barrier, will reach a patient potentially causing unfortunate consequences; an error would have occurred. What causes the error types and error forms to occur? In Figure 3 the anatomy of an error causation pathway, adapted from Reason (1989),

latent failures in the system gives rise to substandard acts occurring.

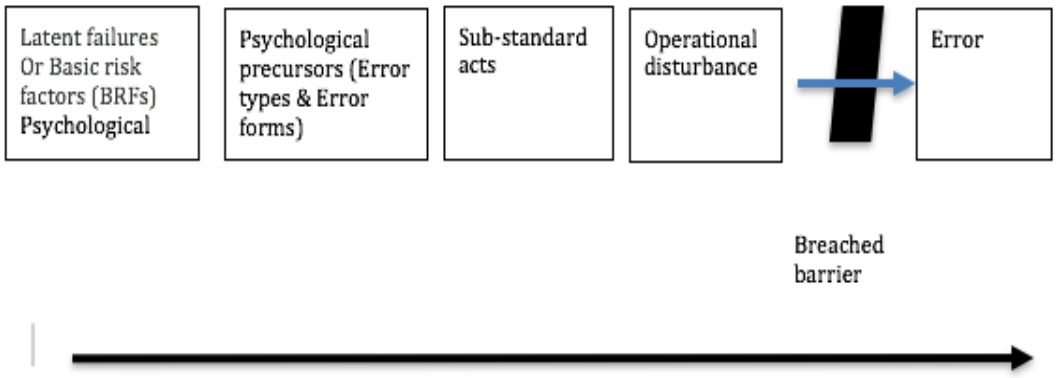

Figure 3 Anatomy of an error causation pathway Groeneweg (2002)

One Error type can give rise to multiple substandard acts that may not be repeated in the same way or same order again. However, controlling the effects of Basic Risk Factors (BRFs) would prevent substandard acts from occurring. There are 11 BRFs , Van der Meeren [22] Meeran Van der (1990) .These are outlined in table 1 Basic Risk Factors.

Basic risk factor	Description
Design	Ergonomically poor design of tools, equipment, offices (not user-friendly).
Hardware	Poor quality, condition, suitability or availability of materials: tools, equipment and components.
Maintenance	None or inadequate performance of maintenance tasks and repairs.
Housekeeping	None or insufficient attention given to keeping the workplace clean or tidy.
Error Enforcing Conditions	Unsuitable physical conditions and other influences that have a disadvantageous effect on human functioning.
Procedures	Inadequate quality, insufficient availability of procedures, instructions and manuals.
Training	None or insufficient competence or experience among employees (not sufficiently suited/inadequately trained).
Communication	None or ineffective communication between the various locations, departments or employees of a company, or with the official bodies.
Incompatible Goals	The situation in which employees must choose between optimal working methods according to the established rules on one hand, and the pursuit of production, financial, political, social or individual goals on the other.
Organisation	Shortcomings in the organisation's structure, philosophy, processes or management strategies, resulting in inadequate or ineffective management of the hospital department or clinical area.
Defence	None or insufficient protection of people, material and environment against the consequences of the operational disturbances

Figure 4 Basic risk factors (BRFs) - Groeneweg (2002)

[22] Meeran Van der, R. (1990). "Generalised accident scenarios. Towards a better understanding of the dynamics of accident causation."

The National Patient Safety Agency (NPSA)[23] NHS (2007) in their booklet *Design for patient safety,* says this *"*Human beings usually make mistakes because the systems, tasks and processes they work within are poorly designed. Effective design can deliver products, services, processes and environments that are intuitive, simple to understand, simple to use, convenient and comfortable, and consequently less likely to lead to errors". The BRFs associated with this statement arguably are *design, Error enforcing conditions, Procedures.* The booklet outlines concepts for good dispensary design, see figure 4 – Dispensary workflow design, and goes on to describe ways in which giving thought to design, particularly workflow and the impact of the environment on those working

Figure 5 Dispensary workflow design from the NPSA booklet: Design for patient safety.

Step 1 is where a prescription enters the system; Steps 2-5 are elements of the dispensing process; Step 6 is where the patient is counselled and step 7 the patient leaves with their medication. (a detailed description can be found below in the section "Strategic Approach-Study 1).

[23] NHS, NPSA (2007). "Design for patient safety- a guide to developing the dispensing environment " (edition 1).

within it, can help to reduce errors from occurring in the dispensing process. Examples of the latter would be *Noise* and *Interruptions.* An additional BRF is *defenses*; the mechanisms put in place to capture *sub-standard* acts from resulting in errors, and ought to be incorporated into good Procedures. Linear workflow is widely accepted to be the most efficient and practical system to adopt to promote efficiency and reduce error rates within a dispensary. What happens, however, when two BRFs are apparently at odds, when for example *design* that suggests linear workflow means that *Noise* and *interruptions* increase by the juxtaposition of workstations?

Interruptions

Noise or disruption and interruptions merit attention; they are part and parcel of the functioning of a large dispensary in which multiple tasks are being carried out simultaneously. Boehm-Davis [24] (Boehm-Davis and Remington 2009) define an interruption as the suspension of one stream of work prior to completion, with the intent of returning to and completing the original stream of work and *disruption* being a momentary lapse of attention on the primary task without a requirement to engage in the distracting task.

Research has shown that Interruptions consume about 28 percent of the knowledge worker's day, Speier (1999)[25] . It was found that interrupted work environments in which complex intellective tasks are performed leads to lower quality decisions and decreased efficiency. Furthermore, even helpful interruptions that are, those that facilitated the completion of simple tasks, were perceived negatively by decision makers. Interruptions are disruptive, just how disruptive depends upon several factors that Trafton (2008) [26] summarises as interruption complexity; see figure 6 the anatomy of an interruption, similarity of the interrupting task to the primary task, how closely the interrupting and primary tasks are related, control over interruption engagement, and the availability of retrieval cues in the

[24] Boehm-Davis, D. A. and R. Remington (2009). "Reducing the disruptive effects of interruption: A cognitive framework for analysing the costs and benefits of intervention strategies." Accident Analysis & Prevention 41(5): 1124-1129.

[25] Speier, C, Valacich, J S, Vessey, I . Influence of task interruption on individual decision making: An information overload perspective, The Decision Sciences, Spring 1999

[26] Trafton.J.G. & Monk, C.M. (2008) Task Interruptions. In D.A. Boehm-Davis, (Ed), Reviews of Human Factors and Ergonomics, Volume 3, Chapter 4 p111-126.2008

primary task.

Figure 6 Anatomy of an Interruption Trafton (2008)

To recover well from an interruption requires pre-planning and preparation. Boehm et al (2009) outline two such approaches. The first is aimed at decreasing the amount of information that needs to be remembered upon resumption of the task. This, it is suggested can be brought about by breaking from the task in hand at a suitable boundary or stage in the task enabling the operative to resume work at the next stage or step in their task process. They may complete producing a medicine label for example, so when they resume they take up the task at packing the completed item into a bag. The second strategy is to increase the probability of recalling the origin task (prospective memory), for example by using approaches to increase internal memory (such as rehearsal) or through the creation of *external memory*, such as leaving notes.

Distractions (i.e. in hospitals) are commonplace and have been identified as a major contributor to medication errors (and medical errors in general). The Medmarx report (2008) [27] lists distractions as the number one contributing factor in error causation in each of its data reports published between 2002 and 2006. There have not been many studies that have looked at methods to reduce distractions in hospitals, Clifton-Koeppel (2008) (2008)[28]. This is

[27] Hicks RW, Becker SC, Cousins DD, eds. (2008). MEDMARX data report. A report on the relationship of drug names and medication errors in response to the Institute of Medicine's call for action. Rockville, MD: Center for the Advancement of Patient Safety, US Pharmacopeia; http://www.usp.org/pdf/EN/medmarx/2008MEDMARXReport.pdf <accessed February 2009>

[28] Clifton-Koeppel,R. ; What Nurses Can Do Right Now to Reduce Medication Errors in the Neonatal Intensive Care Unit; Newborn and Infant Nursing Reviews, Volume 8, Issue 2, Pages 72-82, 2008.

not the case in the aerospace industry however, where accident investigation of a number of airline accidents by the National Transportation Safety Board, USA, such as the Eastern Airlines flight 212, concluded that distractions were a significant error causation factor. The Federal Aviation authority wrote the Sterile cockpit rule, thus in 1981. Flight crewmember duties, rule FAR 121.542 / FAR 135.100—Flight.[29] Section (b) of which states that "no flight crewmember may engage in, nor may any pilot in command permit, any activity during a critical phase of flight which could distract any flight crewmember from the performance of his or her duties or which could interfere in any way with the proper conduct of those duties. Activities such as eating meals, engaging in nonessential conversations within the cockpit and nonessential communications between the cabin and cockpit crews, and reading publications not related to the proper conduct of the flight are not required for the safe operation of the aircraft". This *proscribes* both direct distraction, i.e. conversations, or indirect distraction i.e. a colleague eating food, from being made during critical flight activities. In addition to leading to increased error rates, distractions also have been found to increase anxiety and in situations of high workload situations, decrease performance, Speier (1999) op cit.

A number of theories and mechanisms have been put forward to explain why distractions are so disruptive and to suggest strategies to mitigate the effects of such disruptions. Research carried out by Oulasvirta and Saariluoma (2006)[30] suggests that interruptions are disruptive not because short-term memory becomes overloaded, but rather because information stored in the long-term working memory is poorly encoded. Trafton & Monk[31] (Trafton 2008) outline factors that influence recovery from interruptions. The length of the interruption, similarity between the primary and secondary task, that is the task the operator has been called away to perform, the opportunity to rehearse prior to resuming the primary or main task and the existence of environmental cues, for example a clear marker being left as to where to resume, all affect task resumption performance. Significantly, training in the primary task itself is not by itself sufficient to reduce the impact of task disruption. In addition, training in *how to resume* has been found to be beneficial. Cades, Trafton & Boehm-Davies Cades

[29] http://www.ecfr.gov/cgi-bin/text-idx?SID=51e6ec25df70113f148981a89ed2d944&mc=true&node=se14.3.135_1100&rgn=div8 <accessed August 2009 >

[30] Oulasvirta,A. Saarilouma,P. Long-term working memory and interrupting messages in human-computer interaction. Behaviour and Information Technology, 64,941-961.(2004).

[31] Trafton.J.G. & Monk, C.M. (2008). Task Interruptions. In D.A. Boehm-Davis, (Ed), Reviews of Human Factors and Ergonomics, Volume 3, Chapter 4 p111-126.2008

(2006) [32] .

Multiple task management

Another issue to consider is how the brain manages input presented to it simultaneously Pashler (1994) [33] outlines three possible models which are, capacity Sharing, bottleneck or task-switching and cross-talk models. The first model suggests that people have a finite processing capacity which is shared out between tasks and people carry out multiple tasks quite ably until one task becomes more difficult than the others. When this happens, capacity is switched to the more difficult task at the expense of the less difficult tasks. The Bottleneck or Task-Switching model suggests that parallel processing may be possible until two or more tasks require access to the same processing mechanism or mental operation at the same time then a bottleneck results and one or more of the tasks will become delayed. The third model is that interference may arise when multiple tasks require the same sensory inputs in order to be processed, it could be easier to perform more than one task if they both require the same sensory inputs or harder if they require the same sensory inputs. A further complication is that it is thought to be more difficult to perform multiple tasks if they require the same sensory inputs.

Speier (1999)[34] Outlines two types of interference, Capacity interference is when the number of incoming cues are too numerous for a decision maker to process and structural interference occurs when a decision maker must attend to two inputs that require the same physiological mechanisms, such as two different visual signals. Rubinstein et al (Rubinstein, Meyer et al. 2001)[35] indicate that multi-tasking may be less efficient if a person is switching from a familiar task to an unfamiliar task.

Memory

This leads on to a consideration of memory overload and memory capacity. Baddeley and

[32] Cades,D.M., Trafton,J., & Boehm-Davies,D. (2006). Mitigating disruptions: Can resuming an interrupted task be trained?. Proceedings of the Human factors and Ergonomics society 50th annual meeting (pp368-371). Santa Monica CA: Human Factors & Ergonomics Society.

[33] Pashler, H. (1994). "Dual-task interference in simple tasks: data and theory." Psychol Bull 116(2): 220-244.

[34] Speier, C. S., Cheri; Vessey,Iris (1999/3). " The influence of task interruption on individual decision making." http://www.scopus.com/inward/citedby.url?scp=0038930657&partnerID=8YFLogxK 30.

[35] Rubinstein, J. S., et al. (2001). "Executive control of cognitive processes in task switching." Journal of Experimental Psychology: Human Perception and Performance 27(4): 763-797.

Hitch Baddeley (1974)[36] proposed a three part model consisting of a central executive that is thought to control access to the subsidiary elements of the working memory system. The other two parts of the theory were, a Phonological loop that stores speech based sounds for a limited period and is itself thought to be made up of two parts the phonological store can store sound coded items and an articulatory control process that allows sub vocal repetition of the items stored in the phonological store[37]. The second subsidiary part is called the Visuospatial sketch pad that stores visual spatial information, that is thought to set up and manipulate mental images. The Visuospatial sketch pad also controls attention and processing and organizing information. Baddeley added a third component in 2000 [38](Baddeley) , called the Episodic buffer, responsible for integrating and manipulating material, again has limited capacity and depends heavily on executive processing.

The relevance to this discussion is that working memory also known as short term memory has a limited capacity and is affected by a number of factors such as intelligence, age, lack of sleep, physical fitness, anxiety, emotions and stress and by an appreciation of how individuals are made up and react to external stimuli will inform error avoidance or prediction heuristics. It is worth referencing personality types, although not part of the studies described in this thesis, since an appreciation of how people perceive and process information from their environment will add to any error prediction strategy. Whilst hospital recruitment systems seldom employ personality testing as part of their recruitment process for junior staff at least, an understanding at a rudimentary level of the existence of personality types would help inform responsible officers, senior managers, section leads and supervisors just why individuals react in the way that they do under particular circumstances and in addition would be helpful in the way any *learning from error* strategy is constructed and implemented.

One such systematic approach to personality typing has its origins in the work of C.G.Jung and is known as the Myers Briggs personality type system that consists of 16 distinct personality type indicators[39] here referenced from the Myers Briggs foundation web site. Each of the sixteen personality type indicators give a different combination of an individual's

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[36] Baddeley, A.D., & Hitch, G. (1974). *Working memory.* In G.H. Bower (Ed.), *The psychology of learning and motivation: Advances in research and theory* (Vol. 8, pp. 47–89). New York: Academic Press.

[37] http://aspsychologyblackpoolsixth.weebly.com/working-memory-model.html <accessed August 8th, 2016>

[38] Baddeley, A.D. (2000). "The episodic buffer: a new component of working memory?". *Trends in Cognitive Science*. 4: 417–423. doi:10.1016/S1364-6613(00)01538-2.PMID 11058819

[39] http://www.myersbriggs.org/my-mbti-personality-type/mbti-basics/the-16-mbti-types.htm <accessed August 9th, 2016>.

preferences for perception and judgment, that is how they prefer to process the world around them in information terms. This in turn determines how individuals may differ in their interest, reactions, values, motivations and skills. In terms of work it helps an individual understand how for example how best to manage their time, approaches to decision making and addressing stress. And it would assist an individual's supervisor in how best to develop that individual and how they are likely to react to different situations.

Professionalism and non-professionalism

Professionalism and Non-professionalism is another layer that may impact on an individual's approach to their work and sense of responsibility and how they discharge their duties. A professional is someone who has trained for and is committed to a profession or a vocation and that profession is governed by a set of beliefs or code of conduct. There are other uses of the term and understanding of the concept for example he or she is a professional not an amateur meaning they do that work or use that skill to earn a living by; The Shorter Oxford English Dictionary[40]. The use of the term to which it is employed in this thesis is the former, an individual governed by a code of conduct and ethics a sense of duty or responsibility to, in this case, patients of the hospital and to colleagues. One basis difference between professional and non-professional is that the former may *down tools* promptly at the end of their shift whereas a professional would ensure that patients come first and would work longer to complete a task for the benefit of a patient. Clearly this is a simplistic example but other examples were apparent in sections of the observational work in this thesis quite unexpectedly.

Quality management systems (QMS) and Visual prompts

"A quality management system (QMS) is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organization's activities to meet customer, or service user, and regulatory requirements and improve its effectiveness and efficiency on a continuous basis" AQM.org (2016*)* [41].

[40] The shorter Oxford English Dictionary (2003) The shorter Oxford English Dictionary Oxford University Press. Vol 2: P 2358.
[41] http://asq.org/learn-about-quality/quality-management-system/ <accessed August 9th, 2016>

Quality management systems are commonplace in industry but less so in healthcare, although this is changing as health services come to terms with the economy and the need to provide high quality services by means of productive and efficient organisations. (Coles 2016)[42] Lord Carter of Coles published an independent review into operational productivity in the National Health Service (NHS). The findings were many and included the observation that there was unwarranted variation in the cost of delivery of services across the NHS and efficiency, effectiveness and productivity could be improved and an estimated £5 billion saved as a result. One of the strategies that Industry have deployed to achieve greater productivity have been the implementation of QMS and the use of tools such as lean management, an improvement approach to improve flow and eliminate waste that was developed by Toyota[43]. Visual prompts have a long history in safety strategies in situations where operatives are required to manage complex systems that require multitasking in stressful situations.

The classic example being in the aviation industry where the first checklist was created and introduced in 1935 on October 30th at Wright field, Dayton Ohio, USA, where the United States army were conducting an evaluation of aircraft. One of the contenders was a Boeing 299 which took off, began a smooth climb and then stalled and crashed, both pilots later tragically died of their injuries. The pilots were unfamiliar with the aircraft and the aircraft was too complex for one person to remember everything that had to be done. Later it was determined that pilots needed some way of ensuring that they didn't overlook anything and the checklist was born. [44] Checklists were introduced on a global scale by the work of Dr Atul Gwande and his team on behalf of the World Health Organisation (WHO), Gwande. [45] in his book, "The Checklist Manifesto", Gwande, wrote that "failure in the modern world is really about errors of ineptitude, that is mistakes made because we don't make proper use of what we know. The routine tasks of surgeons, for example, have now become so incredibly complicated that mistakes of one kind or another are virtually inevitable" Gwande (2011). As for pilots, a checklist is one approach to managing complexity and interruption. Quality management and visual prompts such as a checklist and a calculation flow aid play a part in one section of the observational studies.

[42] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/499229/Operational_productivity_A.pdf <accessed February 2016>
[43] http://www.institute.nhs.uk/building_capability/general/lean_thinking.html <accessed August 9th ,2016>
[44] Schamel, J.(2012 updated); http://www.atchistory.org/History/checklst.htm <accessed August 6th, 2016>
[45] Gwande, A. (2011). The CheckLIst Manifesto, Profile.

The elements that have been incorporated into this study therefore are an appreciation of error causation, more specifically relevant basic risk factors (BRFs) that will give insight into the impact of the environment and processes on individuals. An understanding of the way in which individuals process information needs to be considered. Memory and memory capacity together with multi external stimuli capabilities of the brain form another element to this work. The impact of professionalism and non-professionalism is a factor and finally the benefit of quality management systems, lean management and the use of visual prompts complete the research strategy for this thesis and ought to show that it is feasible to identify latent errors in a particular working environment. The environment in this incidence being a paediatric NHS foundation trust hospital pharmacy and ward in a tertiary referral paediatric hospital in England.

Aims and Objectives of the project

Aim To investigate the feasibility of predicting, identifying and mitigating latent system failures in a UK National Health Service paediatric hospital

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Objectives

a) To identify latent risks associated within a specific task set in an NHS paediatric hospital pharmacy department. Then to establish the extent to which these latent risks may be predicted. One specific area of paediatric pharmacy practice, the final accuracy checking process, will be the focus for this study.

b) To investigate the efficiency and effectiveness of the current Incident reporting system (IR1s) in supporting learning from incidents and changing practice.

c) To determine the impact of introducing a Quality Management Approach to process design into one process on a busy Oncology ward in the same paediatric hospital and determine the benefits of this approach including in terms of risk reduction

Research Paradigm

The research paradigm[46] used was predominantly Constructivism, that is the recognition that reality is a product of human intelligence interacting with experience in the real world, Elkind (2004)[47]. There is a problem generated by groups of individuals working in a real world situation (Ontology). In order to understand this problem, the situation in which it occurs needs to be understood that is the underlying events and activities (Epistemology). The theoretical perspective could be said to be interpretivism and the methodology largely action research. Action research starts with a research question and then follows a cycle in which a plan is devised to answer the research question. The plan is followed by an act or action that will allow the question to be investigated. Observations are made and the resulting data analysed and reflected upon. This in turn may lead to further questions and the cycle (Plan, Act, Observe, Reflect) begins again. Methods deployed included Observation (non participant), interviews with theme identification and qualitative and quantitative analysis.

Strategic approach

The aim of this study was to determine if it would be feasible to identify latent risks within a specific set of tasks set in an English National Health Service paediatric hospital environment, then to go on to determine if these identified latent risks could be predicted in a given set of circumstances and a defined set of conditions. In other words, taking an ideographic approach, that is studying individual cases and specific events and interpretive phenomenological type analysis could be carried out. An interpretive phenomenological analysis sets out to give insight into how an individual in a given set of circumstances might react to or make sense of a particular set of phenomena.

A literature review was carried out, described in full in Chapter 2, that looked for papers that had investigated relevant error causation factors such as stress and interruptions or those that discussed error reduction strategies particularly in the setting of a paediatric healthcare system such as a National Health Service Hospital. In addition, papers reviewing the efficiency of incident and error reporting systems in a similar setting were also searched for.

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[46] Patel,S 2015. The research paradigm – methodology, epistemology and ontology – explained in simple language.< http://salmapatel.co.uk/academia/the-research-paradigm-methodology-epistemology-and-ontology-explained-in-simple-language. Accessed September 2017

[47] Elkind,D. 2005. Response to Objectivism and Education: *The Educational Forum* 69(4) 328-334

Four studies were designed following an Action Research cycle, the first cycle developed from the initial research question, a plan was devised around a defined act that is described below. Observations were carried out and the outcome reflected upon. This in turn led to a second action research cycle to investigate a question that arose from the first cycle, namely investigating the impact of interruptions on operatives in a defined environment also described in detail below. The second objective was pursued through a third cycle and the outcomes from this and the first two cycles were reflected upon, a hypothesis developed and tested through the fourth action research cycle. Descriptions of the four studies or cycles follow.

Study 1. Latent risks in Paediatric Pharmacy identified in the dispensing process

It was determined that the first investigation would be carried out in the closely controlled environment of the outpatient and inpatient hospital dispensary at Birmingham Children's Hospital National Health Service Foundation Trust, examining one step in the dispensing process known as accuracy checking. The dispensing process consists of a series of defined reproducible processes some of which comprise of observable multi step tasks. The dispensing process can be considered, in its simplest form, to begin when a request for a medicine is received in the dispensary. The dispensary itself is a clearly defined geographical area within the pharmacy department. The request, in paper form, will be formally received by being recorded into a log, it then is passed to a pharmacist to be screened. The pharmacist will ensure that the right drug, in the right dose has been requested for the right patient to be given at the right time(s) of day by the right route. This is known as the "five" patient rights of medicine administration.

In addition, the correct quantity of medicine is ensured and particularly for paediatric patients, the most suitable presentation of medicine supplied, whether a liquid or solid dosage form such as a tablet. Once satisfied the request will be passed onto the next step in the dispensing process, which entails creating a label to be attached to the final container or pack of medicine and selecting the medicine itself. The correct medicine, container, label together with any ancillaries such as a medicine spoon or oral syringe are then assembled as appropriate.

The final step in the process is known as the accuracy checking step, where an appropriately trained operative ensures that the correct medicine has been correctly labelled for the specified patient according to the request taking into account any amendments the pharmacist may have requested. The operative carrying out this step of the process could be a pharmacy technician or a pharmacist. This final step, unlike other steps in the dispensing

process is self-contained in that everything required is presented to the operative. Any issues that may have existed have been resolved by the screening pharmacist at the outset of the dispensing process and all the elements, the medicine itself plus labels and ancillaries have been assembled prior to reaching the accuracy checking step.

By selecting a relatively simple task within the dispensing process the focus would remain on error causation brought about through the existence of error forcing conditions within the system rather than a particularly complex task and one arguably atypical of the system as a whole. The approach adopted for this study was a non-participant direct observation of one task in the routine dispensing process. Eighteen pharmacy staff comprising nine pharmacy technicians and nine clinical pharmacists were approached and asked if they would be willing to volunteer to be enrolled in the study, specifically to be observed carrying out the final step in the dispensing process, the final accuracy check. They were advised that the observation was not looking at them and their work so much as the impact, if any that the environment may or may not have on them. Each observation lasted no longer than 30 minutes during which time 2 or 3 medicine requests were accuracy checked. The observer recorded observable actions that each operative made whilst checking the assembled components before them and in addition direct and indirect interruptions were recorded, using a simple notation devised for this investigation, for example if the operative was observed calculating a dose then “CAL” was written. “L” stood for logs item out; “PEW” stood for person enters accuracy checkers workspace and so on.

The key elements for this study were that the task was uniformly consistent and reproducible. The environment comprising of various elements, heat, light, temperature, noise, space was constant. The Hawthorne effect, a process whereby subjects being observed change their behaviour because they are being observed, was mitigated against by virtue of the fact that the observations were explicit and carried out on multiple occasions over a significant period of time, between February and December 2008. Operatives became used to an observer sitting unobtrusively making notes.

Workload acted as a proxy measure for stress, the higher the workload it would be reasonable to assume that stress levels would also increase. This was recorded in terms of number of individual medicine requests processed through the dispensary by the hour, at the time that each observation took place. An operatives’ emotional state was gauged using a questionnaire that they could choose to complete on each occasion that they undertook this particular task. The development of the questionnaire is described in Chapter 4. They were asked to do this during a four-month (October 2007-January 2008) period prior to the observations commencing. [APPENDIX].

This part of the study was closed by holding two round-table discussions, one with the nine pharmacy technicians and the other with the nine pharmacists; both facilitated by the investigator who had undertaken the observations. Both groups were asked the same question which was how many steps did they think that it took to accuracy check a medicine. Both groups responded with an answer in the range of 6-8 steps, essentially those listed above as the five rights together with form, quantity and prescriber signature. However, the observed number of steps were 27.9 +/- 16.8 CI 95%(pharmacy technician group average) and 29.6 +/-4.63 CI 95% (pharmacist group average) far exceeded the estimate of either group. The operatives had been clearly distracted during carrying out the accuracy checking process and the most likely cause of distraction were interruptions.

Study 2 Impact of Interruptions

Interruptions again are discussed in detail in chapter 1 and can be defined as ""an externally-generated, randomly occurring, discrete event that breaks continuity of cognitive focus on a primary task",(Coraggio 1990).

Interruptions occur commonly in the busy work spaces of an acute healthcare environment such as a hospital. Whilst they are accepted as being detrimental to safety and efficiency, there are no investigations that I could identify that specifically determine the impact that interruptions have on healthcare operatives, particularly in a paediatric hospital environment.

Determining the significance of interruptions in a paediatric hospital environment and the impact on the efficiency of an operative would give an appreciation of the part they play in error causation and therefore the degree of importance that would need to be attributed to them in error causation. This in turn would impact on any error prevention strategies that might be deployed either to reduce the level of interruptions or introduce interruption recovery strategies such as visual aids for example, or a combination of both approaches.

The next phase of this investigation, chapter 5, was to therefore investigate the impact of interruptions on individuals carrying out the accuracy-checking step of the dispensing process that formed the core task of the first investigation outlined above. Details of the investigation are described in chapter 4. In essence the operatives who participated in the first investigation referred to above were asked to repeat the final task of the dispensing process. They were told that the test prescription and assembled medicines contained no errors that there was nothing included to catch them out. They were asked to accuracy check the medicines presented to them on one occasion in the dispensary as before complete with

direct and indirect interruptions, in other words the normal working environment. Then again, on another occasion in the controlled environment of an office, without any direct or indirect interruptions. Finally, they were asked to undertake the task once more in the office but with a controlled interruption. The results showed that the task took 22% longer to carry out in the dispensary with direct and indirect interruptions than in the office where there were no interruptions of any kind. From the data obtained from the first two arms of the investigation, it was observed that under workload pressure operatives change how they work, either speeding up as workload increases (pharmacy technicians) or slowing down due to concerns for safety (pharmacists).

Study 3 Efficiency of the incident reporting and learning system

Having identified factors that clearly were shown to affect performance and efficiency the question was asked as to what else might be a factor that needs to be taken into consideration? What other sources of information, in addition to the literature review, could be drawn upon in a secondary care paediatric hospital that might add to the understanding of error causation? Then having identified additional sources of incident and error data what could be learnt from this data and how relevant might it be to this research?

One answer was to refer to the National Health Service's National Reporting and Learning System (NLRS). In each hospital error and incident data are collected by means of electronic incident reports (IR1) and these feed into the NLRS system. However, what isn't so clear is how reliable the data collection is, and more significantly how efficiently are the lessons learnt from the IR1 data collection model disseminated? These questions need to be answered in order to determine how useful this data might be to this investigation. In Chapter 6 The incident reporting system and associated processes that existed at the time of this study in Birmingham Children's Hospital was investigated. It was determined to calculate the cost of reporting errors and incidents as a proxy measure from which the efficiency of the system could be assessed and in addition to gain the views of clinicians who had participated in the error and incident collection process as to the effectiveness of the process, in their opinion, used to populate the system.

The detail of this aspect of the research is detailed in chapter 6, in summary, an entire 12 months' data set detailing medicine related incidents and errors was collected and, a sub set was then extracted for detailed analysis. A costing algorithm devised and the total costs relating to the error and incident collection process calculated. To my knowledge this was the first such study carried out to derive such data. In addition, a questionnaire was sent by

email to a sub set of all those healthcare professionals listed as having participated in the completion of the IR1 forms in the extracted data sub-set.

As discussed in chapter 6, the absolute costs derived from the time spent by hospital staff in completing IR1 on-line electronic forms were relatively modest. However, this belies the fact that on average there were 19.61 staff episodes associated with each completed incident form. In other words, multiple inputs were required from several staff. The questionnaires included a free text comment section and from this anecdotal feedback the overwhelming view of those completing the error- incident forms was of report processing fatigue. That is although the process may be low cost those that participate expend their energies on completing the forms rather than disseminating lessons that could be learnt from them and as such the process is arguably bureaucratic and inefficient. In addition, the data contained in the forms was of variable quality and therefore usefulness to this research.

Study 4 The place of Checklists, Standard Operating procedures (SoPs) and multi-disciplinary skill mix in error prevention on an acute ward in a children's hospital

In Chapter 7, the final phase of this research is discussed. Data gained from the first three elements of this research were considered as a whole. Latent risks had been identified in the system and it was demonstrated that these impacted on the efficiency of pharmacy staff and arguably therefore had patient safety implications. A strategy was devised to identify and mitigate against these latent errors and tested in a related but different hospital environment, but still involving Pharmacy personnel.

Examples of approaches that had been deployed in other high risk industries, particularly the airline industry, for managing stress and distractions and the lessons learnt from these examples were adopted and adapted for use in a healthcare setting. From this techniques and approaches were adapted to be deployed on the ward and used by both pharmacy technicians and ward nurses.

To this end a high-risk medicine related process was identified, one that was known to have incidents and errors regularly associated with it, in this case the preparation and administration of intra venous (IV) medicines on an acute oncology ward in the children's hospital. Pharmacy technicians were sought for this project. Nursing staff were engaged and a two senior nurses, one of whom was employed by the pharmacy department and the other was a senior nurse on the ward in question, agreed to mentor the pharmacy technicians. An

educational needs assessment was carried out and additional training given to the pharmacy technicians.

This project showed that by introducing a protocol driven approach incorporating visual aids, in this case a check list and introducing standardization, a calculation flow chart and by controlling the environment and reducing direct and indirect interruptions and finally by adopting a new approach to when complex calculations ought to be carried out. The number of reported incident forms (IR1) completed during the period of this project was seen to reduce; although the reduction was purely anecdotal nevertheless a strong connection was seen.

Chapter 2. Literature Review

In a report prepared for the department of health the costs to the National Health Service in the UK of unsafe acts could be as much as £1 billion a year and quite probably over twice that with drug related events alone costing £770 million a year. Frontier economics (2014) [48] The National Learning and Reporting System (NLRS) receives approximately 1.2 million incidents reports a year from National Health Service Hospitals and it has been estimated that less than 15% of incidents are actually reported Dalton (2014)[49] . In order to be able to identify latent system failures and then establish to what extent these latent risks may be predicted and mitigated against, the literature was searched for research that has been conducted in paediatric pharmacy within the National Health Service in the England.

Aim

The aim of the literature review was to search for studies that had examined the impact of introducing risk and error reducing systems that were particularly mindful of known error causation factors such as stress and interruptions. In addition papers discussing the efficiency of the incident and error reporting systems themselves were also looked for to validate the underpinning error data and to investigate how robust learning from reported errors were deemed to be. The literature review also took into account papers that examined or referenced medicines management policies from paediatric hospitals that considered approaches to safety including error reduction strategies including utilizing teamwork and considering human factors, deploying visual aids and error reducing protocols, all within the given context of paediatric hospital pharmacy within the National Health Service in England. In other words research that demonstrated learning from either their own errors or those that occurred within a similar environment and or other high-risk industries and have as a consequence implemented quality management systems to reduce risk learning from the errors that were made.

[48] Exploring the costs of unsafe care in the NHS; Frontier Economics Ltd, London (2014) <https://www.frontier-economics.com/documents/2014/10/exploring-the-costs-of-unsafe-care-in-the-nhs-frontier-report-2-2-2-2.pdf< accessed 28.11.2016

[49] Building a culture of candour; Dalton,D; Williams,N (2014); Royal College of Surgeons. < file:///Users/anthonysinclair/Downloads/CandourreviewFinal.pdf> accessed 28.11.2016

Search strategy

The literature search strategy deployed including keywords, search terms and databases searched was as follows. The following electronic databases were used with the numbers in parentheses following the name of the database indicating the volume searched. Science Direct (1823), Scopus (1823), Allied and Complementary Medicine (AMED) (1985),British Nursing Index (BNI) (1992), Cumulative Index to Nursing and Allied Health Literature (CINAHL) (1981), EMBASE (1974), Health Business Elite (HMIC) (1922), Health Management Information Consortium (1979),Medline (1946) and PsycINFO (1806.

Exclusion-Inclusion criteria

Articles and publications were then excluded or included based on the following criteria. Inclusion criteria included Peer-reviewed journal articles and systematic reviews on Safety and error prevention; health and non-healthcare' in adults; no-defined age range and also in children and exclusion criteria were non-peer reviewed articles and also magazine reports, conference abstracts and commentaries

The strategy adopted for the literature review for each of these three sections is now described in detail.

Section 1. The impact of introducing risk and error reducing systems that were particularly mindful of known error causation factors such as stress and interruptions

a) Safety systems, error, risk reduction systems in place in paediatrics.

The search terms used to look for articles and publications related to safety systems, error, and risk reduction systems in place in a paediatric setting were as follows; Using Science Direct: - Organisation AND (Strategy OR Management) AND safety AND error AND intervention AND major. Using Scopus, the following words were used, Organisation AND (Strategy OR Management) AND safety AND intervention. Finally, for these databases AMED, BNI, CINAHL, EMBASE, Health Business Elite, HMIC, Medline, PsycINFO the words used were, Organisation AND (strategy OR management) AND (safety OR error OR intervention OR major OR learning). The above search terms were then repeated using paediatric specific search terms.

The search initially found 15,072 citations that were reduced to 11,446 after removal of duplicates. Further refinement based upon the exclusion/inclusion criteria reduced the citations to 746 potentially relevant articles that were healthcare safety systems interventions of which 16 articles matched both the topic and a paediatric setting. The articles fell loosely into four topic categories discussing communication and the use of checklists, improving reporting of adverse events with some also including the impact of introducing blame free cultures; Standardising intra venous infusion bags and finally the importance of identifying the sources of errors and introducing and assessing a safety culture

b) Using Workload as a proxy measure for stress.

This literature search looked for articles that discussed stress in the context of Paediatric Hospital Pharmacy and the impact, if any, that this may have had on efficiency, safety and professionalism. Key words used were, Paediatric, Pharmacy, NHS, Accuracy checking, Efficiency, safety, safety steps, Impact of the environment. The search strategy selected *child* OR *children OR paediatric* OR *adolescent* OR *infant* AND *hospital* OR *secondary care* OR *tertiary care* AND *Pharmacy* AND *medicine* OR *medication* AND *accuracy check OR medicine* OR *medication* AND *final dispensing check* AND *pharmacy technician* OR *pharmacist AND* stress *AND* efficiency *OR* efficient *OR stress reduction* OR *safety measure* OR *errors* OR *adverse event* OR *safety steps*

The keyword search resulted in zero results and so the following approach was adopted *pharmacy* AND accuracy check OR *final dispensing check OR final check* OR *medication check*
This produced 69 results of which four were considered to have some relevance.

c) Interruptions to the dispensing process

The aim of this section of the literature search was to look at the impact on the efficiency of operatives of direct and indirect interruptions whilst carry out a task in the dispensing process. The context for this search was paediatric hospital pharmacy, dispensing, accuracy checking, interruptions, safety and efficiency. Key words used were, *interruptions indirect; interruptions direct; safety; efficiency; paediatric; pharmacy; accuracy checking.*

The search strategy was to use the following key words as follows

Child OR *children* OR *pediatric* OR *paediatric* OR *adolescent* OR *infant* AND *Hospital OR secondary care* OR *tertiary care* AND *pharmacy* AND *interruption* OR *distraction* OR *Interrupt* OR *distract* OR *Multitasking* AND *safety measure* OR *dispensing errors* OR *medication error* OR *supply error* OR *adverse events* OR *safety steps* OR *efficiency* OR *accuracy* OR *accuracy checking* OR *near miss* OR *safety.*

This produced 53 articles of which 2 articles were considered to be relevant and 1 was of interest to review.

Section 2. Economics of the NHS Incident reporting system

In this section the efficiency of the National Health Service (NHS) Incident reporting system as observed at a local level was assessed in terms of effectiveness of achieving its primary goal as set out in the report an organisation with a memory [50], produced by the Department of Health in which was set out the importance of learning from incidents in order to change systems and practice and thereby reduce incident rates.

The context was the incident reporting system effectiveness in English hospitals, in particular as observed in a tertiary paediatric NHS Hospital, and the key word search strategy deployed was as follows. *Hospital* OR *NHS hospital* OR *hospital trust* OR *Acute care* OR *secondary care OR tertiary care* AND *Error reporting* OR *Medication error reporting* OR *Incident reporting* OR *patient safety* OR *safety mechanism* OR *safety report* OR *pharmaco-vigilance* OR *pharmacy safety* OR *medication safety* OR *root cause analysis* AND *cost effectiveness* OR *economic* OR *value* OR *efficiency* OR *safety* OR *risk reduction* OR *risk management* OR *organisational memory* OR *organisational memory* OR *audit* OR *intervention* OR *effectiveness.* This search yielded 193 results of which 4 articles were considered to be relevant.

Section 3. Medicines management policies from paediatric hospitals

(That considered approaches to safety including error reduction strategies including utilizing teamwork and considering human factors, deploying visual aids and error reducing protocols.)

[50] Department of Health (2000). "An organisation with a memory."

This section reviewed NHS hospital medicines management policies with particular attention to paediatric hospitals searching for error reduction strategies that included human factors and or quality management underpinning. The context was NHS hospital medicine management strategies and human factor strategies in relation to error reduction.

Key words used were, *medicines management; medicines administration; safety; error reduction; human factors; team work; flattened hierarchies; visual aids; checklist and protocol.* The search strategy deployed was as follows. *National Health Service OR NHS* AND *Hospital* AND *Medicines management OR Medication management* OR *Administering medicines* OR *medication administration* OR *medicines administration* AND *safety* OR *error reduction* OR *human factor* OR *team work* OR *flattened hierarchies* OR *visual aid OR checklist* OR *protocol.*

This search yielded 52 citations of which 3 were deemed to be relevant, although none of the resulting articles referred to terminology or principles of human factors, teamwork or flattened hierarchies.

Section 4 *Quality Systems and Checklists*

The aim of this section was to consider the impact on safety and efficiency of introducing a quality systems approach into one process on a ward area and this was the preparation and administration if I.V. injections. The context was a paediatric Oncology ward in a tertiary referral paediatric hospital in England and in particular the preparation and administration of Intra Venous (IV) injections using a systems approach consisting of protocols, calculation aides and visual prompts (checklists) by a pharmacy technician and nurse working as a team.

Key words deployed in this literature search were Paediatric Hospital, Oncology Ward, IV injections; medicines administration; Checklists; errors associated with IV injections; Quality Systems and hospital wards; medicines administration protocols; medicines administration and checklists and Protocol driven medicines administration process. The key word search strategy was as follows, *intravenous medication administration* OR *intravenous administration* OR *intravenous injection administration* OR *intravenous infusion administration* OR *medication administration* AND *pharmacy technician* OR *nurse* OR *pharmacist AND quality system* OR *checklist* OR *operational list* OR *checklist* OR *protocol* OR *guideline* OR *standard operational procedure* OR *SoP.* This gave a result of 83 papers of which 5 were considered to be relevant.

I will now go on to discuss the findings from the relevant papers in each of the categories outlined above in detail and in particular their relevance to the research questions stated at the outset of this thesis.

Section 1 The impact of introducing risk and error reducing systems that were particularly mindful of known error causation factors such as stress and interruptions.

a) Safety systems, error, risk reduction systems in place in paediatrics- *Standardising procedures, protocols and medicines*

Johnson et al (2004) conducted a literature search in order to review articles that would yield data to give an understanding of which technologies had the greatest potential to improve patient safety. Key words used included, safety management, risk management, office management, medication errors and adverse events. They repeated the searches including the terms infant, adolescent, childhood, paediatric and paediatric. Subsequently they reviewed sources of journals and articles that listed evidenced- based practice material such as the Cochrane library. The search yielded five types of technology that could improve patient safety in a paediatric context, these were electronic prescribing, electronic guidelines and protocols, internet based disease management resources tele-consultation and electronic patient healthcare records. The authors go on to cite the evidence of the positive impact of using these technologies. The use of electronic prescribing has been shown to reduce medication errors by over 80% in some circumstances. Using National guidelines and treatment protocols has been shown to improve compliance with evidenced based approaches to therapy, yielding better patient outcomes. Tele-consultation, the ability to consult with expert colleagues has been shown in a number of studies, cited by the authors to improve diagnosis and treatment outcomes.[51]

Bullock (2006) [52]set out to determine the impact of implementing standardised intra venous infusions, on the PICU in Mattel Children's Hospital California, on medication errors. The authors observed variability in medication administration practices on their Paediatric intensive care unit (PICU) and a variety of concentrations of IV medication were used, clearly

[51] Johnson, K. B. and C. L. Davison (2004). "Information Technology: Its Importance to Child Safety." Ambulatory Pediatrics **4**(1): 64-72

[52] Bullock, J., D. Jordan, et al. (2006). "Standardizing IV Infusion Medication Concentrations to Reduce Variability in Medication Errors." Critical Care Nursing Clinics of North America **18**(4): 515-521

a safety risk as this could result in an IV medication being prepared of a different concentration to the one previously administered to a patient and administered at an incorrect flow rate resulting in an incorrect dose being given. A retrospective audit of the error reporting system showed that over a 12-month period 26 of 50 (52%) of medication errors were dose related. The aim of this project was to determine the impact of introducing standardised IV infusions on dose administration error rates. The research team undertook three interventions, the first being the introduction of a standardised IV medication list. The second was an education campaign to support the changes and the third intervention was to support implementation of the standardised IV infusions through a system of one to one coaching and mentoring. The project began with data being audited retrospectively between April 2003 and April 2004 (12 months) then the new system introduced and errors were again analysed between June 2004 and December 2004. It was found that errors due to incorrect doses fell from 52% to 21% as a result. Recording errors, analysing the data and understanding the possible causes for errors can lead change in systems that result in significant improvement in patient safety.

Sullivan et al (2004)[53] investigated the benefits of applying lean technology to a pharmacy aseptic unit's compounding workflow in New Haven Hospital's Smilow Cancer Hospital, Connecticut, USA. This was necessary due to a rapid expansion in workload and patient expectations. Baseline workflow data was collected and analysed and it was found that turnaround time was at about 91 minutes for IV chemotherapy compounding. Current processes were subjected to lean methodology review. The review resulted in a reduction to turnaround compounding and delivery times of 20 minutes.

Verschoor (2007)54 and colleagues describe various medicine administration chart audits, carried out in the United States, Britain, Australia and Canada suggest that between 2.9% and 16.6% of hospital patients experience one or more adverse events. A group of women and children's healthcare facilities in British Columbia, Canada have successfully introduced a safety culture across their hospitals. Integral to their safety culture is the importance of a non punitive error reporting culture. This group have also borrowed from the Institute for Healthcare Improvement (IHI), based in Cambridge, Massachusetts and instituted safety briefings and patient safety walkabouts. The later are conducted by senior staff and demonstrate both the hospitals commitment to safety and show a willingness to introduce

[53] Sullivan, J. E. and J. J. Buchino (2004). "Medication errors in pediatrics - The octopus evading defeat." Journal of Surgical Oncology **88**(3): 182-188.

[54] Verschoor, K. N., A. Taylor, et al. (2007). "Creating a Safety Culture at the Children's and Women's Health Centre of British Columbia." Journal of Pediatric Nursing **22**(1): 81-86.

improvements. Reporting and learning from adverse events are a cornerstone, as discussed previously of any safety culture.

Alessandrini et al (2001)[55] set out to create an organised and comprehensive method for assessing paediatric emergency care(PEC), the setting for this work was the emergency department of Cincinnati Children's Hospital Medical Centre, University of Cincinnati College of Medicine, Cincinnati, USA. By devising a measurement framework to they can then assess the quality of care in the paediatric emergency department. The team hypothesise that to adequately measure quality, a range of representative, of all tasks, performance measures would be required. The authors discuss the Donabedian model (Donabedian 2005)[56] that assesses healthcare in terms of a tripartite framework consisting of Structure this element considers facilities, plant and staffing. Also, process, and all the elements of healthcare, including prevention and /or diagnosis together with therapy and finally outcome, the effects of healthcare on patients or a population. The Institute of Medicine (IOM), now the National Academy of Medicine based in Washington DC, USA has a framework of performance consisting of a number of domains by which performance can be assessed. These include, Timeliness, Effectiveness, Efficiency, Safety, Patient centeredness and Equity. Alessandrini and colleagues developed a model based on the IOM domains but adapted for use in a paediatric emergency department. Quite simply measuring the quality of care in a reproducible manner will give a reliable indication of whether care has improved or not!

b) *Using Workload as a proxy measure for stress*

The aim of this section was to consider stress, using workload as a proxy, in the context of a Paediatric Hospital Pharmacy dispensing final checking step and the impact, if any, that this may have had on the efficiency, safety and professionalism of dispensary operatives that is both pharmacists and pharmacy technicians, in the context of a paediatric hospital pharmacy in England. Jee, Schafheutle et al. (2016)[57] explored the process of professional socialization in pharmacy trainees during their pre-registration training. This is a training year that occurs after graduation but before professional registration onto the General Pharmaceutical Council (GPhC) registers. Trainees have to demonstrate a set of

[55] Alessandrini, E. A. and J. Knapp (2011). "Measuring Quality in Pediatric Emergency Care." Clinical pediatric Emergency Medicine **12**(2): 102-112.

[56] Donabedian, A. (2005). "Evaluating the Quality of Medical Care." The Milbank Quarterly **83**(4): 691-729.

[57] Jee, S. D., et al. (2016). "Exploring the process of professional socialisation and development during pharmacy pre-registration training in England." International Journal of Pharmacy Practice **24**(4): 283-293.

competencies and pass a set of professional examinations in order to successful complete the year and qualify as a pharmacist. The researchers implemented a prospective, longitudinal design study following 20 trainee community pharmacists. The study showed the experiences encountered by trainees that affect their professional socialisation. This study was conducted in an environment at variance with the context of this thesis however the principle is pertinent in that professionalism is inculcated deliberately rather than absorbed by happenchance and affects an individuals approach to their work and perceived responsibilities.

Family (2013)[58] set out to investigate the effect of perceived time pressure on pharmacy students' ability to accurately detect dispensing errors. The study comprised a simulated dispensing task set up for 52 final year pharmacy undergraduates who were set dispensing tasks to complete within a fixed time. Each participant then completed the NASA task load index to assess his or her perceived time pressure and mental workload. The NASA task load index was developed by Hart and Staveland (1988)[59] and consists of a set of questions each of which is evaluated using a Likert scale, to evaluate perception of workload. The questions include an assessment of, Mental Demand, Physical Demand, Temporal Demand, Performance, Effort and Frustration. The researcher found that time pressure does indeed impact on work accuracy in the context of dispensing. This piece of work whilst of interest has several limitations, it does connect workload pressure and impact on the quality of work output, however, it was a simulated situation in a university with undergraduates as participants and as such is of limited use for this thesis.

Lynskey (2007)[60] set out to establish the nature of medication errors occurring within community pharmacy and analyse common error patterns. The setting for this study was fifteen community pharmacies within Brighton and Hove City Primary care trust, Sussex. The researchers used an anonymous self-reporting incident form intended for use by the pharmacists when an incident (error) occurred. On completion the data extracted from the forms was analysed using statistical descriptive methods in IBM's SPSS v 11. 145 forms were collected at the end of the study and included 32 errors and 113 near misses (errors

[58] Family, H. E., M. Weiss (2013). "Perceived time pressure and its effect on final dispensing check accuracy." International Journal of Pharmacy Practice **21**(supplement 2): 1-8.

[59] Hart, S. S., L (1988). "Development of NASA-TLX (Task Load Index): Results of Empirical and Theoretical Research." nasa_techdocs.
< http://humansystems.arc.nasa.gov/groups/tlx/downloads/NASA-TLXChapter.pdf> accessed August 3rd, 2016.

[60] Lynskey, D., et al. (2007). "Medication errors in community pharmacy: an investigation into the types and potential causes." International Journal of Pharmacy Practice **15**(2): 105-112.

trapped within the pharmacy itself). The results showed that by far the predominate attributable cause for making an error (66 or 58%) or near miss (20 or 63%) was *business*.

Again this study connects workload pressure with error causation, it could be said that the link is circumstantial, not enough details has been observed to actually attribute error to cause and the context is community pharmacy rather than hospital paediatric pharmacy. None the less this study is useful for this thesis.

Bond (2008)[61] prepared a monograph consisting of an analysis of a data set from the evaluation of the community pharmacy contractual framework. The researchers were commissioned to evaluate the impact on community pharmacy of the new framework. A survey was posted out to all community pharmacies (n=1080) in a stratified random sample of 10%, across all primary care organisations in England and Wales (n=31). The response rate was particularly high, 71% (n=762). The survey included questions on Pharmacy and Pharmacy demography; Job satisfaction; Workload stress and pressure; Satisfaction with incentives and rewards; changed in staffing and roles since the new contract; Training; inter-professional relationships; Included within the results was a statistic related to the fact that the new contractual framework had led to an increased workload for community pharmacies and 57% (237 where n=425) of respondents indicated that they felt stressed at work, the impact of which hasn't been investigated in this study, although there is comment on this fact in the discussion, it does call into question a pharmacists ability to work effectively when clearly stressed and potentially fatigued.

Although the context is once again community pharmacy and not paediatric hospital pharmacy a link is again drawn between stress and workload and conjecture made as to the possible impact that this may have on individuals and the quality of their work and as such supports the work in this thesis but doesn't add to it.

c) *Interruptions to the dispensing process*

The only paper that had even oblique reference to this section was a study by Van der Velde (2010) [62] into chemotherapy prescribing errors and to compare electronic prescribing with pre

[61] Bond, C. B., A;Inch,J; Celino,G; Gray,N (2008). "The effect of the new community pharmacy contract on the community pharmacy workforce." Retrieved 29.4.2016

[62] Velde van der, B., V ; (2010) "Chemotherapy medication error rate in a pediatric hemato-oncology department." European Journal of Oncology Nursing 14(1): 81.

pre-printed prescribing approaches. In order to do this the team reviewed chemotherapy orders generated though the electronic prescribing system (n=373) and pre-printed created chemotherapy orders (n=538) and analysed them for errors. The errors were then categorized using the NCC-MERP index. This is an index created by the American National Coordinating Council for Medication Error Reporting and preventing that classifies incidents according to the severity of outcome. Included in the analysis of errors the researchers identified six that had a causation classified as being due to human related due to high workload [63]/distraction.

Although the context is a paediatric hospital, but located in Ghent, Belgium. The researchers were investigating prescribing not dispensing processes, nevertheless a causative link was made between a cohort of errors and workload or distraction, in a small number of errors (n=6 or 0.66%). This paper is of little substantive relevance apart from confirming a link between distraction and error causation

Section 2 Economics of the NHS Incident reporting system

Armitage et al (2007)[64] set out with the aim of their study being to assess the utility of the incident reporting system at Bradford Teaching Hospitals NHS Trust, England. The methodology that they employed was to collect a 50% random sample of medicine related incident reports that were created between 1993 and 2003 where n= 1253. Free text elements of the incident reports were analysed using a technique known as content analysis, Holsti [65](1969) and described by Stemler (2001) as, "*any technique for making inferences by objectively and systematically identifying specified characteristics of messages"*[66] *.* The authors found that over the five-year period that was analysed, 276 incident reports (27.8%) were incomplete. They also observed that generation of incident reports varied between specialties within the Trust and the reporting rate reduced over the five-year period. This study was carried out across a large NHS hospital trust on multiple sites. It is provides useful confirmation that there is an issue with incident reporting but doesn't investigate the causes

[63] http://www.datix.co.uk/products-services/modules/uk-and-europe/incident-reporting/ <accessed August 4th, 2016)

[64] Armitage, G., et al. (2007). "Reporting drug errors in a British acute hospital trust." Clinical Governance: An International Journal **12**(2): 102-114.

[65] Holsti, R;(1969) Content analysis for the social sciences and humanities; Published by Addison-Wesley & Co publishers

[66] Stemler, S; (2001); Yale University; Copyright PAREonline.net; http://pareonline.net/getvn.asp?v=7&n=17 <accessed August 4th 2016>

for this and as such doesn't impact on the section in this thesis that investigates the efficiency of the incident reporting system in NHS Trusts.

FUNG (2012)[67] set out to synthesise the best available evidence on factors that influence incident reporting by nurses. This was a literature review of primary research studies. Fifty-five papers were identified from the searches based on their titles and abstracts. Nine studies were included in this review. Cultural and demographic factors were the most significant factors in affecting nurses' attitudes towards incident reporting. Major perceived barriers included fear, administrative issues, and the reporting process. Also, nurses were more likely to re Fung, Koh et al. (2012) [68]port incidents that caused direct harm, and if reporting was kept anonymous. This literature review carried out by Fung et al collated data with regard to the attitude and barriers of nurses to completing an incident form rather than look at systems, processes and attitudes that impact on processing completed incident forms and learning from the lessons learnt from completed incident forms and as such does not add to this thesis.

Ginsburg, Chuang et al. (2010) in their paper "the Relationship between organisational Leadership for Safety and Learning from Patient Safety Events", set out with the aim to examine the relationship between organizational leadership for patient safety and five types of learning from patient safety events. The context for their study was forty-nine general acute care hospitals in Ontario, Canada. The approach that they used was to consuct two cross sectional surveys, one of the senior officer in each trust responsible for safety and the other of patient care managers in each organisation. The response rate were as follows, 54 of the 68 (79%) senior managers responded and 282 of the 621(46%) safety managers responded. The authors go on to explain that the data was analysed using multivariate regression analysis was used to test the unique effect of the hospital size; informal leadership for patient safety and then formal organizational leadership for patient safety, and also the interaction between hospital size and leadership variables, defined in the text, on learning from patient safety episodes. The results, in this very well designed study, suggest that firstly smaller hospitals, defined as those with less than one hundred beds are able to engage more with learning from errors than larger hospitals and secondly safety cultures need to be driven from the most senior management in a Trust.

[67] Fung, w. m. k., serena siew Lin; chow, yeow Leng. (2012). "attitudes and perceived barriers influencing incident reporting by nurses and their correlation with reported incidents: a systematic review." bi library of systematic reviews, [s.l.] v. 10(n. 1): p. 1 - 65.

[68] Fung, W. M., et al. (2012). "Attitudes and perceived barriers influencing incident reporting by nurses and their correlation with reported incidents: A systematic review." JBI Database of Systematic Reviews and Implementation Reports 10(1): 1-65.

The context for this study was forty-nine hospitals in Ontario Canada and the study assessed implementation of a safety culture and correlated the size of an institution with effectiveness of learning from errors. In this thesis the efficiency of the reporting system itself is investigated in a single site English Hospital and therefore this study although interesting doesn't impact on the research in this thesis.

Waring (2004) [69] In his study "a qualitative study of the intra-hospital variations in incident reporting", set out with the purpose of determining the relationship between variations in hospital incident reporting and the corresponding attitudes and participation of medical professionals. The setting for the study was a single district general National Health Service hospital trust in the Midlands in England. The study was conducted between 2001 and 20013, initially with a six-month observational study of the management structures within the Hospital and then going on to conduct forty-two face to face interviews with managers and clinicians within the Trust. A further set of interviews was conducted with 25 clinicians from various medical specialties. Waring found that that physicians are inclined to report when there is confidence in the processes and purpose of reporting, where reporting has a meaningful contribution to service development, and typically where these are satisfied through collegial forms of incident reporting.

This study was carried out in a district general hospital in the NHS and a s such has similarities with the studies carried out in and outlined in this thesis. The subject matter overlaps but brings out reasons for possible lack of ownership and engagement in the incident reporting process that add to the knowledge on this topic.

Current thinking underpinning improvement in safety has the underlying concept of learning from errors and in order to do this staff need to be encouraged to report adverse events and in order for this to happen a fair blame culture needs to be introduced into the organisation. This will lead to an increase in the number of incidents occurring, or so it is postulated and learning from these incidents will impact on practice. The outcome of which would be a high reporting culture but lower actual harm to patients.

Bianchi (2009) at the hospital, the Bambino Gesu Children's hospital and Research Centre, Rome, Italy has implemented a system of continuous improvement of Quality. The aim of which was to develop a culture of safety and the adoption of safer practices, integral to which was the introduction of procedures to improve safety and reporting od adverse advents. The project began in February 2007 with a survey of nurses to ascertain their knowledge and

[69] Waring, J. J. (2004). "A qualitative study of the intra-hospital variations in incident reporting." Int J Qual Health Care 16(5): 347-352.

awareness of errors in healthcare. The survey was distributed to 25% of the workforce and consisted of 20 questions. The data does not give a response rate only the results in terms of percentages for each answer and as such is of limited usefulness, however one conclusion drawn is that there needs to be a change in culture from one of blame when an accident occurs to that of no blame in order to encourage incident reporting[70].

The environment for this next study was a paediatric cardiac surgery operating room in at St Louis Children's Hospital, St Louis, USA. The study started with a single surgeon recording all failure events, during the month of April 2008, then extending this to all surgeons until the study ceased in December 2010. Procedural errors were identified and discussed during the post operation briefing session. Error reporting increased from recording incidents in 20% of all procedures to 50% of all procedures. The study showed that recurrent patterns of failure in the operating room might only come to light with this in depth focused systematic review of all failures within the operating room microenvironment. This in turn led to a greater appreciation of system failure with sufficient data to affect system changes in order to reduce incident rates, Bowermaster (2015)[71].

The Neonatal intensive care unit (NICU) at the Boston Paediatric Hospital, Massachusetts, USA, describes the impact of introducing an online system, Safety Event Reporting System (SERS) to record adverse events together with a no blame culture to encourage adverse events reporting and learning from these incidents to improve clinical practice positively, Bradley (2011)[72]. The neonatal intensive care unit created a safety committee with the remit of reviewing incident or error reports collected through the Event reporting system, and then using this information to change practice. An example was, during 2007 an increase in mislabelled laboratory specimens. The Safety group upon reviewing this information introduced a clinician double check with the resulting outcome of that this type of incident has decreased by 55% from 2007 to 2009. This review of and subsequent change in practice and process including the introduction of technology has noticeably reduced error rates.

A project also at Boston Children's Hospital, situated in Boston, Massachusetts, USA, encouraged adverse event reporting by nursing staff, through the Magnet recognition

[70] Bianchi, N., G. Carta, et al. (2009). "Clinical risk management at the Bambino Gesù Children's Hospital." Paediatrics and Child Health 19, Supplement 2(0): S176-S181.

[71] Bowermaster, R., M. Miller, et al. (2015). "Application of the Aviation Black Box Principle in Pediatric Cardiac Surgery: Tracking All Failures in the Pediatric Cardiac Operating Room." Journal of the American College of Surgeons 220(2): 149-155.e143

[72] Bradley, C., E. C. Dewitt, et al. (2011). "Implementing Change in Pediatric Care Practices Based on a Safety Event Reporting System." Newborn and Infant Nursing Reviews 11(1): 10-16.

program, a program that recognises excellence in nursing and was founded in 1990 by the American Nurses Credentialing Centre (ANCC). The rationale being that 59% of adverse events are preventable and so it was determined to focus nursing efforts to reducing errors, as part of the Magnet program. In 2005, the hospital implemented a web-based error reporting system, known as the Safety Event Reporting System (SERS), an on-line anonymous self-reporting system. The hospital also employed a system improvement model that has three elements that include an aim, a review and an outcome action. Then a survey was used to illicit nurses understanding of error reporting, followed by an educational campaign inspired by the results of the survey. The following year, 2010 a follow up survey was launched and sent to 560 nurses and had a 46% response rate. Outcomes indicated that education about the benefits of error reporting wasn't in itself sufficient. In addition the perception of the time it took to complete an incident report discouraged reporting. However, the additional data with regard to incidents was seen as a positive contribution to developing error prevention strategies, and the results showed a 35% increase in adverse events reporting over a two year period, Hession-Laband (2001).73

Kurth (2014) describe the significant benefits of collating adverse event reports on a national scale in the USA, analysing this data using Safety Analytics and Quality improvement and using the outputs to introduce quality improvements in the context of paediatric anaesthesia.[74] This is a national project developed by the American Society of Anesthesia who created a project called Wake Up Safe (WUS) which has been certified by the Agency for Healthcare Research and Quality (AHRQ) as a patient safety organisation in its own right in America. Quality improvement can be described as "a set of values and tools for setting goals and planning, implementing and measuring change"[75] and safety analytics is an examination of the data to identify underlying causes of errors. WUS is made up of 19 institutions and the serious adverse events rate was found to be 1.4 per 1000 anaesthetics. WUS has found that Quality Improvement and Safety Analytics are key strategies to improving patient safety.

A joint Anglo-American research team set out to identify patient safety factors of critically ill children dying in a paediatric intensive care unit (PICU). The setting was a single tertiary

[73] Hession-Laband, E. and P. Mantell (2011). "Lessons Learned: Use of Event Reporting by Nurses to Improve Patient Safety and Quality." Journal of Pediatric Nursing 26(2): 149-155.

[74] Kurth, C. D., D. Tyler, et al. (2014). "National pediatric anesthesia safety quality improvement program in the United States." Anesthesia and Analgesia 119(1): 112-121.

[75] Dawda, P; Jenkins, R; Varnam, R; (2010);Quality Improvement in General Practice ; The King's Fund; http://www.kingsfund.org.uk/sites/files/kf/field/field_document/quality-improvement-gp-inquiry-discussion-paper-mar11.pdf <accessed August 2nd, 2016.

regional PICU in a London Hospital. The investigators examined patients' medical notes, of 47 (7%) patients who had died between January 2007 and December 2008. 22 adverse events contributing to death (AEds) in 17 of the 47 cases (36%). Two AEDs occurred in primary care, 20 in pre-PICU hospital care and none in PICU. As for Critical Incidents (CIs), 37 occurred in 28 of the 47 (60%) cases. After statistical analysis and a careful case notes review a number of deficiencies in care were able to be identified and the researchers call for interventional studies to be undertaken to identify appropriate strategies by which patient safety could be improved. .[76]

Section 3 Medicines management and administration policies

Medicines management and administration policies in paediatric hospital settings in relation to safety, error reduction, human factors, teamwork, flattened hierarchies, visual aids, checklists and protocols

Communication failures are adverse events in their own right that have an adverse impact on patient safety, a negative effect on patients and often require costly additional treatment. Bagnasco (2013) conducted a study in an emergency department of a teaching hospital in Northern Italy. The researchers used two types of analysis, a failure mode analysis (FMEA) and a Failure mode, effects and criticality analysis (FMECA). Failure modes and effects analysis (FMEA) is a step-by-step approach for identifying all possible failures in a design, a manufacturing or assembly process, or a product or service[77] and Failure mode, effects and criticality analysis extends FMEA by including a criticality analysis, which is used to chart the probability of failure modes against the severity of their consequences[78].

The resulting error modes that were identified were then categorised using a model suggested by Vincent[79] (Vincent, Taylor-Adams et al. 1998) that organised factors that influenced clinical practice into seven categories; Institutional context, Organizational and management context, Work environment, team factors, individual (staff) factors, task factors and patient characteristics.

[76] Monroe, K., D. Wang, et al. (2011). "Patient safety factors in children dying in a paediatric intensive care unit (PICU): a case notes review study." BMJ Quality and Safety **20**(10): 863-868.

[77] http://asq.org/learn-about-quality/process-analysis-tools/overview/fmea.html <accessed August 1st, 2016)

[78] https://en.wikipedia.org/wiki/Failure_mode,_effects,_and_criticality_analysis <accessed August 1st, 2016)

[79] Vincent, C., et al. (1998). "Framework for analysing risk and safety in clinical medicine." BMJ **316**(7138): 1154-1157

It was found that poor communication was the main factor that led to patient safety issues and using a structured reporting tool such as the SBAR (Situation, Background, Assessment and Recommendation(s)) as a proposed solution[80].

This research does indeed have some relevance and although of interest only obliquely connects with the research conducted in this thesis. Vincent's[81] taxonomy relates to clinical situations, the background to this thesis draws upon the work of Hudson, Wagenaar and Reason as outlined by Groeneweg (2002) referenced elsewhere in this document, and who sets out the significance of Basic Risk Factors (BRFs) in error causation theory.

Gordon (2014) and his team undertook research into the impact of introducing a specially designed checklist into the context of a paediatric cardiac catheter laboratory situated in the Loma Linda paediatric university hospital California, America. The team retrospectively reviewed the medical notes of patients treated throughout the study period January 2010 to February 2012. Half way through this period patients were allocated to one of two cohorts, those where a checklist was utilised and one where a checklist wasn't used. A survey was conducted amongst staff at the beginning and at the end of the study period. They were asked questions in relation to team communication and attitudes towards team and safety within the department. A five point Likert scale was used in this process and the results analysed statistically using SSPS© software. The authors found that staff that used the checklist thought that it improved pre-operative communication[82]. The main outcome was to do with perception than impact on process or safety and as such has little relevance for this thesis.

Sharma (2013) investigated the benefits of introducing ward round safety checklists in the context of a National Health Service (NHS) tertiary referral paediatric intensive care unit at Great Ormond Street Hospital, London.[83] The aim of this study was to improve ward round communication on the paediatric intensive care unit (PICU). The researchers carried out a prospective, non-blinded observational study between July 2009 and December 2011, on a 12 bed section of PICU. A checklist was designed appropriate to the needs of a PICU unit. The results indicated that there was benefit from having a simply designed spoken checklist

[80] Bagnasco, A., B. Tubino, et al. (2013). "Identifying and correcting communication failures among health professionals working in the Emergency Department." International Emergency Nursing **21**(3): 168-172.

[82] Gordon, B. M., T. S. Lam, et al. (2014). "Utility of Pre-procedure Checklists in the Congenital Cardiac Catheterization Laboratory." Congenital Heart Disease **9**(2): 131-137.

[83] Sharma, S., M. J. Peters, et al. (2013). "'Safety by DEFAULT': Introduction and impact of a paediatric ward round checklist." Critical Care **17**(5).

that appeared to improve team communication and impacted positively on patient safety. The setting of this research was similar enough to be of relevance and the design of the checklist used during this particular research was of interest but the area investigated was sufficiently different not to impact directly on the research in this thesis.

Section 4 Quality Systems and Checklists

Maaskant, Vermeulen et al. (2014) [84] and colleagues conducted a systematic literature review to identify evidence-based interventions to reduce medication errors in hospitalised children. The search strategy that they employed was primary research studies found within the Cochrane Library, the Economic Evaluation Database (EED) and the Health Technology Assessments (HTA) database; MEDLINE, EMBASE, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, ProquestDissertations &Theses,Web of Science (citation indexes and conference proceedings) and the EPOC Register of Studies.

The searches were conducted in November 2013 and November 2014. Neither language nor date limits were applied. What the authors found were seven studies describing five different interventions, these were; participation of a clinical pharmacist in a clinical team (n = 2), introduction of a computerised physician order entry system (n = 2), implementation of a barcode medication administration system (n = 1), use of a structured prescribing form (n = 1) and implementation of a check and control checklist in combination with feedback (n = 1).

The results from this paper yielded one relevent article, that by Lepee, Klaber et al. (2012)[85] who describes the impact of introducing a checklist to improve the prescribing of medication orders by clinicians.Their aim was to assess the impact of introducing such a prescribing checklist on the quality and safety of inpatient prescribing in two paediatric wards in a London teaching hospital. The authors found that whilst there was a reduction in technical errors, there was no discernible improvement in clinical errors.

The introduction of a quality management system, including the use of visual prompts such as checklists does form a part of the content of this thesis and as such that makes this particular article by Leppee (2012) of interest. However, the context, that of prescribing rather than medicines preparation and administration and the fact that it was the intervention as

[84] Maaskant, J., et al. (2014). "PS-126 Interventions For Reducing Medication Errors In Children In Hospital: A Systematic Review." Archives of Disease in Childhood 99(Suppl 2): A156.

[85] Lepee, C., et al. (2012). "The use of a consultant-led ward round checklist to improve paediatric prescribing: an interrupted time series study." Eur J Pediatr 171(8): 1239-1245

opposed to merely an element of an intervention, that is a complete quality management system, preclude it from being useful in the context of this thesis.

Manias, Aitken et al. (2005) [86] conducted a study to determine how graduate nurses use protocols in their medication management activities. In particular, to examine the extent of adherence to various protocols in relation to medication activities and determine how the ward environment impacts on graduate nurses' use of protocols to manage patients' medication. This research team used a descriptive prospective qualitative design for their study. Twelve graduate nurses involved in direct patient care in medical, surgical and specialty wards of a metropolitan teaching hospital in Australia participated in the study. There were six areas of particular interest, availability and use of protocols, scrutinizing patients' identity before medication administration, double-checking certain medications before administration, writing incident reports, following specific policies and timing the administration of medications. Manias and the team carried out participant observations with the graduate nurses during a two-hour period when medications were being administered to patients, followed by In-depth interviews with each nurse immediately afterwards. Protocols associated with medication management activities for the clinical settings were also transcribed. What was found was that graduate nurses adhered to protocols if they were perceived not to impede with other nursing activities. Participants were also more likely to follow protocols if they felt encouraged to make their own decisions and if there was a decreased likelihood that disciplinary action would be involved. Nursing attitude and behaviour does impact on one of the projects in this thesis, however the project in this thesis introduces an approach to improve protocol compliance rather than observe it prior to the intervention. This article has relevance in that it gives background knowledge to nursing culture and behaviour but it doesn't impact directly.

Pape (2013) 87 In her paper entitled, The effect of a five-part intervention to decrease omitted medications, investigated the impact of introducing the MedSafe protocol on the number of admitted doses and nurses being distracted during medicine administration rounds. The setting was a 600-bed hospital situated in the middle of America. The MedSafe protocol consists of a number of steps to prevent nurses engaged in medicines preparation and administration from being interrupted. Signs were placed in the medication preparation area that stated, "STOP, Quiet Zone, do not Interrupt Nurses During Medication

[86] Manias, E., et al. (2005). "How graduate nurses use protocols to manage patients' medications." J Clin Nurs 14(8): 935-944.

[87] Pape, T. M. (2013). "The effect of a five-part intervention to decrease omitted medications." Nurs Forum 48(3): 211-222.

Administration, Avoid Conversation in this Area." In addition, yellow duct tape was used to mark off the medication area as a quiet zone. "Do Not Interrupt signs" were placed on the on the wall in the area; a prepared medication protocol checklist as a reminder of the correct method to administer medications was used; Other personnel working in the same area were requested not interrupt the nurse, but using teamwork to "field" phone calls and other distractions and interruptions during the medication administration cycle; and nurses wore a fluorescent sash when they began to retrieve and administer medications to all assigned patients during the scheduled time. The results demonstrated an 84% decrease (from 142 to 23) in the number of distractions and interruptions that nurses experienced using the five-part intervention compared with the control group that used standard processes. This study was conducted in a 600 bed American hospital. The study introduced a number of measures to prevent nurses administering medicines from being distracted including a check list visual prompt and a s such has superficial similarities with one of the projects in this thesis, but with sufficient variance to make it of interest but not useful.

Raja Lope, Boo et al. (2009)[88] set out to determine the rates of non-adherence to standard steps of medication administration and medication administration errors committed by registered nurses in a neonatal intensive care unit before and after intervention. The setting for the study was the Neonatal intensive care unit (NICU) in the Hospital University Kebangsaan, Malaysia. The method used was an observational study carried out during two, two week phases in 2005 and repeated after introducing remedial interventions in 2006. The baseline assessment, carried out on 2005, showed that the nurses did not carry out at least one of the ten standard administrative steps during the administration of 188 medication doses. Following implementation of remedial action mainly comprising of re-education some improvement was shown. This study was set on a NICU unit in a Malaysian hospital; the approach used as outlined in the paper does not have relevance to the work in this thesis. It does show that re-education alone doesn't generate significant improvement in protocol compliance.

Samaan, Dahlke et al. (2011) [89] describes the safety precautions for the use of U-500 insulin at St. Vincent Indianapolis Hospital, America, a 500-bed community hospital. U-500 insulin is a high strength insulin product range and as such presents a potential safety risk. The hospital has introduced a series of protocols that include specifically designed prescribing

[88] Raja Lope, R. J., et al. (2009). "A quality assurance study on the administration of medication by nurses in a neonatal intensive care unit." Singapore Med J 50(1): 68-72.

[89] Samaan, K. H., et al. (2011). "Addressing safety concerns about U-500 insulin in a hospital setting." Am J Health Syst Pharm 68(1): 63-68.

forms, administration dose guides and picking sheets in order to mitigate the risk. This is set in an American hospital with a product not used in paediatric hospitals in England. The paper describes precautions taken but isn't a study and doesn't contain data but does include the use of checklists as a visual prompt. As such it merits inclusion but isn't of direct relevance to this thesis.

Cottney (2014) set out to assess whether the introduction of automated dispensing cabinets (ADCs) on an inpatient ward in a UK mental health hospital, East London NHS Foundation Trust would replicate the benefits realised in Hospitals in America that have implemented ADCs. The method used was direct observation of nursing staff accessing medicines before the ADCs were implemented and then again after their implementation. The results were as follows, the ADC led to a reduction in the medication administration error rate from 8.9% to 7.2%; however, this reduction was solely accounted for by a reduction in errors of negligible clinical severity. The types of administration errors noted after implementation of the ADC remained largely unchanged from beforehand. The ADC was found to reduce the

amount of time that nurses spent administering medication from 2.94 min per dose to 2.37 min per dose. It is estimated that this reduction could generate around 66 min of additional free nursing time per ward per day. The setting was an NHS mental healthcare trust and the intervention was technology based rather than system based. The results are interesting but not directly relevant to this study.

McLeod, Barber et al. (2015) [90] Set out to identify system factors that facilitate and/or hinder successful medication administration focused on three inter-related areas: nurse practices and workarounds, workflow, and interruptions and distractions. The researchers used a mixed-methods ethnographic approach involving observational fieldwork, field notes, participant narratives, photographs, and spaghetti diagrams to identify system factors that facilitate and/or hinder successful medication administration in three inpatient wards, each from a different English NHS trust. Over a period of 85 hours, 43 different nurses were observed on 56 drug rounds (26 qualitative and 30 quantitative) across the three study wards. This study was very well thought through and designed and the data collected comprehensive and gives possibly for the first time gives insight into nursing behaviour and practice during medicine administration rounds. The authors conclude that to reduce medication administration errors that there ought to be work done to optimise the ward-based medication systems; Reduce interruptions and distractions, and actively encouraging

[90] McLeod, M., et al. (2015). "Facilitators and Barriers to Safe Medication Administration to Hospital Inpatients: A Mixed Methods Study of Nurses' Medication Administration Processes and Systems (the MAPS Study)." PLoS One **10**(6): e0128958.

inpatient involvement with their medications where appropriate. This study gives a wealth of data on nurse behaviour and practice during medicine administration rounds. This thesis, arguably, looks at interventions that may go some way to address aspects of the recommendations made in their paper.

Scott, Williams et al. (2010) [91] undertook an audit of medication interruptions and effectiveness of drug round tabards in Aberdeen Royal Infirmary, NHS Grampian, Scotland. The aim of the project was to evaluate the impact of introducing drug round tabards to three wards in Aberdeen Royal Infirmary, in order to evaluate the impact that this may have on reducing interruptions experienced by nurses administering medicines. The project was carried out over a 5 week period from January to March 2008. During weeks 1 and 2 data were collected on the number of interruptions received by nursing staff while conducting drug rounds. In week 3 drug round tabards were introduced which staff wore during the drug rounds. During weeks 4 and 5 the number of interruptions was again recorded. Views from staff and patients were obtained using questionnaires. The average number of patients per drug round was nine (pre and post tabard) and 95% of drugs rounds analyzed were interrupted (pre and post tabard). It was found that The median number of interruptions was significantly reduced from six interruptions to five interruptions per drug round following the introduction of drug tabards. This project yielded positive results in that interruptions were reduced and medication incidents fell from 19 to 16 over the five-week period of the project, as compared to the same period during the previous year. The data and detail is too little to draw conclusions as to the usefulness of this approach and consequently the relevance to this thesis is adjudged to be small.

Gaps in the Literature

Error reducing systems included technology and the introduction of the standardisation of intra venous bags. Other systems described in the literature cover the benefits of safety cultures and encouraging error reporting and lean management systems. All of which are beneficial in improving patient safety but none explicitly identify error causation at a root cause level, many are arguably reactive rather than proactive. Working leaner improves efficiency but doesn't necessarily improve safety.

[91] Scott, J., et al. (2010). "The effectiveness of drug round tabards in reducing incidence of medication errors." Nurs Times 106(34): 13-15.

Of the articles describing stress related research, two were student or trainee related and two, community pharmacy related and as such not directly relevant to the research questions that this thesis set out to investigate. Business was identified as a causative factor in stress causation but not how to mitigate this.

The only article in the interruptions category described the impact of distraction on the prescribing not the dispensing process. Incident reporting was examined by various authors who looked at the volume of completed incident reports, the connection between organisational culture and reporting of incidents and attitudes to incident form completion by nursing staff. Two further studies examined incident reporting in a theatre unit in the USA and on a Neonatal intensive care unit also at the same hospital in Boston, USA.

Medicines management policy research yielded articles that identified the importance of communication in reducing errors and in particular seven error modes outlined above that reflect, in part at least, the basic risk factors of error causation theory outlined in the introduction in chapter one of this thesis. Adherence to standard operating procedures (SoPs) by nurses was also examined, but interestingly the quality, relevance and usefulness of the SoPs were not. Another team looked at the benefit of introducing quiet zones supported by visual aids such as signs and instructions. The introduction of do not disturb red tabards were also investigated by a team from Aberdeen, Scotland In other words interruptions were accepted as playing a factor in error causation and current practice was adjusted rather than being re thought.

Finally two other teams, on examined the introduction of robotic dispensing units and the other undertake an extremely thorough examination of nursing systems and the impact that they may have on error causation.

The full search strategy for the literature search was outlined above. In total 11896 citations were found and after further review and refinement this number was reduced to thirty-four citations for discussion.

The rationale for this approach was initially to gain a perspective on research carried out in the context of a paediatric NHS hospital in England and Wales, beginning with organizational approaches to safety, risk reduction and interventions. In other words, what was the “big” picture or overview, the strategic approach to learning from errors and therefore going one step further, taking a proactive rather than reactive approach and attempting to reduce the likely hood of the same type of error from reoccurring, that is predicting errors before they took place. Included in this initial literature search were sub topics, for example communication failures as a particular incident grouping; Work on incident reporting itself; the

benefit of standardizing procedures, protocols and medicine strengths and Introducing and assessing a safety culture.

In approaching the literature review in this way it would become clear as to whether or not research to date had identified ways in which to answer the research questions stated as the aims of this thesis that is to identify latent risks associated with in a specific task set in an NHS paediatric hospital pharmacy department. Then to establish the extent to which these latent risks may be predicted. Also to investigate the efficiency and effectiveness of the current Incident reporting system (IR1s) in supporting learning from incidents and changing practice and finally, to determine the impact of introducing a Quality Management Approach to process design into one process on an acute Oncology ward in the same paediatric hospital and determine the benefits of this approach including in terms of risk reduction.

In order to begin to fill in the detail, the next step was to investigate the impact of the environment on operatives working in the defined setting. Could something as simple as the conditions that operatives were expected to work in impacting detrimentally on the ability to function optimally? Were conditions to hot or too cold for example, were systems such as workflows inefficiently designed? Might an operatives emotional state affect their perception of the environment to reduce their operating capacity as much as if the conditions were actually suboptimal.

How might operatives function under stress inducing conditions? Workload capacity is often discussed quite reasonably in many working environments and under many systems and an optimal workload capacity is defined. Not so in pharmacy, where workload is generally managed reactively rather than on the basis of capacity, safety and efficiency. The question to investigate therefore is what is the impact on an operative's work strategy as workload increases and stress levels rise as a consequence. Following on from this it was determined that it was important to investigate how increasing an individual's stress levels affected an individual's approach to the way in which they worked and whether their approach changed and whether this in turn increased or decreased the potential for errors to occur.

Having looked at general safety management strategies, the impact of environment and process design and then how stress impacts on operatives through the proxy of increasing workload the next step was to investigate how efficient the incident reporting process really was. When an error has occurred it was important to discover whether or not the existing error or incident reporting systems work efficiently enough and effectively enough to actually be able to deduce the cause of a particular error and then generate learning that can actually impact on preventing that particular error scenario from re occurring in the future.

Error causation and error prevention strategies are well developed in many high risk industries, the nuclear industry, the Oil industry, Shipping, Pharmaceuticals and classically amongst airlines, but less so within healthcare. Possibly this is due to the fact that healthcare is less organised, less structures less organic that these other industries being staffed in critical areas by independently minded professionals rather than employees and as such changing culture is more difficult than it might otherwise be. However, this is conjecture.

High-risk industries have developed sophisticated Quality Management Systems (QMS), process are developed that are well designed, efficient and safe and continually performance monitored. Standard operating procedures (SoPs) are well written and training is appropriate together with continuous improvement embedded into their cultures. Teamwork and flattened hierarchies are commonplace and the use of visual prompts and other safety strategies ubiquitous. This next section was a proactively designed project to test the hypothesis that QMS could be introduced into healthcare. The literature search for this section looked for the existence of the implementation of QMS and elements of QMS such as visual prompts such as checklists.

Finally, to compliment the QMS section a literature review of research relating to NHS Hospital medicines management policies in relation to safety, error reduction, inclusion of human factor elements, team work, the encouragement of the use of flattened hierarchies, the use of visual prompts such as checklists was carried out.

Conclusion

The literature review indicated that there is indeed a gap in understanding in being able to predict error causation in the context of a paediatric National Health Service hospital pharmacy. That learning from errors or incidents and thereby being enabled to change working cultures in order to reduce system failures and resulting errors, is seldom proactive and when it is, changes are made wholesale so understanding as to what works and why, is arguably missed. Clearly a systematic and reasoned approach to an appreciation of error causation in a paediatric healthcare setting together with the introduction of effective quality management systems culture changing initiatives is required and this was the aim of this thesis.

Chapter 3. Latent risks in Paediatric Pharmacy identified in the dispensing process

Introduction

The primary aim of this thesis was to identify latent risks associated with in a specific task set in an NHS paediatric hospital pharmacy department and then to go on to establish the extent to which these latent risks may be predicted. If a latent risk can be predicted, then it may be possible to mitigate the risk to reduce it or eliminate it entirely and thereby reduce the number of latent risks developing into actual incidents.

In order to do this an understanding of the system, the processes that occur within it including investigating the impact of that system upon those required to work within it needs to be obtained. In addition, existing error prevention barriers put into place to prevent risks from developing into errors needs to be considered and gaps in these noted.

Finally, latent risks known to be an issue from the literature review stress and interruptions to be investigated specifically.

Objectives

- To identify latent risks that exist within one step in the dispensing process, the accuracy checking step, in a paediatric hospital pharmacy
- To observe the accuracy checking process itself in detail
- To investigate the impact of the environment (the dispensary) on operatives working within it.
- To ascertain how operatives, view their working environment
- To establish a link, if it exists, between workload and stress
- To determine if interruptions is a latent risk with particular significance in paediatric pharmacy.

Background

The dispensing process consisted of the following steps; receipt and logging of requests for medicines onto the computer system; a clinical check by a clinical pharmacist; labelling of the medicine using the Ascribe © pharmacy system; assembly; accuracy checking by a qualified Checker Technician and logging out.

The specific dispensing step selected for observation was accuracy checking, a discrete readily observable process. Each task is brought to the accuracy checker complete with everything required to complete the task in a tray and the elements that comprise this task are explicit and immediately observable, unlike the other two steps; Labelling is essentially rule-based selection tasks carried out on the dispensary software system or from a store shelf. Clinical screening is essentially cognitive and difficult to observe. In this process, the operative is required to check that the correct medicine is dispensed for the correct patient. Dose calculations, correct labelling of the items and attachment of all required ancillaries and additional instructions are also checked.

Method

The study environment was the inpatient/outpatient dispensary of Birmingham Children's Hospital (BCH), a tertiary referral specialist Children's Hospital. The study instrument was non-participant, direct observation of routine dispensing tasks. A discrete, clearly identifiable step within the dispensing process was chosen for this study.

In this study nine technicians and nine pharmacists were each observed for up to a 30-minute period. The observations themselves were carried out between February 2008 and December 2008, and during each observational period the subject accuracy-checked items passing through the dispensary. The observations were carried out at different times of the day throughout the week. The overall activity or business of the dispensary was also measured in terms of the number of medicines items being processed within the whole dispensary during each observation period. These data were extracted from the Pharmacy management system, Ascribe©.

Details of the observations made of each study event included background noise and interruptions, and these factors were recorded using a set of codes (Table 1). The codes were derived by reducing the most commonly observed tasks, interruptions and background noises, to a brief description and associated abbreviation. This code set was then used to record each action that an accuracy checker performed, each interruption that occurred and each type of background noise. There were 57 events and associated codes used, examples of these were, AT for air tube, CBl for check bag label, CB for a visual check of a bottle, IP denoted that the medicine request was initialled and so on.

Event	Code
Air Tube	AT
Asked question	AQ
Asks a question	QA
Bags Item(s)	BI
Beeping	BP
Bin (Or Loud Sudden Noise)	B
Bleeped	BD
Calculates	CAL
Check Bag label	CBL
Check Container. Label	CCL
Check prescription	CP
Check printed Label	CPL
Check Contents(I.e. Vial)	CCV
Checks Bottle(Visual check Bottle)	CB
Checks Contents(opens and smells)	CCOS
Checks Contents (tablet strips)	CCTS
Checks For Information	CFI
Checks Items(Recheck)	CIR
Checks Patient Instruction Sheet	CPI
Checks Prescription Protocol	CPP
Communication Note	CN
Correction By Dispenser	CBD
Correction By Checker	CBC
Correction By Labeller	CBLL
Door (person enters or leaves)	D
Error Found	EF
Files prescription	FP
hatch conversation	HC
Initials label	IL
Initials prescription	IP
Logs chart Out	LO
Logs item out	L
Medicine bin	MB
Named patient File	NPF
Next Item	NI
Other Related Task (At Bench)	ORTB
Other Related Task (walks away)	ORTW
Person Enters Checker's Workspace	PEW
Person Walks Close Behind Checker	PW
Person Working Close behind (OR NEAR TO) Checker	PWC
Phone Conversation(Asked for)	PCA
Phone Conversation(background)	PCB
Phone Conversation(makes one)	PCM
Phone Rings	P
Printing	PR
Return To Bench	RTB
Separates Script Copies	SCC
Talking Background	TB
Talking Background Multiple Conversations	TBM
Tray (Items Removed To Bench)	TIR
Tray(New)	TN
Tray(New Brought)	TNB
Tray Away	TA
Tray Search (Many Items-looks for next)	TS
Type	Code
Walks to Fridge	WF
Walks to Pigeon Holes	WP

Table 1 a list of dispensary events, tasks, actions and interruptions together with the codes used to record them.

Eighteen members of the pharmacy staff at Birmingham Children's Hospital staff, comprising of nine Pharmacy technicians and nine Pharmacists were approached by the researcher and invited to participate in the study. This represented 36% (n=25) of the technician workforce and 37.5% (n=24) of the pharmacist workforce in the department. The invitation took the form of an informal interview in which the aim of the study was explained to them. In particular, it was explained that observations were not assessing their work but rather the impact of the environment on them. It was also explained that the study had been submitted into the National Health Service (NHS) ethics approval process and the advice received was that the study was viewed as a service improvement and as such did not require ethics approval. (Appendix 8)

Questionnaires

During the four-month period immediately prior to the observations being carried out, that is October 2007 to January 2008, accuracy checkers were invited to complete a questionnaire, (Appendix 1) consisting of six multiple choice questions that recorded the impressions of the participants on the dispensary environment at a particular moment in time. The survey was developed using material developed by the Health and Safety Executive, HSE (2004)[92], Eurofound – The European foundation for the improvement of living and working conditions[93], The NASA task load index (Hart 2006)[94], and two Survey Monkey survey templates, Employee satisfaction survey questions and Management performance template survey.[9596]

The Questionnaire itself consisted of a set of 6 areas. One area had three sub-sections. The respondent was invited to indicate the degree of impact each area had on them. The areas were Environment, Workloads, Focus, Workspace, Equipment/references and Knowledge base. An example of *degree* for the Area *workspace* asked the respondent to comment on the workspace they were in for that particular duty slot. That is, was the workspace cluttered or spacious or adequate? Another area was *environment* and respondents were asked to indicate on *temperature*, *lighting* and *background noise* levels. There was also a space for comments to be made. The forms were readily available for respondents to complete as often as they chose to do so, one form for each work session.

The questions inquired as to an operative's *impression* of the workload during that session. This was purely an impression and not necessarily factually based, that is workload data wasn't accessed to answer this question. Also they were asked where they thought their focus was during the session. This was an attempt to assess whether they thought that their mind was on the task in hand or whether they felt distracted in some way mentally or emotionally. Views on the workspace, available equipment and reference books also were recorded. They were also asked if they felt that they had the necessary knowledge to deal with the work presented to them during that session. Finally, there was also opportunity to make written comments and those that found a particular session stressful or had made

[92] Health and safety Executive; HSE Management Standards indicator tool; User Manual. (2004)
[93] European foundation for the improvement of living and working conditions; Measuring Job Satisfaction in Surveys- Comparative analytical report.(2007)< http://www.eurofound.europa.eu> accessed July 2013
[94] Hart, S., G. (2006). NASA-task load index (nasa-tlx); 20 years later N.-A. R. Center.

[95] Survey Monkey; Employee Satisfaction Template Survey.pdf (2013)
[96] Survey Monkey; Management Performance Template Survey.pdf;(2013)

errors often elected to complete this section. In total 35 forms were completed by 8 accuracy checkers.

After the observations were made each accuracy checker was interviewed using a semi-structured interview technique. All participants were asked the same set of seven questions (Appendix 1) that produced a framework to elicit their views on how content they were to carry out accuracy checking duties and the work environment itself. Participants were asked to comment on:

- Distractions that occurred
- How they felt about these
- Whether they had their own checking system to which they worked
- An error that they had made and what they thought contributed to making this error and how this had affected them.

Focus Groups

Two focus groups were organised after the observations period had been completed, each with nine participants, one for technicians and one for pharmacists. All of the participants had taken part in the observational study described in this report. Each group was constituted from a single professional group in order to encourage more openness of response and to observe the impact, if any, that professional culture, experience or training would add to the discussions. Each group was convened for a single sixty-minute uninterrupted period and facilitated by the same investigator and who also took notes of the key emerging themes. The groups were tasked with two objectives:

(1) Each group was asked how many steps they thought it took to accuracy check a prescription for a bottle paracetamol liquid.
(2) To compile a process map for the accuracy checking process using basic systems analysis techniques, consisting of processes represented by boxes connected by lines to show the order in which tasks are performed, as used in SSADM (Structured systems analysis design methodology) for example. SSADM is a systems approach to the analysis and design of information systems. SSADM was produced for the Central Computer and Telecommunications Agency, a UK government office concerned with the use of technology in government, from 1980 onwards[97]. The investigator acting as facilitator for the group added the tasks in the sequence suggested, to the A1 paper on a

[97] Wikipedia entry https://en.wikipedia.org/wiki/Structured_systems_analysis_and_design_method <accessed August 7th, 2016>

flip chart, creating a task flow diagram. As a result, a detailed task by task sequential work flow diagram was compiled by each group. (Appendix 4)

Statistics

The linear lines that were added to the graphs were linear regression lines, that is a model in which the conditional mean of *y* given the value of *x* is an affine (connected with) function of *x*. The standard error, or standard error the mean (SEM), that is the standard deviation of the multiple samples means was used rather than simply the mean of the samples. The SEM gives a measure of how well the sample represents the sample. When the sample is representative, the standard error will be small. The division by the square root of the sample size is a reflection of the speed with which an increasing sample size gives an improved representation of the population. An approximation of confidence intervals can be made using the mean + / - standard errors. The SEM can be calculated by dividing the standard deviation of the sample by the square root of the sample size. (Syque 2002-2009)[98]

Results

Observational data and data extracted from the pharmacy management system enabled a data set to be compiled. Comparisons could then be made between both staff groups, showing the relationship between business of the dispensary against a number of parameters including the steps taken to process each medicine request; the number of safety checks and the time taken to check each medicine request. The data is recorded in tables presented before each corresponding graph. In Figures 1-3 data sets for the pharmacists are shown in green and those for technicians in blue. Along the X axis on each of the graphs is an indication of the overall business of the dispensary, measured in number of items processed in each half hour period.

[98] Syque 2002 http://changingminds.org/explanations/research/statistics/standard_error.htm (accessed 2009)

Technician	items per half hour	*Time per Prescription (mins)	Pharmacist	items per half hour	*Time per Prescription (mins)
1	36	3.8	10	38	4.4
2	24	5.0	11	29	3.8
3	22	6.7	12	27	2.3
4	20	6.0	13	22	3.2
5	19	3.8	14	21	3.4
6	15	10.0	15	20	3.3
7	12	7.7	16	19	3.1
8	11	7.5	17	17	3
9	11	4.3	18	14	2.9

Table 2 The average time taken to check an item (pharmacist and technician groups) and the total work activity (number of items) for each 30-minute observation period

*Time here was the average time an individual took during the observed session

The mean for technicians group was 6.09 +/- 1.4 (SEM) and for the pharmacists group was 3.27 +/- 0.4. (SEM)

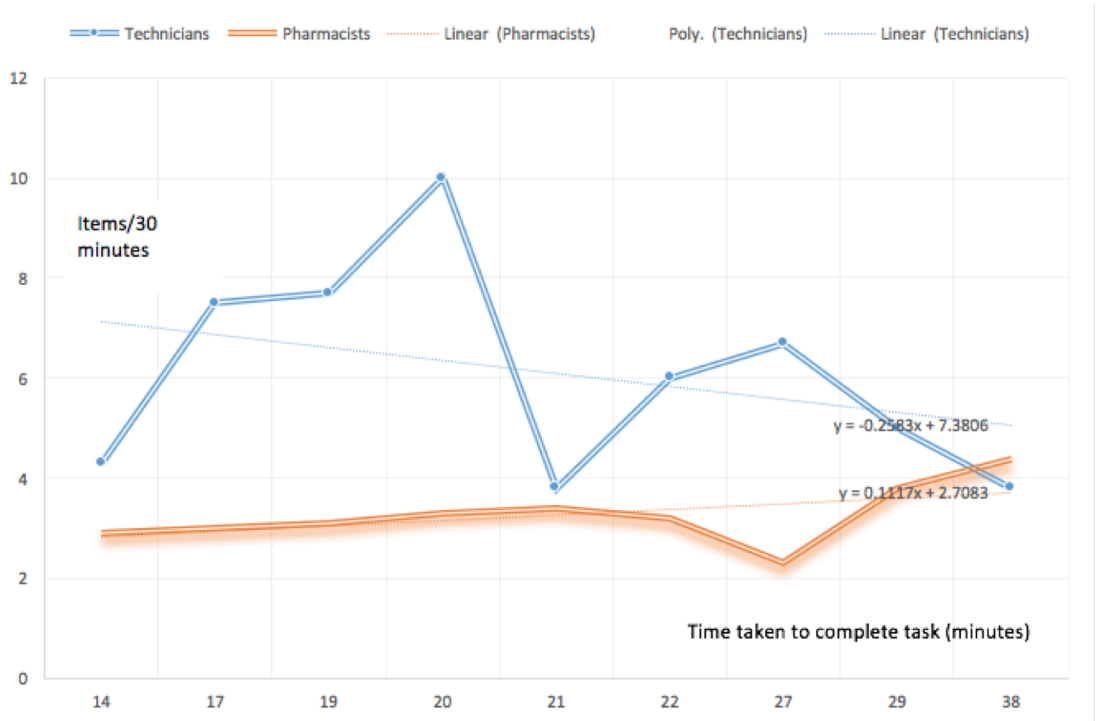

Figure 7 (Graph 1) Shows the average time each participant took to accuracy check an item and how this varied as work activity increases within the dispensary.

The data indicated that as general workloads increased, the time that checking technicians spent on checking an item tended to decrease, whereas the time pharmacists spent on checking showed a trend to increase. The trend lines were calculated by excel, the formula for the technician trend line was The trend lines were calculated by excel, the formula for the technician trend line was y = -0.2583x + 7.3806 and for the pharmacist trend line was y = -0.2583x + 7.3806

Pharmacist	average steps	items per half hour	Technician	items per half hour	average steps
11	35.8	38	1	36	21.0
12	35.8	29	2	24	7.0
13	22.1	27	3	22	26.0
14	23.3	22	4	20	24.4
15	22.2	21	5	19	21.7
16	42.5	20	6	15	90.0
17	26.9	19	7	12	11.0
18	28.7	17	9	11	23.7
19	28.9	14	8	11	26.0

Table 3 The average number of steps* a Technician checker and Pharmacist checker makes per item checked and items passing through the dispensary in a half hour period as a measure of work activity

The mean for the Pharmacist group is 29.6 +/- 4.72 (SEM) and for the Technician group is 27.9 +/- 16.1(SEM). With regard to statistical significant differences between the groups: If the two confidence intervals do not overlap, we can conclude that there is a statistically significant difference in the two population values at the given level of confidence

- Where a ‘Step’ was a clearly observable discrete action, for example reading a label.

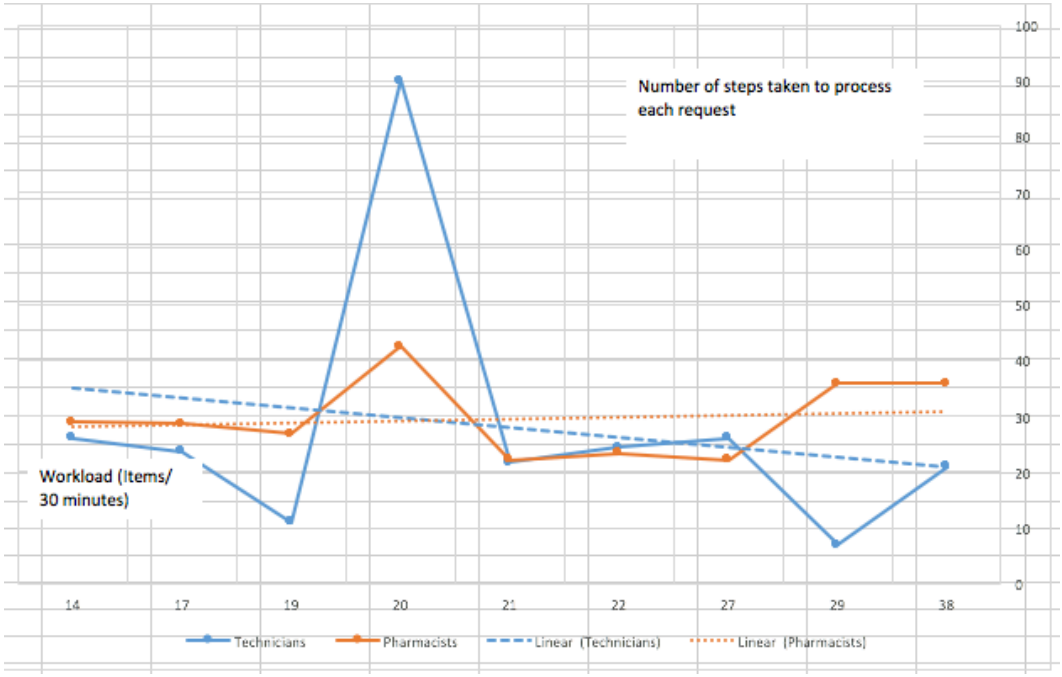

Figure 8 (Graph 2) Workload of Dispensary (number of items processed in a 30 minute period) versus Steps taken to process each request

The graph (Figure 8) shows the variation in the number of steps that an individual carried out in order to accuracy check an item together with workload passing through the dispensary. The trend lines indicate that as workloads increased the number of steps increased for the pharmacist group but decreased for the technician group. The trend lines were calculated by excel, the formula for the technician trend line was y = 1.7617x + 19.058 and for the pharmacist trend line was y = -0.335x + 31.253.

Technicians	Safety checks	items per half hour	Pharmacists	Safety Checks	items per half hour
1	63	36	**10**	75	38
2	19	24	**11**	37	29
3	30	22	**12**	72	27
4	54	20	**13**	40	22
5	49	19	**14**	57	21
6	90	15	**15**	68	20
7	3	12	**16**	82	19
9	57	11	**17**	69	17
8	48	11	**18**	73	14

Table 4 Safety checks carried out and items passing through the dispensary per half hour. The mean for the Pharmacist group is 63.7 +/- 10.5 (SEM) and for the Technician group is 45.9 +/- 17.1(SEM)

(*Where SEM is the standard error of the mean)

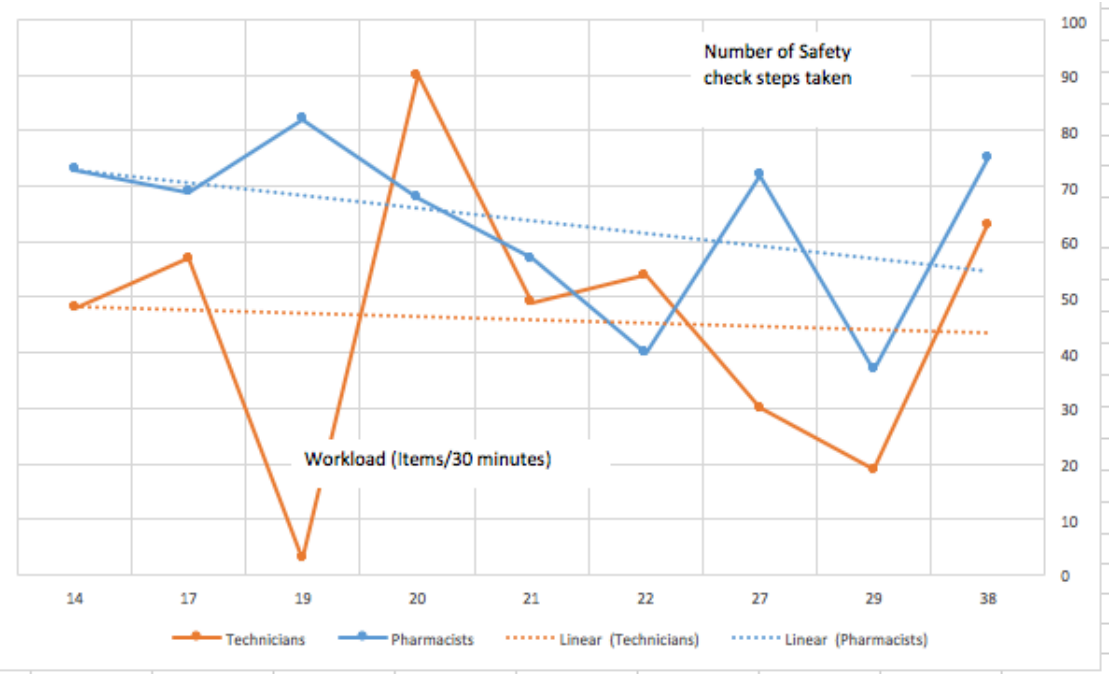

Figure 9 (Graph 3) the number of steps that could be said to have Safety implications* v's Workload (the number of items passing through the dispensary in a 30 minute period)

*A Safety step for example would be to ensure that the dose was correct as compared to a purely functional step for example checking that a medicine spoon was present.

Figure 9 shows that for both groups, as workloads increase the number of steps that could be defined as safety checks changed. The trend for the technician group was for the number of safety groups to increase and for the pharmacist group to decrease. The pharmacist group appeared to carry out more safety checks from the outset.

Questionnaires

Blank questionnaire forms were available in the dispensary during the three-month period prior to the observations starting. The individuals who had agreed to participate in the observations were invited to complete a questionnaire whenever they were assigned to a dispensary accuracy checking session. Individuals could therefore complete more than one questionnaire form should they have been assigned to more than one dispensary accuracy checking session.

Of the 34 questionnaires completed, 5 (15%) contained comments indicating that the respondent had made an error personally. Even though they then went on to correct that error, they were asked to note the fact that an error (sometimes euphemistically called a 'near miss') had been made. The respondents were also asked to comment on several potential influencing factors that included environmental observations, for example they were asked to indicate whether the dispensary felt hot or cold or comfortable and to rate the lighting and also background noise levels. Other factors examined were workloads, focus (a range from "on the job in hand" to "day dreaming"), work space, references available and adequacies or otherwise of their knowledge to perform the tasks expected of them.

Number of completed forms* n=34	Did they feel challenged or out of their depth in that session	Were Noise levels Distracting	Did the dispensary feel too cold or too hot	Was the lighting Harsh	Did the work place appear to be Cluttered	Did they feel Stressed in that session	Did they make an error during That session
Busy	13	8	9	5	14	10	4
20	65%	40%	45%	25%	70%	50%	20%
Not busy	3	2	5	1	2	2	1
14	21%	14%	36%	7%	14%	14%	7%
Stressed	7	6	7	2	9		5
12	58%	50%	58%	17%	75%	-	42%
Not Stressed	9	4	7	3	7	-	0
22	41%	18%	32%	14%	32%	-	0%

Table 4 Summary of Questionnaire results, of how an individual perceived the dispensary environment that is how it was impacting on them during a particular dispensary session

* Individuals were asked to complete a questionnaire as often as they wanted, during a 16-week period. One questionnaire was completed for an individual checking session

The results showed that 20 out of 34 questionnaires were completed after a *busy* checking session in the dispensary, that is *busy* as perceived by the individual completing the form, and 14 questionnaires were completed after a quiet session or one with a reasonable workload. Respondents were more likely to feel challenged or out of their depth in a busy session (81%) than in a non-busy session (19%). They were more likely to find noise levels distracting in a busy session (40%) than in a non-busy session (14%), similarly the dispensary temperature was more likely to be uncomfortably either too hot or too cold in a busy session (45%) than a non-busy session (36%); the lighting to be too harsh (25%) compared with (7%); the dispensary to appear to be cluttered (70%) to (14%) and to feel stressed (50%) as compared with (14%). The results correlate with feeing stressed and non-stressed. This confirmed that business was a reasonable proxy measure for stress.

Participants recorded that they felt *stressed* during 12 of the 34 occasions that a form was completed (35.3%) and errors were made and noted on 5 questionnaires (41.7%). No errors were noted on the questionnaires completed after a checking session during which the participants didn't feel stressed. People felt stressed only one session in three but when they did they were 5 times more likely to make an error.

Date	Time	Initials	Environment -Noise	Environment -Temp	Environment - Lighting	Workload	Focus	Workspace	Equipment /references	Knowledge base	Error reported	Items range	Items average	Items	Initials
28/01/2008	15:00-17:30	MS	EN2	ET1	EL1	WL1	F1	WS2	E1	K1	Y				MS
06/02/2008	13:45-15:00	KM	EN2	ET1	EL1	WL1	F1	WS2	E1	K1	N			77	KM
07/02/2008	12:30-13:45	KM	EN2	ET2	EL2	WL3	F1	WS3	E1	K1	N			135	KM
18/02/2008	12:30-13:45	SM	EN1	ET1	EL1	WL3	F1	WS1	E1	K2	N			165	SM
07/02/2008	15:00-16:30	LW	EN3	ET1	EL1	WL2	F5	WS3	E3	K1	N			109	LW
18/02/2008	10:00-11:20	DR	EN2	ET1	EL1	WL2	F5	WS2	E3	K1	N			28	DR
25/01/2008	11:15-12:30	LW	EN3	ET1	EL1	WL2	F5	WS3	E3	K1	N				LW
01/02/2008	11:15-12:30	KM	EN1	ET1	EL1	WL2	F5	WS2	E1	K2	N			69	KM
31/01/2008	12:30-13:45	LW	EN2	ET1	EL1	WL2	F5	WS3	E2	K2	N				LW
25/01/2008	14:30-16:16	KM	EN1	ET1	EL1	WL3	F1	WS3	E1	K1	N				KM
24/01/2008	12:30-13:45	LW	EN2	ET1	EL1	WL2	F5	WS3	E3	K1	N				LW
23/01/2008	13:45-15:00	KM	EN1	ET1	EL1	WL2	F1	WS2	E1	K1	N				KM
22/01/2008	15:00-16:30	KM	EN1	ET1	EL1	WL1	F1	WS3	E1	K2	N				KM
04/02/2008	15:00-16:30	LW	EN1	ET2	EL1	WL3	F5	WS1	E2	K2	N				LW
19/11/2007	15:00-16:40	SM	EN3	ET1	EL1	WL3	F5	WS1	E1	K2	Y				SM
17/12/2007	16:15-17:30	MS	EN2	ET1	EL1	WL4	F5	WS2	E1	K1	N				MS
14/02/2008	11;15-13:30	RB	EN2	ET3	EL2	WL3	F1	WS1	E1	K2	N				RB
15/02/2008	11:15-13:30	RB	EN2	ET3	EL2	WL3	F1	WS1	E1	K2	N				RB
21/02/2008	11:15-13:10	RB	EN2	ET1	EL2	WL2	F1	WS3	E1	K2	N				RB
13/02/2008	11:15-13:30	RB	EN2	ET3	ET2	WL3	F1	WS1	E1	K2	N				RB
12/02/2008	11:00-12:30	RB	EN2	ET3	EL2	WL3	F1	WS3	E1	K1	Y				RB
23/07/2007	13:45-15:00	LW	EN1	ET3	EL1	WL3	F3	WS1	E3	K1	Y				LW
03/12/2007	13:45-15:15	SO	EN3	ET3	EL1	WL3	F5	WS1	E3	K1	N	19-71	39	34	SO
18/01/2008	11:15-12:30	RB	EN2	ET3	EL1	WL3	F1	WS1	E1	K1	Y	17-48	32	48	RB
30/11/2007	16:30-18:30	MS	EN2	ET1	EL1	WL4	F5	WS3	E4	K3	N	13-74	34	29	MS
04/12/2007	14:00-16:30	MS	EN3	ET3	EL1	WL3	F1	WS3	E1	K2	Y	55-134	92	94	MS
05/12/2007	08:30-13:30	RB	EN3	ET2	EL2	WL4	F1	WS1	E1	K3	N	172-272	196	172	RB
07/12/2007	11:15-13:30	SO	EN2	ET3	EL1	WL2	F1	WS3	E3	K1	N	17-48	32	29	SO
06/12/2007	08:30-13:30	RB	EN2	ET3	EL1	WL3	F1	WS1	E3	K2	N	140-229	174	156	RB
02/11/2007	11:15-17:30	RB	EN3	ET3	EL2	WL4	F1	WS1	E1	K1	N	17-48	32		RB
25/02/2008	12 :30-13:45	MM	EN3	ET1	EL1	WL4	F3	WS1	E1	K2	Y				MM

Table 5 Showing results from the Questionnaire

Key: The letters indicate the parameter, for example WL = Workload, ET= Environmental Temperature and so on. The numbers indicate where on the "Likert", Allen,E (2007)[99] scale the respondents felt they were. A Likert scale is a simple linear scale used to represent people's views with regard to an issue. The scale may be numerical for example with the numbers 1-3, or 1-5, or 1-10 and have words associated with the numbers for example 1(do not agree), 2 (Have no opinion), 3 (agree). A respondent is then given a statement and asked to indicate which of the options most closely matches their point of view with regard to the question asked. Some parameters, for example ET had a scale consisting of three options indicating that the environmental lighting was "Comfortable", "Harsh" or "Dark". This was recorded as ET1, ET2 or ET3 and so on. Some parameters, Workload (WL) for example had a Likert Scale consisting of 5 options.

Of the respondents who had indicated that they had felt stressed during the session that they had selected to complete a questionnaire for, 53% (n-19) had also replied that the dispensary workload seemed busy or very busy (manic) to them as compared with 17% (n=12) who thought that the workload was "quiet" or "reasonable". The inference being that there is

[99] Allen, E; Seaman, C; Likert Scales and data Analyses; Quality Progress; July 2007;< http://asq.org/quality-progress/2007/07/statistics/likert-scales-and-data-analyses.html>

indeed a link between workload and an individual feeling stressed, and that workload is a reasonable proxy measure for stress.

n=34	Busy	Not Busy	Comparison (Busy:_Not Busy)
Distracted by background noise	40%(8)	5.90%(2)	4
Felt stressed	50%(10)	2.90%(1)	10
Made an error	20%(4)	0%(0)	4
Distracted by background noise and felt stressed	14.70%(5)	2.90%(1)	5
Distracted by background noise and felt stressed and made an error	5.80%(2)	0%(0)	2

Table 6 Summary of Questionnaire Results Analysis Selecting responses related to noise, stress and errors

Table 5, above, shows that operatives are four times (40%, n=8) as likely to be distracted by a background noise when they feel busy than not (5.9%, n=2), 10 times as likely to feel stressed (50%,n=10), four times more likely to make an error (20%,n=4), 5 times as likely to be distracted by a background noise and feel stressed (14.7&,n=5) and twice as likely to feel distracted, stressed and make an error (5.8%,n=2). There would appear to be evidence to indicate that feeling busy is stressful increases the probability of the existence of distracting background noise and these error generating mechanisms or sub-standard acts, Groeneweg (2002) leads to errors.

The Interviews

The interviews consisted of seven questions and the responses were analysed using a qualitative analysis key theme methodology. The questions elicited views on the accuracy checking workstation, for example where it was positioned in the dispensary. Interviewees were asked about interruptions and how they managed these. Checkers were also invited to talk about an error that they had made. For all participants key words themes revolved around Interruptions (Noise, “being the person to ask”, that is perceived as the person who will know the answer ; Environment; workplace design) and Errors (training and procedures;

emotions; work pressure and design of paperwork). Five key themes emerged from the interviews. Each time a theme was raised by an interviewee it was noted, the figures in brackets denote percentage occurrence of a theme amongst the interviewees. (n=18)

1. Design either of the paperwork being used or the dispensary itself. (39%)
2. Interruptions such as background noise, being asked questions and the phone being left to ring (100%)
3. Emotions such as anger or feeling pressured by expectations of others whether colleagues or patients/carers (70%)
4. Processes not being followed that resulted in incomplete information being available to the checker, for example incomplete patient drug records on the pharmacy computer system. Lack of training would be a subset of this theme (40%)
5. Workloads, simply being too busy. (70%)

In addition to describing an error, each interviewee was asked to mention any causal factors that led to the error being made. 45% of interviewees attributed the error to being *busy* and so feeling stressed or distracted. 6% attributed the error to the emotional state they were in at the time (angry) and 6% of interviewees attributed the error to the poor design of the paperwork used.

Focus groups

Two focus groups were organised after the observations period had been completed. One group consisted of the nine pharmacy technicians and the second group of nine pharmacists. Each group was asked how many steps they thought it took to accuracy check a prescription for a bottle paracetamol liquid. Interestingly both groups suggested that it took 5-6 steps to check a medicine although as will be seen later the actual number of steps for both groups was significantly higher than this, in fact the mean number of steps taken for the Pharmacist group was 29.6 +/- 4.72 (SEM) and for the Technician group was 27.9 +/- 16.1(SEM).

Discussion

The initial phase of the present study set out to identify latent risks associated with a specific paediatric pharmacy process, the final accuracy check, and then to establish the extent to which latent risks inherent within the system may be predicted.

This investigation took the form of observations, interviews, questionnaires and focus groups. Eighteen members of the pharmacy staff at Birmingham Children's Hospital FT participated in the study, which was carried out over an eight-month period. Each participant agreed to take part in the study and was observed whilst accuracy-checking medicine orders for a 30-minute period. Nine of the participants were pharmacy technicians qualified to accuracy-check medicine orders and nine were pharmacists. The questionnaires were completed during a four-month period prior to the observations being made. Ethics approval was deemed not to be required as the study was seen as a service improvement.

The observations were reduced to three data sets. Firstly, the impact that increasing workload, the number of items being processed by the dispensary in a 30-minute period, had on the time each participant took to process items. This could be considered to be an indication or simple measure of the impact of increasing stress on an individual. Secondly, the number of steps or actions taken whilst checking an item was also recorded and how this changed as a function of workload in the dispensary. Thirdly, a sub set of the number of steps was plotted against increasing workloads. This sub set consisted only of steps that were considered to be *safety* steps as opposed to process steps. An example of a safety step would be *checking the strength of the drug* and an example of a purely process step might be *packing items into a bag*. In addition, the technicians and pharmacists were treated as two distinct groups.

The first data set measured the average time an individual took to check items during a particular observational session as a function of increasing workload. The more items passing through the dispensary during each observational, 30-minute period, was taken as an indication of workload pressure each individual experienced. The results showed that for the pharmacy technician group, as work pressure increased the time taken to accuracy check an item decreased. For the pharmacist group the reverse occurred, that is as workload pressure increased so did the time taken accuracy checking items. The pharmacist group, in other words, spent more time checking items the more they felt under workload pressure. This indicates that each group seems to have a different approach to this task. It is also worth noting that the mean time for the pharmacist group was almost half that for the technician group notwithstanding the fact that this group slowed down as work pressure increased.

The second data set measured the average number of steps that a participant took to check an item as a function of workload pressure. The results showed that as workload pressure increased the number of checking steps that individuals took varied. As workload pressure increased, the technician group reduced the number of checking steps that they made and

conversely the pharmacist group increased the number of checking steps as workload pressure increased.

The third data set, measured *safety* steps which as explained above in the 'Method' section is a sub-set of the *steps* taken data set as a function of workload pressure and, for both groups, as workload pressure increased the number of safety related steps again changed. For the technician group the number of safety checks increased, whilst for the pharmacist group the number of safety checks decreased as workload pressure increased. Although the number of the safety checks for the pharmacist group decreased with increasing work pressure, this group appeared to carry out more safety checks from the outset. The number of safety steps decreased from a higher number of safety steps carried out than that carried out in the technician group and remained at a higher level in comparison to those of the technician group. There was a noticeable difference between the two groups in their approach to managing increasing workloads, the technician group appeared to be task focused, intent on managing the increased workload. By comparison the Pharmacists appeared to be more safety conscious. This raises the question as to what was the reason for the difference in approach between the two groups? The pharmacy technician group collectively had more dispensing experience than the pharmacist group. Clearly the degree of education was a variance between the groups, the Pharmacists all possessed master's degrees whereas the pharmacy technician group had lesser educational qualifications. It could be argued however; that education would only be relevant if the underlying competencies required performing the tasks being observed was a factor. One clear difference between the pharmacist group and the pharmacy technician group, at the time of observation, was the fact that the pharmacists were regulated by a professional body that required adherence to a code of practice. In other words, professionalism may have been the determining factor to account for the difference in approach between the two groups.

Questionnaire

The questionnaire forms were available for participants to complete on an as and when basis over a four-month period prior to the Observations being carried out. Individuals completed a form after one of their regular accuracy checking work sessions in the dispensary. The number of forms completed by an individual varied and a total of 34 forms were completed in all. An analysis of the results indicated that a definite link existed between making an error and an awareness of the surroundings that an operative, in this case an accuracy checker, was working in. Respondents only felt stressed on one session in three but when they did

feel stressed they were four times as likely to be distracted by a background noise when they felt busy than when they didn't feel busy, 10 times more likely to feel stressed, four times more likely to make an error 5 times more likely to be distracted by a background noise and feel stressed and twice as likely to feel distracted, stressed and make an error. There would appear to be evidence to indicate that feeling busy is stressful increases the probability of the existence of distracting background noise and these errors generating mechanisms or sub-standard acts, Groeneweg (2002) leads to errors.

It is not surprising that when workloads are high, then it is likely that background noise and interruptions will increase, that work spaces will be more cluttered, an individual's knowledge base will be challenged and an individual's stress levels will rise as indicated by the results of the questionnaire. Clearly, both background noise and direct interruptions impact directly on an operative, as does to a lesser extent, the ambient environment (heating and lighting etc) or perhaps how the ambient temperature and lighting are perceived as in the dispensary in a hospital theses variables tend to be kept constant.

Interviews

These findings were corroborated by a thematic qualitative analysis of the interviews. Key themes that emerged included *Pressure to work faster*, *noise, Training & Procedures, workplace design, distracted, emotion* and *paperwork design.* All but *distracted* and *emotion* can be recognised as having Basic Risk Factor (BRF) antecedents.

The Focus Groups

Both groups suggested that it would require 6 or 8 steps to check an unambiguous prescription for a bottle of Paracetamol liquid for a child. Both groups then went on to outline a 40-50-step checking work stream when asked to break the process down task by task. The Observational study found that the actual number of steps each group took as being far higher. This would indicate that in practice there may currently be redundant steps in the checking process. Redundant in the sense of unnecessarily repeating steps most likely as a consequence of a direct or indirect interruption, an example of a direct interruption would be being asked a question and an indirect interruption could be noise generated from a telephone ringing. Without the use of a visual aid an operative would be uncertain as to how far they had reached in the process and would automatically retrace their steps to a known break point. In addition, the number of steps varied, either decreasing or increasing with increasing work pressure.

What explanation could account for the marked difference in observational results between the two groups? Arguably, the strategy and work ethos for each group investigated was a function of training and perceived differential responsibilities existing between the two groups, in other words the differences being due to either being task driven or carrying legal and professional responsibility for dispensing outcomes.

Project limitations

It was recognised that the sample size for this study was small in number, 18 operatives in total, and the results should be interpreted in this context. The investigation was itself substantial. The intention was to examine the prediction of errors in paediatric pharmacy using one task in the dispensing process. Therefore the results are valid in this setting. Recording and coding observations without the use of technology, arguably also has its limitations. These criticisms are mitigated somewhat by there being one observer undertaking all the observations with attendant consistency.

It should also be noted that medicines items requiring dispensing for children can be inordinately complex, take significantly longer to dispense than a similar medicine for an adult and consequently have the potential for more errors associated with the process. Processes and systems applied to the paediatric pharmacist setting that lead to the development of safer dispensing environments would therefore be able to be transferred to the arguably less demanding adult general hospital dispensary setting.

The results were somewhat unexpected and showed that as workloads (stress) increased the time spent on checking an item decreased for the technician group but increased for the pharmacist group. This trend was repeated in the second data set that is, as workloads (stress) increased the number of steps taken to check an item reduced for the technician group but increased for the pharmacist group. Interestingly, the number of purely safety checks increased for the technician group and showed a decrease for the pharmacist group as workloads (stress) increased. Although it can be seen from the graph that whilst the number of safety checks is reducing for the pharmacist group, the total number of safety checks is higher when compared with the technician group.

Professionalism

A Profession according to The Merrisam-Webster on line dictionary is *a calling requiring specialized knowledge and often-intensive academic preparation*; it continues *a principal vocation or employment*. The word Profess derived from profiteri to declare aloud and fateri to declare and derived from fabula fable (The concise Oxford dictionary of Etymology (1996)

editor Hoad T.F P372; to avowal of belief in a religion; an Occupation. A Professional is someone therefore who has trained for and is committed to a profession, a vocation and one with a set of beliefs or code of conduct, although it also carries multiple other meanings today. Usually for a professional it is mandated that they belong to a Professional body that is regulated and has a code of conduct by which members are expected to follow. For example, the Chartered society of Physiotherapy has a code of Professional values and behaviour[100] that expects its members to take responsibility for their actions, behave ethically, deliver an effective service and to strive to achieve excellence. As a minimum, professionals are required to follow the various rules and regulations that govern their practice but has so clearly set out in the code of professionalism by the Medical School of the university of Massachusetts [101]an individual covered by the code is expected to take on appropriate responsibilities *willingly*. A professional doesn't down tools when the clock strikes 17:00 or whatever time a shift ends, for example but ensures patient care, in the case of a healthcare professional is a priority.

An unexpected result that emerged from the observations was that there was a noticeable variance in approach to work between the two groups of healthcare workers. Pharmacy technicians didn't become a mandated registered profession until July 2011 whilst the observations made in this section of the thesis were initially made three years earlier in 2008, in other words pharmacy technicians at the time that the observations were made were not *professionals* in the sense of being governed by a code of conduct, expected to follow a set of ethics and regulated by professional body, in the case of Pharmacy, the General Pharmaceutical Council (GPhC). From 2011 this variance was no longer the case, although discovering professionalism quite reasonably is a journey to be travelled not an instantaneous event.

From the results we can see that the two groups of workers, Pharmacists and Pharmacy technicians behaved differently through the three sets of observations.

In the first set of observations the two groups were observed carrying out a simple final accuracy-checking task with the time taken to complete the task being plotted against workload, as proxy measure for stress. In other words, the greater the work volume the greater the stress an individual would experience. The interesting and very unexpected observation was that the two cohorts of staff acted uniformly as groups. The Pharmacy

[100] < http://www.csp.org.uk/professional-union/professionalism/csp-expectations-members/code-professional-values-behaviour <accessed August 7th, 2016>
[101] http://www.umassmed.edu/uploadedfiles/professionalism.pdf <accessed August 7th, 2016>

technicians speeded up their work rate in order to get the work completed, whereas the Pharmacists, under increased pressure and presumably with other imperatives, actually slowed down as a group. This could be interpreted in many ways but it is certainly consistent with taking into account responsibility towards their patients' well being and being mindful of their code of ethics.

In the second set of observations, the number of steps taken to complete a task was plotted against workload. As workload increased and staff felt under increasing pressure, the number of steps that pharmacy technicians took decreased, presumably in order to get through the workload as rapidly as possible, in contrast the number of steps that the Pharmacists took to complete the assigned tasks actually increased. Again, the presumption is that this was due to wanting o take extra care when they felt rushed and under pressure.

In the third and final set of observations a sub set of task steps were again plotted against workload, but on this occasion, only steps that could be considered to be *safety* steps, that is any task that would impact on the level of safety in the process, were counted. The result is informative and complex but essentially this time the number of safety orientated steps carried out by the pharmacy technicians increased and by contrast the number of safety steps carried out by the pharmacist cohort decreased. This at first would seem at odds with the first two sets of observations. However, the pharmacists' number of safety oriented steps decreased from a higher number and therefore the outcome was that although they decreased they were still significantly higher than the number of safety steps that the pharmacy technicians took. One conclusion that could be drawn from this, is the fact that professionals and non-professionals behave differently, guided by different sets of values and ethics.

Themes that emerged from this study that impacted upon error generation included dispensary design from the perspective of distracting background noise generation. Dispensary design is driven by a number of factors that are pragmatic in nature, including, for example, affordable space, workflow within that available space with some consideration to ergonomics and some background noise, also professionalism of individual operatives and their ethical approach to work responsibilities.

Two key themes that stood out above others were Stress, whatever the source impacted on personal performance and interruptions, which appears frequently in healthcare safety literature. In the next chapter the part interruptions play in error causation in paediatric hospital pharmacy will be investigated.

Chapter 4. The impact of interruptions on individuals carrying out the accuracy-checking step of the dispensing process

Introduction

Interruptions are included in the list Basic Risk Factors in error causation theory and one of these, Error enforcing conditions, described by Groeneweg (2002) as “influences that have a disadvantageous effect on the human condition and, interruptions, could be said to fall into this definition. Many articles refer to the impact that interruptions have on individuals and task performance, Speier, C (1997); Trafton, G et al (2008); Coraggio, I (1990) and in the aeronautics and space industry regulations have been introduced specifically to limit the probability of interruptions from occurring at critical times, Electronic code of federal regulations (2009), known as the sterile cockpit rule. In the healthcare environment, specifically in hospitals for example during medicine administration rounds, this has been addressed by requiring staff to wear visible indications, for example a nurse wearing a red tabard during the medicine administration round, that alert people not to interrupt the wearer of the tabard. However, there is little in the literature that evidences the impact of interruptions on operatives in a paediatric hospital pharmacy setting, nor for that matter evidences the detrimental effect or otherwise of interruptions on performance at all. In this chapter the part that interruptions play in error causation in paediatric hospital pharmacy will be investigated.

Dispensary design concerns itself with workflow and seldom considers the impact that the dispensary environment has on individuals. Classically the two cognitively intense tasks within the dispensing process, clinical screening and accuracy checking, occur at the beginning and at the end of the dispensing process. Clinically screening is when a pharmacist reviews a prescription to identify and assess the clinical impact that the prescribed drugs may or may not have on an individual at the doses requested. Accuracy checking ensures that the dispensed medicines have been accurately dispensed. These two tasks are usually carried out where most interruptions and distractions are likely to occur. The impact that these interruptions have on the efficiency and work rate of individual operatives is unclear. This study is designed to investigate the impact that interruptions have on those individuals carrying out the accuracy-checking step in the dispensing process.

Background

In a report,"The Cost of Not Paying Attention: How Interruptions Impact Knowledge Worker Productivity", Spira (Spira 2005)[102] writes that the cost of interruptions consume 28% of a knowledge worker's day. Spier (Spier, Valacich et al. 1999) [103] outline several propositions characterizing interruptions including that decision-making performance on complex tasks degrades when the frequency of interruptions increases. Hohenhaus relates that in a 200-multisite study of voluntary reporting of error in neonatal intensive care units (NICU), 27% of reports were associated with inattention, 22% with a communication problem, and 12% with distractions.[104]

So, in addition to introducing inefficiency, Interruptions are clearly disruptive, and a major cause of error in healthcare. An interruption can be defined as ""an externally-generated, randomly occurring, discrete event that breaks continuity of cognitive focus on a primary task",(Coraggio 1990)[105] . Tafton (2008)[106] outlines characteristics of interruptions that make them particularly disruptive and these include the following the complexity of the interruption; similarity of the interrupting task to the primary task; how closely the interrupting and primary tasks are related; control over interruption engagement, and the availability of retrieval cues in the primary task.

A question arises as to how does the brain manage when more than one task presents itself simultaneously? Pashler [107](Pashler 1994) summarises three possible theories and these are, Capacity Sharing, Bottleneck or task-Switching and Cross-Talk models. The first model hypothesizes that people have a finite processing capacity, which is shared out between

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[102] Spira, J. B. F., J.B (2005). The Cost of Not Paying Attention: How Interruptions Impact Knowledge Worker Productivity.

[103] Spier, C., et al. (1999). "The Influence of Task Interruption on Individual Decision Making: An Information Overload Perspective." Decision Sciences **30**(2): 337-360.

104 Susan M. Hohenhaus, Stephen M. Powell; Distractions and Interruptions: Development of a Healthcare Sterile Cockpit; Newborn and Infant Nursing Reviews - June 2008(Vol. 8, Issue 2, Pages 108-110, DOI: 10.1053 2008

[105] Coraggio, L. (1990).P19 "Deleterious effects of intermittent interruptionson the task performance of knowledge workers: a laboratory investigation

[106] Trafton, J. G., & Monk, C. M. (2008). Task Interruptions. In D. A. Boehm-Davis (Ed.), Reviews of Human Factors and Ergonomics, Volume 3, chapter 4 p111-126. 2008

[107] Pashler, H. (1994). "Dual-task interference in simple tasks: data and theory." Psychol Bull **116**(2): 220-244.

tasks and people carry out multiple tasks quite ably until one task becomes more difficult than the others. When this happens, capacity is switched to the more difficult task at the expense of the less difficult tasks. In the Bottleneck or Task-Switching model suggests that parallel processing may be possible until two or more tasks require access to the same processing mechanism or mental operation at the same time then a bottleneck results and one or more of the tasks will become delayed. The third theory is that interference may arise when multiple tasks require the same sensory inputs in order to be processed, it could be easier to perform more than one task if they both require the same sensory inputs or harder if they require the same sensory inputs. However, most theorists opt for the view that it's more difficult to perform multiple tasks if they require the same sensory inputs.

Spier [108](Speier 1999/3) Explains two types of interference, Capacity interference which is when the number of incoming cues are too numerous for a decision maker to process and Structural interference occurs when a decision maker must attend to two inputs that require the same physiological mechanisms, such as two different visual signals.

Allport, Antonis et al. (1972)[109] Hypothesized that the brain has a multi-channel not single channel processing capability and demonstrated that people can indeed attend to and repeat back continuous speech at the same time as taking in complex, unrelated visual scenes, or even while sight-reading piano music. That in both cases, performance with divided attention was very good, and in the case of sight-reading was as good as with undivided attention. There was little or no effect of the dual task on the accuracy of speech shadowing.

However, ability to process multiple sensory inputs simultaneously is not the same as being able to process the data efficiently or productively. Worthy of note is that aging also has an impact on working memory and therefore how an individual manages interruptions Clapp and Gazzaley (2012) [110] explain that interference is known to negatively impact the ability to maintain information in working memory, an effect that is exacerbated with aging, which they explain by excessive attentional allocation to distracting (indirect interruptions) stimuli, and a distinct mechanism for the impact of interruption on working memory performance.

[108] Speier, C. S., Cheri; Vessey,Iris (1999/3). " The influence of task interruption on individual decision making." http://www.scopus.com/inward/citedby.url?scp=0038930657&partnerID=8YFLogxK **30**.

[109] Allport, D. A., et al. (1972). "On the division of attention: a disproof of the single channel hypothesis." Q J Exp Psychol **24**(2): 225-235.

[110] Clapp, W. C. and A. Gazzaley (2012). "Distinct mechanisms for the impact of distraction and interruption on working memory in aging." Neurobiology of aging **33**(1): 134-148.

To recover well from an interruption requires pre-planning and preparation. Boehm (2009)[111] outlines two such approaches. The first is aimed at decreasing the amount of information that needs to be remembered upon resumption of the task. This can be achieved by breaking from the task in hand at a suitable boundary or stage in the task and thereby enabling the operative to resume work at the next stage or step in their task process. Dispensary staff may complete producing a medicine label for example, so when they resume they take up the task at the next stage in the process e.g. packing the completed item into a bag. The second strategy is to increase the probability of recalling the origin task (prospective memory), for example by using approaches to increase internal memory (such as rehearsal) or through the creation of *external memory*, such as leaving notes.

Distractions in hospitals are commonplace and have been identified as a major contributor to medication errors (and medical errors in general). Medmarx[112], a registry of adverse drug events in the U.S, with over 400 healthcare facilities, lists *distractions* as the number one *contributing* factor in error causation in each of its data reports published between 2002 and 2006. There are few published studies that have looked at methods to reduce distractions in hospitals. Accident investigation of a number of airline accidents by the National Transportation Safety Board, USA, such as the Eastern Airlines flight 212, concluded that distractions were a significant error causation factor. The Federal Aviation authority wrote the *sterile cockpit rule*, as a result in 1981. The rule 121.542 *Flight crewmember duties*[113] prohibit direct, i.e. conversations, or indirect i.e. a colleague eating food, distractions from being made during critical flight activities. In addition to leading to increased error rates, distractions also have been found to increase anxiety and decrease performance, in situations of high workload. Speier (1999).[114] Clearly direct or indirect interruptions are disruptive and the impact they cause needs to be mitigated. Research carried out by Oulasvitra (2004)[115] suggested that interruptions are disruptive not because short-term

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[111]) Boehm-Davis, D.A., Remington, R., Reducing the disruptive effects of interruption: A cognitive framework for analysing the costs and benefits of intervention strategies. Accid. Anal. Prev. (2009), doi:10.1016/j.aap.2009.06.029

[112] https://www.medmarx.com/

[113] Electronic code of federal regulations; Title 14: Aeronautics and Space PART 121—OPERATING REQUIREMENTS: DOMESTIC, FLAG, AND SUPPLEMENTAL OPERATIONS Subpart T—Flight Operations http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=1e08bf9191ec5ce00b88432261a1b3b7&rgn=div8&view=text&node=14:3.0.1.1.4.20.3.8&idno=14 <accessed August 2009>

114) Speier, C., Valacich, J. S., & Vessey, I. (1999). The influence of task interruption on individual decision-making: An information overload perspective. Decision Sciences, 30(2), pp. 337-360.
115 Oulasvirta A, Saariluoma, P. long-term working memory and interrupting messages in human-computer interaction Behaviour & Information Technology Volume 23 Issue 1, January-February 2004

memory becomes overloaded but rather that information stored in the long-term working memory is poorly encoded.

Trafton (2008)[116] outline factors that influence recovery from interruptions. The length of the interruption, similarity between the primary and secondary task, that is the task the operator has been called away to perform, the opportunity to rehearse prior to resuming the primary or main task and the existence of environmental cues, for example a clear marker being left as to where to resume, all affect task resumption performance. Significantly, training in the primary task itself is not sufficient in and of itself to reduce the impact of task disruption. In addition, training in *how to resume* has found to be beneficial. Cades, Trafton & Boehm-Davies (2006).[117]

Interestingly, Prakash, Koczmara et al. (2014) [118] observed a difference in the effectiveness of certain kinds of interventions, for example the introduction of a quite area where no interruptions were permitted, the introduction of a standardised nursing workflow; speaking allowed when verifying a task; using timers when giving injections by a manual push method. The impact that these had depending upon the type of task and whether it was one of commission, that is verifying volumes contained in syringes and programmed in ambulatory pumps however, no statistically significant differences were observed however, for other medication verification tasks, such as verifying a patient's identity or the name of a medicine or the dose of a medicine.

A checklist, is an example of a visual prompt or environmental clue and are often proposed as a technique to be deployed to mitigate against interruptions and task complexity. In 1935 on October 30th at Wright field, Dayton, Ohio, USA the United States army were conducting an evaluation of aircraft. One of the contenders was a Boeing 299. IT took off, began a smooth climb and then stalled and crashed, both pilots later tragically died of their injuries. The Pilots were unfamiliar with the aircraft and the aircraft was too complex for one person to

116 Trafton, J. G., & Monk, C. M. (2008). Task Interruptions. In D. A. Boehm-Davis (Ed.), Reviews of Human Factors and Ergonomics, Volume 3, chapter 4 p111-126. 2008

117 Cades, D. M., Trafton, J. G., & Boehm-Davis, D. A. (2006). Mitigating Disruptions: Can Resuming an Interrupted Task Be Trained? Proceedings of the Human Factors and Ergonomics Society 50th Annual Meeting

118 Prakash, V., et al. (2014). "Mitigating errors caused by interruptions during medication verification and administration: interventions in a simulated ambulatory chemotherapy setting." BMJ Quality & Safety **23**(11): 884-892.

remember everything that had to be done. Later it was determined that pilots needed some way of ensuring that they didn't overlook anything and the checklist was born. [119]

Gwande (2011) [120] in his book, "The Checklist Manifesto", says that failure in the modern world, he writes, is really about errors of ineptitude that is mistakes made because we don't make proper use of what we know. The routine tasks of surgeons, for example, have now become so incredibly complicated that mistakes of one kind or another are virtually inevitable. As for pilots, a checklist is one approach to managing complexity and interruption.

The research environment

One aspect of the dispensing process, accuracy checking, within a hospital pharmacy department was selected for observational analysis. The dispensing process at Birmingham Children's hospital consists of the following steps; -

1. Clinical screening or review of the prescription or drug request to ensure that the drug or drugs requested are therapeutically appropriate singularly and in combination for the designated patient and are safe and in addition that doses are correct and quantities requested reasonable.
2. Labelling of the medicine containers with the correct patient demographic, name, form, strength and quantity of the drug being supplied, clear and unambiguous instructions, date of dispensing and other required warning labels.
3. Assembly of the required drugs in the expected quantities along with associated devices to assist administration.
4. Accuracy checking of the complete drug order to ensure that steps 2 & 3 have been carried out correctly.

This study sought to answer the question, what impact if any does the dispensary environment have on those working within it, in particular direct (For example an operative being asked a direct question whilst accuracy checking) or indirect interruptions (For example a background noise, such as a telephone ringing)? Pharmacy staff authorised to perform the final checking step in the dispensing process are Pharmacy Technicians and Pharmacists. UK Pharmacists are masters level educated and are required to be registered with the General Pharmaceutical Council (GPhC). Hospital pharmacists are encouraged to have a

[119] Schamel, J.(2012 updated); http://www.atchistory.org/History/checklst.htm <accessed August 6th, 2016>
[120] Gwande, A. (2011). The CheckLIst Manifesto, Profile.

post-graduate qualification at least at Clinical Diploma level. The GPhC regulates practice and standards of its members. Pharmacy technicians began t be regulated by the GPhC on June 30th 2011. The training for these two staff groups is intensive but varies significantly between the groups. A technician requires a NVQ level 3, usually obtained through a day release program over a two-year period during which time the student attends college once a week and compiles a portfolio of their experience during their training. Qualified pharmacy technicians can then go on to train to become accuracy checkers at Birmingham Children's Hospital by undertaking a period of further training and assessment. This qualification is validated by the regional workforce group on behalf of the NHS regional chief pharmacists and is based on nationally recognised standards. Pharmacists are qualified in their own right to carry out the accuracy-checking step in the dispensing process.

Method

A medicine request requiring that two bottles of medicines, representing a typical and uncomplicated prescription, be dispensed was written for the purposes of the study. The medicines were, labelled and placed in a checking tray together with the required paperwork, additional spoons or oral syringes and a dispensing bag. Each prescription asked for pharmaceutically routine items such as paracetamol liquid and codeine linctus to be supplied. The operatives volunteered to participate and were told that they would be timed during the accuracy checking process and that the object of the observations was to measure the impact of the environment on their work and not to assess their individual performance. They were also informed that the prescriptions that they would be checking were straightforward and didn't contain errors by design. Each observation consisted of two arms as determined by a Latin square. A Latin square is used in experimental designs in which one wishes to control for two known sources of variation. A Latin square ensures that all possible variants were carried out.

The observations were carried out in the dispensary during normal working hours and in an office; the later ensured a noise and interruption controlled environment. Finally, a designed interruption was introduced into certain variants. The interruption consisted of the individual being stopped and asked to check a dose calculation. Each observation and each interruption were timed and recorded on a MS Excel© spread sheet.

Individuals were timed whilst they accuracy checked a prepared prescription consisting of two simple medicines under controlled conditions and in different locations. There were four possible combinations of conditions and locations. That is, individuals were timed whilst dispensing in an office or in the dispensary, with or without a controlled interruption. Each

variant comprised of any two of these possibilities or arms and could be carried out in any sequence. In summary, there were 12 variants, consisting of two arms, accounting for all possible variations. Each variant was repeated three times, with different operatives, giving a total data set of 36 results or observational sets.

Each participant was observed carrying out one or more variant. See Table 1 below in which describes how each possible variant. The "i" denotes when a controlled, but unknown to the operative, interruption occurred. Variant 1 for example was where the operative was asked to dispense the test medicine request in the dispensary first without a controlled interruption and then asked to repeat the exercise but this time with a planned interruption.

	Disp 1st	Disp_i_1st	Office 1st	Office_i 1St	Disp 2nd	Disp_i 2nd	Office 2nd	Office_i 2nd
Variant 1								
Variant 2								
Variant 3								
Variant 4								
Variant 5								
Variant 6								
Variant 7								
Variant 8								
Variant 9								
Variant 10								
Variant 11								
Variant 12								

Table 7 Latin Square depicting all possible variations of Observations made.

Results

The results were then analysed using Minitab statistical analysis software to determine whether or not there was a statistically significant difference between the variants. The tests included, a General Linear Model for time versus location, interruption, and individual. An Analysis of Variance for time, using Adjusted Sum of Squares for Tests and least square means for time.

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#	Subject	Date		Variant	Timing Dispensary	Timing Di	Timing Office	Timing Oi	Timing Interruption	Timing Difference net of interruption	Timing % change
1	SM	10/05/2010		5	-	168.01	113.48	-	6.18	161.83	142.61%
2	R	12/05/2010		5	-	212.92	155.39	-	8.44	204.48	131.59%
3	KV	17/05/2010	10:30	5		122.8	118.51	-	4.56	118.24	99.77%
4	SO	20/05/2010		8	-	200.36	153.07	-	24.12	176.24	115.14%
5	DB	20/05/2010		8		120.06	106.7		14.94	105.12	98.52%
6	R	03/09/2010	12:08	12	-	-	130.2	164.41	34.21	145.82	112.00%
7	RS	03/09/2010	12:25	12	-	-	97.22	139.73	10.38	129.35	133.05%
8	SM	03/09/2010	12.4	12	-	-	105.32	123.54	19.18	104.36	99.09%
9	MM	03/09/2010	12:50	5	-	120.08	98.2	-	22.33	107.75	109.73%
10	DR	03/09/2010	13:00	4	96.92	127.07	-	-	17.88	109.19	112.66%
11	C	04/11/2010	12:15	4	225	264.67	-	-	15.00	249.67	110.96%
12	DR	04/11/2010	12:45	3	73.01	-	-	97.67	16.86	80.81	110.68%
13	SO	04/11/2010	13:15	4	119.45	195.67	-	-	40.95	154.72	129.53%
14	SO	22/11/2010	11:05	3	112.95	-	-	99.73	23.24	76.49	67.72%
15	AH	22/11/2010	11:16	3	134.82	-	-	138.8	20.01	118.79	88.11%
16	IP	22/11/2010	11:28	2	75.86	-	65.61	-	-	-	115.62%
17	DB	22/11/2010	11:35	2	94.7	-	81.09	-	-	-	116.78%
18	HU	22/11/2010	11:45	2	151.61	-	74.09	-	30.00	121.61	164.14%
19	JA	22/11/2010	11:55	1	143.67	132.77	-	-	21.70	111.07	77.31%
20	SC	22/11/2010	12:10	1	111.98	133.39	-	-	16.35	117.04	104.52%
21	TG	22/11/2010	12:30	1	107.77	127.2	-	-	10.36	116.84	108.42%
22	JW	22/11/2010	12:40	7	127.98	-	155.77	-	25.00	130.77	97.87%
23	DR	22/11/2010	12:55	7	128.16	-	125.22	-	-	-	102.35%
24	CH	25/11/2010	11:00	7	93.22	-	111.34	-	-	-	83.73%
25	KM	25/11/2010	11:58	6	-	126.63	-	125.33	-	-	101.04%
26	P	25/11/2010		6	-	235.36	-	132.18	-	-	178.06%
27	NR	25/11/2010		6	-	163.18	-	138.86	-	-	117.51%
28	BB	25/11/2010	11:46	10	74.07	-	-	108.92	11.98	96.94	130.88%
29	SO	25/11/2010	11:50	10	109.45	-	-	110.73	11.15	99.58	90.98%
30	MM	25/11/2010	11:52	10	62.89	-	-	102.32	17.01	85.31	135.65%
31	TA	25/11/2010	11:15	11	-	53.01	-	79.1	-	79.1	67.02%
32	IP	25/11/2010	11:30	11	-	68.39	-	110.26	-	-	62.03%
33	JA	25/11/2010		11	-	103.93	-	132.45	14.46	117.99	78.47%

KEY
Di= Dispensary with interruption
Oi= Office with interruption

Table 8 observed times for each variant by individual subject; the date on which the observation took place and, which variant was being observed. Key; Disp= Dispensary; Di = Dispensary with a controlled interruption; Oi = Office with a controlled interruption; Office=Office

The time differences were calculated net of any interruption that was made.

Statistics

The data was analysed in Minitab using a General linear model that analyses balanced or unbalanced ANOVA (analysis of variance) models with crossed or nested and fixed or random factors. Variance was tested against length of interruption, location, individuals and order in which events took place. There were 44 timed events, carried out by 12 individuals in

two locations. Although all the variants had an impact the two that were most significant were the length of the interruption (p=0.012) and the individual (p=. 001).

Source	DF	Seq SS	Adj Sum	Adj Mean	F	P
Location	1	3502.2	1289.9	1289.9	3.44	0.073
Interruption	1	2530.2	2681.3	2681.3	7.16	**0.012**
Subject No	11	51771.4	51771.4	4706.5	12.56	**0.001**
Error	30	11240.6	11240.6	374.7		
Total	43	69044.5				

Table 9 Table of an analysis of variance for time using adjusted sum of the squares for tests

Seq SS is sequential sum of squares, Adj Sum is adjusted sum of squares, Adj mean is adjusted mean, F stands for the F statistic and P is the probability.

An Analysis of Variance for time, using Adjusted Sum of the squares (SS) for Tests was carried out. Adjusted SS is used in General Linear Models without orthogonality that is where the factors are not completely independent of each other. The total variation was 69044.5 and the variable that caused the greatest variation was the individual (p=0.001). The order of location, that is the sequence in which the tests were carried out, whether in the dispensary first and then the office and so on, was shown to be insignificant (p=0.140).

A plot of least square means for time showed that it takes 22% longer (155.63-121.2) when interrupted in the dispensary than in the office.

		Means (LSM)
Location		
Dispensary		138.42
Office		124.80
Interruption		
0		123.44
1		139.78
Location*interrupt		
Dispensary	(no interruption)	121.20
Dispensary	(interruption)	**155.63**
Office	(no interruption)	125.67
Office	(interruption)	123.92

Table 9 Least Squares Means (LSM) for time

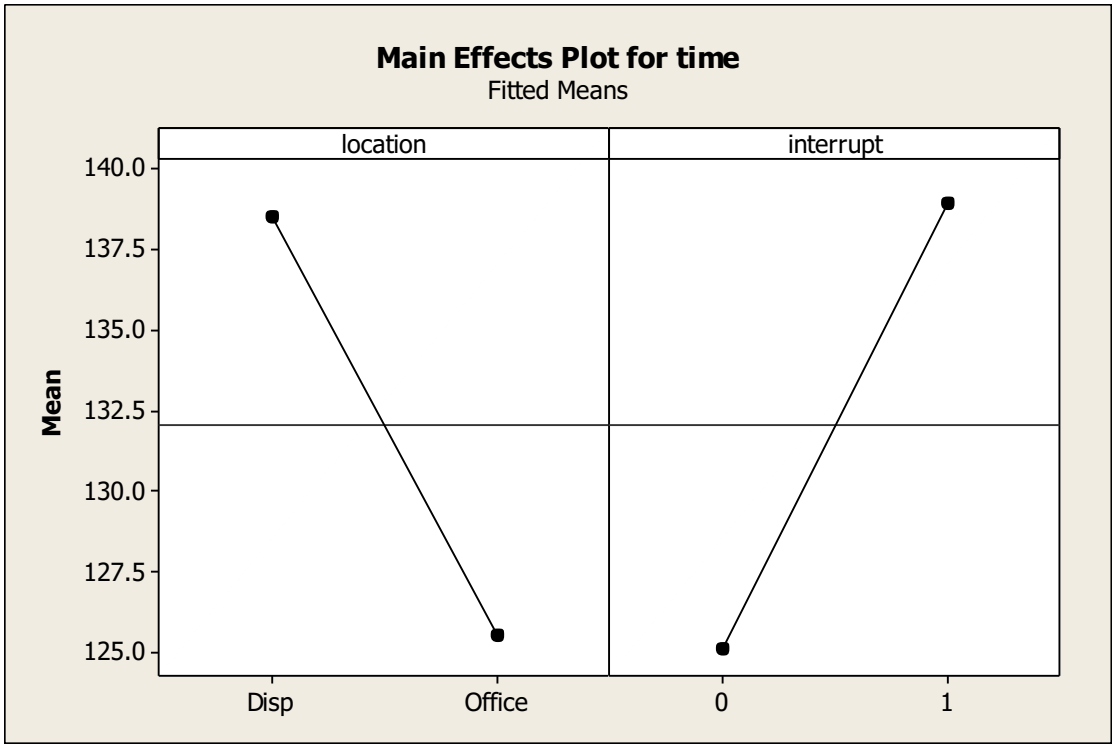

Figure 10 Showing graphically a main effects plot for time shows that it takes longer when interrupted in the dispensary than when not interrupted in the office.

Discussion

Twelve pharmacy technicians and nine pharmacists participated in the observations. Thirty-six sets of observations were carried out each consisting of two arms as determined by a Latin square. As the observations were made the methodology evolved in response to observed outcomes. For example, the first three observational sets all included an additional observation in the dispensary before going on to make observations in the office and in the office with an interruption. It was considered that this additional step wasn't necessary and so was discontinued. After the first six observational sets a standardised interruption was introduced. During the last 10 observational sets the two arms of each set were separated by a significant time delay, of at least 48 hours, and were not carried out immediately one arm after the other to observe whether this had any significant impact on outcomes or not.

The most significant impact on the observations was noticed not between individuals but between professional groups that is between Pharmacy Technicians and Pharmacists. All

operatives were asked to simply accuracy check the medicine request, that is to ensure that the correct medicines had been supplied, that the demographic data on the labels matched that of the prescription along with the quantity, dose and prescriber's instructions. The operatives were advised that there were no deliberate errors and that they were to consider the prescription to be clinically correct. In other words, the only task that was required of them was to accuracy check the dispensed prescription. With two exceptions, the pharmacists took additional time looking for non-existent errors they thought had been set to catch them out, asking additional questions or in clinically checking rather than simply carry out the task requested, that was simply accuracy checking the medicine request. In addition, some (n=3) refused the interruption during the observation even though interruptions are an accepted part of their day-to-day work in the dispensary. By comparison the pharmacy technicians did as they were instructed and complied with the requirements of the study. Many of the pharmacists (n=5) were non-compliant with the study protocol and consequently these observations (n=11) had to be excluded from the final results, leaving 25 observations out of a total of 36.

It should also be noted that the dispensary itself was seldom without inherent interruptions in addition to the planned interruption and a variable was created in the statistical analysis to take this into account.

The results were calculated by subtracting the time the interruption took from the timing of that arm of the observation to give a net time. Of the 25 usable results 20 (80.0%) showed that when interrupted an operative took 22 % longer to accuracy check a prescription in the dispensary when compared to when they accuracy checked the standardised prescription in an office without an interruption.

When an operative was subject to a direct planned interruption or indirect interruptions as is experienced working in a noisy environment then in 32.0% of the observations it took an additional 10-18% to carry out a standard task and in 28 % of observations it took an additional 29%-48% of time to carry out a standard task.

Dispensary design is driven by a number of factors that are pragmatic in nature, including, for example, affordable space, workflow within that available space with some consideration to ergonomics and background noise.[121] This is a welcome start but more consideration should be given to error causation and how intelligent dispensary design could contribute to reducing latent errors from the system. Little was found in the literature as to the impact of the environment upon dispensary operatives.

121 Design for patient safety: A guide to the design of the dispensing environment; NPSA, 2007 edition 1

Project limitations

It is recognised that the sample size for this study was small in number, initially 17 individuals in total and this was reduced to 12 individuals for reasons outlined elsewhere in this article. The results should be interpreted in this context. The intention was to examine the impact that one element of the working environment, interruptions, have on the performance of individuals in paediatric pharmacy using one task in the dispensing process. Therefore, the results are valid in this setting.

It should also be noted that medicines items requiring dispensing for children can be inordinately complex, take significantly longer to dispense than a similar medicine for an adult and consequently, in our experience, have the potential for more errors associated with the process. Processes and systems applied to the paediatric pharmacy setting that lead to the development of safer dispensing environments would therefore be able to be transferred to the arguably less demanding adult general hospital dispensary setting.

Conclusion

This study set out to investigate the impact that interruptions have on those individuals carrying out the accuracy-checking step in the dispensing process, to assess what impact if any the working environment has on individuals carrying out critical tasks. The mean additional time taken to complete a standard task in one phase step within the dispensing process, accuracy checking, was observed to be 18.75%. The additional time that one third of individuals took was observed to be between 30% and 48%. Interruptions, an accepted part of dispensary routine, directly reduce an individual's efficiency and have the potential consequently to therefore impact upon safety. Interruptions have been shown to be latent system failures in the paediatric hospital pharmacy accuracy checking, the final step in the dispensing process.

Interruptions are a recognised Basic Risk Factor, Groeneweg (2002) under the category "error enforcing condition", but little has been done in healthcare to investigate just what the impact of interruptions are on operatives working in a healthcare setting, in this case, paediatric hospital pharmacy. One explanation for this lack or research may possibly be because the National learning and Reporting System's (NLRS) incident data has failed to identify interruptions as a significant theme or alternatively if it has identified interruptions as

a significant error causation theme then organisations have failed to learn from this error type.

In the next chapter a review of the Children's hospital own incident reporting system will be investigated from the perspective of efficiency both in terms of cost and of learning from errors reported through the system.

Chapter 5. Investigating the costs of incident reporting and the impact on safety in a specialist paediatric NHS hospital

Introduction

It is argued that a safe culture is an informed culture and this, in turn, depends upon creating an effective reporting culture122. The NHS has become increasingly effective at reporting incidents through the National Reporting and Learning System (NLRS). The NLRS holds data on over 4 million incident reports submitted since its inception in 2003, with over 600,000 of these having been reported between October 2014 and March 2015 alone123. The goal of every NHS trust is to have a high reporting low harm culture, and one that learns from its errors. The incident reporting system is clearly good at collecting data, but the system needs to be good enough at a local hospital level to in addition to collecting incident data but to go on to learn from the data in a way that would impact on practice sufficiently to reduce the numbers and types of error that are taking place. This next study investigates the efficiency of the learning from incident system within the hospital.

Background

The term Safety Culture was first used in the accident investigation report generated after the nuclear accident at Chernobyl (1986)124. On April 26 1986, two explosions blew off the 1000-ton concrete cap sealing the Chernobyl-4 reactor, releasing molten core fragments into the immediate vicinity and fission products into the atmosphere. It was the worst accident in the history of commercial nuclear power generation. It has so far cost over 30 lives, contaminated approximately 400 square miles around the Ukrainian plant and significantly increased the risk of cancer deaths over a wide area of Scandinavia and Western Europe Reason (1990).

In 1987 a fire broke out in the machine room under a wooden escalator at Kings Cross underground station tragically killing 27 people. In the investigation report, a structured safety

[122] Reason J; Achieving a safe culture: theory and practice ; Work & Stress, 1998, vol. 12, no. 3 293-306; <http://aml-safety.com.au/AMLstores/_images/pdf-files/21may09-JReason.pdf> accessed December 2015.

[123] Organisation Patient Safety Incident Reports - data workbooks September 2015; < http://www.nrls.npsa.nhs.uk/resources/?entryid45=135465> accessed February 2016

[124] A Synthesis of Safety Culture and Safety Climate Research; Douglas A. Wiegmann, Hui Zhang, Terry von Thaden, Gunjan Sharma, and Alyssa Mitchell

regime (Culture?) and a more open approach to the exchange of information within an organisation, was called for, Fennell125(1988). "A safe environment is not one in which there is an absence or a low number of serious injury incidents, but rather, results from the active participation of management and staff in identifying hazards and then doing something positive about them. In other words, the absence of accidents is a negative measure largely dependent on luck, while the identification then prompt elimination or control of hazards is a positive step and is essential to the discharge of our duties under current legislation."126

According to Meshkati (1997)[127], the turning point for safety culture in the United States was the tragic crash of Continental Express Flight 2574, a scheduled domestic passenger airline flight travelling from Laredo International Airport in Laredo, Texas, to Bush Intercontinental Airport in Houston, Texas. On September 11, 1991. The plane lost a wing and crashed as it was approaching the runway for landing, killing all 14 people on board. An analysis cited the failure of management to establish "a corporate culture which encouraged and enforced adherence to approved maintenance and quality assurance procedures".

Safety culture is the enduring value and priority placed on worker and public safety by everyone in every group at every level of an organization. It refers to the extent to which individuals and groups will commit to personal responsibility for safety, act to preserve, enhance and communicate safety concerns, strive to actively learn, adapt and modify (both individual and organizational) behaviour based on lessons learned from mistakes, and be rewarded in a manner consistent with these values. Wiegmann (2002)[128]. A key concept made by Zhang (2002) is that, a *Safety culture is reflected in an organization's willingness to develop and learn from errors, incidents, and accidents.* To be clear, a safety culture is a learning culture. Organizations with a healthy safety focus are constantly learning. They learn from their mistakes and those of others. Information regarding prior incidents and accidents is shared openly and not suppressed, Sumwalt (2011).[129] A safety culture is one therefore in which individuals within an organisation are empowered to communicate safety concerns

[125] Fennell D QC. Technical Report ARL-02-3/FAA-02-2 .June 2002
[126]McKinnon R C; Safety Management: Near Miss Identification, Recognition, and Investigation; CRC Press; 2012

[127]Meshkati, N. (1997, April). Human performance, organizational factors and safety culture. Paper presented on National Summit by NTSB on transportation safety. Washington, D.C.

[128] Safety Culture: a review. http://www.mtpinnacle.com/pdfs/Safety%20Culture-%20A%20Review.pdf accessed August 2015
[129]Sumwalt R. The Role of Organizational Culture, Safety Culture, and Safety Climate in Aviation and Aerospace Safety. <http://app.ntsb.gov/doclib/speeches/sumwalt/Sumwalt_121007b.pdf> accessed April7th, 2015.

Weigmann (2002) and the organisation itself is willing to develop and learn from errors and incidents.

Reliability is both dynamic and invisible, invisible because people don't know how many mistakes they could have made but didn't Weick (1987)[130]. Reliability is also invisible because reliable outcomes are constant, so there is nothing to pay attention to. In the absence of frequent bad events, the best way to induce and then sustain a state of intelligent and respectful wariness is to gather the right kinds of data Reason (1990). A safety culture is one in which data is proactively collected, not just incidents and errors but near misses and concerns. This information is collated and analysed and from the outcomes lessons are learnt and practice changed. In other words, a safety culture is also a reporting culture.

A Safety culture is reflected in an organization's willingness to develop and learn from errors, incidents, and accidents. Wiegmann (2002) [131] in a review of safety culture for the federal aviation administration Illinois, USA describe five components of a safety culture and these are as follows. Firstly, comes organizational commitment that is that the senior management of an organization are committed to implementing a safety culture. That it is seen one of the organization's core principles and senior management are willing to support the implementation of safety strategy as a priority both with management support and financially. Secondly, management enforce the importance of complying with the organisations safety culture. Thirdly, that employees are empowered to make a difference that implementation of a safety culture is seen as emanating from the "shop-floor" as well as the board room or "top-down". Fourthly, they outline the importance of having a reward system as a key component to the organisations safety strategy. That safe practice is reinforced and encouraged and unsafe practice is discouraged. Fifthly and finally, the organization is a reporting culture that the reporting of incidents is encouraged without fear of retribution or punishment.

So, to be clear, a safety culture is a learning culture. Organizations with a healthy safety focus are constantly learning. They learn from their mistakes and those of others. Information regarding prior incidents and accidents is shared openly and not suppressed, Sumwalt

[130]Weick K; Organisational Cultural as a source of high reliability. California management review. Vol XXIX, number 2 , winter 1987. The regents of the university of California.
[131] Wiegmann, D. Z., H. Von Thaden, T.Sharma, G. Alyssa Mitchell,A. (2002). "A Synthesis of Safety Culture and Safety Climate Research." Aviation Research Lab, Institute of Aviation, University of Illinois at Urbana-Champaign

1 Airport Road , Savoy, Illinois 61874

(2011).[132] In the absence of frequent bad events, the best way to induce and then sustain a state of intelligent and respectful wariness is to gather the right kinds of data Reason (1990). A safety culture is one in which data is proactively collected, not just incidents and errors but near misses and concerns. This information is collated and analysed and from the outcomes lessons are learnt and practice changed. In other words, a safety culture is also a reporting culture.

In an average NHS acute hospital 2.5 million doses of medicines are administered a year. There are 215,000 administration errors and 45,000 prescribing errors per year.[133] In the year 2000 a report, "An Organisations with as memory", produced by the department of Health by a committee chaired by the Chief Medical Officer for England, Professor Sir Liam Donaldson in 2000 (Health 2000)[134] .The report outlined the development of untoward incident guidance, building on recommendations first issued in 1955 by the then Department of Health[135] , that stated that "a brief report should be prepared by the Secretary of the Board of Governors or Hospital Management Committee as soon as possible after any occurrence of the kind in question, giving the name of any person injured, the names of all witnesses, details of the injuries and the full facts of the occurrence and of the action taken at the time".

The report called for lessons to be learnt from incidents and errors within the NHS and as a result the National Learning and Reporting System (NLRS) was created two years later in 2003. After the recent reorganization of the NHS the responsibility for patient safety passed from the NPSA to NHS England in June 2012. Each NHS organisation and others providing healthcare such as General Practitioner Surgeries (GPs) and Community Pharmacies collects details of Incidents, reporting each occurrence through completing an incident form, known as an IR1. This is achieved using IR1 reporting software such as Datix, although other systems exist which is passed onto the NLRS gateway and the data aggregated and analysed.

The intention, as outlined in the report "an Organisation with a Memory", that by collecting this data it would be possible to identify themes and causes for the occurrence of errors and then learn from these incidents and adapt or change systems and processes to reduce error rates. To be able to achieve this at a local level there needs to be efficient local systems in place to encourage error or incident reporting, analyse the reports, draw out themes and

[132]Sumwalt R. The Role of Organizational Culture, Safety Culture, and Safety Climate in Aviation and Aerospace Safety. <http://app.ntsb.gov/doclib/speeches/sumwalt/Sumwalt_121007b.pdf> accessed April7th, 2015.
[133]Medication safety in the NHS faults and remedies. NHSE March 2015
[134] Health, DoH (2000). "An organisation with a memory."
[135]http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_4936867 <accessed August 5th,2016>

lessons that can be learnt from the incident and them disseminate this learning across the organisation. The steps in the process therefore include, encourage reporting, understand what went wrong, address the causes, implement changes to systems and /or implement and disseminate learning arising from the analysis.

So the theme of a reporting culture was first introduced across the NHS after the report, an Organisation with as memory, DoH (2000)[136] was published. Four aspects of a Safety culture were outlined as being a Reporting Culture, one in which near misses were systematically reported. A Just culture, not an absence of blame but one in which an atmosphere of trust prevailed the term *Fair Accountability* has also been coined. A Flexible culture being one in which control is allowed to pass to experts at the frontline and a Learning culture, a willingness to learn from errors and change practice.

The NHS strategy to reduce errors was to develop the concept of a safety culture, a term first introduced by the International Nuclear Safety Group (INSAG)[137] and given meaning by Reason (1998)[138], who listed the key elements of a safety culture as one that is Open, Just, reports, learns and adapts. The Department of Health outlined its own safety strategy in its paper, an organization with a memory (2000) requiring NHS organisations to report errors. Through the National Learning and Reporting system (NLRS). The system enables patient safety incident reports to be submitted to a national database. This data is then analysed to identify hazards, risks and opportunities to improve the safety of patient care.

Since the NRLS was established, over four million incident reports have been submitted through the NLRS system by healthcare staff.139The NHS has become increasingly effective at collecting incident data, for the six months October 2014 to March 2015 in specialist and acute trusts there were 642,098[140] incidents reported of which those categorised as severe amounted to 0.38%(2423). These figures would indicate that the system is effective but the question is could it be improved further either with regard to safety outcomes and/or from a cost perspective?

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[136] DoH. (2000). An Organisation with a Memory.

[137]Summary Report on the Post-Accident Review Meeting on the Chernobyl Accident

INSAG (1988)

[138]Achieving a safety culture: theory and practice. Reason J. WORK & STRESS, 1998, VOL. 12, NO. 3 293-306

[139]http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/about-reporting-patient-safety-incidents/ accessed April 2015

[140]Organisation Patient Safety Incident Reports - data workbooks September 2015<http://www.nrls.nhs.uk/resources/?entryid45=135465> accessed December 2015.

The literature lacks data on the actual process costs of recording IR1s. To our knowledge, this study was the first to investigate the incident reporting process (IR1s), to calculate the costs of reporting incidents in this context and to gain an indication of how economic the process was and whether it could be improved to yield better outcomes. A literature search reviewed studies that had key words that included, *error reporting, patient safety, risk management, organizational memory, intervention and safety management* and also terms that explored *economics, cost* and *effectiveness* and set in the context of NHS hospitals in the United Kingdom. The search yielded 193 papers of which 4 were deemed to have some relevance and 14 were considered to be remotely relevant.

Armitage (2007)[141] set out with the aim of their study being to assess the utility of the incident reporting system at Bradford Teaching Hospitals NHS Trust, England. The methodology that they employed was to collect a 50% random sample of medicine related incident reports that were created between 1993 and 2003 where n= 1253. Free text elements of the incident reports were analysed using a technique known as content analysis, Holsti [142](1969) and described by Stemler (2001) as, "*any technique for making inferences by objectively and systematically identifying specified characteristics of messages*"[143] . The authors found that over the five-year period that was analysed, 276 incident reports (27.8%) were incomplete. They also observed that generation of incident reports varied between specialties within the Trust and the reporting rate reduced over the five-year period

Fung[144] (2010) Set out to synthesise the best available evidence on factors that influence incident reporting by nurses. This was a literature review of primary research studies. Fifty-five papers were identified from the searches based on their titles and abstracts. Nine studies were included in this review. Cultural and demographic factors were the most significant factors in affecting nurses' attitudes towards incident reporting. Major perceived barriers included fear, administrative issues, and the reporting process. Also, nurses were more likely

[141] Armitage, G., et al. (2007). "Reporting drug errors in a British acute hospital trust." Clinical Governance: An International Journal **12**(2): 102-114.

[142] Holsti, R;(1969) Content analysis for the social sciences and humanities; Published by Addison-Wesley & Co publishers

[143] Stemler, S; (2001); Yale University; Copyright PAREonline.net; http://pareonline.net/getvn.asp?v=7&n=17 <accessed August 4th 2016>

[144] Fung, M; koh, lin, S; Leng,Y. attitudes and perceived barriers influencing incident reporting by nurses and their correlation with reported incidents: a systematic review; bi library of Systematic Reviews, [S.l.]v 10;issue 1 ;P1-65.Jan 2012.

to re Fung, Koh et al. (2012) [145]port incidents that caused direct harm, and if reporting was kept anonymous.

Ginsburg [146] (2010) in their paper "the Relationship between Organizational Leadership for Safety and Learning from Patient Safety Events", set out with the aim to examine the relationship between organizational leadership for patient safety and five types of learning from patient safety events. The context for their study was forty-nine general acute care hospitals in Ontario, Canada. The approach that they used was to consuct two cross sectional surveys, one of the senior officer in each trust responsible for safety and the other of patient care managers in each organisation. The response rate were as follows, 54 of the 68 (79%) senior managers responded and 282 of the 621(46%) safety managers responded. The authors go on to explain that the data was analysed using multivariate regression analysis was used to test the unique effect of the hospital size; informal leadership for patient safety and then formal organizational leadership for patient safety, and also the interaction between hospital size and leadership variables, defined in the text, on learning from patient safety episodes. The results, in this very well designed study, suggest that firstly smaller hospitals, defined as those with less than one hundred beds are able to engage more with learning from errors than larger hospitals and secondly safety cultures need to be driven from the most senior management in a Trust.

Finally Waring (2004) [147] In his study "a qualitative study of the intra-hospital variations in incident reporting", set out with the purpose of determining the relationship between variations in hospital incident reporting and the corresponding attitudes and participation of medical professionals. The setting for the study was a single district general National Health Service hospital trust in the Midlands in England. The study was conducted between 2001 and 20013, initially with a six-month observational study of the management structures within the Hospital and then going on to conduct forty-two face to face interviews with managers and clinicians within the Trust. A further set of interviews was conducted with 25 clinicians from various medical specialties. Waring found that that physicians are inclined to report when there is confidence in the processes and purpose of reporting, where reporting has a meaningful contribution to service development, and typically where these are satisfied through collegial forms of incident reporting.

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[145] Fung, W. M., et al. (2012). "Attitudes and perceived barriers influencing incident reporting by nurses and their correlation with reported incidents: A systematic review." JBI Database of Systematic Reviews and Implementation Reports **10**(1): 1-65.

[146] Ginsburg, L. R., et al. (2010). "The relationship between organizational leadership for safety and learning from patient safety events." Health Serv Res **45**(3): 607-632.

[147] Waring, J. J. (2004). "A qualitative study of the intra-hospital variations in incident reporting." Int J Qual Health Care **16**(5): 347-352.

Objective

The objective of this study was to investigate the incident reporting process (IR1s), to calculate the costs of reporting incidents in this context and to gain an indication of how economic the process was and whether it could be improved to yield better outcomes. Also, to gain a sense of whether the system encouraged learning from the errors reported.

Method

Study design and setting

A retrospective analysis from medication incident report summaries, generated at Birmingham Children's Hospital (BCH), a specialist tertiary referral pediatric center was done. Our hospital has 350 inpatient beds, 39,000 inpatient admissions and 150,000 outpatient appointments each year. In addition, questionnaires were sent to a cohort of those staff who had been involved with processing an IR1 incident report.

Incident reporting process

The process for completing an IR1 is a composite process initiated by an individual who has identified that an error has taken place. This individual may then approach a colleague for additional input. Once completed the IR1 is submitted electronically and transmitted to the manager of the location where the incident took place for investigation, and in addition to a list of individuals with a related responsibility with that area or incident either managerial or clinically. Once resolved each individual connected no matter how remotely with that incident receives an email summary relaying the outcome of the investigation or a link to where the outcome may be found. In addition, some clinical areas have their own Safety team that reviews the incident in detail for example the Paediatric Intensive Care Unit (PICU). The PICU safety team consists of 12 staff that is made up of Doctors, Nurses and Pharmacists.

Finally, all members of the unit or ward where an incident took place are notified of the fact. The incident summaries record the following data, the time and date of the incident, which staff were involved, a brief outline of the incident, an assessment of the impact that the incident may have had on the patient and the staff who was informed of the incident after the form was completed.

Incident reporting process analysis

The complete incident report summaries data set for 2014 were extracted (n=5147) and the medicine related errors isolated (n=1432). Of medicine, related incidents, a sub set (n=149), 10.41% of the data was randomly selected, from across the whole period, for detailed analysis to calculate a costing algorithm that could be applied to the whole.

Analysis

The analysis recorded the numbers of staff by profession and grade involved in the incident, the actual impact, whether additional therapy was required as a result of the incident and the numbers of staff informed by email of the incident. In addition, the outcomes of the incident report and the error type were also noted using sets of standardised responses for each.

In addition, a questionnaire was sent by email to a sub set of staff (n=97) (33.21%) out of a total staff listed on the incident summaries' circulation list, on the extract sub set, as having been informed of that incident. Three questions were asked of those to whom a questionnaire was sent; 1. When you or colleagues complete an incident form entry, how long approximately do you spend? 2. When you are notified of an incident (via email), how much time do you spend processing it? 3. If your ward has a ward safety team, how long would the team spend discussing a particular incident, on average? (Only two wards have safety teams). Free text comments were also invited.

Calculating the costs

The professional roles of the staff listed on the incident forms were categorized into one of six groupings that matched as closely as possible to the groups described in the reference compiled by the Personal Social Services Research Unit (PSSRU). The categories were, Ward Sister/manager, Deputy Ward sister/Deputy Manager, Nurse, Consultant, Pharmacist, Pharmacy technician. The PSSRU reference then gave the composite costs per hour for each category of Staff including all associate costs. (Employment, administration, Human Resources, Training & Education). In addition, staff categories that were not considered to be clinical roles for example, management or administration roles, these were costed using NHS agenda for change pay scales for 2014 and a standard NHS on-cost of 23% was included. Staffing costs were then calculated per 1 minute and 10 minute units of time.

Results

Analysis of the subset of Incident report summaries (n=149) for the year reviewed, 2014, showed that there 2105 staff episodes in total, comprised of 148 Nursing inputs, 49 Doctor inputs, 21 pharmacist inputs, 9 general manager inputs and 9 other staff category inputs. Individual staff being involved on multiple occasions during the incident form completion process. Staff was involved in completing the forms either directly that is completing the incident form themselves or indirectly through being consulted when the incident form was being completed. On the subset of 149 Incident report summaries, 262 individual staff were listed.

Questionnaire

The first thirty Incident form summaries, from January 2014 were selected and the staff (n=97) listed on these forms was sent a questionnaire, with 8 staff having left the Trust, 89 staff received the questionnaire. As there was more than one incident form having been completed per ward area contained in this subset some individuals were involved with more than one incident.

The questions asked for an estimate of the time that they thought that they spent, completing an IR1 incident form summary. Respondents were given the option to select from several time ranges in minutes, 1-5; 6-10;11-15;16-20; 21-30; 30-45 and more and a not relevant option. The time that they thought they spent on reviewing and responding to associated emails, investigating an incident if relevant time spent reviewing the incident form summaries with a ward based Safety team. The Paediatric Intensive Care Unit has created a multidisciplinary team that meets to review Incident report summaries. The questionnaire received a response rate of 40.45% (36/89) and from this it was possible to calculate the average time spent by each respondent on the various tasks that they were involved with. The results of the questionnaire are tabulated in table 1 below.

Answers / Person	Time taken to Complete an IR (minutes)	Time (minutes) spent on emails received by circulation list	Time (minutes) spent Investigating an IR1	Safety team meeting reviewing an IR1
1	11-15	delete email if it is not a risk at level 6 or above	Never investigate	Incidents
2	16-20	1-5	30-45 and more	1-5
3	no answer	1-5	30-45	6-10
4	Around 10	10	21-30	1-5
5	6-10	1-5	11-20	1-5
6	11-15	11-15	30-45	1-5
7	11-15	6-10	30-45	6-10
8	depends	6-10	30-45	16-20
9	6-10	1-5	30-45	1-5/6-10
10	16-20	1-5	21-30	6-10
11	10-15	1-5	depends	no meeting
12	depends	11-15	30-45	6-10
13	16-20	6-10	30-45	6-10
14	depends	6-10	21-30	no meeting
15	11-15	1-5	11-20	no meeting
16	1-5	delete if it is not his/her ward	21-30	1-5
17	depends	1-5	30-45	no meeting
18	11-15	6-10	30-45	1-5
19	16-20	6-10	11-20	1-5
20	depends	1-5	depends	1-5
21	16-20	1-5	30-45	6-10
22	depends	1-5	depends	an hour
23	6-10	6-10	21-30	no meeting
24	11-15	1-5	6-10	no meeting
25	11-15	6-10	21-30	
26	depends	11-15	11-20	no meeting
27	6-10	1-5	11-20	1-5
28	11-15	6-10	30-45	no meeting
29	11-15	6-10	30-45 and more	11-15
30	6-10	1-5	21-30	6-10
31	1-5	1-5	11-20	1-5
32	6-10	6-10	30-45	1-5
33	11-15	6-10	21-30	6-10
34	1-5	1-5	depends	6-10
35	1-5	1-5	21-30	1-5
36	11-15	6-10	30-45	11-15

Table 11 Results of Questionnaire to ascertain time spent on various stages of the Incident Summary review and investigation process.

Then in table 12 that follows, there is a summary of the findings, also expressed in graphs 1-4.

Time (minutes) spent	Completed IR
1-5	4
6-10	6
11-15	11
16-20	5
depends	7
no answer	1
Total Responses	34

Time (minutes) spent	Time spend on a circulation list
1-5	17
6-10	13
11-15	3
16-20	0
delete if it is not a risk 6	0
delete if it is not his/her ward	1
Total Responses	34

Time (minutes) spent	Investigate on an IR
1-10	0
11-20	6
21-30	9
30-45	13
depends	4
Total Responses	32

Time (minutes) spent	Safety team meeting
1-5	12
6-10	9
11-15	2
16-20	1
an hour	1
no meeting	8
Total Responses	33

Table 12 Summary of the number of responses by category of the Questionnaire to ascertain time spent on various stages of the Incident Summary review and investigation process

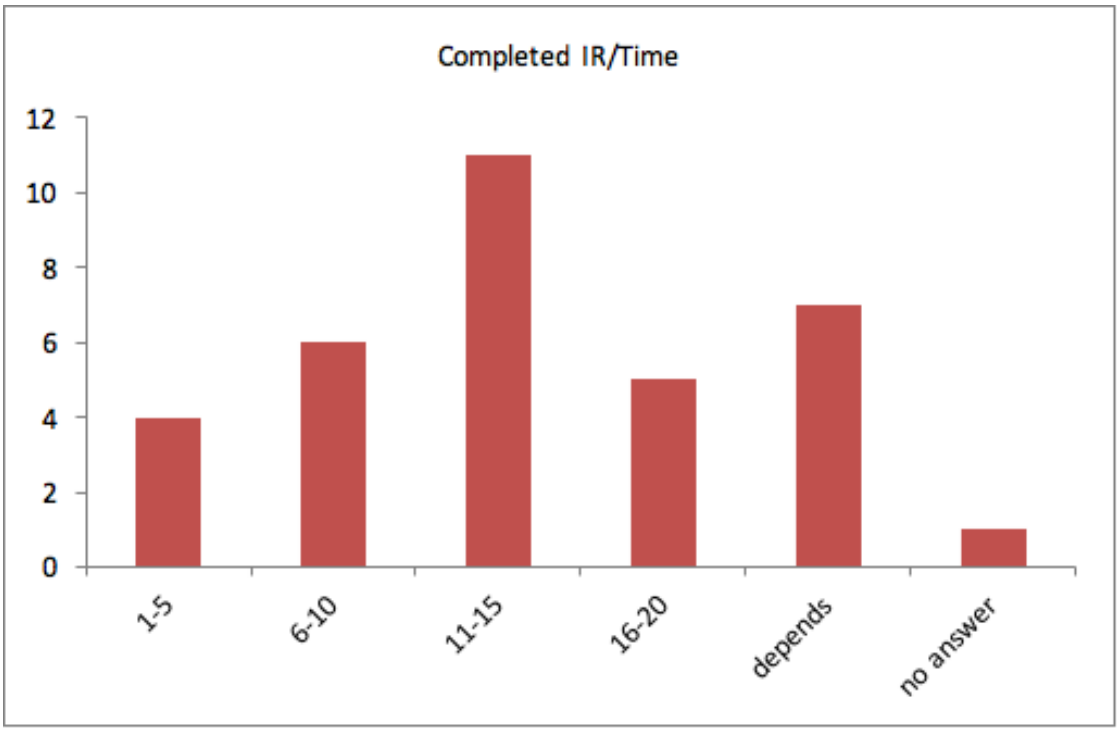

Figure 11 (Graph 4) the number of responses (Y axis) and time taken in 5-minute blocks to complete an Incident form.

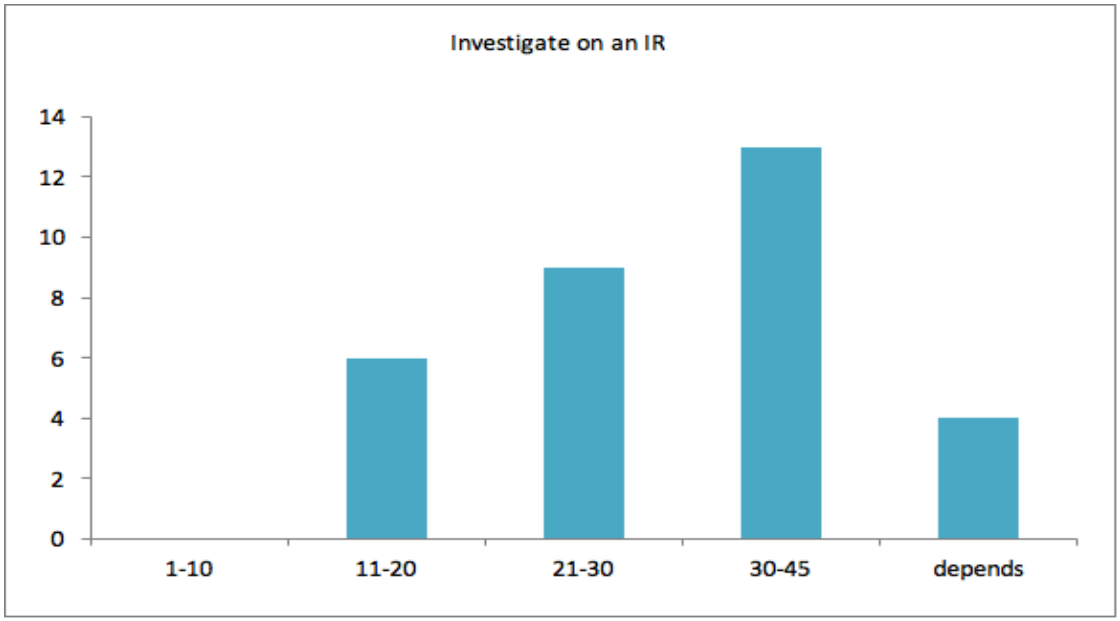

Figure 12 (Graph 5) The number of responses (Y axis) and the time taken in time blocks (minutes) to investigate an Incident.

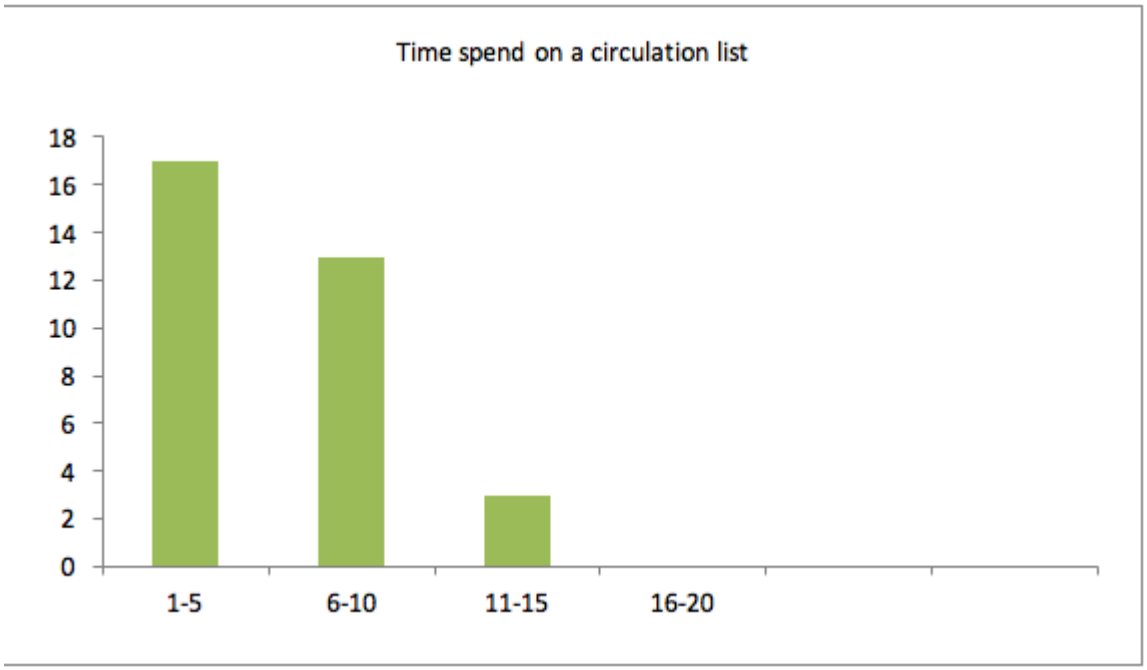

Figure 13 (Graph 6) the number of respondents (Y axis) and the time spent (again in 5 minutes' time blocks) processing incident summary related emails.

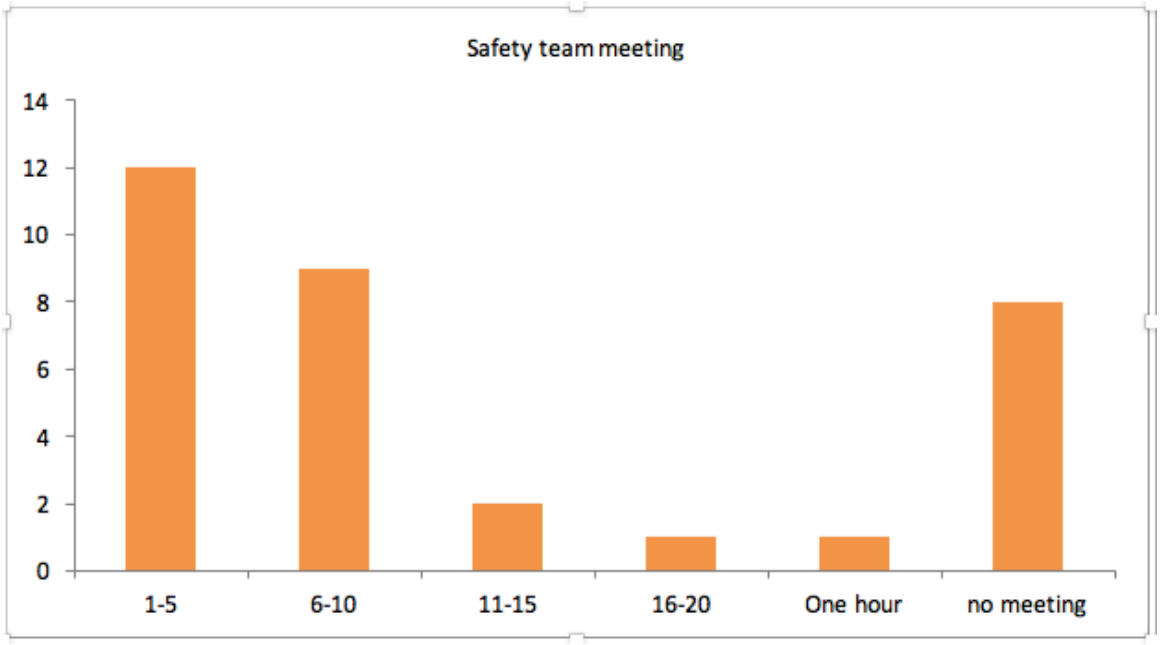

Figure 14 (Graph 7) Number of responses (Y axis) and 5-minutetime blocks for time spent discussing Incidents in the PICU safety team meetings.

Calculating the costs

Staffing costs were calculated per unit as outlined above, and the results tabulated in tables 3-5 below.

	per hour	For every 10 minutes	Per hour with patient contact	For every 10 minutes	per minute
Nurse manager	£57.00	£9.50	£139.00	£23.17	£2.32
Deputy Manager	£49.00	£8.17	£119.00	£19.83	£1.98
Staff Nurse	£41.00	£6.83	£100.00	£16.67	£1.67
Pharmacist	£47.00	£7.83	£94.00	£15.67	£1.57

Table 13 Costs for one minute of various staff categories' time

Medics	per hour	Per 10 minutes	Per hour with patient contact	Per 10 minutes with patient contact	per minute
Consultant	-	-	£139.00	**£23.17**	£2.32
Registrar	£59.00	£9.83	£71.00	**£11.83**	£1.18
FY2	£40.00	£6.67	£48.00	**£8.00**	£0.80
Average of Consultant and Registrar per one minute					**£1.75**

Table 14 Calculating a proportionate rate for one minute of Doctors time

	Numbers of staff in each professional group	Unit Cost	Total Costs
Ward sister/manager	4	£20.67	£82.67
deputy manager/junior sister	2	£17.33	£34.67
Nurse	2	£14.00	£28.00
Pharmacist	1	£14.00	£14.00
Consultants	3	£17.00	£51.00
10-minute block of time	12		£210.33
1 minute block of time cost for complete team			£21.03

Table 15 The PICU safety team members and unit staffing costs

From the questionnaire, the average time spent dealing with the first notification was found to be 5.71 minutes. The second email notification was read cursorily. There were 2942 email occurrences to 262 individuals. The PICU ST (Safety team) consists of 12 staff, removing duplication of emails to PICU ST and the individuals directly gave 1773 staff email episodes.

	Numbers in each professional group	Costs to Process Initial email notification (average time spent per email 5.71 minutes)	Costs to Process follow up email notification (average time spent per email 0.5 minutes)
Consultants	277	£2,688.84	£235.45
Doctors	85	£572.71	£50.15
Directorate Managers	202	£1,810.87	£158.57
Ward managers	137	£1,744.46	£152.76
Nurses	883	£8,420.02	£737.31
Pharmacists	183	£1,640.54	£143.66
Others	31	£47.79	£4.19
PICU ST	51	£6,124.15	£536.27
		£23,049.39	£2,018.34
	Total per IR1		£167.12

Table 16 Costs associated with processing initial email and in addition follow up email notifications.

	Investigating Manager	Nurses	Doctors	Pharmacist	Others	email distribution	Ward Distribution	PICU Safety team (12 people)
Time (minutes)	24.69	9.97	5	9.97	9.97	-	-	10
Numbers of IR1 forms processed	150	148	49	21	9	-	-	53 (35%)
Costs per minute	£1.70	£1.40	£2.05	£1.40	£0.38	-	-	£21.00
cost per IR1	£41.97	£13.96	£10.25	£13.96	£3.79	-	-	£210.00
Total costs per IR1	£41.97	£13.77	£3.35	£1.95	£0.02	£167.12	£37.58	£71.40

Table 17 Showing costs for each element of the IR1 process.

The Total cost for processing an IR1 was £337.16. For the 149 IR1s reviewed, 262 individuals were involved on multiple occasions (2942) giving 19.74 staff episodes per IR1. There were on average 12.96 staff individuals associated with the processing of each IR1 incident form report.

Free text comments were very few and therefore not analysed in any detail. The few respondents that did comments indicated that the IR1 incident process seemed to be both cumbersome and time consuming.

Discussion

It was not the purpose of this study to review the quality of the data captured on IR1 incident reports or even the volume of IR1 reports completed nor was the aim to evaluate the effectiveness of the IR1 recording process but rather to investigate the costs associated with it and in particular, incidents that were classified as resulting in no patient harm and therefore didn't require additional therapy at additional cost. Incidents that result in causing harm to patients, follow a more comprehensive investigative pathway and the costs would be higher to take into account additional therapy that may be required.

What the study did show was that although costs were low, staff episodes required to complete the process were high and calls into question the design of the process and whether or not this level of staffing input would not be better allocated to learning from these errors rather than recording them? The few anecdotal free text comments that were made on

the questionnaires did allude to this. The real reason for recording errors, after all, is to be able to learn from them and improve patient safety, it would seem that energies went into processing incident 9IR1) reports rather than identifying themes in the errors reported and changing practice accordingly.

Conclusion

The costs associated with reporting, investigating and processing an incident report (IR1) of £337.16 on average did not appear to be unduly high considering the acknowledged positive impact for patient safety. However, the numbers of staff involved (19.74 staff episodes on average) in the process particularly as a result of the email distribution activity did appear to have room for efficiencies. Anecdotally, feedback through the free text element of the survey indicated a certain incident reporting *processing fatigue* amongst staff that hinted at disengagement from the process. It could be argued that an element of what many perceive as unproductive processing time could be diverted away from less important tasks in the process to supporting learning from the incidents instead?

The second objective of this piece of research was, to investigate the efficiency and effectiveness of the current Incident reporting system (IR1S) in supporting learning from incidents and changing practice. This investigation showed that the current process efficiency could be improved in terms of learning from incidents. It also showed that the IR1 incident reporting system couldn't add substantively to this research any more than a review of the literature could.

In the next chapter, chapter 7, the outcomes from the studies outlined in chapter 4 and Chapter 5 together with lessons learnt from error causation theory outlined in chapter 1, will be brought together into a unique, as far as paediatric hospital pharmacy is concerned, risk reduction strategy and tested in a different but related healthcare environment and implemented with pharmacy staff.

Chapter 6. The place of Checklists, Standard Operating procedures (SoPs) and multi-disciplinary skill mix in error prevention on an acute ward in a children's hospital

The introduction of pharmacy technicians onto an acute ward, onto one medicine round a day, as part of the nursing team and partnered with a nurse, and tasking them with intravenous (IV) medicine preparation and patient administration duties has had a direct and measurable impact on reducing medicine related incidents and therefore on patient safety.

The pharmacy technician and nurse team are supported with a specially designed protocol, inspired by the World Health Organization (WHO) Safer Surgery checklist, and based on the five rights of medicines administration that in addition has a calculation aide tool on the reverse. The pharmacy technicians, after a learning needs assessment was carried out, received additional training in IV medicine administration including administration pumps together with an introduction to patient assessment skills. A senior medicines management nurse who is based within the pharmacy department oversaw the project. The pharmacy technician-nurse team was a genuine multidisciplinary skill mix team. The pharmacy technicians brought a protocol driven proactive medicine safety approach to the partnership, whilst the nurse added the necessary Patient assessment, medicines administration skills and knowledge of the specialty.

Initial anecdotal data collected through the month of June 2015 indicated that the addition of a pharmacy technician to the medicines administration process prevented 1-3 incidents (IR1s) a day from being reported. The pharmacy technicians proactively addressed errors or potential errors before proceeding with the IV preparation process, questioning ambiguity or actually errors on the medicines administration charts. In paediatric hospitals, two qualified nurses, that is nurses who have a degree in nursing from a recognized institution and are registered with the Nursing and Midwifery Council (NMC), are required to check medicines before they are administered to patients. Another positive outcome realized from the project was in a timelier fashion. If for no other reasons than they were an additional pair of hands and less likely to be called away from preparing medicines than a nurse would be, which in itself contributes to medicines safety. Finally this was arguably a significant role development that pharmacy technicians have made since they became a profession that didn't emanate from pharmacists.

Introduction

NHS providers and commissioners ended 2015/16 with an aggregate deficit of £1.85 billion (unaudited), a threefold increase on the previous year. This is the largest aggregate deficit in NHS history [Source The King's Fund[148]]. In a BBC interview on May 22nd 2016, Simon Stevens the chief executive of the NHS has warned that leaving the EU could damage the health service. Elsewhere in this thesis it has been discussed that Lord Carter of Coles published an independent review into operational productivity in the National Health Service (NHS). The findings were many and included the observation that there was unwarranted variation in the cost of delivery of services across the NHS and efficiency, effectiveness and productivity could be improved and an estimated £5 billion saved as a result. Included in the report was the recommendation that NHS Hospital resort less to agency staff in order to control expenditure (Coles 2016). Current imperatives to increase efficiency, to use resources more effectively, to improve patient safety set against a backdrop of reducing length of stay and moving healthcare to where the patient is, leads us to continually consider better ways of working.

Many hospitals in England are struggling to recruit adequate numbers of nurses to staff their wards. Some 92% of the 225 acute hospital trusts in England did not manage to run wards with their planned number of nurses [149],[150]. It should also be noted that paediatric trained nurses are fewer in number than general trained nurses[151]. In a paediatric hospital, nurses are tasked with the selection, preparation or more accurately reconstitution including if necessary dilution and administration of IV drugs to patients. It is mandated by the Trust medicines policy that tasks making up these processes are checked by a second competent individual, typically another nurse, so two nurses are actually involved in the preparation and administration process.

Moreover, nursing staff is the professional group more than any other that actively record errors and incidents. Ross (2000)l[152], in a study conducted in a paediatric teaching hospital in

[148] http://www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/Deficits_in_the_NHS_Kings_Fund_July_2016_1.pdf <accessed August 8th, 2016>

[149] BBC News. NHS nursing levels: Nine in 10 hospitals missing targets. 2015.

http://www.bbc.co.uk/news/health-35148920 (accessed May 2016).

[150] ITV News. 'Shortage' of nurses on wards. 2013.

http://www.itv.com/news/story/2013-09-18/shortage-of-nurses-on-nhs-wards/ (accessed May 2016).

[151] Nursing and Midwifery Council. https://www.nmc.org.uk/registration/search-the-register/ (accessed May 2016).

[152] Ross LM, Wallace J, Paton JY. Medication errors in a paediatric teaching hospital in the UK: five

England reported a medication error rate of about 0.15% and nurses were responsible for 59% of these errors. The seemingly high nursing involvement in these error types should not be surprising when one appreciated that it's nurses more than any other healthcare professional who are involved in administering IV medication.

The use of medicines carries risks of adverse events, which are greater in the paediatric population because of many factors, notably the increased use of compounding inherent to sterile and non-sterile named patient prepared medicines (Sharek 2006) [153] in their literature review of adverse drug event rates in paediatric inpatients have quotes as high as 1.8 to 4.8 times that occurring in adult studies, although, fortunately the majority of reported adverse drug events in paediatric patients appears to be of low severity. In another study, [154] found that adverse drug events in paediatrics were three times high than those for adults. Furthermore intravenous drug administration is a riskier route than almost any other used in a hospital setting, Hicks RW (2008)[155] , Kaushal (2001). This project investigated the practicality of using pharmacy technicians to support the workload of nursing teams. There is a growing body of literature that describe the expanding role of Pharmacy technicians. (Adams 2011) [156],Shane (2011).[157]

Pharmacy technicians[158] are a part of the pharmacy team, working under the supervision of a pharmacist. They prepare medicines and other healthcare products and supply them to patients. They also take an active role in providing patients with guidance on taking Kaushal (2001)[159] medicines. The training of Pharmacy technicians consists of two years consecutive work-based experience under the direction of a pharmacist to whom the trainee is directly accountable for not less than 14 hours per week. Qualification requires completion of both a GPHC-approved competency-based qualification and a knowledge-based qualification. Pharmacy technicians are registered with the General Pharmaceutical Council. The question

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years operational experience. Arch Dis Child2000;83:492–7

[153] Sharek PJ, Classen D. The incidence of adverse events and medical error in pediatrics. Pediatr Clin North Am 2006;53(6):1067-77

[154] Kaushal, R., et al. (2001). "Medication errors and adverse drug events in pediatric inpatients." JAMA **285**(16): 2114-2120.

[155] Hicks RW, B. S., Cousins DD (2008). MEDMARX data report.

[156] Adams, A. J., et al. (2011). ""Tech-check-tech": a review of the evidence on its safety and benefits." Am J Health Syst Pharm **68**(19): 1824-1833.

[157] Shane, R. (2011). "Advancing technician roles: an essential step in pharmacy practice model reform." Am J Health Syst Pharm **68**(19): 1834-1835.

[158] https://www.pharmacyregulation.org/education/pharmacy-technician <accessed August 8th 2016>
[159] Kaushal, R., et al. (2001). "Medication errors and adverse drug events in pediatric inpatients." JAMA **285**(16): 2114-2120.

asked was, could pharmacy technicians be up skilled to undertake what has traditionally been considered a nursing role and thereby release valuable nurse time to care? An acute ward in a paediatric hospital was selected for the project.

In addition, the question was asked, what could the Health service learn from other high risk industries, such as the airline industry with regard to the use of Quality Management Systems to reduce risks and increase efficiency? We discussed earlier in this thesis the work of Dr Atul Gwande, Gwande (2011), author of the "The Checklist Manifesto", who wrote that failure in the modern world, he writes, is really about errors of ineptitude, that is mistakes made because we don't make proper use of what we know. The routine tasks of surgeons, for example, have now become so incredibly complicated that mistakes of one kind or another are virtually inevitable. As for pilots, a checklist is one approach to managing complexity and interruption. Would the introduction of a protocol driven into the medicines administration process impact positively?

Project Overview

Pharmacy technicians were allocated to this project for a three-month period in the first instance. They were given additional training and supported with a specially designed checklist protocol together with a calculation tool. A senior medicines management nurse led the team supported by nurse trainers and nurse educators and mentors for the pharmacy technicians.

The pharmacy technicians were assigned to the busiest medicine round particularly to IV (intra venous) medicine preparation and administration. They also recorded any interventions that they made or concerns that they had. Finally, an unstructured questionnaire was conducted to evaluate what the nurses on the ward felt about the project.

Context

In a paediatric hospital, Nurses are tasked with the selection, preparation or more accurately reconstitution including if necessary dilution and administration of IV drugs to patients. It is mandated by the Trust medicines policy that tasks making up these processes are checked by a second competent individual, typically another nurse.

IV monographs prepared by the pharmacy department give guidelines as to what options are available for reconstituting a particular drug, what precautions might need to be taken and what routes and in which way a particular drug may be administered. For example which diluent to use, whether the final preparation needs to be given slowly over a long period or in

fact could be administered over a matter of minutes. Depending upon the route and method of administration selected, the dilution calculations will vary and are usually complex. This is all the more the case when individual patient factors are taken into account for example, ease of access for IV lines, fluid restrictions that may apply to an individual patient and the patient's diagnosis.

There is therefore no one correct way to approach these tasks and each nurse is likely to have determined a strategy based upon their knowledge and experience. In addition, calculations may be carried out with the aid of calculators usually without a record being kept of the rationale used to derive the final answers, which makes checking the results arguably more complex.

In addition, treatment rooms where these medicines are prepared are seldom quiet. Nurses are often interrupted either directly by colleagues asking questions or indirectly by a range of activity and noises around them.

A variety of techniques have been deployed to make medicine related critical processes safer with varying degrees of success. Examples of these strategies include reducing the likelihood of direct interruptions by staff engaged in medicines administration wearing red tabards, these indicate that the operative must not be interrupted. Indirect interruption strategies include having designated quiet work areas. Interruptions have been shown to reduce work efficiency by 18.75%, Sinclair A.G. (2012)[160].

Project Introduction

Joint Nursing Pharmacy medicines administration project.

The aim of the project was to pair a nurse and a pharmacy technician as a team to carry out the medicine rounds on the ward, exclusively with IV drugs and to introduce an administration and calculation protocol.

An acute ward was chosen for the project because of the engagement of the senior nursing team on the ward and a willingness to support the project. Experienced pharmacy technicians were assigned and the project led by a senior nurse who works in the pharmacy department. Initially a training needs assessment was undertaken for the pharmacy technicians and additional training delivered by senior nurse trainers was given, particularly in

[160] Sinclair, AG; The impact of interruptions on individuals carrying out the accuracy-checking step of the dispensing process; March 2012

IV management including syringe drivers and introduction to basic patient assessment skills. In addition an investigation into the legal and professional implications of working in this way was carried out and advice sought from relevant professional bodies and discussed with senior hospital management.

The Pharmacy technicians brought with them and implemented approaches that are normal ways of working for pharmacy staff for example adherence to protocols in the form of worksheets, a proactive stance with regard to errors or incipient errors and recording of near misses. It should also be noted that nursing staff are the professional group more than any other that actively record errors and incidents.

In addition, a Checklist was devised, influenced by the World Health Organisation (WHO) safer surgery checklist together with a calculation aide, designed by the project team. The Checklist itself (Appendix 7) consisted of the five rights, the right patient, the right medicine, the right dose, the right route and the right time. On the reverse of the checklist was the calculation aide that was duplicated so each person involved in the process could complete his or her own independently. A complete record of an independent double check having taken place was retained.

Method

The study design was a retrospective analysis of reported intervention data over a four-week period on an acute Oncology ward at Birmingham Children's Hospital.

The Kotter[161] (Kotter 2015) model of change management, usually used as a tool for achieving meaningful change and accelerating practice change in the pharmacy setting, we used it to conduct our change.[162] The model consists of eight well defined steps and these are; Establish a sense of urgency; Form a powerful coalition; Create a vision; Communicating the vision; Empower other to act on the vision; Plan for and create short term wins; Consolidate improvement and produce still more change and finally Institutionalize the new approaches.

The Pharmacy technicians were integrated into the nursing team. At the outset there was a sense of urgency due to the fact that there was a shortfall in the number of nursing to staff on the ward. A team (coalition) was created to manage the project. A vision and supporting

[161] Kotter, J. (2015). "The 8-Step process for leading change." 2016, from <http://www.kotterinternational.com/our-principles/changesteps/changesteps.>
[162] Guérin A, Hall K, Lebel D, et al. Change management in pharmacy: a simulation exercise and identification of change barriers by pharmacy leaders. Int J Pharm Pract 2015.

strategies developed together with supporting documentation and the team strengthened through various team meetings. The vision was communicated to the rest of the nursing team on the unit. Employees were empowered to take action by organising bespoke training sessions for the pharmacy technicians, carried out by a senior nurse trainer and in addition recruiting nurses on a voluntary basis to take part in the pilot study. Short-term gains were identified by means of a pilot study and improvements consolidated into practice with the promise of future developments and finally improvements were embedded into current practice.

Legal and professional implications

An investigation into the legal and professional implications of working in this way was carried out and advice sought from relevant professional bodies, such as the Nursing and Midwifery Council (NMC) and national guidance and the results were discussed with senior hospital management. This did result in changing elements of the protocol for example the NMC guidance clearly states in Standard 14[163] of the NMC standards for medicines management that registrants must not administer medication drawn into a syringe or container by another practitioner when not in their presence. The team therefore had to ensure that the nurse member of the team was involved in the preparation of each Intra Venous (IV) syringe. Initially the preparation was to be carried out solely by the technician, so this part of the protocol was amended.

The Team

A senior medicines management nurse employed by the pharmacy department led the team and also assumed the role of mentor to the pharmacy technicians. in addition, the technicians were supported by a senior nurse trainer and nurse educator. Pharmacy technicians selected to become members of the nurse team were working on the oncology unit prior to the commencement of the project and were known to the nursing team and with ward practice. Their pharmacy duties on the ward included medicine stock maintenance, reviewing patients' own medicines for suitability for use during their inpatient stay and surveying medicine administration charts for medicine availability.

[163] https://www.nmc.org.uk/globalassets/sitedocuments/standards/nmc-standards-for-medicines-management.pdf <accessed August 10th,2016>

New pharmacy technician's role

The pharmacy technicians were assigned to the busiest medicine round particularly to intravenous medicine preparation and administration. A nurse volunteer was paired with a pharmacy technician for the preparation and administration of intravenous drugs for that medicines round. For this pilot study, the pharmacy technicians acted as the second checker to the nurse during preparation and administration of medicines. The second check included a strict control of all steps of the process using a checklist especially designed for this purpose.

Assessment

Pharmacy technician's intervention Three pharmacy technicians recorded prospectively any interventions that they made that included the number of intravenous preparations and the number of IV administrations performed and concerns that they had. For example, the number of near misses that occurred during the double-checking activity, or when a dose wasn't checked prior to administration.

Technician training and management

A training needs assessment was undertaken for the pharmacy technicians and additional training (30 hours) delivered by senior nurse trainers was given, particularly in intravenous management including syringe drivers and an introduction to nursing basic patient assessment skills. The areas of competency and awareness that must be demonstrated by pharmacy technicians

A Quality Management System strategy was introduced, and this included a strictly protocol-driven approach to the process, augmenting the nurses' clinical and professional skills. This included the introduction of a specially designed checklist, influenced by the WHO safer surgery checklist and inspired by a visit by one of the investigators to an airline pilots' revalidation session. On the reverse of the checklist was a calculation aide. The checklist itself was made up of the five patient rights and these are, the right patient, the right medicine, the right dose, the right route and the right time. In addition, the preparation area was taken over by the project and became a 'quiet area' and was used in preference to the noisy bedside area where distractions, both direct and indirect abound. Flow rate calculations

and complex calculations were made in this quiet area rather than at the patient's bedside as previously.

Finally, two staff survey were conducted of nursing staff involved in the project. The first an unstructured survey collecting general views of the project from 15 (25.9%; n= 58) ward nursing staff who were present on the ward on the day shift over three days in July 2015. The second was a structured interview in the form of a questionnaire.

Results

Pharmacy technician's intervention

Three pharmacy technicians were trained and participated in the study. The preparation and administration activity consisted of 304 hours of actual cover over 76 days during this period, and 509 intravenous injection preparation and administration assisted by the three pharmacy technicians that is an average of 35 min per intravenous injection activity out of a possible 1123 preparations (45%) of all intravenous preparation and administration on the ward during the study period. The pharmacy technicians were available to work on the project during the busy late morning–lunchtime medicine round.

Interventions were recorded during 1 week of the project and pharmacy technicians recorded 15 near misses. Table (1) summarizes the near misses recorded. The addition of a pharmacy technician to the medicines administration process appeared to prevent 1–3 medicine related incidents (IR1s) a day from occurring.

DATE	Comment if not checked / prepared - Reason why or interventions
08/06/15	The IV Tazocin or indicated when the last IV dose was to be administered. The patient had been written up for oral Flucloxacillin and it was here that the instructions for the IVs were had also been written on the prescription. The Instruction said to stop all IV antibiotics and commence orals from 12 noon. The Doctor hadn't verbally communicated this to the nurse and she hadn't noticed the new instructions so had continued to proceed with the preparation of the Tazocin. I (technician) pointed out the new instructions and asked the Doctor to clarify what was required.
09/06/15	Wrong volume of water drawn up - 19.1ml instead of 19ml - It was planned to bolus the dose but I advised that it must be infused after 15-30 minutes as it is 40mg/kg
09/06/15	The intention was to give as a bolus over 3-5 minutes - Advised that the dose must be infused as 21mg/kg over a minimum of 15 minutes
09/06/15	It was planned to administer the dose as a bolus over 3-5 minutes however as it is prescribed as 40mg/kg I advised that it needed to be given over 15-30 minutes as a bolus. Also advised her to change maintenance fluid to saline as glucose not compatible with Meropenem
10/06/15	Vancomycin was prepared in error - left on side for 30 minutes while Meropenem was being infused.
11/06/15	Drug was going to be given as a bolus - but should be administered as an infusion because of the dose
17/06/15	Flow rate wrong at bedside - needed help
17/06/15	Concern- pushed in one movement and not given over 5 minutes
17/06/15	Concern- pushed in one movement and not given over 5 minutes
18/06/15	1ml drawn up instead of 2ml (intervention)
19/06/15	Intention was to dilute to 20ml - changed to 30ml
22/06/15	Wrong dose prescribed - Doctor amended
23/06/15	**Concerns over speed of bolus preps**
24/06/15	Query Rasburicase 3mg should have been given @ 5am - nurse chasing (due @ 5am given at 2:40pm) Supply sorted by tech as IP needed it as soon as possible
30/06/15	Level due @ 6pm - rate needs to be at least 90minutes - discussion: talked through monograph and explained how to work out rate over 90 minutes rather than 60 minutes.

Table 18 Summary of near misses (15) recorded during June 2015

It should be noted that although many medicine monographs require a bolus to be given over significant lengths of time it is practically very difficult to actually give a bolus injection over 3-5 minutes or longer. Table (2) lists observed bolus rates administration variances and the required administration times over a 4 day period in June 2015..

Drug and bolus rates	Actual bolus rates
Metoclopramide Slow bolus to be given over at least **5 minutes**	1.20, 0.58,1.22,1.04,1.07,0.29,3.36
Ondansetron Slow bolus to be given over **2 to 5 minutes (**MHRA warning[164])	0.59,0.59,1.09,0.59,0.13,0.21
Ranitidine Slow bolus to be given over **3 to 5 minutes**	1.32,2,59,0.59,1.07,1.04
Meropenum 20mg/kg/dose or below bolus over **3 to 5 minutes**	0.19,0.56,1.04

Table 19 Required Bolus rates and observed bolus rates, observed over 4 days (June 2015, 22nd-25th).

Survey - Staff Nursing Satisfaction

Fifteen nurses were interviewed, which represented 25.9% (n=58) of the total possible ward nursing compliment. Regarding the nurses interviewed, 100% (n=15/15) were satisfied with the introduction of a pharmacy technician as part of their team.

[164] https://www.gov.uk/drug-safety-update/ondansetron-zofran-important-new-intravenous-dose-restriction accessed July 2015

Comments collected through unstructured interviews with ward nursing staff

"The timings of support is not long enough; staff have to adjust administration times to fit in with clinical activity and procedures and therefore an increase in the technician time on the ward would further support this flexibility".

"The team would like support with the oral drug rounds. We have discussed this and had hoped to start this but due to resources this has been delayed. We discussed trying to take this forward once a member of staff returned from maternity leave."

"The team have asked if the pharmacy technician team can "take charge" of the treatment room ensuring stock is available; cupboards are well organised etc. They feel this overall management of the room would have supported the availability of drugs, which have been stored incorrectly or not dispensed in a timely way, and assist in ensuring out of date medication is removed rather than having to be sorted out of hours."

"Overall they welcomed the pilot and would like to see it extended to impact on more of the ward rather than just the main ward; some commented to extend to HDU where there is an increase in medication administration per patient would be beneficial."

"The team recognise this would also help embed the staff in the ward team."

Discussion

Although slips are vastly more common than mistakes, health care has typically responded to all errors as if they were mistakes, resorting to remedial education and/or added layers of supervision. Such an approach may have an impact on the behaviour of an individual who committed an error, but does nothing to prevent other frontline workers from committing the same error, leaving patients at risk of continued harm unless broader, more systemic, solutions are implemented[165].

An axiom of human factors engineering is that processes should be standardized whenever possible[166], whether to improve safety or improve efficiency. This approach is at the heart of all Quality systems strategies such as Lean Six Sigma, Total Quality management (TQM), ISO9000 and other such quality systems.

[165] http://psnet.ahrq.gov/primer.aspx?primerID=21 accessed July 2015
[166] http://psnet.ahrq.gov/primer.aspx?primerID=20 accessed July 2015

Working to standardised protocols and visual cues are particularly beneficial when working in busy time pressured, high-risk situations and where staff is subject to direct or indirect distractions. Checklists, evidence-based protocols are particularly helpful in ensuring that each necessary step in a process has been completed. In the project the use of a standardised protocol in the form of a checklist together with a calculation tool was particularly useful in trapping errors and giving assurance to those involved that they hadn't made an error.

Incorrect awareness of the time over which a bolus injection had actually been given was a function of multiple contributory causes not least of which was the impracticality of attempting to give a bolus over a prolonged period, two minutes has been suggested as a practical threshold beyond which compliance becomes difficult. The lack of a ready available means of monitoring the time, however even with such a means available, interruptions and workload pressure are likely to have reduced situational awareness as the operative would need to manage competing multiple pulls on their attention. This becomes an example of the normalization of deviance from accepted practice. The risk of non-adherence to a recommended bolus times is a condition known as Speed Shock Speed which occurs when a foreign substance usually a medication is rapidly introduced into the circulation; symptoms and side effects include, dizziness, facial flushing, headache, tightness in the chest, hypotension, irregular pulse, progression of shock. Rapid injection leads to the concentration of medication in the blood to reach toxic levels, the heart and brain being particularly susceptible[167]

Errors in flow rate calculations could be attributed to attempting these complex data manipulations at a stage in the process that is subject to most interruptions whether direct, being asked a question by a colleague or a patient's parent or indirect that is locational, working within a noisy workspace at the patient bedside. A simple solution would be to complete the complex decisions at the start of the process in a controlled environment such as a treatment room rather than at the bedside. In addition, observing pilots undergoing revalidation[168] it was noticed that complex fuel calculations were undertaken in the cockpit at the outset of the journey and before other routine business commenced.

This concept was proposed to the nursing team and emulated in that the task of performing complex infusion flow rate calculations, typically carried out at the patient's bedside where

[167] Phillips, L et al; Manual of I.V. Therapeutics: Evidence-Based Practice for Infusion Therapy; 2014 6th ed F.A Davis
[168] Easyjet Pilot revalidation observation; Haywards Heath Sussex; (Oct 2015).

the environment can be noisy and distractions abound were transferred to the quiet of the treatment room, and performed at the outset of the preparation sequence. In this way the nurses were less hurried and less distracted.

IV administration is known to be a high risk procedure, the then National Patient Safety Agency (NPSA) published an alert[169] that in the introduction had the following:-

"The National Patient Safety Agency (NPSA) received around 800 reports a month to its National Reporting and Learning System (NRLS) relating to injectable medicines between January 2005 and June 2006. This represents approximately 24 per cent of the total number of medication incidents. The majority of these resulted in no or low harm to patients. However, there were 25 incidents of death and 28 of serious harm reported between January 2005 and June 2006. Research evidence indicates that the incidence of errors in prescribing, preparing and administering injectable medicines is higher than for other forms of medicine. In one study, at least one error occurred in 49 per cent of intravenous medicine doses prepared and administered on hospital wards; one per cent were judged to be potentially severe errors; and 29 per cent potentially moderate errors".

In Paediatrics, IV administration is known to be a high-risk procedure due to the additional complexities associated with administration and dose calculations that children require. An analysis of 12 months' complete data set of medicine related incident reports from across the hospital, January to December 2013, was undertaken. Of the 1473 incident summaries, medicine related incidents (IR1s) reviewed as part of this analysis 736 (49.97%) were categorised as being within the general category of administration related. Further analysis revealed that of these 173 (11.74%) were identified as arising during the IV administration process and 175 (11.88%) were identified as having been omitted.

Human factors also referred to as Crew resource management has it that many accidents are blamed on the actions or omissions of an individual who was directly involved in operational or maintenance work. This typical but shortsighted response ignores the fundamental failures, which led to the accident. These are usually rooted deeper in the organisation's design, management and decision-making function[170].

[169] www.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=2269 <accessed 10th August 2016>

[170] Reducing Error and Influencing Behavior ; HSE 2nd ed 1999.
<http://www.hse.gov.uk/pubns/priced/hsg48.pdf> accessed July 2015

It is accepted that hospital wards are stressful, from the sense of workload pressure, environments in which distractions are common place and coping mechanisms may well include deviation from protocol as an acceptable approach.

Conclusion

This pilot was a brief snapshot in time and more data is required before definitive conclusions can be drawn. However, a sufficient indication was derived as to the benefits of drawing from the approach, knowledge and competencies of two professional groups to merit a more in depth investigation into this strategy. In addition an approach for integrating lessons learnt from other high-risk industries, in this case the airline industry, into the culture and environment of the health service was developed.

Chapter 7. Thesis Discussion

Introduction

This thesis set out to answer three questions, firstly to investigate whether it would be feasible to identify latent risks associated with in a specific task set in a National Health Service (NHS) paediatric hospital pharmacy department and then to establish the extent to which these latent errors could be predicted. Secondly to investigate the efficiency and effectiveness of the current Incident reporting system (IR1s) in supporting learning from incidents and changing practice. Should the error reporting and investigation processes, not work sufficiently well, including engaging the staff of the organisation then it will be highly unlikely that learning from these errors will take place. If learning from errors that have occurred does not take place then practice won't change and latent errors will remain in the system waiting to give rise to an error. To put it another way, an efficient error reporting system is an approach to predicting latent system risks.

An analysis of the outcomes from the first two phases enabled the development of an innovative and unique strategy that put in place a system that mitigated against latent errors or risks that were found to be predictable. In order to test the robustness of the strategy it was implemented with pharmacy staff who were asked to carry out accuracy checking tasks, similar to those that took place in phase one of the research, but for this phase, phase 3, the tasks were carried out as part of an Intravenous Injection (IV) medicine administration round on a busy Oncology Ward. The impact was immediate and observable with predictable error types being trapped and in addition perceived stress felt by staff reducing.

Any investigation into the predictability or otherwise of identifying latent errors must demonstrate in the first instance a clarity as to existing error causation theory and then to proceed to review what research is known in the discipline of error causation in general and then in particular in the context of paediatric hospital pharmacy set in the National Health Service in England and Wales. Finally, existing research would have informed current practice, also it would have influenced the formulation of national guidance and standards and therefore this also needs to be taken into account.

Theoretical background

Latent risks or errors have been defined as," A defect in the design, organization, training or maintenance in a system that leads to operator errors and whose effects are typically delayed" (Safety 2005)[171] . The report goes on to say that "Latent errors pose the greatest threat to safety because they often go unrecognised for years, workers simply work around defects in the system". The classic text book examples cited are the cases of the National Aeronautics Agency and Space Administration (NASA) space shuttle *Challenger* incident that occurred on January 28th, 1986 when the shuttle broke apart, within 73 seconds into its flight, with the deaths of seven crew members. This was attributed to a faulty O-Ring seal in its right solid rocket booster. The O-ring was simply not designed to fly under the unusually cold conditions generated in a launch scenario, Committee on Science and Technology, House of Representatives (1986)[172]. Also the Three-Mile Island disaster, another much cited accident disaster [173](Commission 2013) that occurred on march 28th, 1979, and was the most serious accident in American commercial nuclear power plant history. A combination of equipment malfunctions, system errors, design problems and operator failures led to a partial nuclear meltdown and a very small off-site release of radioactivity, Report of the President's Commission (1979)[174].

Error Types

Professor J Reason, one of the most influential thinkers in the field of error causation and the application of error prevention management strategies in the field of healthcare, in an article in the British Medical Journal Reason(2000)[175] describes two approaches that theorists use in understanding human fallibility and these he outlines as the human approach and the system approach. The human approach takes the view that errors arise due to human

[171] World Alliance for Patient Safety; . (2005). WHO Draft Guidelines for Adverse Event Reporting and Learning Systems. < http://osp.od.nih.gov/sites/default/files/resources/Reporting_Guidelines.pdf accessed August 20th, 2016.

[172] Investigation of the challenger accident report of the committee on science and technology house of representatives ninety-ninth congress second session . U.S. government printing office washington : 1986 < https://www.gpo.gov/fdsys/pkg/GPO-CRPT-99hrpt1016/pdf/GPO-CRPT-99hrpt1016.pdf> accessed May 2017.

[173] Commission, U. S. N. R. (2013). "Three Mile Isalnd Accident." <accessed 29.10.2016>

[174] The President's Commission on the Accident at Three Mile Island; October 1979 <

[175] Reason, J. (2000). "Human error: models and management." BMJ : British Medical Journal 320(7237): 768-770.

weakness; individuals are careless, perverse, inattentive or simply incompetent. The System approach favours the view that actually before error forcing conditions reach an individual, the system that they are working in fails to trap errors from occurring. In reality, both approaches are valid and so we find that individuals bring about errors and a variety of error types have been defined and these are slips and lapses, mistakes and violations. Reason describes these in his book Human Error (Reason 1990)[176], Slips and lapses, he writes, "are errors which result from some failure in the execution and or storage of an action sequence. Whereas mistakes may be defined as deficiencies or failures in the judgmental or inferential processes in the selection of an objective or in the specification of the means to achieve it". Slips occur at the execution of a task stage; Lapses are related to memory failure and mistakes occur when planning an action.

This later error type has further implications that Broadbent et al (Broadbent, Cooper et al. 1982)[177] describe in their stress-vulnerability hypothesis in which they suggest that those who work in high stressful jobs, and make mistakes , are prone to or are more vulnerable to showing the bad effects of stress. Stress doesn't cause them to make errors, rather stressful work may give rise to errors and this in turn may give rise to inappropriate behaviours. Rasmussen[178] (Rasmussen and Jensen 1974) developed a framework for describing error types. These were Skill based errors, repeated sequences of actions requiring minimal cognitive input. Rule based errors that require an operative to follow a set of instructions and knowledge based errors that require active cognitive analysis. In addition to error types there are error forms, Reason (1980) which are shortcuts human memory uses to handle particularly underspecified cognitive operations, basically heuristics to locate the necessary missing information. One is similarity matching that looks at the degree of similarity between the current task and what has happened in the past and the other is frequency gambling, how often something has occurred previously and seemed to work.

Basic Risk Factors

Groeneweg [179](Groeneweg 2002) and colleagues outline that behind each error sits one or more substandard act but these themselves are brought about by an issue with one or more

[176] Reason, J. (1990). Human Error, Cambridge University Press.

[177] Broadbent, D. E., et al. (1982). "The Cognitive Failures Questionnaire (CFQ) and its correlates." Br J Clin Psychol **21 (Pt 1)**: 1-16.

[178] Rasmussen, J. and A. Jensen (1974). "Mental procedures in real-life tasks: a case study of electronic trouble shooting." Ergonomics **17**(3): 293-307.

[179] Groeneweg, J. (2002). Controlling the Controllable: Preventing Business Upsets, DSWO Press.

flawed basic Risk Factor (BRF). The Basic Risk Factors, of which there are eleven can combine to generate innumerable substandard acts that in turn lead to errors. The Basic Risk Factors have been named, Groeneweg (2002) as being; Design (User unfriendly tools); Hardware; Maintenance Management, Housekeeping; Error enforcing conditions, Procedures, Training, Communication, Incompatible goals (ethics and world view of the organisations versus those of the works in that company); Organization and finally defences (Business continuity plans).

This can be illustrated by referring to the Herald of Free Enterprise disaster. The Herald of Free Enterprise was a roll on roll of (Ro-Ro) ferry that capsized minutes after leaving the Belgium port of Zeebrugge on the 6th of March 1987[180] killing 193 passengers and crew. The immediate cause of the accident was attributed to the negligence of a junior crewmember for not closing the bow doors before departure. Further investigation showed that actually the root cause of the accident was due to a combination of pressure from the parent company to speed up transit times, poor equipment or a lack of equipment that the bridge officers didn't know that the bow doors hadn't been closed and the lack of procedures that would've prevented the ship from leaving port without closing the bow doors. Probably at least three of the Basic Risk Factors, contributed to the errors that led to this accident happening and these were, Hardware, Communication and Procedures.

Memory and Multiple stimuli

Error and error causation theory form part of the underlying required knowledge required to achieve the aims of this thesis, another body of knowledge required would be to understand how memory works, how the brain manages multiple stimuli. Operatives working in healthcare environment are more often than not working in stressful situations carrying out complex tasks requiring heavy cognitive input and in an environment that is replete with distractions, both direct and indirect interruptions.

The Skill-Rule-Knowledge based framework explains the type of error that has occurred. Basic Risk factors will describe the root cause or root causes of an accident and knowing what a root cause is or root causes are will enable redesign of the system. The final piece in predicting latent risks and so to be able to predict errors in paediatric pharmacy is an understanding of how the brain works in processing information particularly multiple stimuli.

[180] https://en.wikipedia.org/wiki/MS_Herald_of_Free_Enterprise <accessed August 20th, 2016>

Relevance of the theory in the context of this study

Retrospective analysis of an incident will only give “and” gate analysis trees not “or” gate understanding Groeneweg (2002). That is, what did happen not what also could have happened. Retrospective analysis won’t recognise any other weaknesses that might exist in the system. Furthermore, if the system that allows learning from errors to take place is weak, then lessons may be learnt from an error that has occurred but for a short period only. Any system that is designed to generate learning from errors, itself needs to be efficient and robust. In chapter 6 the efficiency of the reporting system in the hospital was investigated and was found to be relatively inexpensive to administer, but inefficient in terms of learning from errors.

Staff who work in a paediatric hospital pharmacy department whether in the dispensary or on the wards find themselves working more often than not in busy environments, filled with direct and indirect interruptions and often as not under stressful conditions. That is, with a high workload together with time expectations and required to undertake complex cognitive tasks. Multiple models for how the brain processes multiple tasks simultaneously was discussed earlier in this thesis and the three main theories were outlined, these were the Capacity sharing, task switching and Cross-talk models.

The type of interruption or interference was described and could be either Capacity interference which is when the number of incoming cues are too numerous for a decision maker to process or Structural interference which is when a decision maker must attend to two inputs that require the same physiological mechanisms, such as two different visual signals. It should be noted that the ability to process multiple sensory inputs simultaneously is not the same as being able to process the data efficiently or productively. In addition, mitigating interruptions is well documented, however the factors that influence recovery from interruptions themselves, less so and the work of Trafton and Monk (2008) and Prakash (2014) is of significance in this regard.

An appreciation of Error causation, Error types and Error forms or heuristics together with an appreciation of human fallibility, Reason (1990) including the part that human approach and system approach plays and a knowledge of basic risk factors that give an understanding of error root causes and finally adding in how the brain processes multiple stimuli and memory functioning will give the basis for the work outlined in this thesis.

An understanding of the relevant error causation and related theory has been discussed, the next step was to review the literature to search for current work and relevant understanding on this topic in the selected setting and discuss where the research in this thesis sits.

Literature Review and National Guidance

The literature search looked for research papers that had conducted research into Safety systems, Error management; Risk reduction systems; Interruptions to the dispensing process; Economics and efficiency of the NHS Incident reporting system; Quality Systems and Checklists and finally Medicines management and administration policies. The context looked for was that of a paediatric hospital setting in relation to safety, error reduction, human factors, teamwork, flattened hierarchies, visual aids, checklists and protocols**.** The full search strategy has been outlined elsewhere in this document together with the key words used for each section. In total 11,896 citations were found but after careful review and refinement this number was reduced to thirty-four citations that were deemed to have some relevance and these were discussed in detail to ascertain what they might add to the area of research covered in this thesis.

Another approach to determining the extent of research into paediatric related medicine errors prevention strategies of any kind, and if medicine is referred to there would be a pharmacy connection, is to review national guidance. National Guidance will be generated for multiple reasons for example as an outcome of significant research and associated data collection or the occurrence of a significant incident. The later itself would then prompt the interest of researchers. Therefore, the existence of relevant National Guidance would be an indication that a particular topic has been given due consideration and in all likelihood research either prompted it or has been prompted by it.

In 2007 the then National Patient Safety Agency (NPSA) published guidance in the form of an alert that was issued jointly by the National Reporting and Learning Service and the National Institute for Health and Clinical Excellence[181]. It aimed to reduce medication errors, which occur most commonly on transfer between care settings and on admission to hospital. However, according to Huynh et al [182] (Huynh, Wong et al. 2013) the UK national guidance excludes the paediatric population and yet it was widely acknowledged at the time, as it is to this day, that Medication reconciliation is an important process in reducing medication errors in many countries including Canada, the USA, and UK, all of whom have incorporated

[181] http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59878 <accessed August 20th ,2016>
[182] Huynh, C., et al. (2013). "Medication Discrepancies at Transitions in Pediatrics: A Review of the Literature." Pediatric Drugs 15(3): 203-215.

medication reconciliation, for adult patients as a priority area for national patient safety initiatives and goals.

A second National patient safety campaign called the Patient Safety Thermometer[183], first introduced in 2012/2013 and that includes a variety of patient safety related metrics and in the words of the campaign, was developed for the NHS by the NHS as a point of care survey instrument, the NHS Safety Thermometer provides a 'temperature check' on harm that can be used alongside other measures of harm to measure local and system progress in providing a care environment free of harm for our patients. However, it omitted paediatrics due to the lack of suitable knowledge from which to derive relevant metrics.

Very few research papers were found to have relevance to the aim of this thesis and of the 11,896 citations collected by the literature review only thirty-four had some relevance. We will now discuss what these citations add to this area of research. This research is multifaceted and as such it was necessary to review existing literature that discussed each area deemed to be relevant and having the common connecting context of paediatric healthcare. Safety systems in general and error causation and error management together with an appreciation of risk management and risk reduction together formed the first area for review. These are areas that have received considerable attention from researchers, reflected in the fact that the initial search found over 15,000 citations that through the refining process reduced to 746 articles relevant to healthcare and only 16 articles pertinent to paediatric healthcare. Of these sixteen articles, five investigate the benefit of introducing checklists in order to improve communication.

Interruptions, Communication and Visual prompts

Communication has been identified as a risk factor that needs mitigation, Bagnasco (2013), Gordon (2014) and Sharma (2013). Interruptions, also have long been recognized as being detrimental to efficiency, for example in open plan offices (Brennan, Chugh et al. 2002)[184] (Davis, Leach et al. 2011)[185] and Safety, the *Sterile Cockpit* rule as set out by the American

[183] https://www.safetythermometer.nhs.uk/ <accessed August 20th, 2016>
[184] Brennan, A., et al. (2002). "Traditional versus Open Office Design: A Longitudinal Field Study." Environment and Behavior **34**(3): 279-299.

[185] Davis, M. C., et al. (2011). The Physical Environment of the Office: Contemporary and Emerging Issues. International Review of Industrial and Organizational Psychology 2011, John Wiley & Sons, Ltd**:** 193-237.

Federal Aviation Authority (FAR 121.542 and FAR 135.100 - 2009) that prohibits unnecessary distraction at critical times in the operation of a civil aviation aircraft.

Bagnasco (2013) investigates where failures lie in the existing systems found in an emergency department in Northern Italy. Gordon et al (2014) investigated the impact of introducing a checklist into the work flow of a very specific and specialized area, the catheter laboratory in an American Paediatric hospital situated in California, but again this was as a communication aid to improve pre-operative communication. The research attempted to assess perception of the benefit of introducing a checklist rather than actually measure the impact in some way. Sharma (2013) investigated the benefits of introducing a checklist, again to improve communication between staff participating in a ward round on a paediatric intensive care unit in a large National Health Service hospital in London, England. Poor communication is a well-established error causation Basic Risk Factor (BRF), Groeneweg (1992) and as such a component of unsafe acts that in turn lead to errors occurring.

The introduction of Red Tabards (Scott, Williams et al. 2010)[186] for nursing staff to wear during medicines administration rounds in hospitals convey the message that the wearer is not to be disturbed whilst engaged in administering medicines to patients. Scott (2011) undertook an audit of medicine rounds and the number of interruptions that occurred together with assessing the effectiveness of nursing staff wearing distinctive tabards during the medicine round that indicate that the nurse should not be interrupted. The audit took place in a Scottish Hospital, the Aberdeen Royal Infirmary. The audit was carried out over a five-week period and found that wearing a distinctive tabard the nurse administering medicines was interrupted less often than when a distinctive tabard wasn't worn. The number of interruptions per medicine round fell from 6 to 5 on average over the study period and medication administration errors fell from 19 to16 over the same five-week period.

These papers describe how this particular Basic Risk Factor has been mitigated in very specific healthcare circumstances, overlaying a minor adaptation, a checklist, onto existing processes. In reality, error causation has multiple root causes embedded in complex situations and merit a more fundamental review of the work context. Staff may simply forget to communicate relevant facts to colleagues in a hand over meeting or the work culture may be hierarchical and not encourage input from junior members of the team. It may be that in a particular environment the team is dysfunctional.

In each of these studies an error causing condition was identified and a solution introduced without an investigation of the environment in which the errors were occurring. The analysis

[186] Scott, J., et al. (2010). "The effectiveness of drug round tabards in reducing incidence of medication errors." Nurs Times 106(34): 13-15

stopped with one Basic Risk Factor or one latent error (substandard act). In reality, errors seldom have one causative element and therefore it is inadequate to construct a solution based upon one causative factor alone. In addition, the way operatives work in a particular environment needs to be taken into account before developing solutions. By contrast and, as described in chapter 4, not only was empirical research conducted that identified the existence of multiple error enforcing conditions but also the impact these may have had on operatives was considered. The outcome was the development of the strategy described in chapter 7 that was multi-layered in order to address multiple readily predictable latent errors (Chapter 4), that were shown to impact on operatives (chapter 5) and to allow the inclusion of visual cues and prompts to improve further risk mitigation. This approach is arguably more comprehensive than those described to date in the literature.

Error Reporting and Learning from Errors

Learning from errors is a key plank in the National Health Service Strategy for reducing harm caused by errors or incidents, as discussed in detail elsewhere in this document. The National Learning and Reporting System (NLRS) collects and collates details of incidents from across the National Health Service and themes are identified from these reports that form the basis for safety initiatives and alerts. In a report published by the Patient Safety Observatory, Safety in Doses: medication safety incidents in the NHS, this organisations fourth report (2007) it says that, "developing a culture of reporting and learning from medication incidents. Increased reporting will allow practitioners and NHS trusts to identify the risks associated with medicines, and track progress in addressing these risks to improve patient safety" (NHS 2007)[187] The intention is to learn from errors. The National Advisory Group for The Safety Of Patients in England published a recommendation written by Professor Don Berwick in which described the number one aim and objective was that *The NHS should continually and forever reduce patient harm by embracing wholeheartedly an* ethic of learning [188](Berwick 2013). In other words the National Health Service in England should become a learning organisation. This raises the question, what is a learning Organisation and how could one be formed?

[187] NHS, N. P. S. A. (2007). Safety in doses: medication safety incidents in the NHS: The fourth report from the Patient Safety Observatory.

[188] National Advisory Group on the Safety of Patients in England (2013). "Improving the Safety of Patients in England." < https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf> accessed 11/9/2016

A learning Organisation

The seminal work in this area was contributed by Senge, P (1990, 2006) and described in the book, The Fifth Discipline.[189] In which a learning organisation is defined as one in which, " people continually expand their capacity to create results they truly desire, where new and expansive patterns of thinking are nurtured. Where people are continually learning how to learn together."

Creating a learning organisation is critical to the survival of an organisation and history shows that companies that don't learn these lessons struggle to survive. Senge proposes that five component technologies need to be nurtured in order to bring about and sustain a learning organisation and these are, systems thinking, personal mastery, mental models, building shared vision and team learning.

Of these, Systems thinking gives the framework that underpins the four other disciplines. It gives the means to integrate the other disciplines once they come into practice. It helps us see the bigger picture and appreciate that actions we take locally can impact on the organisation as a whole.

Personal mastery, acknowledges that organisations learn through individuals that learn. Senge describes this discipline as one of "continually clarifying and deepening one's personal vision and of seeing reality objectively". Team learning on the other hand requires individuals to suspend assumptions and engage in dialogue with other members of the team, and enter into genuine thinking "together".

Mental Models are "deeply ingrained assumptions that influence how we understand the world and how we act". This discipline requires us to be able to review our mental models and be prepared to reassess them. Finally, Shared vision is where there is a genuinely shared vision then people learn and excel because they want to not because they have to.

Each of these elements would need to find their place in the final proposed model if a truly new approach with aspirations for lasting impact were to be introduced.

Conspicuous by their absence from the literature were reviews that investigated the efficiency of the current National Reporting and Learning System (NRLS) from which themes are identified, lessons learnt and new practice developed. If the system is inefficient then current analyses drawn from the system may be incomplete and any new practice developed may not take into account, all relevant factors. According to phase 2 of the project the average

[189] Senge, P; The Fifth Discipline ; Random House. (1990, 2006)

time spent investigating an incident from beginning to end was 24.69 minutes, barely sufficient time enough to discover the substandard act that led to the incident.

In figure1 taken from Groeneweg (2002) the way in which Basic Risk Factors can combine to form substandard acts or latent errors that in turn can lead to errors or accidents occurring. The combinations in which the Basic Risk factors can combine are many. It is therefore unlikely that they will combine in just the same way in the same environment with the same operatives on more than one occasion. Most investigations only go as far as to identify the substandard act that led to the error occurring. Due to the relative uniqueness of the substandard acts it is not possible to change practice meaningfully and so most learning from errors brings useful but superficially changes to practice.

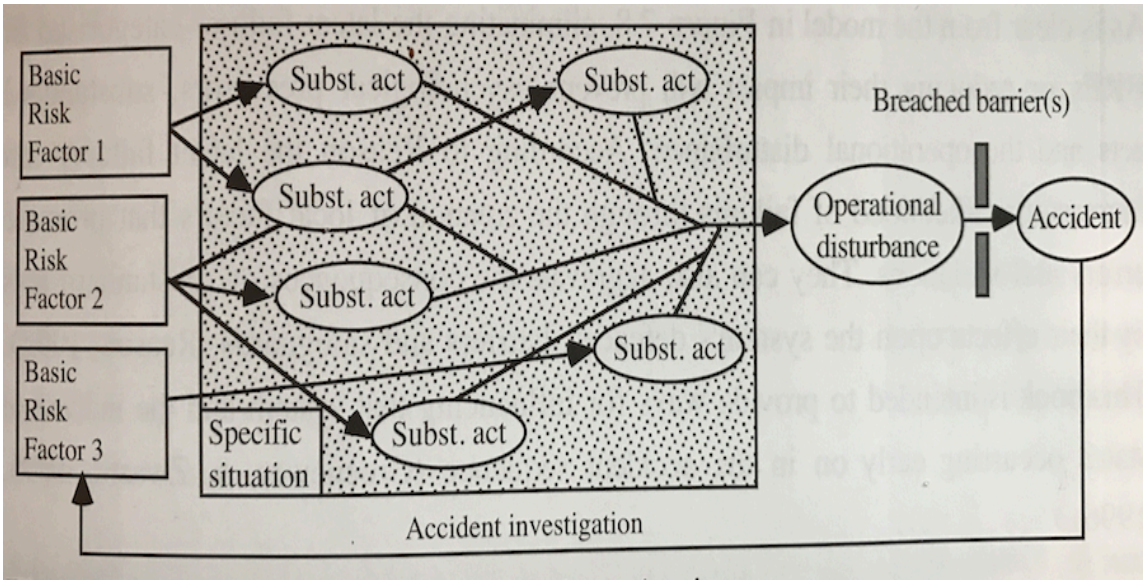


Figure 15 Shows how Basic Risk Factors combine to create substandard acts (latent errors) that in turn can lead to an error (Accident) or incident occurring.

Clearly this strategy will only ever be minimally effective unless and until the reporting of medication errors and incidents becomes embedded into the culture of the National Health Service and the data collection systems collect useful data, that is data that is clear and unambiguous and sufficiently detailed. Armitage (2007) investigated the incident reporting system at Bradford teaching hospitals NHS Trust in England. They retrospectively analysed incident data collected over a ten-year period between 1993 and 2003, collecting and then analyzing 1253 incident reports. They found that 27.8% (n=276) of the reports were incomplete and furthermore that the rate of reporting reduced over the period investigated. Fung (2012) conducted a literature review looking for papers that investigated the attitudes of

nurses to incident reporting. It was concluded that barriers existed to completing incident reports and these concluded, fear of the consequences of reporting an error, administrative issues and the process itself.

Ginsburg (2010) investigated the link between Organizational leadership with regard to safety and learning from patient safety events. Essentially the attitude of senior management to Safety will directly influence the attitude of their employees. If a safety culture is a priority to the executive, then the hospital will buy into the importance of generating a safety culture. A safety culture has to be led by and shown to be a priority by senior management of an organization. Waring (2004) was interested in investigating the variations that exist in reporting of incidents between National Health Service Hospital Trusts and the corresponding attitudes and buy in of medical professionals. The study showed that if a doctor had confidence in the reporting process and the reason for reporting incidents and that the outcomes of the error reporting process would result in improved services, then they would be inclined to participate.

These four studies and one report show that whilst there is agreement in the recognition of the importance between reporting errors and incidents and the subsequent learning from these incidents and errors not all health care staff are inclined to participate with equal enthusiasm. Ginsberg (2010) describes the importance of strong organizational leadership as a prerequisite for the creation of a safety culture. Fung (2012) the need to remove barriers that may dissuade staff from using the reporting system and Waring (2004) the importance of conveying the benefits of reporting errors and incidents and how the learning that results can improve hospital clinical systems. Armitage (2007) conveys the reality that enthusiasm fades over time, although this study didn't give any reasons as to why this happened.

Bianchi et al (2009) conducted an investigation in a hospital in Rome, Italy in which nursing staff was interviewed in order to ascertain their awareness of errors in healthcare. The authors conclude that there needs to be a change in culture from one of blame to no blame in order to encourage incident or error reporting. In the environment of a paediatric cardiac surgery operating room, Bowermaster (2015) encouraged surgeons to record their errors. The impact was an increase in error reporting from 20% of all procedures to 50% of all procedures. This increase in error reporting was sufficient to enable an analysis to reveal endemic system failures and consequentially to make changes and reduce error rates.

An initiative introduced at Boston Paediatric Hospital, Massachusetts, USA, looked at the impact of introducing an on-line safety event reporting system (SERS) together with a no-blame culture to encourage reporting and learning from these incidents. Bradley (2011). The SERS system was also used to support an initiative through the magnet recognition program,

an initiative introduced by the American Nurses Credentialing Centre (ANCC) to recognise excellence in nursing practice. The program centred on educating nurses with regard to the benefits of error reporting. It ran for a period and two years' data analysis showed a 35% increase in nurse error reporting, Hession-Laband (2011).

Kurth et al (2014) demonstrated the benefits or error reporting in order to identify error-causing patterns in practice and to then bring about quality improvements. The project was called *Wake Up Safe and developed by the American Society of Anesthesia.* Monroe (2011) led a joint Anglo-American team investigating patient safety factors of critically y ill children on an intensive care unit in a single tertiary regional Paediatric Intensive Care Unit in a London Hospital. The study identified a number of deficiencies and called for further studies to develop strategies by which safety might be improved.

The literature proposes many reasons why error reporting in hospitals is not as efficient and effective as it might be. The reasons include the need to have a safety culture led by the senior management of the trust, Ginsburg (2010); Lack of confidence in the outcomes of the reporting system, Waring (2004); The need to educate operatives as to the benefits of error reporting, and to introduce a fair blame culture (Parliament 2009)[190].

Lacking from published research was a composite strategy that included each of these components and in addition suggested a solution to the problem of how it would be possible to introduce an approach whereby learning from errors could be introduced in a way that changes practice for the better and would be flexible enough to be transferable to a related but different healthcare setting. In other words, learning from errors is a local matter but sharing the resulting good practice, a universal lesson.

In chapter 7 such a model was described, in which recording incidents and error data and then learning from those errors in a way that changed practice was observed. At each step of the study when a significant error or latent error was identified practice was changed to address the issue. The enablers that made this unusual was that the nurse-pharmacy technician team were empowered and knew changes could be made. They could see the outcomes to changes made rapidly and the reasons for the changes to be made and on occasion personally felt the benefit of the new model, for example in a reduction in perceived stress. The team owned the process and felt proprietorial responsibility for it and felt supported through the regular meetings with senior management.

[190] Parliament, H. o. (2009). "Patient safety policy since 2000."

Professionalism

Professionalism, a concept with many and varied definitions and attached concepts, impacts both on an operatives' attitude to work and in addition their competency to carry out a piece of work. A *professional* is expected to work to a defined set of standards and to have the required competencies to carry out the task to the required standard. In addition, they will demonstrate a commitment to the task that goes beyond simply completing the task to the minimum standard. Put simply, a non-professional worker might down tools the minute their shift finishes whereas a *professional* might reasonably expected to continue after their shift has ended to complete a task that has been started for some other esoteric principle such as discharge of an organization's values or for the good of a patient.

During the course of this research it was observed that Pharmacists who belong to a profession that is regulated, by the General Pharmaceutical Society (GPhC) and has a code of conduct and standards, written by the Royal Pharmaceutical Society (RPS) approached their tasks differently to Pharmacy technicians who at the time of this research did not belong to a regulated professional body and therefore were not professionals. This can be seen in the section of work where nine pharmacists and nine pharmacy technicians were observed carrying our one step in the dispensing process, the final accuracy checking step. This is the step where an item has passed through the pharmacist clinical screening step that ensures that the seven patient rights have been compiled with; that the right medicine has been prescribed for the right patient in the right dose by the right route at the right time for the right condition with the right documentation. The next step is for a label to be generated and the product to be selected and labelled and together with any ancillary items, such as a medicine syringe or spoon and a bag, is passed to the final accuracy checker to ensure everything has been assembled correctly.

Jee et al (2016) investigated the process of professional socialization in pharmacy trainees during their pre-registration year. The pre-registration year is a year which all pharmacists must undertake after graduation from university and before registration a s a pharmacist with the General Pharmaceutical Council (GPhC). The researchers followed twenty pre-registration pharmacist students and concluded that the training experienced during this year did affect their professional socialisation, although how and in what way wasn't described.

It could be argued that professionalism could be distilled into three components, responsibility, competent and identity. Responsibility to always endeavour to produce outputs to the appropriate standard, usually these is regulated by a professional body such as the General Pharmaceutical Council (GPhC) in the case of Pharmacists. Another component is

competence, to ensure one works at the appropriate level and in addition maintains once competence though continuing education and a sense of belonging and pride in so doing. At the time of this study pharmacy technicians were not professionals in the sense of belong to a regulatory body, for example the GPhC. In chapter 4 a variance was observed in the way the pharmacist cohort approached their work and the way in which the pharmacy technician cohort behaved. No such anomaly was observed in the composite ward team describe in chapter 7, that was between the nursing members who belong to a regulated body and the pharmacy technicians who at the time didn't belong to a regulatory body. It could be argued that the pharmacy technician ward team members demonstrated professionalism inculcated through means of the model itself, which contained the three components of professionalism namely, responsibility, competency and identity.

Workload and Stress

Workload was used as a proxy measure for stress and unexpectedly the two staff groups, the Pharmacists and Pharmacy Technicians reacted differently. During the first set of observations, the number of steps an individual took to complete a final accuracy check was counted. A step was any observable relevant action, such as performing a calculation or checking a bag label, in total fifty-seven actions were identified during the observations and recorded. As workload increased the number of steps carried out by the pharmacy technician group decreased but for the pharmacist group, the number of steps observed increased, this was consistent across both groups of operatives. Unsurprisingly, the time spent accuracy checking followed this pattern that is the time spent accuracy checking each dispensed medicine increased for the pharmacist group but decreased for Pharmacy technician group. The final observation observed and recorded only those steps that could be considered to be *safety* orientated steps, for example checking a spoon is present might be considered a process step but checking a dose could be considered a safety step. The result is interesting in that the number of safety steps that the Pharmacist carried out, as pressure increased, decreased as compared with the number of steps that the Pharmacy technicians performed. However, the number of safety steps that the Pharmacists carried out started at a higher number at the outset, as compared to the Pharmacy Technician group and although the number of safety steps decreased in the Pharmacist group and increased in the pharmacy Technician group, the Pharmacists carried out a higher number of safety steps even under stressful conditions. The reason for this variance between professional and non-professional healthcare workers merits further investigation but is beyond the scope of this thesis.

Family (2013) investigated the impact of time pressure on pharmacy students in the context of dispensing exercises. The researchers used the National Aeronautics and Space

Administration's (NASA) work –load index, developed by Hart and Staveland (1988) to evaluate a participant's perception of workload. The index assesses a respondent's response in five areas and these are, mental demand, temporal demand, physical demand, performance and effort and frustration. The outcome was that time pressure (stress) does indeed impact on work accuracy in the given context.

Lynsksey (2007) investigated fifteen community pharmacies that lay within the Brighton and Hove City Primary Care Trust, Sussex. The researchers used self-reporting anonymised questionnaires to record errors that had occurred during the study period. The results showed that by far the main attributable cause for making an error was being too busy. Although this was set in a different context to that of this thesis and the underlying reasons for the errors not explicit, nevertheless the perception of the pharmacists who had participated was of interest.

Bond et al (2008) investigated the impact that the introduction of a new community pharmacy contract might have on the workforce, paying particular attention to factors such as workload and stress. The study was conducted through the instrument of a postal survey sent to all community pharmacies (n=1080) located in a stratified random sample of Primary care Organisations located across England and Wales. The response rate was high at 71% (n=762). A significant number 57%, 237 (n=425 for this question) made clear that they felt stressed at work and although the researchers didn't investigate the impact of this they did comment to the effect that this increased stress does call into question a pharmacist's ability to *work effectively* when *clearly stressed* and *potentially fatigued*.

Stress clearly is an error enforcing condition (A Basic Risk Factor) when seen in the context of work pressure. In chapter 4 the observable impact that stress had on operatives was recorded. As workload increased and here workload was a proxy measure for stress, the work pattern of operatives changed, in a way that increased the likelihood of an error occurring. The pharmacy technician cohorts' work rate increased and for both the pharmacy technician cohort and the pharmacist cohort, the number of steps that operatives took that were considered to be safety steps decreased, which also could be considered to increase the likelihood of an error occurring. There are other sources of stress to take into consideration that may not be work related but nevertheless are present and arguable could impact on an operative's work performance. The model introduced in chapter 7 controls both work rate by virtue of following a standard operating procedure and included visual prompts to assist an operative's focus.

Quality Management

The next element of the literature review was to look for research that investigated the impact of introducing Quality Management Systems including related tools and techniques developed in other high-risk industries, such as the Checklist. The studies that referred to in this section describe studies that look at compliance with existing systems or investigate ways of trying to make existing systems safer, none of the studies deemed to be even remotely relevant have considered the need to actually change the existing way of working and underlying culture in order to bring about improved efficiency and safety.

Standardising procedures, protocols and medicines interestingly only yielded two papers through a literature search, where more could have been reasonably expected due to the interest that these attract in healthcare. An example would be the national initiative introduced by NHSE (NHSE 2016)[191] to force standardization of chemotherapy doses for intravenous injection. Standardising procedures could be introduced by introducing an electronic prescribing system. This would force users to work in a particular way by limiting their options. Johnson et al (2004) conducted a literature review of patient safety enhancing technologies and concluded that in paediatrics the five technologies that could improve patient safety were Electronic prescribing, electronic Guidelines and protocols, internet based disease management resources, tele-consultation and electronic patient healthcare records. It is a truism that before you introduce electronic systems one needs to have reviewed how efficient the manual system is and has introduced lean working at the pre-electronic stage, or one could replicate inefficiencies in process electronically, and hence the development of systems analysis in the late 1970's. Systems analysts are qualified to investigate paper-based systems or people based systems, and then to analyse and interpret information flows.

Bullock (2006) determined the impact of introducing standardised intravenous infusions onto a Paediatric Intensive Care Unit in Mattel Children's Hospital, California, USA. The outputs were significant with error rates for incorrect doses falling from 52% to 21% as a result. Standardization of processes clearly reduced errors for so many reasons but in order to introduce standardised procedures there is a bargain to be struck as standardization arguably erodes professional independence.

[191] NHSE (2016). "CA2 Nationally Standardised Dose Banding Adult Intravenous SACT."

Van der Velde (2010) compared error rates arising from during the prescribing process when two different approaches to generating prescriptions (orders for medication) were used. The two approaches were to use an electronic prescribing system to generate prescriptions or a system of pre-printed forms. The team-reviewed prescriptions generated by means of electronic prescribing (n=373) and pre-printed forms (n=538) and analysed the errors found using the NCCMERP (National Coordinating Council for Medication Error Reporting and Prevention) in the USA, NCCMERP (2016)[192] that categorizes medication errors according to the degree of harm that they caused. Of relevance to this thesis was the fact that the researchers identified six errors that had the causative factor attributed to high workload distraction.

Another strategy, described by Lepee (2012) would be introducing a checklist. Here described having been introduced onto a medical round in a busy London hospital paediatric ward in order to help a prescriber focus on the job in hand. The researchers found that although the quality of prescription writing improved slightly after the intervention of a prescribing checklist was introduced and figures were cited of a reduction in technical errors from 10.8% to 7.3%, there was no impact was perceived in the clinical error rate. A technical error might be the omission of the prescriber's contact details for example. Significantly the investigators comment that a change in *culture* may be needed to realise any significant improvements.

Manias (2005) investigated how nurses actually use protocols in relation to medicines management tasks, in other words do they actually follow the protocol? They observed 12 graduate nurses working on a busy surgical ward in a metropolitan hospital in Australia. More specifically they observed the nurses during two-hour medicine administration rounds where patients are given their medication. What the discovered was that nurses followed the protocols provided they didn't impede other nursing duties. They were also more likely to follow the protocols if they could also make decisions in their own right and if it decreased the likelihood of disciplinary action. This does raise the issue of healthcare professionalism, that is healthcare workers see themselves as independent practitioners and have a tendency to prefer not to follow protocols. This was discovered to be a reason for non-participation or partial participation in one of the studies that comprise this thesis where nurses were invited to participate in a quality systems approach to medicines preparation and administration on a busy paediatric oncology ward in my hospital.

[192] NCCMERP (2016). "MERP index."; < http://www.nccmerp.org/sites/default/files/algorColor2001-06-12.pdf> [accessed 12/09/2016].

Pape (2012) investigating the impact of introducing the MedSafe protocol in a 600-bed hospital situated in Middle America. The MedSafe protocol consists of a number of steps to prevent nurses engaged in medicines preparation and administration from being interrupted. Through a series of measures that reduce interruptions, for example using visible signs such as notices on walls, yellow duct tape on the floor to indicate quiet zones and wearing a sash all to indicate that the wearer is not to be interrupted, error rates reduced significantly during the study period. In England, in some hospitals, nurses engaged in a medicines administration round, wear a red tabard the significance of which is that they are not to be interrupted. In both cases the system doesn't change but by introducing minor superficial amendments, impressive improvements can be realised. It is less clear whether tinkering around the edge in this way delivers long term sustainable improvements and it has been said that if you want to find a nurse on a busy ward, the one wearing a bright red tabard or sash is certainly easy to identify!

Other researchers concluded that standardization of procedures and protocols and indeed medicines will yield improved safety outcomes, Johnson (2004), Bullock (2006). Several papers already mention in passing the requirement to introduce a safety culture, Verschoor (2007) describes an initiative introduced into a group of Women and Children's' healthcare facility in British Columbia, Canada describing the introduction of initiatives that help to do just this, that is introduce a safety culture from the top down rather than through the means of a specific project, by virtue of the introduction of safety walkabouts and safety briefings and the fact that senior management are willing to introduce improvements to improve safety. No data is introduced in the paper that quantifies the benefits or otherwise of this approach. Sullivan (2004) describes the beneficial impact of introducing lean methodology into an aseptic compounding unit in New Haven Hospital, Connecticut, USA and as a result reduced the turnaround times for compounding chemotherapy intra venous injections from 91 minutes to 20 minutes. Improved efficiency could be argued due to a thorough review of practice may also impact on safety.

Raja (2009) investigated compliance to medicines administration protocols on a neonatal intensive care unit in a hospital in Malaysia. The study revealed less than complete adherence to the medicines administration protocols by nurses and as a consequence the nurses were given remedial re-education, which does sound vaguely, disciplinary in nature. After this remedial re-education took place some improvement was realised but the implication was that this approach enjoyed limited success. For completeness, a report by Samman (2011) has been included that describes a safety improvement strategy being introduced at St Vincent Indianapolis community hospital in America to address safety concerns over the management of a very high strength insulin injection. The hospital

introduced a series of guides, prescribing forms and picking sheets to mitigate the risk but no data were presented in the report.

The most impressive and thorough piece of work carried out by McLeod and Barber (2015) that utilized a variety of study approaches to comprehensively map and understand what took place during medicines administration rounds in three National Health Service Trusts in England. The study conducted over 85 hours, observing 43 nurses during 56 drug rounds across three hospital wards. The investigators concluded that to reduce medication administration errors the medicines administration processes need improving, that interruptions both direct and indirect need to be reduced and they also go on to add that patients ought be more involved with their medication where appropriate.

Cottney (2014) investigated the benefit or otherwise of introducing automated drug cabinets onto an inpatient ward in an English Hospital in regard to reducing medication administration related errors. These cabinets consist of locked doors and drawers that require an operator to access via a computer control system. The software requires an operator to identify themselves; the patient that they intend administering a medicine to, the medicine itself and the quantity. The resulting data actually showed that implementing automated drug cabinets impacted little on error rates but did save a small amount of nursing time. Presumably reducing time that it took to locate a particular patient's medication in a previously cluttered medicine trolley or cupboard in the treatment room.

McLeod (2015) empirically investigated a healthcare environment to discover what issues might be present but don't go on to suggest a strategy to address the issues that were revealed. By contrast, the other authors describe a solution to a single problem that had been identified.

Implications

Notwithstanding the fact that error causation theory is well understood, a literature search failed to find work that conducted empirical research into the impact on operatives of Basic Risk Factors, such as error enforcing conditions, in the context of a healthcare environment. Latent errors were identified, which included interruptions, stress, communication, and training. In addition, the issue of professionalism was considered as was reporting and learning from errors in a way that changed practice. The significance and importance of creating a genuine learning culture was considered, Senge (2006). All of these elements were combined into a quality management approach.

The Model

The proposal or strategy that resulted from this work contains the following elements;

1. Staff groups were selected by virtue of their work cultural style approach to tasks. Pharmacy technicians particularly pay attention to detail, are protocol driven and risk adverse were paired with nursing staff who have a clinical and patient work culture focus.
2. Pharmacy technicians were inculcated with a professionalism, a responsibility to the task. This was brought about in a number of ways. They received additional training at a high level for the new task that they were required to undertake. This included training from a senior nurse trainer, to the same level that nurses received. They were given ownership of the project and responsibility for delivering on it.
3. The environment, in which the teams worked, the ward treatment room, was tightly controlled and kept both quiet and uncluttered.
4. The standard operating procedure (SoP) to which the operatives worked included a checklist, which acted as a visual prompt, steps within the task were listed and ticked off when completed, so operatives always knew where in the SoP they were at any given time that is what task they had completed and what tasks remained to be carried out. A visual aid was also included that led operatives through the necessary complex calculations required of them. All operatives carried out calculations therefore in the same way.
5. The nurse member of the team was encouraged to undertake complex flow rate calculations in the quiet of the treatment room at the outset of the process rather than at the end of the process at the patients' bedside where they were prone to distraction and interruption.
6. Errors or near misses were recorded and discussed with the senior ward and pharmacy staff at a later stage with changes being made to practice as necessary.

The Future

The aim and objectives of this research have been achieved and has produced measurable and positive results. In phase 1 the objective was to identify latent errors in one step of the dispensing process in a paediatric hospital pharmacy. In phase two the objective was to investigate the error reporting and learning process and determine the efficiency of the process and finally in phase 3 the objective was to analyse the outcomes from the first two phases together with error causation theory and relevant published research, if any, and develop and test a new risk mitigation model.

There would be merit in extending the project to another ward area and collecting data over an extended period of time, before proceeding to replicate the approach in another National Health Service Hospital followed by a hospital set in a different but related culture for example on mainland Europe.

Chapter 8. Conclusion

Error causation theory was discussed at length and the two approaches that theorists use, the human approach that is errors arise due to human weakness to the fact that individuals can be careless, inattentive, perverse or simply incompetent. The second approach being that of flawed systems, flawed in the sense that error enforcing conditions, emanating from basic risk factors, lie dormant in systems but the systems are poorly designed and fail to trap these flaws from making themselves known as errors.

An appreciation of how memory works and how the brain responds to multiple stimuli formed another arm of the foundational theory required for this research.

A comprehensive literature review revealed that to date little consideration had been given to either an appreciation of how individual operatives react in a stressful healthcare environment containing multiple stimuli impacting continually on these individuals or the implication of professionalism for how operatives approach their work.

This first study, showed that there was a measurable connection between workload, used as a proxy measure for stress and performance. It was noted that the pharmacist cohort and the pharmacy technician cohort behaved in explicitly different ways to each other, raising the question of professional versus non-professional behaviour. Interruptions appeared to cause both sets of operatives to become distracted and lose awareness of what they had completed and what task remained to be completed and this led to unnecessary task repetition.

It was widely accepted, a priori; in the literature that interruptions lead to errors rather than post priori that is from observation. It was therefore determined to establish whether interruptions in reality actually impacted adversely on operatives leading to errors occurring or whether this was merely an assumption but in reality something else was happening.

If the sole cause of errors in healthcare task related scenarios were due to external interruptions, then introducing a do not interrupt zone would work effectively. On the other hand, if the causes were multiple then the solution would arguably be more complex.

This reasoning led to the next project in this research and that was to establish the impact that interruptions whether direct or indirect actually had on an operative performing a designated controlled task. This post priori approach was unique in the literature in a healthcare setting. It was found that interruptions did in fact impact adversely on efficiency and output performance.

To test the reliability of incident evidence, consideration was given to the process of recording incidents and errors collected by National Health Service organisations, through the National Learning and Reporting System (NLRS). Data submitted through the NLRS is collected electronically by means of free text data entry. The project analysed 12 months IR1 incident forms to determine cost and attitude towards the process. It was found that the process was relatively inexpensive to manage but inefficient when it comes to learning from the incidents themselves.

The question remained as to whether interruptions were the critical failure in the system or were there other factors that needed to be taken into consideration. In order to predict latent errors in paediatric hospital pharmacy it was thought necessary to explore the impact that other relevant elements of the system might have. To this end it was determined to observe a similar but unrelated high-risk industry environment and observe how risks had been predicted, controlled and mitigated against. This led to a visit to a revalidation exercise for airline pilots. This comprised a 4.5-hour flight simulator exercise in which various incidents were given to the pilots and observations made followed by debrief and analysis of their performance. The similarities are many both healthcare operatives work as teams in high risk, high stress often-unpredictable situations and are required to make high impact decisions at short notice and subject to interruptions.

Finally a project, described fully above, was devised in which the emergent hypothesis was tested. Pharmacy technicians partnered ward-nursing staff on specific medicine administration ward rounds. The medicine administration process was completely redesigned completely taking into account data collected during the course of this research and lessons learnt from error causation theory and error reports from other high-risk industries.

Time was allowed in which current approaches could be reviewed and reassessed and a new-shared vision developed. In which, the team itself took ownership of the project and had space to challenge their existing mental models and develop new ones.

A protocol driven approach was introduced to ensure standardised working with clear operating procedures, together with a checklist based upon the five patient rights. Visual aids help operatives pick up where they've left off after an unplanned distraction, for example an interruption. In addition, a dose, volume and flow rate calculator guide that not only documents calculations but ensures they are carried out in the same way was also included. The treatment room, where the intravenous injections were prepared, was designated a quiet area.

Double-checking of doses, medicines and patient identity, a practice deemed necessary in paediatric healthcare because of the complexity of the medicines and vulnerability of the patients, was ensured by the process and documented. This in itself is quite unique and probably the first time this has been achieved and evidenced.

Complex flow rate calculations, necessary for setting up the infusion pump that controls administration of the drug into the patient that previously were undertaken at the patient's bedside and the operative subject to interruptions and distractions was moved to the quiet of the treatment room.

Finally, errors or latent errors were recorded and reported in real time and team meetings held to consider how to respond and whether or not to make process changes.

In other words, a combination of designed process, the use of visual aids and prompts and a controlled environment together with appropriate training was introduced. This package of approaches was utilised in a different but related paediatric healthcare environment to undertake medicine related accuracy related tasks.

The outcome was that during the study period the incident reporting system for the hospital reported an unaccountable fall in incidents and errors on the oncology ward. The number of these increased at the end of the project. Whilst the link between the fall in incidents for the duration of the project must be regarded as anecdotal due to the fact that a direct causal link hasn't been established and indeed falls outside of the remit of this project, however the coincidence was overwhelming.

The Objectives of this project were threefold

1. To identify latent risks associated with in a specific task set in an NHS paediatric hospital pharmacy department. Then to establish the extent to which these latent risks may be predicted. One specific area of paediatric pharmacy practice, the final accuracy checking process, will be the medium for this study

2. To investigate the efficiency and effectiveness of the current Incident reporting system (IR1s) in supporting learning from incidents and changing practice.
3. To determine the impact of introducing a Quality Management Approach to process design into one process on a busy Oncology ward in the same paediatric hospital and determine the benefits of this approach including in terms of risk reduction.

The latent risks have been identified, the impact of introducing a quality management approach systematic approach taking into account error causation theory, published research and data collected during the course of this project has been successful it would appear in impacting upon error and incident rates. The IR1 incident and error reporting system is efficient but less so in generating learning from those errors.

Appendix 1 - Questionnaire (Chapter 4)

The following questionnaire, described in chapter 4, was available in the dispensary to be completed on a voluntary ad hoc basis that is a participant operative was invited to complete a form as often as they went into the dispensary to undertake a dispensary duty. These dispensary "duties" would typically last between 60-120 minutes on each occasion.

Name:						
Date:			Day			
Time:	Start:		End:			
1. Environment						
	Background noise levels	unaware	present but low	distracting		
	Temperature		comfortable	Hot/Stuffy	Cold	
	Lighting		comfortable	Harsh	Dark	
2. Work Loads	quiet	reasonable	Busy	Manic		
3. Focus	On job in hand	On Another job	On a Conflict	Day dreaming	Multi Tasking	Personal issue
4. Work Space	Cluttered	Spacious	Adequate			
5. Equipment/ references	Available	Helped	N/A	Unavailable		
6. Knowledge base	Comfortable	Challenged	Out Of depth at times		Out of depth most of the time	
7. Comments						

The following extract from a worksheet summarises the domain of interest and the scale of feeling experienced towards it.

		1	2	3	4	5	6	
Environment (EN)	Noise	unaware	present but low	distracting				
Environment (ET)	temperature	comfortable	Hot/Stuffy	Cold				
Environment (EL)	lighting	comfortable	Harsh	Dark				
Workloads(WL)		quiet	reasonable	busy	manic			
Focus (F)		on job in hand	on another job	on a conflict	day dreaming	multi tasking	personal issue	
WorkSpace (WS)		cluttered	spacious	adequate				
Equipment (E)		available	helped	n/a	unavailable			
Knowledge base (K)		comfortable	challenged	out of depth at times	out of depth most of the time			
Comments								

Appendix 2 – Extract of results from the questionnaire (Chapter 4)

Date	Time	Initials	Environment -Noise	Environment -Temp	Environment - Lighting	Workload	Focus	Workspace	Equipment /references	Knowledge base	Error reported	Items range	Items average	Items	Initials
28/01/2008	15:00-17:30	MS	EN2	ET1	EL1	WL1	F1	WS2	E1	K1	Y				MS
06/02/2008	13:45-15:00	KM	EN2	ET1	EL1	WL1	F1	WS2	E1	K1	N			77	KM
07/02/2008	12:30-13:45	KM	EN2	ET2	EL2	WL3	F1	WS3	E1	K1	N			135	KM
18/02/2008	12:30-13:45	SM	EN1	ET1	EL1	WL3	F1	WS1	E1	K2	N			165	SM
07/02/2008	15:00-16:30	LW	EN3	ET1	EL1	WL2	F5	WS3	E3	K1	N			109	LW
18/02/2008	10:00-11:20	DR	EN2	ET1	EL1	WL2	F5	WS2	E3	K1	N			28	DR
25/01/2008	11:15-12:30	LW	EN3	ET1	EL1	WL2	F5	WS3	E3	K1	N				LW
01/02/2008	11:15-12:30	KM	EN1	ET1	EL1	WL2	F5	WS2	E1	K2	N			69	KM
31/01/2008	12:30-13:45	LW	EN2	ET1	EL1	WL2	F5	WS3	E2	K2	N				LW
25/01/2008	14:30-16:16	KM	EN1	ET1	EL1	WL3	F1	WS3	E1	K1	N				KM
24/01/2008	12:30-13:45	LW	EN2	ET1	EL1	WL2	F5	WS3	E3	K1	N				LW
23/01/2008	13:45-15:00	KM	EN1	ET1	EL1	WL2	F1	WS2	E1	K1	N				KM
22/01/2008	15:00-16:30	KM	EN1	ET1	EL1	WL1	F1	WS3	E1	K2	N				KM
04/02/2008	15:00-16:30	LW	EN1	ET2	EL1	WL3	F5	WS1	E2	K2	N				LW
19/11/2007	15:00-16:40	SM	EN3	ET1	EL1	WL3	F5	WS1	E1	K2	Y				SM
17/12/2007	16:15-17:30	MS	EN2	ET1	EL1	WL4	F5	WS2	E1	K1	N				MS
14/02/2008	11;15-13:30	RB	EN2	ET3	EL2	WL3	F1	WS1	E1	K2	N				RB
15/02/2008	11:15-13:30	RB	EN2	ET3	EL2	WL3	F1	WS1	E1	K2	N				RB
21/02/2008	11:15-13:10	RB	EN2	ET1	EL2	WL2	F1	WS3	E1	K2	N				RB
13/02/2008	11:15-13:30	RB	EN2	ET3	ET2	WL3	F1	WS1	E1	K2	N				RB
12/02/2008	11:00-12:30	RB	EN2	ET3	EL2	WL3	F1	WS3	E1	K1	Y				RB
23/07/2007	13:45-15:00	LW	EN1	ET3	EL1	WL3	F3	WS1	E3	K1	Y				LW
03/12/2007	13:45-15:15	SO	EN3	ET3	EL1	WL3	F5	WS1	E3	K1	N	19-71	39	34	SO
18/01/2008	11:15-12:30	RB	EN2	ET3	EL1	WL3	F1	WS1	E1	K1	Y	17-48	32	48	RB
30/11/2007	16:30-18:30	MS	EN2	ET1	EL1	WL4	F5	WS3	E4	K3	N	13-74	34	29	MS
04/12/2007	14:00-16:30	MS	EN3	ET3	EL1	WL3	F1	WS3	E1	K2	Y	55-134	92	94	MS
05/12/2007	08:30-13:30	RB	EN3	ET2	EL2	WL4	F1	WS1	E1	K3	N	172-272	196	172	RB
07/12/2007	11:15-13:30	SO	EN2	ET3	EL1	WL2	F1	WS3	E3	K1	N	17-48	32	29	SO
06/12/2007	08:30-13:30	RB	EN2	ET3	EL1	WL3	F1	WS1	E3	K2	N	140-229	174	156	RB
02/11/2007	11:15-17:30	RB	EN3	ET3	EL2	WL4	F1	WS1	E1	K1	N	17-48	32		RB
25/02/2008	12 :30-13:45	MM	EN3	ET1	EL1	WL4	F3	WS1	E1	K2	Y				MM

The table recorded the time and date of the dispensary duty to which the completed form referred to and the initials of who completed the form. The next eight columns record the domains of interest from Environmental noise (EN) across to Knowledge Base (K). The numbers express the degree of feeling as shown in the second table in appendix 1. Participants were also asked to note if they had made an error. Workload was also noted.

Appendix 3 – Individual interviews relating to the study in Chapter 4

Each participant was interviewed individually using a semi structured interview technique and then the transcripts were analysed using Action Research methodology identifying key themes from reoccurring words (bold typeface) . The content of the interviews were made by means of the interviewer taking notes.

It was decided not to use the resulting data, as although of interest it didn't add to the outcomes data sufficiently to be of use.

Key Themes and Comments

MS 20/02/08

- What does experienced checker technician mean?
  - Confident?
- Reasons for Checkers being interrupted include
  - To clarify something on a prescription often by technicians not used to being in the dispensary **TRAINING**
  - To clarify something that a Clinical Checker has passed i.e. incomplete documentation of clinical decisions **CLARIFICATION**
  - Loud noise can be intrusive. **NOISE**
  - Would prefer to sit but its quicker to stand and also doesn't obstruct gangway. **WORKPLACE DESIGN**

- **ERROR** missed an expiry date→missed step in checking process CLUTTERED **PRESCRIPTION→ PAPERWORK DESIGN**
- Labels are difficult to check on ASCribe
  - Reasoning as to why a particular quantity was selected
  - Also to identify just who produced the label
- PMRs There is no uniform approach and drug amendments are not being moved into History and so can easily select incorrect dose. **TRAINING & PROCEDURES**

MMcM 18/03/08

- Content to check
- Prefer to stand
- **DISTRACTIONS**

- Pressure from wards **PRESSURE TO WORK FASTER**
- Pressure if know patient is waiting at Hatch **PRESSURE TO WORK FASTER**
- Door opening and closing **NOISE**
- Phone ringing, especially if left to ring

- Position in Dispensary not an issue
- Checking system
  - Check prescription
  - Check item
  - Check dose and volume (Calculate)
  - Check
    - Name
    - Strength
    - Date
    - Name on label
    - Drug and dose
- **ERROR**
  - Returned from ward and found no staff …felt angry **EMOTION**
  - Needed a drug releasing from bond for a patient who had already been down three times **PRESSURE**
  - Staff absent at a safety group meeting **OWNERSHIP**
- When there's pressure to check more rapidly or to check items out of sequence **PRESSURE**

SO 27/3/08

- Mood acceptable
  - Mood affects session if away from normal work i.e. ward and know that work on ward is backing up **DISTRACTED**
  - Also if in dispensary for several back to back sessions i.e. dispensing and then checking
- Prefers to Stand
- Positioning of workstation **WORKPLACE DESIGN**
  - Long walks helps to clear mind
  - a/c too cold
  - Hatch is distracting
- Interruptions include
  - Bleep
  - Asked questions about Ward 15 work **PRESSURE →EXPECTATIONS** to know everything
  - Noise
  - Phone
    - When distracted start again
- Length of session is OK 75 minutes
- **ERROR**
  - Dispensing Omeprazole MUPS
    - Checked Box
    - Checked label
    - Took strips out and checked them
    - Bagged items
    - Had second thoughts and rechecked contents and found that one tablet strip was an incorrect strength
    - Was busy and felt distracted **PRESSURE**

- Distractions
  - Name called out allowed in dispensary particularly if its sounds like my name
  - When checking try to zone out **NOISE**
  - People walking down gangway directly behind me **WORKPLACE DESIGN**
  - People working close by me **WORKPLACE DESIGN**

- Retain some outers and discard others?
  - Retain box to protect bottle
  - Discard box to prevent wards confusing item with ward stock
- If harassed by ward feel **PRESSURE**

LW 28/3/08

- Content to check
- Prefer to stand
- Don't like to walk to pigeon holes as can get called to the Hatch, as feel worried that I'm not checking, but can't ignore people at hatch **WORKPLACE DESIGN** **PRESSURE**
- Interruptions
  - At lunchtime am often the only available technician so get asked questions, including from Pharmacists who just pop in and out →annoying **EMOTION**
  - My Own ward phones to speak with me
  - Have to block out noises **NOISE**
  - As am skilled with computer often get asked how to do things, if busy have to say NO! **EMOTION** **PRESSURE**
  - Also if tired tell people not to ask questions! **EMOTION**
  - Multiple interruptions
  - A/C distracting as too cold **ENVIRONMENT**
  - Being near to Hatch
  - Colleagues walking close behind in gangway **WORKPLACE DESIGN**
  - Colleagues working close behind in gangway **WORKPLACE DESIGN**
- Sessions are right length (75 minutes)
- **ERROR**
  - late night, very busy and feeling tired at end of long extended day **EMOTION**
  - worrying about drug being dispensed (Thalidomide)
  - also about quantity being issued
  - was most senior technician on duty….felt responsibilities **PRESSURE**
  - Phones ringing **NOISE**
  - Colleague (the Porter) harassing to be able to leave **PRESSURE** **DISTRACTION**
  - Labelling error with respect to the strength
- Procedures
  - We don't use tracker properly **TRAINING**
  - Clinical pharmacists do not make their decisions clear so that anyone could simply dispense what they are recommending. **TRAINING**
  - Insufficient workspace **WORKPLACE DESIGN**
  - People have a Lack of confidence in using ASCribe **TRAINING**
  - PMRS colleagues do not put the same thing in the record and hence on the label as on the prescription. **TRAINING**

- Labels are attached to containers obscuring information **TRAINING**

DR 28/3/08

- Content to Check
- Prefer to sit
- Workplace positioning
  - It's a problem if too near to the Hatch
  - Walking to various destinations is ok
  - Not distracted by people walking in gangway or working behind me
  - Noise not an issue
  - A/C not an issue
  - Talking if too loud does distract **NOISE**
  - **Too** crowded **WORKPLACE DESIGN**

- Distractions
  - Students asking questions **DISTRACTED**
  - Phone Calls
  - Being called to the hatch to deal with an issue
  - Often am asked questions because of my role as dispensary senior technician
  - If distracted then start checking again
  - Takes 10 minutes to get into checking *zone*. If asked a question especially if one knows the answer then drop out of checking *zone* **EMOTION DISTRACTION**
- Checking session is right length (75 minutes)
- **ERROR**
  - Incorrect paracetamol dose on label that had dispensed.
  - Calculated dose in Head and volume required was incorrect and as was dose.
    - It was a busy Monday p.m. **PRESSURE**
    - Worried about late night coming up **EMOTION**
    - Varied from own usual checking procedure **DISTRACTED**
    - Brain *saturated frazzled* **EMOTION**
    - Cut corners

SM 31/3/08

- Neutral to checking
  - Usually stand unless dealing with a complex prescription i.e. cystic then prefer to sit and to be somewhere quieter **NOISE WORKPLACE DESIGN**
- Walking to destinations is OK otherwise become uncomfortable
- Interruptions
  - Labellers ask what my labelling preferences are! **TRAINING**

- Sounds can distract as can complete silence **NOISE SILENCE**
- Might ask for person to be quiet
- If interrupted will start checking item again

- Length of session is ok (75 minutes)
- **ERROR**
  - Complex Outpatient prescription
  - 11-12 items on prescription **FORM DESIGN CLUTTERED**
  - missed a dose i.e. was 2.5mLs but gave 5mLs
  - spotted by parent at home
  - Felt *Gutted* as a result
  - Was removed from checking rota as was third error in six months (!!!)
- Processes
  - Dispensary bench becoming cluttered
  - If other colleagues are working too close to me **WORKPLACE DESIGN**
  - Hatch is an issue i.e.
    - If people are looking at me , *burning eyes* or
    - Get caught at the hatch to deal with something
  - Talks out load to self through checking steps

RA 14/4/08

- Neutral to checking
- Prefers to Sit
- Sitting of accuracy checking station not good as often get interrupted but getting up to walk to places is ok. **WORKPLACE DESIGN**
- Interruptions tend to be due to
  - Hatch
  - Phone Calls
  - Dispensing and labelling queries **TRAINING**
  - **NOISE** i.e. Children outside hatch
  - Blocks out dispensary hubbub……not too much of a distraction…get used to it.
- If interrupted half way through checking an item then will start again from where interruption occurred
- Prefer shorter time slots i.e. 1.25 hours is Ok even up to 2 hours but if longer then will split the time with someone else.
- **ERROR** prescription was for Codeine tablets tds
  - Directions were correct but the warning was left unchanged which said that no more than four doses to be taken in 24 hours.
  - Comment: was dealing with a problem on a prescription with a pharmacist but was called back to check this prescription urgently as someone was waiting. **PRESSURE**
- Dispensary System
  - Previously labelled *and* dispensed but now these two functions have been separated.
  - Harder to track the person who had labelled an item .
  - Now the dispenser is asked to be responsible for their work
  - PMRs are completed by the clinical pharmacist but the same information isn't put onto the prescription and so intention is not communicated with rest of team. **INFORMATION/TRAINING?**
  - Don'\t go by PMR
    - Incorrect item is often selected by the Pharmacist
    - Or wrong form
    - Or wrong treatment length

- Or wrong directions
- Or information has been added by a tech and not a pharmacist

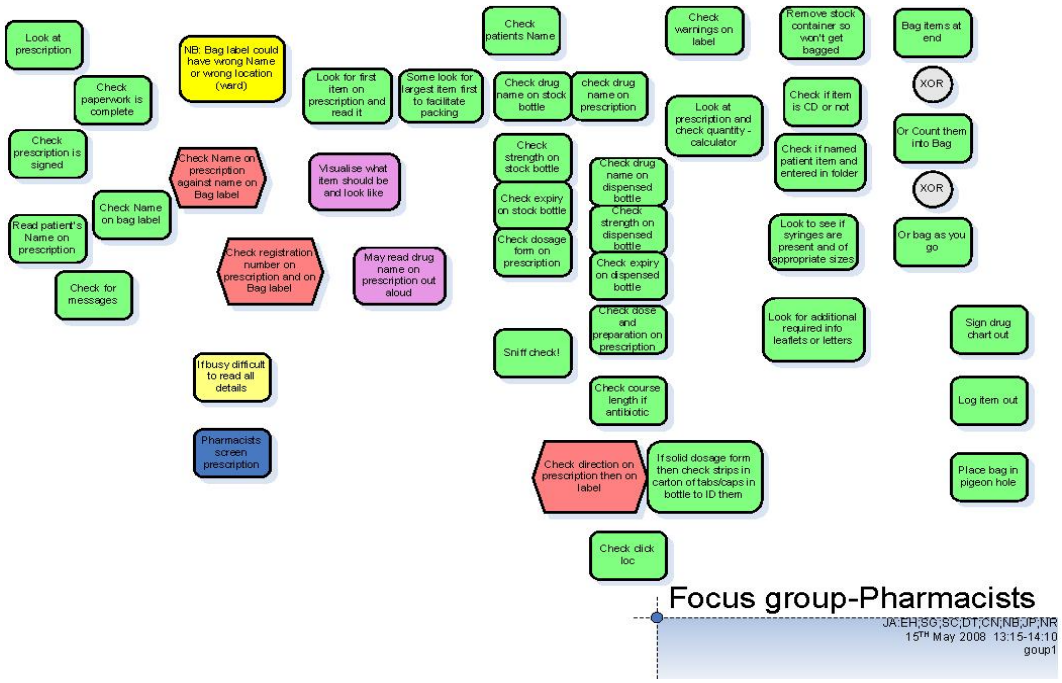
TRAINING

Appendix 4 – Focus groups (Chapter 4)

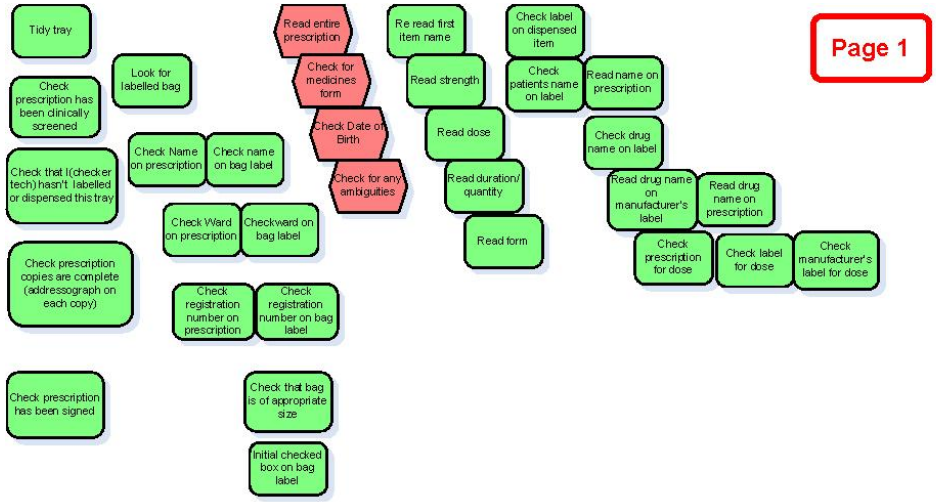
The final stage of the study described in chapter 4 was to hold two focus groups, one for the pharmacist cohort and one for the technician cohort. These lasted 60 minutes and each cohort was asked the same question, “How many steps do you think it takes to accuracy check a simple medicine request, for example a request for Paracetamol liquid”? Each group answered as a group having taken a consensus and then this response was compared with the observations made and described in chapter 4.

Then each group was asked to describe the individual steps that comprise the accuracy checking process and these were mapped using SSADM (Structured system and design methodology) flow diagrams. The steps asked for, were what they actually did not what they thought needed to be done. These flow diagrams were constructed one for each group, using a flip chart with A1 paper.

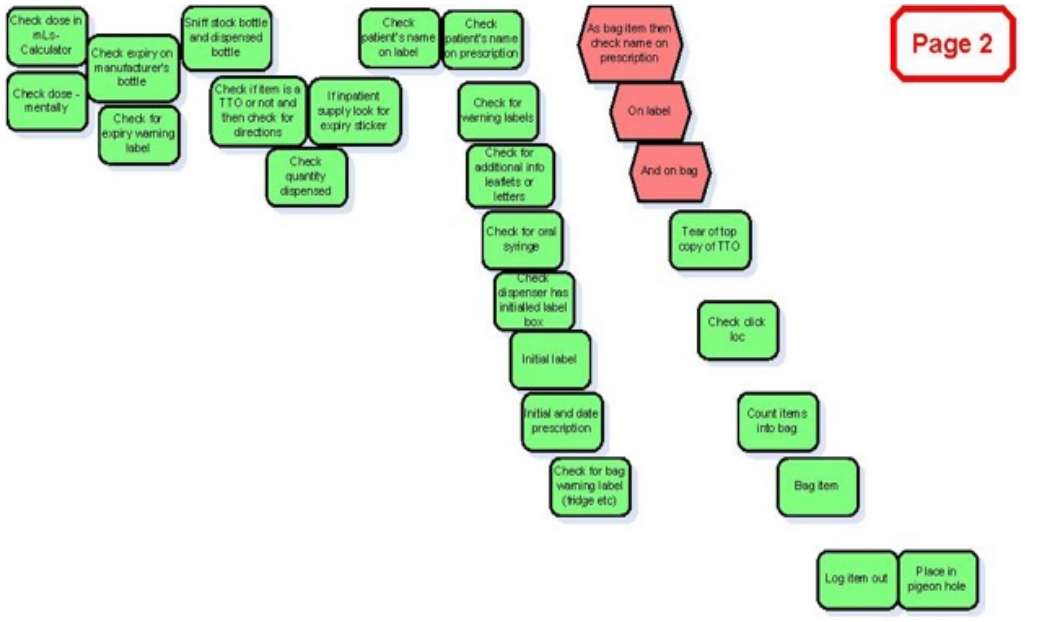
The Pharmacists’ group response



The technician group's response required two A1 sheets.



Focus_Technicians1
DR;SO;LW;SM;MS May 27th,2008



Focus_technicians1
DR;SO;LW;SM;MS May 27th,2008

Appendix 5- Publications related to the studies in this thesis

Publication 1 (Chapter 4) Published in the British Journal of Clinical Pharmacy; Vol 2. 2010
Page 1

Publication 2 (Chapter 5) To investigate how disruptive interruptions are on paediatric dispensary accuracy checkers

Eur J Hosp Pharm 2012;**19**:90 doi:10.1136/ejhpharm-2012-000074.15

Eur J Hosp Pharm 2012;**19**:90 doi:10.1136/ejhpharm-2012-000074.15

Abstracts

General and Risk Management, Patient Safety (including: medication errors, quality control)

To investigate how disruptive interruptions are on paediatric dispensary accuracy checkers

A. Sinclair, D. Terry, M. Slimm

+ Author Affiliations

Abstract

Background It is well documented that interruptions adversely affect task performance. What is less well known is the impact of interruptions in the context of the paediatric dispensary accuracy checking process.

Purpose To measure the effect that interruptions have on dispensary accuracy checkers.

Materials and methods The study instrument was non-participant, direct observation of a discrete, clearly identifiable step within the dispensing process (the accuracy-checking phase of the dispensing process). A prescription requiring two bottles of medicines to be dispensed was created. The medicines were labelled and placed in a tray together with the required paperwork, additional spoons or oral syringes and a dispensing bag. The operatives, both pharmacists and pharmacy technicians, volunteered to participate and were told that they would be timed accuracy checking a prescription and that the object of the observations was to measure the effect of the environment on their work only and that they themselves were not being assessed. They were also advised that the prescriptions were non-complex, had been clinically screened, and did not contain any errors by design. Each observation (n=34) consisted of two arms as determined by a Latin square. The observations were undertaken in the dispensary and in an office; the latter ensured a quiet environment. In addition a designed interruption was introduced into some of the variants.

Results A statistical analysis of variables was carried out using Minitab. A calculation of least squared means for time showed that individuals were 28.41% less efficient when interrupted in the dispensary. The mean time taken to accuracy check the standard prescription increased from 121.20 s to 155.63.

Conclusions It was found that interruptions adversely affected dispensary accuracy checkers who were checking a standardised prescription of two items in the dispensary at BCH. Dispensary design should support the reduction of interruptions in critical areas.

Publication 3 (Chapter 6) Investigating the cost and efficiency of incident reporting in a specialist paediatric NHS Hospital and impact on patient safety.

http://ejhp.bmj.com/content/24/2/91

Publication 4 (Chapter 7) The Introduction of pharmacy technicians onto a busy oncology ward.

Sinclair A, et al. Eur J Hosp Pharm 2016;0:1–4. doi:10.1136/ejhpharm-2016-000951

http://ejhp.bmj.com/content/early/2016/06/07/ejhpharm-2016-000951

Appendix 6 Other Publications

Terry,D; Petridis,K; Aiello,M; **Sinclair, A**; et al. The potential for pharmacists to manage children attending emergency departments. Archives of Disease in Childhood 101(9):e2.1-e2 · September 2016 DOI: 10.1136/archdischild-2016-311535.1

Aston,J ; Wilson,K; **Sinclair, A**; Terry,D. A telephone survey to determine the experiences of children and their parents/carers, following the initiation of a new medicine; European Journal of Hospital Pharmacy. August 2016; DOI: 10.1136/ejhpharm-2016-000925

Sinclair, A; Eyre,C; Petts,H; Guerin, A; Introduction of pharmacy technicians onto a busy oncology ward as part of the nursing team. European Journal of Hospital Pharmacy · June 2016 DOI: 10.1136/ejhpharm-2016-000951

Sinclair, A; Guerin, A; Robin, C; Dey,P; Investigating the cost and efficiency of incident reporting in a specialist paediatric NHS hospital and impact on patient safety; European Journal of Hospital Pharmacy · May 2016 DOI: 10.1136/ejhpharm-2016-000926

Huynh,C; Tomlin, S;Jani, Yogi; **Sinclair, A**; et al; An evaluation of the epidemiology of medication discrepancies and clinical significance of medicines reconciliation in children admitted to hospital; Archives of Disease in Childhood 101(1) · November 2015 DOI: 10.1136/archdischild-2015-308591

Bird, C; Hartshorn, S**; Sinclair, A.** Safety of "single checker" patient group directives for selected medications during initial nurse assessment in the emergency department (ed) Archives of Disease in Childhood 100(Suppl 3):A34-A34 · April 2015 DOI: 10.1136/archdischild-2015-308599.80

Gutermann, I; Decottignies, A; Sharif, K; Sinclair, A ; et al. Parents and carers of patients who had liver transplants: opinions and experiences of medication issues. European Journal of Hospital Pharmacy 21(6):339 · December 2014 DOI: 10.1136/ejhpharm-2013-000439

Huynh, C; Tomlin, S; Yogi, Yani; **Sinclair, A** ; Wilson, K; et al. Medication Discrepancies at Transitions in Pediatrics: A Review of the Literature. Paediatric Drugs 15(3) · May 2013 DOI: 10.1007/s40272-013-0030-8 · Source: PubMed

Terry,D; **Sinclair, A;** Prescribing for children at the interfaces of care**;** Archives of Disease in Childhood - Education and Practice 97(4):152-6 · August 2012 DOI: 10.1136/archdischild-2011-301254 · Source: PubMed

Terry,D; **Sinclair, A**; Ubhi, H; DasGupta, M; Cost benefit of hospital led supplies of unlicensed medicines for children at home; Archives of Disease in Childhood 97(5):e15-e15 · April 2012 DOI: 10.1136/archdischild-2012-301728.31

Sinclair, A; Terry,D; Slimm,M; To investigate how disruptive interruptions are on paediatric dispensary accuracy checkers**;** European Journal of Hospital Pharmacy 19(2):90-90 · March 2012 **;** DOI: 10.1136/ejhpharm-2012-000074.15

Terry,D; Sinclair, A**;**Patel, I; Wilson, K; Cost benefits of UK hospital pharmacy interventions: unlicensed medicines dispensed in the community**;** European Journal of Hospital Pharmacy 19(2):237-237 · March 2012**;** DOI: 10.1136/ejhpharm-2012-000074.399

Sinclair, A; Terry, D; How education should link with career paths; *Clinical Pharmacist*, Vol. 3, p312 | URI: 11088358; November 2011

Terry, D; **Sinclair, A;** Marriott, J; Wilson, J; Problems dispensing hospital prescriptions in community pharmacy: a survey of primary-care pharmacists; Archives of Disease in Childhood 96(4) · March 2011 DOI: 10.1136/adc.2011.211243.4

Norton, C; **Sinclair, A**; Marriott, J; Supporting MCRN research through improving clinical trial delivery by hospital pharmacies; Archives of Disease in Childhood 96(4) · March 2011 ; DOI: 10.1136/adc.2011.211243.11

Terry,D; **Sinclair, A**; Marriott,J; Davies, P; Medication access in primary care for paediatric home-patients: involvement and opinions of medical staff in a UK paediatric hospital; Archives of Disease in Childhood 96(4) · March 2011 DOI: 10.1136/adc.2011.211243.13

Terry,D; **Sinclair, A;** Marriott,J; Slimm,M**;** Children's "specials" need to be more easily available; *The Pharmaceutical Journal*, Vol. 286, p196 | URI: 11068833; February 2011

Sinclair, A; Terry, D; Slimm,M; Marriott, J**;** Errors in hospital pharmacy: How predictable are they; EJHP Practice 17(2):62-63 · January 2011

Sinclair, A; Miljkovic, B;Is there a need for a hospital pharmacist specialization; EJHP Practice 17(3):22-22 · January 2011

Terry, D; Solanki, G; **Sinclair, A**; Marriott, J; Wilson, K; Clinical significance of medication reconciliation in children admitted to a UK pediatric hospital: observational study of neurosurgical patients; Paediatric Drugs 12(5):331-7 · October 2010 ;DOI: 10.2165/11316230-000000000-00000

Terry, D; **Sinclair, A**; Marriott, J; Wilson, K;An evaluation of urgent medication supplies from a paediatric hospital pharmacy at the request of parent-carers of children in primary care; Archives of Disease in Childhood 95(6) · June 2010 ; DOI: 10.1136/adc.2010.190322.3

Terry,D; **Sinclair, A**; Marriott, J; Daniels, A; Access to medicines in primary care for paediatric patients: involvement of hospital clinical nurse specialists and advanced nurse practitioners; Archives of Disease in Childhood 95(6) · June 2010 ; DOI: 10.1136/adc.2010.190322.12

Sinclair, A; Terry, D; Slimm, M; Marriott, J**;** How predictable are errors in paediatric hospital pharmacy?**;** Archives of Disease in Childhood 95(6) · June 2010; DOI: 10.1136/adc.2010.190322.2

Appendix 7 The Checklist and calculation guide (Chapter 7)

DRUG	DOSE	Patient initials
Date & Time due	Nurse	Technician

BRIEF (Includes specific risks /considerations for patient, drug, staff)

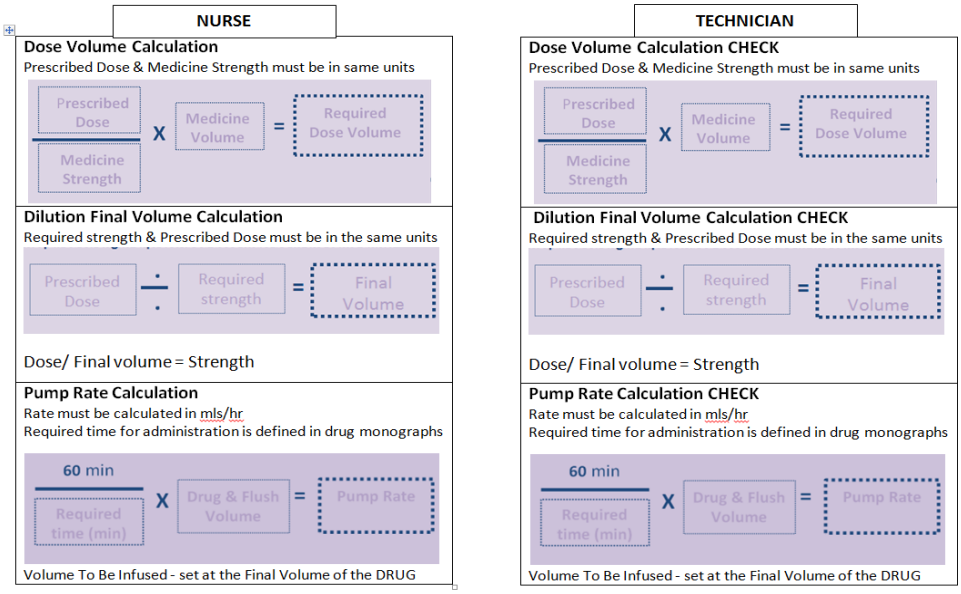
PROMPTS	Prescription	Preparation	Administration	5 RIGHTS CHECK
Right Patient	○ Patient details on prescription chart complete		○ Patient ID matches prescription chart	☐ RIGHT PATIENT
Right Drug	○ Prescription is complete ○ Not contraindicated for allergies ○ Prescribed drug is selected & is in date	○ Drug is labelled with name & dose ○ Appropriate flushes / diluents used	○ Labelled drug selected ○ (Burette) Correct Diluent attached to burette	☐ RIGHT DRUG
Right Dose	○ Dose is within range referenced in BNFC or Oncology Guidelines for route & indication for age / weight of child ○ Calculations of dose volume match	○ Reconstitution volume appropriate ○ Calculated dose volume drawn up ○ Calculated Diluent volume added	○ (Burette) Correct Diluent volume added	☐ RIGHT DOSE
Right Route	○ Route correctly prescribed	○ Equipment & technique appropriate for route	○ Right Route selected	☐ RIGHT ROUTE
Right Time	○ Prescribed time matches & has not previously been signed as administered ○ Administration time (device rate) calculations match	○ Administration time appropriate for dose or volume	○ Due now ○ Administration time (device rate) correctly set up	☐ RIGHT TIME

Please turn over for useful calculations check

Signed by Technician & Nurse

Version 1.0.2 check list

The Checklist used in the oncology ward pharmacy technician project



The Calculation guide also used in the same project

Appendix 8 National Research Ethics Service (NRES) - Ethics approval email

Sinclair Anthony (RQ3) BCH

From: Queries[redacted]
Sent: 20 November 2007 13:16
To: Sinclair Anthony (RQ3) BCH
Subject: RE: application

The following reply has been provided by[redacted]

Thank you for your query.

Our leaflet "Defining Research", which explains how we differentiate research from other activities, is published at:

http://www.nres.npsa.nhs.uk/applicants/help/guidance.htm#audit

Based on the information you provided, I would deem this service evaluation. Our advice is that the project is not considered to be research according to this guidance. Therefore it does not require ethical review by a NHS Research Ethics Committee.

If you are undertaking the project within the NHS, you should check with the relevant NHS care organisation (s) what other review arrangements or sources of advice apply to projects of this type. Guidance may be available from the clinical governance office.

Although ethical review by a NHS REC is not necessary in this case, all types of study involving human participants should be conducted in accordance with basic ethical principles such as informed consent and respect for the confidentiality of participants. When processing identifiable data there are also legal requirements under the Data Protection Act 2000. When undertaking an audit or service/therapy evaluation, the investigator and his/her team are responsible for considering the ethics of their project with advice from within their organisation. University projects may require approval by the university ethics committee.

This response should not be interpreted as giving a form of ethical approval or any endorsement of the project, but it may be provided to a journal or other body as evidence that ethical approval is not required under NHS research governance arrangements.

However, if you, your sponsor/funder or any NHS organisation feel that the project should be managed as research and/or that ethical review by a NHS REC is essential, please write setting out your reasons and we will be pleased to consider further.

Where NHS organisations have clarified that a project is not to be managed as research, the Research Governance Framework states that it should not be presented as research within the NHS.

I hope this helps.

Regards

Queries Line
[redacted]

Website: www.nres.npsa.nhs.uk
Email: Queries@nationalres.org.uk

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